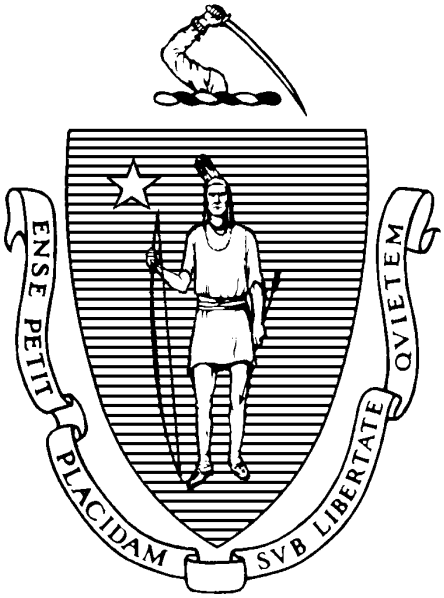
Issue: 1373, Date: September 7, 2018



The Massachusetts Register

Published by:
The Secretary of the Commonwealth,
William Francis Galvin, Secretary **$15.00**

Issue: 1373, Date: 9/7/18

THE COMMONWEALTH OF MASSACHUSETTS

Secretary of the Commonwealth - William Francis Galvin

The Massachusetts Register

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MASSACHUSETTS REGISTER (THE) (ISSN-08963681) is published biweekly for $300.00 per year by the Secretary of the Commonwealth, State House, Boston, MA 02133. Second Class postage is paid at Boston, MA. POSTMASTER: Send address change to: Massachusetts Register, State Bookstore, Room 116, State House, Boston, MA 02133.

958 CMR Health Policy Commission

Acts 2018

CHAPTER NUMBER	BILL NUMBER	TITLE	DATE
214	S 2559	Authorizng the Commissioner of Capital Asset Management and Maintenance to Modify and Relocate an Easement in the Town of West Boylston.	8/9/2018
215	S 2582	Authorizing the Commissioner of Capital Asset Mangement and Maintenance and the Town of Hingham to Grant Certain Easements Upon Certain Land Located in the Town of Hingham.	8/9/2018
216	S 2603	Authorizing the Division of Capital Asset Management and Maintenance to Grant Easements to NSTAR Electric Company in Return for NSTAR Releasing or Modifying Easements for the Benefit of the Commonwealth.	8/9/2018
217	S 2614	Relative to the Creation of the Commonwealth Technical Rescue Regions and Coordinating Council.	8/9/2018
218	S 2632	Relative to Veterans' Benefits, Rights, Appreciation, Validation and Enforcement.	8/9/2018
219	S 2646	Protect Animal Welfare and Safety in Cities and Towns.	8/9/2018
220	H 4116	Relative to Alzheimer's and Related Dementias in the Commonwealth.	8/9/2018
221	H 4253	Relative to the Classification of Certain Employees of the South Essex Sewerage District.	8/9/2018
222	H 4523	Further Regulating the Buzzards Bay Water District.	8/9/2018
223	H 4636	Authorizing the Division of Capital Asset Management and Maintenance to Convey Certain Parcels of Land in the Town of Grafton.	8/9/2018
224	H 4757	Releasing Certain Land in Northfield From the Operation of an Agricultural Covenant.	8/9/2018
225	H 4812	Ensure Compliance with Federal Standards Regarding the Handling of Federal Tax Information.	8/9/2018
226	H 4853	Relative to the Release of Certain Land in Rowley from Operation of an Agricutural Covenant.	8/9/2018
227	H 4857	To Advance Clean Energy.	8/9/2018

Acts 2018

CHAPTER NUMBER	BILL NUMBER	TITLE	DATE
228	H 4732	Relative to Economic Development in the Commonwealth. *This bill was returned on August 10, 2018, by the Governor to the House of Representatives, the branch in which said bill was originated, with his objections in writing to the following items therein:* *Items Disapproved: SECTIONS 20 and 62.* *Pursuant to Article 56, as amended by Article 90, Section 3, of the Amendments to the Constitution, the Governor sent a separate letter to the Senate and the House of Representatives setting forth recommended amendments to Section: 15, 18, 57, 63, 65, and 73.* *The remainder of the bill was approved by the Governor on August 10, 2018 at two o'clock and forty minutes, P.M.*	8/10/2018
229	H 4030	Authorizing the Appointment of Special Police Officers in the Town of Burlington.	8/17/2018
230	H 4608	Directing the City of Boston Police Department to Waive the Maximum Age Requirement for Police Officers for Hugh Trong Ngo.	8/17/2018
231	H 4554	Establishing a Sick Leave Bank for Jodi Cipriano, an Employee of the Department of Developmental Services.	8/17/2018
232	H 4403	Establishing a Sick Leave Bank for Bethany Powers, an Employee of the Hampshire County Sheriff's Deparment.	8/17/2018
233	H 1327	Authorizing the Appointing Authority of the Town of Mansfield to Appoint Police Cadets to the Police Department of the Town.	8/22/2018
234	H 4389	Authorizing the Town of Hopkinton to Establish a Means-Tested Senior Citizen Property Tax Exemption.	8/22/2018

STATE REGISTER OF HISTORIC PLACES

WEEKS OF: May 29, 2018 – August 10, 2018

For further information call the Massachusetts Historical Commission (617-727-8470)

ACTIONS TAKEN UNDER 950 CMR 71.00

Town/Property/Agency	Finding	Date
NONE		

ADDITIONAL LISTINGS UNDER 950 CMR 71.00

Town/Name/Address	Designation	Date	Number of Properties
Bedford			
Fitch, Jeremiah Tavern 12 The Great Rd	PR	05/31/2018	2
Blackstone			
East Blackstone Friends Meetinghouse 197 Elm St	PR	07/02/2018	3
Boston (Dorchester)			
Columbia Road–Strathcona Road Historic District Columbia Rd, Strathcona Rd, Washington St	NRDIS	08/03/2018	9
Dartmouth			
Russell Garrison Fort St	NRIND	08/06/2018	6
Granville			
Rose, John and Ruth, House 944 Main Rd	NRIND	08/10/2018	9
Hanover			
Cardinal Cushing Center Historic District 369, 405, 423 Washington St	NRIND	08/10/2018	21
Middleborough			
Leonard, Shaw & Dean Shoe Factory 151 Peirce St	NRIND	08/03/2018	2
Newburyport			
Merrimac Arms Manufacturing Company 260 Merrimac St	PR	06/01/2018	2
Rockland			
Emerson Shoe Company 51 Maple St	NRIND	06/01/2018	3

The Commonwealth of Massachusetts
Executive Office of Health and Human Services
One Ashburton Place, Room 1109
Boston, Massachusetts 02108

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KARYN E. POLITO
Lieutenant Governor

MARYLOU SUDDERS
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Administrative Bulletin 18-18

101 CMR 614.00: Health Safety Net Payments and Funding

Effective October 1, 2018

Health Safety Net Interim Payment Policies for Acute Hospitals and Community Health Centers

The Health Safety Net (HSN) must update its systems to comply with the Massachusetts Executive Office of Technology Services and Security requirements. The initial updates will occur from October 2018 through December 2018. During this time, both HSN payment processes and the INET system will be affected.

While payment systems are affected from October 2018 through December 2018, the HSN will make interim payments to acute hospitals and community health centers as set forth below.

The HSN will determine providers' monthly interim payments by calculating a provider's average monthly demand over a 12 month period from September 2017 through August 2018. Demand is the amount of a provider's Reimbursable Health Services (RHS), including pharmacy and dental services, as reimbursed in accordance with 101 CMR 614.06 or 614.07, without application of the shortfall under 101 CMR 614.03(2)(b).

The interim payment amount for acute hospitals will be calculated as follows:

The interim total allowable RHS will incorporate the payments providers received on 837I, 837P, dental services (if applicable to that facility), POPS (pharmacy claims), emergency room bad debt recoveries, and free care endowment income. HSN will utilize the monthly average of RHS over a 12 month period from September 2017 through August 2018 to calculate the interim payment amount for each month during the interim payment period from October 2018 through December 2018.

The interim payment amount for community health centers will be calculated as follows:

The interim total allowable RHS will incorporate the payments providers received on 837P, dental services, and POPS (pharmacy claims). For the interim averages of 837P, dental services, and POPS, HSN will utilize the monthly average of RHS over a 12 month period from September 2017 through August 2018.

A community health center's average monthly interim payment will be the sum of the three averages determined through the process described above.

Providers must continue to submit claims during the interim payment period from October 2018 through December 2018. These claims will be paid in January and used for the interim payment recovery.

Interim Payment Recovery

The interim payment recovery period will begin in January 2019. During the interim payment recovery period, a provider's monthly payment will be reduced by the interim payment recovery to reflect the actual payments made during the interim payment period.

The interim recovery amount for acute hospitals will be calculated as follows:

For each month, beginning in January 2019, the interim payment recovery will be determined by comparing a provider's monthly demand, based on claims submitted to MassHealth, to POPS (for pharmacy claims), or for dental claims (DentaQuest and/or 837D), and the monthly interim payment balance. The adjustment is calculated as follows:

(a) If monthly demand is less than two times the one month interim payment amount, then the recovery will be equal to half of monthly demand, up to the amount of the remaining interim payment balance; or

(b) If monthly demand is greater than or equal to two times the one month interim payment amount, then the recovery will be equal to monthly demand minus the one month interim payment amount, up to the amount of the remaining interim payment balance.

If an interim payment balance remains in the April 2019 payment cycle, the recovery amount for the April 2019 payment cycle will be equal to the remaining interim payment balance.

The interim recovery amount for community health centers will be calculated as follows:

For each month, beginning in January 2019, the interim payment recovery will be determined by comparing a provider's monthly demand, based on claims submitted to MassHealth, to POPS (for pharmacy claims), or for dental claims (DentaQuest and/or 837D), and the monthly interim payment balance. The adjustment is calculated as follows:

(a) If monthly demand is less than two times the one month interim payment amount, then the recovery will be equal to half of monthly demand, up to the amount of the remaining interim payment balance; or

(b) If monthly demand is greater than or equal to two times the one month interim payment amount, then the recovery will be equal to monthly demand minus the one month interim payment amount, up to the amount of the remaining interim payment balance.

The HSN will continue with the recovery formula for community health centers until the entire interim payment balance has been recovered.

The HSN is available to answer any questions or address any concerns specific facilities may have with the calculations or processes described above. HSN Helpdesk can be reached at HSNHelpDesk@State.MA.US.

THE COMMONWEALTH OF MASSACHUSETTS

Secretary of the Commonwealth - William Francis Galvin

NOTICES OF PUBLIC REVIEW OF PROSPECTIVE REGULATIONS PUBLISHED IN COMPLIANCE WITH M.G.L. c. 30A, §§ 2 AND 3

September 7, 2018

State Lottery Commission	961 CMR 2.00	9/20/18 @ 10:00 A.M. Written comments accepted until 9/21/18 @ 5:00 P.M.

THE LOTTERY **Massachusetts State Lottery Commission**

DEBORAH B. GOLDBERG
Treasurer and Receiver General

MICHAEL R. SWEENEY
Executive Director

NOTICE OF PUBLIC HEARING

Notice is hereby provided that in accordance with M.G.L. c. 30A, §2, the Massachusetts State Lottery Commission will hold a public hearing for purposes of gathering comments relative to proposed amendments to 961 CMR 2.00: Rules and Regulations. The amendments are authorized by M.G.L. c. 10, §24.

The amendments define a High-Frequency Prize Winner as a person who submits at least 20 claims for Lottery prizes, each with a value of at least $1,000, within any period of 365 days. The regulations also set forth the penalties and hearing process for a High-Frequency Prize Winner's claims for Lottery prizes that are determined to be factually or statistically improbable. The Lottery is mandated to collect outstanding child support liabilities, taxes and fees owed to the Commonwealth. These regulations will assist the Lottery with enforcement against a High-Frequency Prize Winner to protect the integrity of the Lottery, and to protect against potential avoidance of child support and or tax liabilities, money laundering, consumer fraud, and tax fraud. These regulations will also assist with responsible gambling awareness. These regulations are governed by M.G.L. c. 10, §24 and M.G.L. c. 30A.

The public hearing will take place on Thursday, **September 20, 2018**, at **10:00 a.m.** at the Headquarters of the Massachusetts State Lottery Commission, 60 Columbian Street, Braintree, Massachusetts.

A copy of the proposed amendments referenced above may be downloaded by visiting www.masslottery.com. Anyone wishing to offer comments may appear at the public hearing at the designated date and time or submit written comments. Those who wish to receive a written copy of the proposed amendments, or to submit written comments, may do so by sending an email to cporche@masslottery.com, or by mail to Cecelia Porche, Massachusetts State Lottery Commission, 60 Columbian Street, Braintree, MA 02184. Written comments must be received by 5:00 p.m. on September 21, 2018.

Additionally, attached please find the accompanying Small Business Impact Statement in accordance with M.G.L. c.30A, §2.

THE LOTTERY Massachusetts State Lottery Commission

DEBORAH B. GOLDBERG
Treasurer and Receiver General

MICHAEL R. SWEENEY
Executive Director

SMALL BUSINESS IMPACT STATEMENT

The Massachusetts State Lottery Commission ("Commission") hereby files this small business impact statement in accordance with G.L. c.30A, §2 relative to the proposed amendments in 961 CMR 2.00: Rules and Regulations; notice of which was filed this day with the Secretary of the Commonwealth.

The amendments define a High-Frequency Prize Winner as a person who submits at least 20 claims for Lottery prizes, each with a value of at least $1,000, within any period of 365 days. The regulations also set forth the penalties and hearing process for a High-Frequency Prize Winner's claims for Lottery prizes that are determined to be factually or statistically improbable. The Lottery is mandated to collect outstanding child support liabilities, taxes and fees owed to the Commonwealth. These regulations will assist the Lottery with enforcement against a High-Frequency Prize Winner to protect the integrity of the Lottery, and to protect against potential avoidance of child support and or tax liabilities, money laundering, consumer fraud, and tax fraud. These regulations will also assist with responsible gambling awareness. These regulations are governed by M.G.L. c. 10, §24 and M.G.L. c. 30A.

These amendments apply to individuals determined to be a High-Frequency Prize Winner. Accordingly, these amendments are unlikely to have an impact on small businesses. In accordance with G.L. c.30A, §2, the Commission offers the following responses:

1. Estimate of the number of small businesses subject to the proposed regulation:

   There are no small businesses that the Commission anticipates will be impacted by these regulations as they apply solely to individuals determined to be a High-Frequency Prize Winner.

2. State the projected reporting, recordkeeping and other administrative costs required for compliance with the proposed regulation:

   There are no projected reporting, recordkeeping or administrative costs created by these regulations that would affect small businesses as these regulations apply solely to individuals determined to be a High-Frequency Prize Winner.

3. State the appropriateness of performance standards versus design standards:

   These regulations do not implicate a design or performance standard.

4. Identify regulations of the promulgating agency, or of another agency or department of the commonwealth, which may duplicate or conflict with the proposed regulation:

   The Commission is not aware of duplicate or conflicting regulations.

5. State whether the proposed regulation is likely to deter or encourage the formation of new businesses in the commonwealth:

   These regulations govern the penalties and hearing process for a High-Frequency Prize Winner's claims for Lottery prizes that are determined to be factually or statistically improbable and therefore are not likely to deter or encourage the formation of new businesses in the Commonwealth.

MASSACHUSETTS STATE LOTTERY COMMISSION,

By: _____
MICHAEL R. SWEENEY,
EXECUTIVE DIRECTOR

Date: 8/21/18

THE COMMONWEALTH OF MASSACHUSETTS

Secretary of the Commonwealth - William Francis Galvin

2018 CUMULATIVE TABLE TO THE MASSACHUSETTS REGISTER
1356 - 1373

The Cumulative Tables lists all regulations and amendments thereto published in the Massachusetts Register during the current year. The Table is published in each Register.

State agencies are listed in the Table as they appear in the Code of Massachusetts Regulations (CMR or Code) in CMR numerical order which is based on the cabinet structure. For example, all Human Service agencies are prefaced by the number "1" and are designated as 101 CMR through 130 CMR.

The Cumulative Tables published in the last issue of previous years will have a listing of all regulations published for that year. These Registers are:

April 6, 1976 - 1977	Register:	# 88	Date: 1998	Register:	# 859
1978		138	1999		885
1979		193	2000		911
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1981		292	2002		963
1982		344	2003		989
1983		396	2004		1016
1984		448	2005		1042
1985		500	2006		1068
1986		546	2007		1094
1987		572	2008		1120
1988		598	2009		1146
1989		624	2010		1172
1990		650	2011		1198
1991		676	2012		1124
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1994		755	2015		1302
1995		871	2016		1329
1996	Supp. # 2	807	2017		1355
1997		833			

		Issue	Effective Date
310 CMR	**Department of Environmental Protection**		
7.00	Air Pollution Control	S1360	3/9/18
		S1360	3/9/18
		S1360	3/9/18
		S1360	3/9/18
	- *Correction* (MA Reg. # S1360)	1361	3/9/18
	- *Correction* (MA Reg. # S1360)	1363	3/9/18
	- *Correction* (MA Reg. # S1360)	1366	3/9/18
	- *Correction* (MA Reg. # S1360)	1370	3/9/18
		1371	8/10/18
313 CMR	**Division of Water Supply Protection**		
4.00	Interbasin Transfer	1361	3/23/18
321 CMR	**Division of Fisheries & Wildlife**		
3.00	Hunting	1356	1/12/18
		1364	5/4/18
		1369	7/13/18
322 CMR	**Division of Marine Fisheries**		
4.00	Fishing and Shellfish Equipment - *Correction* (MA Reg. # 1336)	1368	4/7/17
6.00	Regulation of Catches	1363	4/20/18
	- *Correction* (MA Reg. # 1363)	1366	4/20/18
	- *Emergency*	1365	4/30/18
	- *Correction* (MA Reg. # 1365)	1368	4/30/18
	- *Emergency*	1365	5/4/18
		1370	7/27/18
12.00	Protected Species - *Emergency*	1365	4/25/18
	- *Emergency*	1366	5/15/18
323 CMR	**Office of Law Enforcement**		
6.00	Commercial Whitewater Use	1370	7/27/18
330 CMR	**Department of Agricultural Resources**		
31.00	Plant Nutrient Application Requirements for Agricultural Land, Non-agricultural Turf and Lawns	1356	1/12/18
402 CMR	**Economic Assistance Coordinating Council**		
2.00	Economic Development Incentive Program	1372	8/24/18
430 CMR	**Department of Unemployment Assistance**		
4.00	Benefit Series	1356	1/12/18
21.00	Employer Medical Assistance Contribution Supplement	1360	3/9/18
	- *Emergency*	1365	4/27/18
		1369	7/13/18

THE COMMONWEALTH OF MASSACHUSETTS

Office of the Secretary of the Commonwealth

NOTICE OF EXPIRATION OF EMERGENCY REGULATION

CHAPTER NUMBER: **322 CMR 12.00**

CHAPTER TITLE: **Protected Species**

AGENCY: **Division of Marine Fisheries**

THIS REGULATION WAS ORIGINALLY ADOPTED AS AN EMERGENCY:

EFFECTIVE: **05/15/2018**

Published in Massachusetts Register Num **1366** *Date:* **06/01/2018**

There having been no action by the agency in compliance with the public review provisions of M.G.L. c. 30A, section 2 or 3 during the three months after this regulation was filed with the State Secretary, this emergency is deemed to have expired and is removed from all current records of the Code of Massachusetts Regulations. Emergency expired effective:

08/15/2018

Docket # 66

THE COMMONWEALTH OF MASSACHUSETTS
William Francis Galvin
Secretary of the Commonwealth

Regulation Filing *To be completed by filing agency*

CHAPTER NUMBER: **970 CMR 2.00**

CHAPTER TITLE: **Political Expenditures**

AGENCY: **Office of Campaign and Political Finance**

SUMMARY OF REGULATION: *State the general requirements and purposes of this regulation.*

The referenced regulation is being added, on an emergency basis, to ensure accurate and timely disclosure of independent expenditures in accordance with the intent of M.G.L. c. 55, s. 18A.

REGULATORY AUTHORITY: **M.G.L. c. 30A, s. 2 and M.G.L. c. 55, s. 3**

AGENCY CONTACT: **Sarah Hartry** PHONE: **617-979-8300**

ADDRESS: **1 Ashburton Place, Room 411, Boston, MA 02108**

Compliance with M.G.L. c. 30A

EMERGENCY ADOPTION - *if this regulation is adopted as an emergency, state the nature of the emergency.*

M.G.L. c. 55, s. 18A requires the disclosure of independent expenditures ("IEs") and outlines an enhanced reporting schedule intended to capture IEs utilized shortly before an election, to ensure disclosure before said election. The 2018 Primary Election date is preceded by Labor Day, and without this emergency regulation some IEs may not be disclosed prior to the Primary Election.

PRIOR NOTIFICATION AND/OR APPROVAL - *If prior notification to and/or approval of the Governor, Legislature or others was required, list each notification, and/or approval and date, including notice to the Local Government Advisory Commission.*

N/A

PUBLIC REVIEW - *M.G.L. c. 30A sections 2 and/or 3 requires notice of the hearing or comment period, including a small business impact statement, be filed with the Secretary of the Commonwealth, published in appropriate newspapers, and sent to persons to whom specific notice must be given at least 21 days prior to such hearing or comment period.*

Date of public hearing or comment period: **N/A**

FISCAL EFFECT - *Estimate the fiscal effect of the public and private sectors.*

For the first and second year: **none**

For the first five years: **none**

No fiscal effect: **none**

SMALL BUSINESS IMPACT - *M.G.L. c. 30A section 5 requires each agency to file an amended small business impact statement with the Secretary of the Commonwealth prior to the adoption of a proposed regulation. If the purpose of this regulation is to set rates for the state, this section does not apply.*

Date amended small business impact statement was filed: **N/A**

CODE OF MASSACHUSETTS REGULATIONS INDEX - *List key subjects that are relevant to this regulation:*
Disclosure of independent expenditures relating to the 2018 Primary Election

PROMULGATION - *State the action taken by this regulation and its effect on existing provisions of the Code of Massachusetts Regulations (CMR) or repeal, replace or amend. List by CMR number:*

Adds new 2.17(11)

ATTESTATION - *The regulation described herein and attached hereto is a true copy of the regulation adopted by this agency.* ATTEST:

SIGNATURE: SIGNATURE ON FILE DATE: **Aug 21 2018**

Publication - *To be completed by the Regulations Division*

MASSACHUSETTS REGISTER NUMBER: **1373** DATE: **09/07/2018**

EFFECTIVE DATE: **08/21/2018**

CODE OF MASSACHUSETTS REGULATIONS

Remove these pages:	*Insert these pages:*
This is an Emergency Regulation.	**There are no Replacement Pages.**

A TRUE COPY ATTEST
WILLIAM FRANCIS GALVIN
SECRETARY OF THE COMMONWEALTH
DATE 08/21/2018 CLERK RB

2.17: continued

2. Subsequent "Seven Business Day" Reports. After the initial seven business day report is filed, additional seven business day reports shall be filed each time goods or services obtained through independent expenditure(s) aggregating more than $250 are utilized, unless such independent expenditures are disclosed in a 24-hour report in accordance with 970 CMR 2.17(6)(b). The reporting period for each IE report shall commence on the date following the last date included in the previous seven business day report and be complete through the date of the expenditure(s) disclosed.

(b) "24-Hour" Reports. If goods or services obtained by independent expenditure(s) exceeding $250 are utilized within ten days before an election, but more than 24 hours before an election, a report disclosing the independent expenditure(s) must be filed within 24 hours of when the goods or services are utilized. The report shall disclose the information required by 970 CMR 2.17(6)(a). Additional 24-hour reports shall be filed when additional expenditures exceeding $250 are made within the ten-day period before an election, in accordance with M.G.L. c. 55, § 18A(b).

(c) Traditional political action committees that make independent expenditures remain subject to limits on contributions that may be received and made, that are applicable to traditional political action committees when raising funds.

(7) Disclosure of Independent Expenditures Made by Political Committees Other than Independent Expenditure PACs, or Ballot Question Committees, That File with the Director to Support or Oppose Local Candidates. Political committees other than independent expenditure PACs or ballot question committees, which file reports with the Director, may, in addition to making independent expenditures to support or oppose candidates who file with the Director, make independent expenditures to promote the election or defeat of one or more candidates who file with a city or town clerk.

(a) If such independent expenditures are made and the aggregate amount of the independent expenditures exceeds $250 during any calendar year, the committee must, in addition to disclosing the expenditures in the committee's periodic campaign finance report that is filed with the Director, also file a report of independent expenditures with the city or town clerk in the city or town in which the candidate is on the ballot.

(b) The independent expenditure reports filed with the city or town clerk must be filed in accordance with the schedule in 970 CMR 2.17(6).

(c) Traditional political action committees that make independent expenditures remain subject to limits on contributions that may be received and made, that are applicable to traditional political action committees.

(8) Disclosure of Independent Expenditures Made by Traditional PACs That File with a City or Town Clerk. A traditional PAC, which files reports with a city or town clerk, may, in addition to making expenditures to support or oppose candidates who file with the clerk, make independent expenditures to promote the election or defeat of one or more candidates who file with the Director.

(a) If such independent expenditures are made and the aggregate amount of the independent expenditures exceeds $250 during any calendar year, the committee must, in addition to disclosing the expenditures in the committee's periodic campaign finance report that is filed with the city or town clerk, also file a report of independent expenditures with the Director.

(b) The independent expenditure reports filed with the Director must be filed electronically, in accordance with M.G.L. c. 55, § 18C, in accordance with the schedule in 970 CMR 2.17(6).

(c) Traditional political action committees that make independent expenditures remain subject to contribution limits applicable to traditional political action committees when raising funds.

(9) Disclosure of Independent Expenditures Relating to Multiple Candidates. Reports of independent expenditures and IE PAC reports reflecting expenditures that support or oppose multiple candidates must identify each candidate referenced in a communication, and the proportionate value of the expenditure attributable to each candidate referenced in the communication.

(10) No candidate or individual holding elective public office shall establish, finance, maintain, control, or serve as a principal officer of an IE PAC.

2.17: continued

(11) If goods or services obtained by independent expenditure(s) exceeding $250 are utilized on or after August 23, 2018, but more than 24 hours before the 2018 Primary Election, a report disclosing the independent expenditure(s) must be filed within 24 hours of when the goods or services are utilized. The report shall disclose the information required by 970 CMR 2.17(5)(a). Additional 24 hour reports shall be filed when additional expenditures exceeding $250 are made on or after August 23, 2018, but more than 24 hours before the 2018 Primary Election, in accordance with M.G.L. c. 55, § 18A(b). This requirement shall apply to all persons, entities, or political committees required to file Reports of Independent Expenditures pursuant to M.G.L. c. 55, § 18A and 970 CMR 2.17.

2.18: Subvendor Reporting

(1) Location for Filing of Reports. Reports required to be filed by M.G.L. c. 55, § 18D are electronically filed with the Director, or if the expenditure concerns a local candidate who does not file with the Director, or a local ballot question, with the clerk.

(2) Vendor Accounting of Expenditures. A vendor that makes an expenditure on behalf of a political committee or on behalf of an individual or group required to file a report of ballot question expenditures under M.G.L. c. 55, § 22, shall, once the vendor has made expenditures to a particular subvendor that aggregate $500 during a calendar year, provide the political committee, individual or group with a detailed account of the expenditures within five days, in accordance with M.G.L. c. 55, § 18D(b). Vendors are not required to provide this information to the committee, individual or group, prior to reaching the $500 threshold. Upon reaching the $500 threshold, the detailed account provided to the committee, individual or group shall describe all expenditures made, including those made prior to reaching the threshold.

(3) Definition of Subvendor. A Subvendor is any individual who provides goods or services to a vendor or who contracts with a vendor to provide goods or services to a committee, or to an individual or group required to file a report of ballot question expenditures under M.G.L. c. 55, § 22, except the following persons or businesses are not considered subvendors under M.G.L. c. 55, § 18D.

(a) A person who is an employee of a vendor, and has been an employee of the vendor for a period of at least three consecutive months prior to any month in which a committee, individual or group is required to file a subvendor report.

(b) An individual or business that provides goods or services to another business or individual in the usual course of business. For example, a business that has an existing agreement to provide a printing company with paper and ink is not a subvendor.

(c) An individual or business that provides goods or services to a subvendor.

(4) Obligation of Political Committee, Individual or Group to Obtain Subvendor Information.

(a) A political committee, or an individual or group required to file a report of ballot question expenditures under M.G.L. c. 55, § 22, which makes a payment to a vendor of $5,000 or more in the aggregate during a calendar year, or which incurs liabilities to a vendor in that amount, must make inquiry, in writing, to the vendor regarding whether subvendors were paid by the vendor. A committee, individual or group satisfies this requirement by asking at least once for subvendor information.

(b) A political committee, or an individual or group required to file a report of ballot question expenditures under M.G.L. c. 55, § 22, which does not receive an account of subvendor expenditures from a vendor shall keep a copy of any written correspondence it sends to the vendor seeking such information.

(c) A vendor is not required to provide subvendor information to a committee if the vendor provides a statement to OCPF annually certifying that the vendor does not use subvendors. Vendors that provide this statement to OCPF must notify OCPF if circumstances change.

(5) Provision of In-kind Contributions. An individual or entity that provides an in-kind contribution to a political committee of $5,000 or more in the aggregate during a calendar year is a "vendor" for purposes of M.G.L. c. 55, § 18D and must provide the political committee with the full name and address of any subvendors who received payments from the vendor of more than $500 in connection with the in-kind contribution during the calendar year.

2.18: continued

(6) Subvendor Reporting by Independent Expenditure PACs. An independent expenditure PAC that makes expenditures requiring the filing of a subvendor report under M.G.L. c. 55, § 18D, shall electronically file a subvendor report disclosing the expenditures as part of the independent expenditure PAC's year-end report filed in accordance with 970 CMR 2.17(4)(c).

2.19: Reporting of Ballot Question Expenditures by Individuals, or by Corporations, Associations, Organizations or Other Groups of Persons

(1) A corporation, association, organization or other group of persons, other than a political committee, or an individual which makes an expenditure to influence or affect the vote on a ballot question must file a report disclosing the expenditure, pursuant to M.G.L. c. 55, § 22 unless such expenditures:

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Docket # 1,227

THE COMMONWEALTH OF MASSACHUSETTS
William Francis Galvin
Secretary of the Commonwealth

Regulation Filing *To be completed by filing agency*

CHAPTER NUMBER: **105 CMR 120.000**

CHAPTER TITLE: **The Control of Radiation**

AGENCY: **Department of Public Health**

SUMMARY OF REGULATION: *State the general requirements and purposes of this regulation.*

Regulations govern the activities of any persons who receive, possess, use, transfer, own or acquire any source of radiation. The amendments implement changes to maintain compatibility with U.S. Nuclear Regulatory Commission regulations.

REGULATORY AUTHORITY: **M.G.L. c. 111, secs. 3 and 5M-5P**

AGENCY CONTACT: **Jim Ballin** PHONE: **617-624-5220**

ADDRESS: **250 Washington Street, Boston, MA 02108**

Compliance with M.G.L. c. 30A

EMERGENCY ADOPTION - *if this regulation is adopted as an emergency, state the nature of the emergency.*

PRIOR NOTIFICATION AND/OR APPROVAL - *If prior notification to and/or approval of the Governor, Legislature or others was required, list each notification, and/or approval and date, including notice to the Local Government Advisory Commission.*

Notice to Executive Office of Communities and Development and the Massachusetts Municipal Association on June 15, 2018.

PUBLIC REVIEW - *M.G.L. c. 30A sections 2 and/or 3 requires notice of the hearing or comment period, including a small business impact statement, be filed with the Secretary of the Commonwealth, published in appropriate newspapers, and sent to persons to whom specific notice must be given at least 21 days prior to such hearing or comment period.*

Date of public hearing or comment period: **July 24, 2018**

FISCAL EFFECT - *Estimate the fiscal effect of the public and private sectors.*

For the first and second year: _____

For the first five years: _____

No fiscal effect: **No fiscal effect expected**

SMALL BUSINESS IMPACT - *M.G.L. c. 30A section 5 requires each agency to file an amended small business impact statement with the Secretary of the Commonwealth prior to the adoption of a proposed regulation. If the purpose of this regulation is to set rates for the state, this section does not apply.*

Date amended small business impact statement was filed: **August 22, 2018**

CODE OF MASSACHUSETTS REGULATIONS INDEX - *List key subjects that are relevant to this regulation:*
Radiation control

PROMULGATION - *State the action taken by this regulation and its effect on existing provisions of the Code of Massachusetts Regulations (CMR) or repeal, replace or amend. List by CMR number:*

Amends 105 CMR 120.000

ATTESTATION - *The regulation described herein and attached hereto is a true copy of the regulation adopted by this agency.* ATTEST:

SIGNATURE: SIGNATURE ON FILE DATE: **Aug 24 2018**

Publication - *To be completed by the Regulations Division*

MASSACHUSETTS REGISTER NUMBER: **1373** DATE: **09/07/2018**

EFFECTIVE DATE: **09/07/2018**

CODE OF MASSACHUSETTS REGULATIONS

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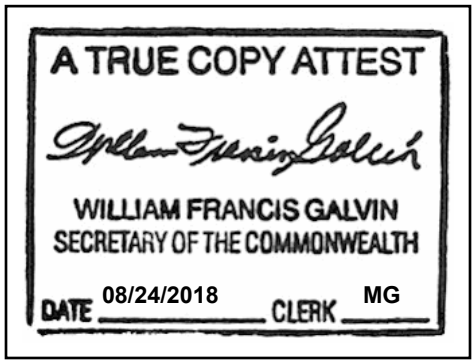

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105 CMR 120.000: THE CONTROL OF RADIATION

Section

Section: continued

Section: continued

RADIOLOGICAL CRITERIA FOR LICENSE TERMINATION

RECORDS

REPORTS

Section: continued

Section: continued

Section: continued

Section: continued

120.001: GENERAL PROVISIONS

120.002: Purpose and Scope

Except as otherwise specifically provided, 105 CMR 120.000 apply to all persons who receive, possess, use, transfer, own, or acquire any source of radiation; provided, however, that nothing in 105 CMR 120.000 shall apply to any person to the extent such person is subject to regulation by the U.S. Nuclear Regulatory Commission (NRC). Regulation by the Commonwealth of source material, byproduct material, and special nuclear material in quantities not sufficient to form a critical mass is subject to the provisions of the agreement between the State and the NRC and to 10 CFR Part 150 of the NRC's regulations.

120.003: Regulatory Authority

The authority for the Department of Public Health to promulgate 105 CMR 120.000 is found in: M.G.L. c. 111, §§ 3, 5M, 5N, 5O, and 5P.

120.004: Citation

105 CMR 120.000 shall be known and may be cited as the Massachusetts Regulations for the Control of Radiation (MRCR).

120.005: Definitions

As used in 105 CMR 120.000, these terms have the definitions set forth in 105 CMR 120.005. Additional definitions used only in a certain Section will be found in that Section.

105 CMR 120.000 means all Sections of the Massachusetts Regulations for the Control of Radiation.

Absorbed Dose means the energy imparted by ionizing radiation per unit mass of irradiated material. The units of absorbed dose are the gray (Gy) and the rad.

Accelerator means any machine capable of accelerating electrons, protons, deuterons, or other charged particles in a vacuum and of discharging the resultant particulate or other radiation into a medium at energies usually in excess of 1 MeV. For purposes of Accelerator, "particle accelerator" is an equivalent term.

Accelerator-produced Material means any material made radioactive by a particle accelerator.

Activity means the rate of disintegration or transformation or decay of radioactive material. The units of activity are the becquerel (Bq) and the curie (Ci).

Adult means an individual 18 years of age or older.

Agency means the Radiation Control Program of the Massachusetts Department of Public Health.

Agreement State means any State with which the U.S. Nuclear Regulatory Commission or the U.S. Atomic Energy Commission has entered into an effective agreement under § 274b of the Atomic Energy Act of 1954, as amended (St. 1973, c. 689).

Airborne Radioactive Material means any radioactive material dispersed in the air in the form of dusts, fumes, particulates, mists, vapors, or gases.

120.005: continued

Qualitative Fit Test (QLFT) means a pass/fail fit test to assess the adequacy of respirator fit that relies on the individual's response to the test agent.

Quality Factor (Q) means the modifying factor, listed in 105 CMR 120.014: *Tables I* and *II*, that is used to derive dose equivalent from absorbed dose.

Quantitative Fit Test (QNFT) means an assessment of the adequacy of respirator fit by numerically measuring the amount of leakage into the respirator.

Rad means the special unit of absorbed dose. One rad is equal to an absorbed dose of 100 erg per gram or 0.01 joule per kilogram (0.01 gray).

Radiation means alpha particles, beta particles, gamma rays, x-rays, neutrons, high-speed electrons, high-speed protons, and other particles capable of producing ions. For purposes of 105 CMR 120.000, ionizing radiation is an equivalent term. Radiation, as used in 105 CMR 120.000, does not include non-ionizing radiation, such as radiowaves or microwaves, visible, infrared, or ultraviolet light.

Radiation Area means any area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.05 mSv (0.005 rem) in one hour at 30 centimeters from the source of radiation or from any surface that the radiation penetrates.

Radiation Dose (*See* Dose).

Radiation Detector means a device which, in the presence of radiation, provides by either direct or indirect means a signal or other indication suitable for use in measuring one or more quantities of incident radiation.

Radiation Machine means any device capable of producing radiation except, those devices with radioactive material as the only source of radiation.

Radiation Safety Officer means an individual who has the knowledge and responsibility to apply appropriate radiation protection regulations and programs and has been assigned such responsibility by the licensee or registrant.

Radioactive Material means any solid, liquid, or gas which emits radiation spontaneously.

Radioactivity means the transformation of unstable atomic nuclei with the emission of radiation.

Radiobioassay (*See* Bioassay).

Registrant means any person who is registered with the Agency and is legally obligated to register with the Agency pursuant to 105 CMR 120.000 and M.G.L. c. 111, §§ 3, 5M, 5N, 5O, and 5P.

Registration means registration with the Agency in accordance with the regulations adopted by the Agency.

Regulations of the U.S. Department of Transportation (U.S. DOT) means the regulations in 49 CFR Parts 100 through 189.

Rem means the special unit of any of the quantities expressed as dose equivalent. The dose equivalent in rem is equal to the absorbed dose in rad multiplied by the quality factor (one rem = 0.01 Sv).

Research and Development means:

(1) theoretical analysis, exploration, or experimentation; or

120.005: continued

(2) the extension of investigative findings and theories of a scientific or technical nature into practical application for experimental and demonstration purposes, including the experimental production and testing of models, devices, equipment, materials, and processes. Research and development does not include the internal or external administration of radiation or radioactive material to human beings.

Residual Radioactivity means radioactivity in structures, materials, soils, groundwater, and other media at a site resulting from activities under the licensee's control. This includes radioactivity from all licensed and unlicensed sources used by the licensee, but excludes background radiation. It also includes radioactive materials remaining at the site as a result of routine or accidental releases of radioactive materials at the site and previous burials at the site, even if those burials were made in accordance with the provisions of 105 CMR 120.200.

Restricted Area means an area, access to which is limited by the licensee or registrant for the purpose of protecting individuals against undue risks from exposure to sources of radiation. Restricted area does not include areas used as residential quarters, but separate rooms in a residential building may be set apart as a restricted area.

Roentgen means the special unit of exposure. One roentgen (R) equals 2.58×10^{-4} coulombs/kilogram of air (*see* Exposure).

Scattered Primary Radiation means that scattered radiation that has been deviated in direction only by materials irradiated by the useful beam.

Scattered Radiation means ionizing radiation emitted by the interaction of ionizing radiation with matter, the interaction being accompanied by a change in direction of the radiation.

Sealed Source means any radioactive material that is used as a source of radiation and is encased in a capsule designed to prevent leakage or escape of the radioactive material.

Sealed Source and Device Registry means the national registry that contains the registration certificates, generated by both the Nuclear Regulatory Commission (NRC) and the Agreement States, that summarize the radiation safety information for sealed sources and devices, and describe the licensing and use conditions approved for the product.

Self-contained Breathing Apparatus (SCBA) means an atmosphere-supplying respirator for which the breathing air source is designed to be carried by the user.

Shallow Dose Equivalent (H_s), which applies to the external exposure of the skin or an extremity, means the dose equivalent at a tissue depth of 0.007 centimeter (7 mg/cm^2).

Shutter means a device attached to the tube housing assembly which can totally intercept the useful beam and which has a lead equivalency not less than that of the tube housing assembly.

SI means the abbreviation for the International System of Units.

Sievert means the SI unit of any of the quantities expressed as dose equivalent. The dose equivalent in sievert is equal to the absorbed dose in gray multiplied by the quality factor (one Sv = 100 rem).

Site Area Emergency means events may occur, are in progress, or have occurred that could lead to a significant release of radioactive material and that could require a response by off-site response organizations to protect persons offsite.

Site Boundary means that line beyond which the land or property is not owned, leased, or otherwise controlled by the licensee or registrant.

Source Material means:

(1) uranium or thorium, or any combination thereof, in any physical or chemical form; or

120.005: continued

(2) ores which contain by weight $^{1}/_{20}$ of one percent (0.05%) or more of:
(a) uranium;
(b) thorium; or
(c) any combination thereof.
Source material does not include special nuclear material.

Source Material Milling means any activity that results in the production of byproduct material as defined by 105 CMR 120.005: Byproduct Material(2).

Source of Radiation means any radioactive material or any device or equipment emitting, or capable of producing, radiation.

Source Traceability means the ability to show that a radioactive source has been calibrated either by the national standards laboratory of the National Institute of Standards and Technology (NIST), or by a laboratory which participates in a continuing measurement quality assurance program with NIST or other equivalent national or international program.

Special Form Radioactive Material means radioactive material which satisfies the following conditions:
(1) It is either a single solid piece or is contained in a sealed capsule that can be opened only by destroying the capsule;
(2) The piece or capsule has at least one dimension not less than five millimeters (0.2 inch); and
(3) It satisfies the requirements of 10 CFR 71.75. A special form encapsulation designed in accordance with the Nuclear Regulatory Commission requirements of 10 CFR 71.4 in effect on June 30, 1983 (*see* 10 CFR part 71, revised as of January 1, 1983), and constructed prior to July 1, 1985, may continue to be used. A special form encapsulation designed in accordance with the Nuclear Regulatory Commission requirements of 10 CFR 71.4 in effect on March 31, 1996 (*see* 10 CFR part 71, revised as of January 1, 1996), and constructed prior to April 1, 1998, may continue to be used. Special form material that was successfully tested before September 10, 2015 in accordance with the Nuclear Regulatory Commission requirements of 10 CFR 71.75(d) in effect before September 10, 2015 may continue to be used. Any other special form encapsulation must meet the specifications of Special Form Radioactive Material.

Special Nuclear Material means:
(1) Plutonium, uranium-233, uranium enriched in the isotope 233 or in the isotope 235, and any other material that the U.S. Nuclear Regulatory Commission, pursuant to the provisions of § 51 of the Atomic Energy Act of 1954, as amended, determines to be special nuclear material, but does not include source material; or
(2) Any material artificially enriched by any of the foregoing but does not include source material.

Special Nuclear Material in Quantities not Sufficient to Form a Critical Mass means uranium enriched in the isotope U-235 in quantities not exceeding 350 grams of contained U-235; uranium- 233 in quantities not exceeding 200 grams; plutonium in quantities not exceeding 200 grams; or any combination of them in accordance with the following formula: For each kind of special nuclear material, determine the ratio between the quantity of that special nuclear material and the quantity specified above for the same kind of special nuclear material. The sum of such ratios for all of the kinds of special nuclear material in combination shall not exceed one. For example, the following quantities in combination would not exceed the limitation and are within the formula:

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$$\frac{175 \text{ (grams U-235)}}{350} + \frac{50 \text{ (grams U-233)}}{200} + \frac{50 \text{ (grams Pu)}}{200} = 1$$

Supplied Air Respirator (SAR) or Airline Respirator means an atmosphere supplying respirator for which the source of breathing air is not designed to be carried by the user.

Survey means an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, and/or presence of sources of radiation. When appropriate, such evaluation includes, but is not limited to, tests, physical examinations, and measurements of levels of radiation or concentrations of radioactive material present.

Test means the process of verifying compliance with an applicable regulation.

Tight-fitting Facepiece means a respiratory inlet covering that forms a complete seal with the face.

Total Effective Dose Equivalent (TEDE) means the sum of the effective dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures).

Total Organ Dose Equivalent (TODE) means the sum of the deep dose equivalent and the committed dose equivalent to the organ receiving the highest dose as described in 105 CMR 120.267(A)(6).

Traceable to National Standard (*See* Instrument Traceability or Source Traceability)

U.S. Department of Energy means the Department of Energy established by Public Law 95-91, August 4, 1977, 91 Stat. 565, 42 U.S.C. 7101 *et seq*., to the extent that the Department exercises functions formerly vested in the U.S. Atomic Energy Commission, its Chairman, members, officers and components and transferred to the U.S. Energy Research and Development Administration and to the Administrator thereof pursuant to sections 104(b), (c) and (d) of the Energy Reorganization Act of 1974 (Public Law 93-438, October 11, 1974, 88 Stat. 1233 at 1237, effective January 19, 1975) and retransferred to the Secretary of Energy pursuant to section 301(a) of the Department of Energy Organization Act (Public Law 95-91, August 4, 1977, 91 Stat. 565 at 577-578, 42 U.S.C. 7151, effective October 1, 1977).

Unrefined and Unprocessed Ore means ore in its natural form prior to any processing, such as grinding, roasting, beneficiating, or refining. Processing does not include sieving or encapsulating of ore or preparation of samples for laboratory analysis.

Unrestricted Area (Uncontrolled Area) means area access to which is neither limited nor controlled by the licensee or registrant. For purposes of 105 CMR 120.000, Uncontrolled Area is an equivalent term.

User Seal Check (Fit Check) means an action conducted by the respirator user to determine if the respirator is properly seated to the face. Examples include negative pressure check, positive pressure check, irritant smoke check, or isoamyl acetate check.

Vendor means a supplier of products or services to be used by a licensee or registrant or a licensed or registered facility or activity.

Very High Radiation Area means an area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual receiving an absorbed dose in excess of 5 Gy (500 rad) in one hour at one meter from a source of radiation or one meter from any surface that the radiation penetrates. [*Note*: At very high doses rates, units of adsorbed dose, gray and rad, are appropriate, rather than units of dose equivalent, sievert and rem].

120.005: continued

Waste means those low-level radioactive wastes containing source, special nuclear, or byproduct material that are acceptable for disposal in a land disposal facility. For the purposes of this definition, low-level radioactive waste means radioactive waste not classified as high-level radioactive waste, transuranic waste, spent nuclear fuel, or byproduct material as defined in 105 CMR 120.005: Byproduct Material(2) and (3).

Waste Handling Licensees means persons licensed to receive and store radioactive wastes prior to disposal and/or persons licensed to dispose of radioactive waste.

Week means seven consecutive days starting on Sunday.

Whole Body means, for purposes of external exposure, head, trunk including male gonads, arms above the elbow, or legs above the knee.

Worker means an individual engaged in work under a license or registration issued by the Agency and controlled by a licensee or registrant, but does not include the licensee or registrant.

Working Level (WL) means any combination of short-lived radon daughters in one liter of air that will result in the ultimate emission of 1.3E+5 MeV of potential alpha particle energy. The short-lived radon daughters are -- for radon-222: polonium-218, lead-214, bismuth-214, and polonium-214; and for radon-220: polonium-216, lead-212, bismuth-212, and polonium-212.

Working Level Month (WLM) means an exposure to one working level for 170 hours - 2,000 working hours per year divided by 12 months per year is approximately equal to 170 hours per month.

Year means the period of time beginning in January used to determine compliance with the provisions of 105 CMR 120.000. The licensee or registrant may change the starting date of the year used to determine compliance by the licensee or registrant provided that the change is made at the beginning of the year and that no day is omitted or duplicated in consecutive years.

120.006: Exemptions

(A) General Provision. The Agency may, upon application therefore or upon its own initiative, grant such exemptions or exceptions from the requirements of 105 CMR 120.000 as it determines are authorized by law and will not result in undue hazard to public health and safety or property.

(B) U.S. Department of Energy Contractors and U.S. Nuclear Regulatory Commission Contractors. Any U.S. Department of Energy contractor or subcontractor and any U.S. Nuclear Regulatory Commission contractor or subcontractor of the following categories operating within this Commonwealth is exempt from 105 CMR 120.000 to the extent that such contractor or subcontractor under his contract receives, possesses, uses, transfers or acquires sources of radiation:

(1) Prime contractors performing work for the U.S. Department of Energy at U.S. Government-owned or Government-controlled sites, including the transportation of sources of radiation to or from such sites and the performance of contract services during temporary interruptions of such transportation;

(2) Prime contractors of the U.S. Department of Energy performing research in, or development, manufacture, storage, testing, or transportation of, atomic weapons or components thereof;

(3) Prime contractors of the U.S. Department of Energy using or operating nuclear reactors or other nuclear devices in a United States Government-owned vehicle or vessel; and,

(4) Any other prime contractor or subcontractor of the U.S. Department of Energy or of the U.S. Nuclear Regulatory Commission when the State and the U.S. Nuclear Regulatory Commission jointly determine:

120.016: continued

(c) Denial, Modification, Limitation, Revocation or Refusal to Renew a License or Certificate of Registration; Orders to Cease an Activity; Civil Penalties:

1. All adjudicatory proceedings shall be conducted in accordance with M.G.L. c. 30A and 801 CMR 1.00: *Standard Adjudicatory Rules of Practice and Procedures*.

2. Except for circumstances specified in 105 CMR 120.016(F)(4)(b), if the Department determines that a license or certificate of registration should be denied, modified, limited, revoked, or refused renewal, and/or that a facility should cease an activity, and/or that a civil penalty should be imposed, and if the Department notifies the applicant, licensee or registrant of its intended action, upon receipt of a Notice of Claim for an Adjudicatory Proceeding, the Department shall initiate a hearing pursuant to 801 CMR 1.00: *Standard Adjudicatory Rules of Practice and Procedures*.

3. The Hearing Officer shall determine whether the Department has proved by a preponderance of the evidence that the license or certificate of registration should be denied, modified, limited, revoked or refused renewal; that an activity should be ceased; and/or that a civil penalty be imposed based on relevant facts as they existed at or prior to the time the Department initiated the hearing procedure.

4. If the Hearing Officer finds any single ground for denial, modification, limitation, revocation, suspension, or refusal to renew a license or certificate of registration; for a cessation of an activity; and/or for imposition of a civil penalty, then the Hearing Officer shall render a recommended decision affirming the issuance of the Department's Order.

(d) Final Agency Decision and Judicial Review:

1. The recommended decision of a Hearing Officer in any adjudicatory proceeding conducted under 105 CMR 120.000 shall be reviewed by the Commissioner. The Commissioner's decision upon this review shall constitute a final agency decision in an adjudicatory proceeding subject to judicial review pursuant to M.G.L. c. 30A, § 14.

2. Any applicant, licensee or registrant that fails to exercise its right to an adjudicatory proceeding under 105 CMR 120.000 waives its right to an adjudicatory hearing, its right to administrative review by the Commissioner and its right to judicial review pursuant to M.G.L. c. 30A, § 14.

(G) Civil Penalties.

(1) If the Department determines, after a notice has been issued and an opportunity for a hearing has been provided, that a licensee, registrant or vendor has not complied with an order issued pursuant to M.G.L. c. 111, § 5O or with any provision of M.G.L. c. 111, §§ 5N through 5P or with any applicable rule, regulation, license or certificate of registration adopted or issued thereunder, the Department, in *lieu* of, or in addition to suspending, denying, modifying, limiting, revoking, or refusing renewal of a license or certificate of registration, may assess civil penalties in an amount not exceeding $100,000 per violation. Such civil penalty may be assessed whether or not the violation was willful.

(2) The decision whether to issue a civil penalty and the amount of any civil penalty depends on the facts of each case. Generally, civil penalties are most likely to be imposed for Severity Level I violations and if mitigating circumstances are absent, for Severity Level II violations. Civil penalties are considered for Severity Level III violations, and may be imposed for Severity Level IV violations that are similar to previous violations that occurred after the date of the last inspection or within two years, whichever period is greater for which the licensee did not take effective corrective action.

(3) Civil penalties may be assessed for known and conscious violations of the reporting requirements of 105 CMR 120.000 and for any willful violation of any Agency requirement including those at any severity level.

(4) Payment of civil penalties imposed under M.G.L. c. 111, § 5O shall be made by check, draft, or money order payable to the Commonwealth of Massachusetts, and mailed to the Radiation Control Program.

(5) Factors in Determining the Amount of Penalty. In determining the amount of the civil penalty, the Department shall consider the following:

(a) The willfulness of the violation;

(b) The actual and potential danger to the public health or the environment;

(c) The actual or potential costs of such danger to the public health or the environment;

120.016: continued

(d) The actual or potential damage or injury to the public health or environment;
(e) The actual and potential cost of such damage or injury;
(f) The actual or potential cost to the Commonwealth of enforcing provisions of 105 CMR 120.000;
(g) Whether the person being assessed the civil penalty did everything reasonable to prevent failure to, to come into compliance promptly, and to remedy and mitigate whatever harm might have been done as a result of the failure to comply;
(h) Whether the person being assessed the civil penalty has previously failed to comply with any order issued pursuant to M.G.L. c. 111, §§ 5N through 5P;
(i) Whether imposition of a civil penalty is likely to deter future non-compliance;
(j) The financial condition of the person being assessed the civil penalty; and
(k) The public interest.

(H) Escalation of Enforcement Sanctions.
(1) The Department considers violations of Severity Levels I, II or III to be of significant regulatory concern. When Severity Level I, II or III violations occur, the Department will, where necessary, issue orders in conjunction with civil penalties to achieve immediate corrective actions and to deter further recurrence of serious violations. The Department carefully considers the circumstances of each case in selecting and applying the sanction(s) appropriate to the case in accordance with the criteria described in 105 CMR 120.016(D).
(2) The progression of enforcement actions for similar violations will usually be based on similar violations at an individual facility and not on similar violations under the same license. However, under some circumstances, *e.g.*, where there is common control over some facet of facility operations, similar violations may be charged even though the second violation occurred at a different facility or under a different license. For example, a health physics violation at one division of a dual unit hospital that repeats an earlier violation of the other division might be considered similar.

(I) Criminal Enforcement. The Department may elect to enforce any section of 105 CMR 120.000 or provision of M.G.L. c. 111, § 5P by seeking to have criminal sanctions imposed. Any person who violates M.G.L. c. 111, § 5N or § 5O or any rule, regulation, license, registration, or order adopted or issued under said M.G.L. c. 111, § 5N or § 5O shall be fined not less than $100 nor more than $2,000, or be imprisoned for a period of not more than two years, or both. Any person who continues to violate the provisions of the aforementioned laws after due notice by the Department shall be fined not less than $1,000 nor more than $20,000 or be imprisoned for a period of not more than 20 years, or both. After due notice has been issued by the Department, each day of such violation shall constitute a separate offense.

(J) Judicial Enforcement. The Department may apply directly to the Supreme Judicial Court or Superior Court to enforce any provision of M.G.L. c. 111, §§ 5N through 5P and/or any rule or regulation, license, registration, or order adopted and issued thereunder by the Department. When a person is engaged in or about to engage in any act or practice which constitutes or will constitute a violation of such provision, rule, regulation, license, registration, or order, the Department may seek to restrain such act or practice or the use or occupation of premises or parts thereof or such other equitable relief as public health and safety requires.

(K) Nonexclusivity of Enforcement Procedures. None of the enforcement procedures contained in 105 CMR 120.000 are mutually exclusive. Any enforcement procedures may be invoked simultaneously if the situation so requires.

(L) Deliberate Misconduct.
(1) Any licensee; certificate of registration holder; quality assurance program approval holder; applicant for a license or certificate of registration or quality assurance program approval; employee of a licensee, certificate of registration holder, quality assurance program approval holder or applicant; or any contractor (including a supplier or consultant), subcontractor, employee of a contractor or subcontractor of any licensee or certificate of registration holder, quality assurance program approval holder or applicant for a license or certificate of registration or quality assurance program approval, who knowingly provides to any licensee, applicant, certificate holder, quality assurance program approval holder, contractor, or subcontractor, any components, equipment, materials, or other goods or services that relate to a licensee's, certificate holder's, quality assurance program approval holder's or applicant's activities in this part, may not:

120.016: continued

(a) Engage in deliberate misconduct that causes or would have caused, if not detected, a licensee, certificate of registration holder, quality assurance program approval holder or applicant to be in violation of any rule, regulation, or order; or any term, condition, or limitation of any license or certificate of registration or quality assurance program approval issued by the Agency; or

(b) Deliberately submit to the Agency, a licensee, certificate of registration holder, quality assurance program approval holder, an applicant, or a licensee's, certificate holder's, quality assurance program approval holder's or applicant's contractor or subcontractor, information that the person submitting the information knows to be incomplete or inaccurate in some respect material to the Agency.

(2) A person who violates 105 CMR 120.016(L)(1)(a) or (b) may be subject to enforcement action in accordance with the procedures in 105 CMR 120.016.

(3) For the purposes of 105 CMR 120.016(L)(1)(a), deliberate misconduct by a person means an intentional act or omission that the person knows:

(a) Would cause a licensee, certificate of registration holder, quality assurance program approval holder or applicant to be in violation of any rule, regulation, or order; or any term, condition, or limitation, of any license issued by the Agency; or

(b) Constitutes a violation of a requirement, procedure, instruction, contract, purchase order, or policy of a licensee, certificate of registration holder, quality assurance program approval holder, applicant, contractor, or subcontractor.

120.017: Severability

The provisions of 105 CMR 120.000 are severable. If any section, subsection, paragraph or provision is declared unconstitutional or invalid by a court of competent jurisdiction, the validity of the remaining provisions shall not be so affected.

120.018: Public Disclosure of Enforcement Actions

In accordance with M.G.L. c. 30A, the Administrative Procedures Act, all enforcement actions and licensees' responses are publicly available for inspection. In addition, press releases may be issued for civil penalties related to violations at Severity Level I, II, or III.

120.019: Appendix A – Severity Categories

The following examples of severity levels are neither exhaustive nor controlling. They reflect only the seriousness of the violation and not the intent of the violator, the history of the violator, the amount necessary to deter future violations, or efforts to correct the violation.

(A) Severity Level 1 – Most Significant Violations.

(1) Health Physics.

(a) Single exposure of a worker in excess of 25 rems of radiation to the whole body, 150 rems to the skin of the whole body, or 375 rems to the feet, ankles, hands or forearms;

(b) Annual whole body exposure of a member of the public in excess of 2.5 rems of radiation;

(c) Release of radioactive material to an unrestricted area in excess of ten times the limits of 105 CMR 120.253;

(d) Disposal of licensed material in quantities or concentrations in excess of ten times the limits of 105 CMR 120.253;

(e) Exposure of a worker in restricted areas of ten times the limits of 105 CMR 120.212.

(2) Transportation.

(a) Annual whole body radiation exposure of a member of the public in excess of 0.5 rems of radiation; or

(b) Breach of package integrity resulting in surface contamination or external radiation levels in excess of ten times the Agency limits.

(3) Materials Operations.

(a) Radiation levels, contamination levels, or releases that exceed ten times the limits specified in the license;

(b) A system designed to prevent or mitigate a serious safety event not being operable when actually required to perform its design function.

120.019: continued

(4) Miscellaneous Matters.

(a) A Material False Statement (MFS)[1] in which the statement made was deliberately false;

(b) Falsification of records which the Agency requires be kept of significant information in which the records were deliberately falsified by or with the knowledge of management; or,

(c) A knowing and intentional failure to provide any notice required by 105 CMR 120.000.

(d) Possession of licensable quantities of radioactive material without a license, or loss of control of a source of radiation.

(e) Refusing authorized Agency personnel access to facilities, records and/or equipment to conduct inspections or investigations.

(5) Emergency Preparedness. In an emergency, licensee failure to promptly:

(a) correctly identify the event;

(b) make required notifications to responsible Federal, State, and local agencies; or

(c) respond to the event (*e.g.*, assess actual or potential offsite consequences, activate emergency response facilities, and augment shift staff).

(B) Severity Level II -- Very Significant Violations.

(1) Health Physics.

(a) Single exposure of a worker in excess of 10 rems total effective dose equivalent, 30 rems to the lens of the eye or 100 rems to the skin of the whole body, or to the feet, ankles, hands or forearms or to any other organ or tissue;

(b) Annual whole body exposure of a member of the public in excess of 0.5 rems of radiation;

(c) Release of radioactive material to an unrestricted area in excess of five times the limits of 105 CMR 120.222;

(d) Failure to make an immediate notification as required by 105 CMR 120.282(A), and (B);

(e) Disposal of license material in quantities or concentrations in excess of five times the limits of 105 CMR 120.253;

(f) Exposure of a worker in restricted areas in excess of five times the limits of 105 CMR 120.212.

(g) An x-ray system having a malfunction such that inadvertent exposures could occur *e.g.*, a system such that when the exposure switch is activated, not one but repeated exposures occur, or the timer fails to terminate exposure, or exposure initiated without utilizing the exposure switch.

(h) A fluoroscopic x-ray system with a tabletop entrance exposure rate of greater than or equal to 25 R/min. at the point where the center of the useful beam enters the patient, except:

a. During recording of fluoroscopic images; or,

b. When an optional high level control is activated.

(i) A fluoroscopic system such that the entire x-ray beam is not intercepted by the primary protective barrier; or,

(j) Therapy systems which exhibit excessive leakage and/or inoperable door interlocks, shutters, timers, *etc*.

(k) Therapy system, with improper operator/patient communication/observation.

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[1] In essence, a Material False Statement is a statement that is false by omission or commission and is relevant to the regulatory process. As can be seen in the examples, in determining the specific severity level of a violation involving material false statements or falsification of records, consideration will be given to such factors as the position of the person involved in the violation (*e.g.*, first line supervisor or senior manager), the significance of the information involved, and the intent of the violator (*i.e.*, negligence not amounting to careless disregard or deliberateness). The relative weight given to each of these factors will be dependent on the circumstances of the violation.

120.070: continued

(B) The results of the review, along with any recommendations, must be documented. Each review report must identify conditions that are adverse to the proper performance of the security program, the cause of the condition(s), and, when appropriate, recommend corrective actions, and corrective actions taken. The licensee shall review the findings and take any additional corrective actions necessary to preclude repetition of the condition, including reassessment of the deficient areas where indicated.

(C) The licensee shall maintain the review documentation for three years.

120.071: Reporting of Events

(A) The licensee shall immediately notify the LLEA after determining that an unauthorized entry resulted in an actual or attempted theft, sabotage, or diversion of a category 1 or category 2 quantity of radioactive material. As soon as possible after initiating a response, but not at the expense of causing delay or interfering with the LLEA response to the event, the licensee shall notify the Agency by telephone. In no case shall the notification to the Agency be later than four hours after the discovery of any attempted or actual theft, sabotage, or diversion.

(B) The licensee shall assess any suspicious activity related to possible theft, sabotage, or diversion of category 1 or category 2 quantities of radioactive material and notify the LLEA as appropriate. As soon as possible but not later than four hours after notifying the LLEA, the licensee shall notify the Agency by telephone.

(C) The initial telephonic notification required by 105 CMR 120.071(A) must be followed within a period of 30 days by a written report submitted to the Agency by an appropriate method listed in 105 CMR 120.054. The report must include sufficient information for Agency analysis and evaluation, including identification of any necessary corrective actions to prevent future instances.

PHYSICAL PROTECTION IN TRANSIT

120.072: Additional Requirements for Transfer of Category 1 and Category 2 Quantities of Radioactive Material

A licensee transferring a category 1 or category 2 quantity of radioactive material to a licensee of the Agency, U.S. Nuclear Regulatory Commission, or an Agreement State shall meet the license verification provisions of 105 CMR 120.072(A) through (D) instead of those listed in 105 CMR 120.140(D):

(A) Any licensee transferring category 1 quantities of radioactive material to a licensee of the Agency, U.S. Nuclear Regulatory Commission, or an Agreement State, prior to conducting such transfer, shall verify with the NRC's license verification system or the license issuing authority that the transferee's license authorizes the receipt of the type, form, and quantity of radioactive material to be transferred and that the licensee is authorized to receive radioactive material at the location requested for delivery. If the verification is conducted by contacting the license issuing authority, the transferor shall document the verification. For transfers within the same organization, the licensee does not need to verify the transfer.

(B) Any licensee transferring category 2 quantities of radioactive material to a licensee of the Agency, U.S. Nuclear Regulatory Commission, or an Agreement State, prior to conducting such transfer, shall verify with the NRC's license verification system or the license issuing authority that the transferee's license authorizes the receipt of the type, form, and quantity of radioactive material to be transferred. If the verification is conducted by contacting the license issuing authority, the transferor shall document the verification. For transfers within the same organization, the licensee does not need to verify the transfer.

120.072: continued

(C) In an emergency where the licensee cannot reach the license issuing authority and the license verification system is nonfunctional, the licensee may accept a written certification by the transferee that it is authorized by license to receive the type, form, and quantity of radioactive material to be transferred. The certification must include the license number, current revision number, issuing agency, expiration date, and for a category 1 shipment the authorized address. The licensee shall keep a copy of the certification. The certification must be confirmed by use of the NRC's license verification system or by contacting the license issuing authority by the end of the next business day.

(D) The transferor shall keep a copy of the verification documentation as a record for three years.

120.073: Applicability of Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material During Transit

(A) For shipments of category 1 quantities of radioactive material, each shipping licensee shall comply with the requirements for physical protection contained in 105 CMR 120.074(A) and (E); 120.075; 120.076(A)(1), (B)(1) and (C); and 120.077(A), (C), (E), (G), and (H).

(B) For shipments of category 2 quantities of radioactive material, each shipping licensee shall comply with the requirements for physical protection contained in 105 CMR 120.074(B) through (E); 120.076(A)(2) and (3) and (B)(2), and (C); and 120.077(B), (D), (F), (G), and (H). For those shipments of category 2 quantities of radioactive material that meet the criteria of 105 CMR 120.790(B), the shipping licensee shall also comply with the advance notification provisions of 105 CMR 120.790.

(C) The shipping licensee shall be responsible for meeting the requirements of 105 CMR 120.072 through 120.077 unless the receiving licensee has agreed in writing to arrange for the in-transit physical protection required under 105 CMR 120.072 through 120.077.

(D) Each licensee that imports or exports category 1 quantities of radioactive material shall comply with the requirements for physical protection during transit contained in 105 CMR 120.074(A)(2) and (E); 120.075; 120.076(A)(1), (B)(1), and (C); and 120.077(A), (C), (E), (G), and (H) for the domestic portion of the shipment.

(E) Each licensee that imports or exports category 2 quantities of radioactive material shall comply with the requirements for physical protection during transit contained in 105 CMR 120.076(A)(2) and (3), and (B)(2); and 120.077(B), (D), (F), (G), and (H) for the domestic portion of the shipment.

120.074: Pre-planning and Coordination of Shipment of Category 1 or Category 2 Quantities of Radioactive Material

(A) Each licensee that plans to transport, or deliver to a carrier for transport, licensed material that is a category 1 quantity of radioactive material outside the confines of the licensee's facility or other place of use or storage shall:

(1) Pre-plan and coordinate shipment arrival and departure times with the receiving licensee;

(2) Pre-plan and coordinate shipment information with the governor or the governor's designee of any State through which the shipment will pass to:

(a) Discuss the State's intention to provide law enforcement escorts; and

(b) Identify safe havens; and

(3) Document the pre-planning and coordination activities.

(B) Each licensee that plans to transport, or deliver to a carrier for transport, licensed material that is a category 2 quantity of radioactive material outside the confines of the licensee's facility or other place of use or storage shall coordinate the shipment no-later-than arrival time and the expected shipment arrival with the receiving licensee. The licensee shall document the coordination activities.

120.102: continued

(7) Building of service facilities (*e.g.*, paved roads, parking lots, railroad spurs, exterior utility and lighting systems, potable water systems, sanitary sewerage treatment facilities, and transmission lines);
(8) Procurement or fabrication of components or portions of the proposed facility occurring at other than the final, in-place location at the facility; or
(9) Taking any other action that has no reasonable nexus to radiological health and safety.

Decommissioning Funding Plan means a written document that contains a cost estimate for decommissioning and a description of the method for assuring for decommissioning, including means of adjusting cost estimates and associated funding levels periodically over the life of the facility.

Facility means the location within one building, vehicle, or under one roof and under the same administrative control:
(1) at which the possession, use, processing or storage of radioactive material is or was authorized; or
(2) at which one or more radioactivity-inducing machines are installed or located.
Facility may also mean multiple such locations at a site or part of a site.

Financial Surety means the method of assuring that sufficient funds will be available at the time of license termination and decommissioning of the facility to cover all costs associated with the decommissioning.

Site means the area contained within the boundary of a location under the control of persons generating or storing radioactive materials.

Site Area Emergency means events may occur, are in progress, or have occurred that could lead to a significant release of radioactive material and that could require a response by offsite response organizations to protect persons offsite.

120.103: Source Material

(A) Any person is exempt from 105 CMR 120.100 to the extent that such person receives, possesses, uses, owns, or transfers source material in any chemical mixture, compound, solution, or alloy in which the source material is by weight less than $^{1}/_{20}$ of 1% (0.05%) of the mixture, compound, solution, or alloy.

(B) Any person is exempt from 105 CMR 120.100 to the extent that such person receives, possesses, uses, or transfers unrefined and unprocessed ore containing source material; provided that, except as authorized in a specific license, such person shall not refine or process such ore.

(C) Any person is exempt from 105 CMR 120.100, 120.200 and 120.750 to the extent that such person receives, possesses, uses, or transfers:
(1) any quantities of thorium contained in:
(a) incandescent gas mantles;
(b) vacuum tubes;
(c) welding rods;
(d) electric lamps for illuminating purposes provided that each lamp does not contain more than 50 milligrams of thorium;
(e) germicidal lamps, sunlamps, and lamps for outdoor or industrial lighting provided that each lamp does not contain more than two grams of thorium;
(f) rare earth metals and compounds, mixtures, and products containing not more than 0.25% by weight thorium, uranium, or any combination of these; or
(g) personnel neutron dosimeters, provided that each dosimeter does not contain more than 50 milligrams of thorium;
(2) source material contained in the following products:
(a) glazed ceramic tableware manufactured before August 27, 2013, provided that the glaze contains not more than 20% by weight source material;
(b) glassware containing not more than 2% by weight source material or, for glassware manufactured before August 27, 2013, 10% by weight source material; but not including commercially manufactured glass brick, pane glass, ceramic tile, or other glass or ceramic used in construction;

120.103: continued

(c) glass enamel or glass enamel frit containing not more than 10% by weight source material imported or ordered for importation into the United States, or initially distributed by manufacturers in the United States, before July 25, 1983; or

(d) piezoelectric ceramic containing not more than 2% by weight source material.

(3) photographic film, negatives, and prints containing uranium or thorium;

(4) any finished product or part fabricated of, or containing, tungsten-thorium or magnesium-thorium alloys, provided that the thorium content of the alloy does not exceed 4% by weight and that this exemption shall not be deemed to authorize the chemical, physical, or metallurgical treatment or processing of any such product or part;

(5) uranium contained in counterweights installed in aircraft, rockets, projectiles, and missiles, or stored or handled in connection with installation or removal of such counterweights, provided that:

(a) each counterweight has been impressed with the following legend clearly legible through any plating or other covering: "DEPLETED URANIUM"[1];

(b) each counterweight is durably and legibly labeled or marked with the identification of the manufacturer and the statement: "UNAUTHORIZED ALTERATIONS PROHIBITED"[1]; and

(c) this exemption shall not be deemed to authorize the chemical, physical, or metallurgical treatment or processing of any such counterweights other than repair or restoration of any plating or other covering.

(6) natural or depleted uranium metal used as shielding constituting part of any shipping container, provided that:

(a) the shipping container is conspicuously and legibly impressed with the legend "CAUTION - RADIOACTIVE SHIELDING - URANIUM"; and

(b) the uranium metal is encased in mild steel or equally fire resistant metal of minimum wall thickness of ⅛ inch (3.2 mm);

(7) thorium or uranium contained in or on finished optical lenses and mirrors, provided that each lens or mirror does not contain more than 10% by weight of thorium or uranium or, for lenses manufactured before August 27, 2013, 30% by weight of thorium; and that this exemption shall not be deemed to authorize either:

(a) the shaping, grinding, or polishing of such lens or mirror or manufacturing processes other than the assembly of such lens or mirror into optical systems and devices without any alteration of the lens or mirror; or

(b) the receipt, possession, use, or transfer of thorium or uranium contained in contact lenses, or in spectacles, or in eyepieces in binoculars or other optical instruments.

(8) thorium contained in any finished aircraft engine part containing nickel-thoria alloy, provided that:

(a) the thorium is dispersed in the nickel-thoria alloy in the form of finely divided thoria (thorium dioxide); and

(b) the thorium content in the nickel-thoria alloy does not exceed 4% by weight.

(D) The exemptions in 105 CMR 120.103(C) do not authorize the manufacture of any of the products described.

(E) No person may initially transfer for sale or distribution a product containing source material to persons exempt under 105 CMR 120.103(C), or equivalent regulations of the NRC or an Agreement State, unless authorized by a license issued by the NRC under 10 CFR 40.52 to initially transfer such products for sale or distribution. Persons authorized to manufacture, process, or produce these materials or products containing source material under a specific license issued by the Agency, and persons who import finished products or parts, for sale or distribution must be authorized by a license issued by NRC under 10 CFR 40.52 for distribution only and are exempt from the requirements of 10 CFR 19, 20 and 40.32(b) and (c).

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[1] The requirements specified in 105 CMR 120.103(C)(5)(a) and (b) need not be met by counterweights manufactured prior to December 31, 1969; provided that such counterweights were manufactured under a specific license issued by the Atomic Energy Commission and are impressed with the legend, "CAUTION - RADIOACTIVE MATERIAL - URANIUM", as previously required by 105 CMR 120.000.

120.104: continued

2. Each instrument contains no more than ten exempt quantities. For purposes of this requirement, an instrument's source(s) may contain either one or different types of radionuclides and an individual exempt quantity may be composed of fractional parts of one or more of the exempt quantities in 105 CMR 120.196: *Appendix B, Table 1*, provided that the sum of such fractions shall not exceed unity.

3. For americium-241, 0.05 microcurie (1.85 kBq) is considered an exempt quantity under 105 CMR 120.104(C)(1)(f).

(g) 1. Static elimination devices which contain, as a sealed source or sources, byproduct material consisting of a total of not more than 18.5 MBq (500 µCi) of polonium-210 per device.

2. Ion generating tubes designed for ionization of air that contain, as a sealed source or sources, byproduct material consisting of a total of not more than 18.5 MBq (500 µCi) of polonium-210 per device or of a total of not more than 1.85 GBq (50 mCi) of hydrogen-3 (tritium) per device.

3. Such devices authorized before October 23, 2012 for use under the general license then provided in 105 CMR 120.122(A) and equivalent regulations of the U.S. Nuclear Regulatory Commission and Agreement States and manufactured, tested, and labeled by the manufacturer in accordance with the specifications contained in a specific license issued by the U.S. Nuclear Regulatory Commission.

(h) Any person who desires to apply byproduct material to, or to incorporate byproduct material into, the products exempted in 105 CMR 120.104(C)(1), or who desires to initially transfer for sale or distribution such products containing byproduct material, should apply to the Nuclear Regulatory Commission for a specific license pursuant to 10 CFR 32.14, which license states that the product may be distributed by the licensee to persons exempt from the regulations pursuant to 105 CMR 120.104(C)(1) or equivalent regulations of the Nuclear Regulatory Commission, 10 CFR 30.15(a).

(2) Self-luminous Products Containing Radioactive Material.

(a) Tritium, Krypton-85, or Promethium-147. Except for persons who manufacture, process, produce, or initially transfer for sale or distribution self-luminous products containing tritium, krypton-85, or promethium-147, any person is exempt from 105 CMR 120.100 to the extent that such person receives, possesses, uses, transfers, owns, or acquires tritium, krypton-85 or promethium-147 in self-luminous products manufactured, processed, produced, or initially transferred in accordance with a specific license issued by the NRC pursuant to 10 CFR Part 32, § 32.22 which license authorizes the transfer of the product to persons who are exempt from regulatory requirements.

Any person who desires to manufacture, process, or produce, or initially transfer for sale or distribution self-luminous products containing tritium, krypton-85, or promethium-147 for use under 105 CMR 120.104(C)(2), should apply to the NRC for a license under 10 CFR 32.22 and for a certificate of registration in accordance with 105 CMR 120.128(N). The exemption in 105 CMR 120.104(C)(2) does not apply to tritium, krypton-85, or promethium-147 used in products primarily for frivolous purposes or in toys or adornments.

(b) Radium-226. Any person is exempt from 105 CMR 120.100 to the extent that such person receives, possesses, uses, transfers, or owns articles containing less than 0.1 microcurie (3.7 kBq) of radium-226 which were acquired prior to March 11, 1994.

(3) Gas and Aerosol Detectors Containing Radioactive Material.

(a) Except for persons who manufacture, process, produce, or initially transfer for sale or distribution gas and aerosol detectors containing byproduct material, any person is exempt from the requirement of a license set forth in 105 CMR 120.100 to the extent that such person receives, possesses, uses, transfers, owns, or acquires byproduct material in gas and aerosol detectors designed to protect health, safety, or property provided that detectors containing byproduct material shall have been manufactured, processed, produced, or initially transferred in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to 10 CFR Part 32, § 32.26, which license authorizes the initial transfer of the product for use under 105 CMR 120.104(C)(3). 105 CMR 120.104(C)(3) also covers gas and aerosol detectors manufactured or distributed before November 30, 2007 in accordance with a specific license issued by a State under comparable provisions to 10 CFR 32.26 authorizing distribution to persons exempt from regulatory requirements.

120.104: continued

(b) Any person who desires to manufacture, process, or produce gas and aerosol detectors containing byproduct material, or to initially transfer such products for use pursuant 105 CMR 120.104(C)(3)(a), should apply to the NRC for a license pursuant to 10 CFR 32.26 and for a certificate of registration in accordance with 105 CMR 120.128(N).

(4) Radioactive Drug: Capsules Containing Carbon-14 Urea for *In Vivo* Diagnostic Use for Humans.

(a) Except as provided in 105 CMR 120.104(C)(4)(b) and (c), any person is exempt from the requirements for a license set forth in M.G.L. c. 111, § 5P and from 105 CMR 120.100 and 120.500 provided that such person receives, possesses, uses, transfers, owns, or acquires capsules containing 37 kBq (1μ Ci) carbon-14 urea (allowing for nominal variation that may occur during the manufacturing process) each, for *in vivo* diagnostic use for humans.

(b) Any persons who desires to use the capsules for research involving human subjects shall apply for and receive a specific license pursuant to 105 CMR 120.500.

(c) Any person who desires to manufacture, prepare, process, produce, package, or transfer for commercial distribution such capsules shall apply, to NRC, for and receive a specific license pursuant to 10 CFR 32.21.

(d) Nothing in 105 CMR 120.104(C)(4) relieves persons from complying with applicable FDA, other Federal, and State requirements governing receipt, administration, and use of drugs.

(5) Certain Industrial Devices.

(a) Except for persons who manufacture, process, produce, or initially transfer for sale or distribution industrial devices containing byproduct material designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation leakage, or qualitative or quantitative chemical composition, or for producing an ionized atmosphere, any person is exempt from the requirement of a license set forth in 105 CMR 120.100 to the extent that such person receives, possesses, uses, transfers, owns, or acquires byproduct material, in these certain detecting, measuring, gauging, or controlling devices and certain devices for producing an ionized atmosphere, and manufactured, processed, produced, or initially transferred in accordance with a specific license issued by the NRC under 10 CFR 32.30, which license authorizes the initial transfer of the device for use under 105 CMR 120.104(C)(5). This exemption does not cover sources not incorporated into a device, such as calibration and reference sources.

(b) Any person who desires to manufacture, process, or produce, or initially transfer for sale or distribution industrial devices containing byproduct material for use pursuant 105 CMR 120.104(C)(5), should apply to the NRC for a license under 10 CFR 32.30 and for a certificate of registration in accordance with 105 CMR 120.128(N).

120.120: Types of Licenses

Licenses for radioactive materials are of two types: general and specific.

(A) The Agency issues a specific license to a named person who has filed an application for the license under the provisions of 105 CMR 120.124.

(B) A general license is provided by regulation, grants authority to a person for certain activities involving radioactive material, and is effective without the filing of an application with the Agency or the issuance of a licensing document to a particular person. However, registration with the Agency may be required by the particular general license.

120.121: General Licenses - Source Material

(A) A general license is hereby issued authorizing commercial and industrial firms; research, educational, and medical institutions; and state and local government agencies to receive, possess, use, and transfer uranium and thorium, in their natural isotopic concentrations and in the form of depleted uranium, for research, development, educational, commercial, or operational purposes in the following forms and quantities:

120.121: continued

(1) No more than 1.5 kg (3.3 lb) of uranium and thorium in dispersible forms (*e.g.*, gaseous, liquid, powder, *etc.*) at any one time. Any material processed by the general licensee that alters the chemical or physical form of the material containing source material must be accounted for as a dispersible form. A person authorized to possess, use, and transfer source material under 105 CMR 120.121(A)(1) may not receive more than a total of 7 kg (15.4 lb) of uranium and thorium in any one calendar year; and

(2) No more than a total of 7 kg (15.4 lb) of uranium and thorium at any one time. A person authorized to possess, use, and transfer source material under 105 CMR 120.121(A)(2) may not receive more than a total of 70 kg (154 lb) of uranium and thorium in any one calendar year. A person may not alter the chemical or physical form of the source material possessed under 105 CMR 120.121(A)(2) unless it is accounted for under the limits of 105 CMR 120.121(A)(1); or

(3) No more than 7 kg (15.4 lb) of uranium, removed during the treatment of drinking water, at any one time. A person may not remove more than 70 kg (154 lb) of uranium from drinking water during a calendar year under 105 CMR 120.121(A)(3); or

(4) No more than 7 kg (15.4 lb) of uranium and thorium at laboratories for the purpose of determining the concentration of uranium and thorium contained within the material being analyzed at any one time. A person authorized to possess, use, and transfer source material under 105 CMR 120.121(A)(4) may not receive more than a total of 70 kg (154 lb) of source material in any one calendar year.

(B) Any person who receives, possesses, uses, or transfers source material pursuant to the general license issued in 105 CMR 120.121(A):

(1) Is prohibited from administering source material, or the radiation therefrom, either externally or internally, to human beings except as may be authorized by the Agency in a specific license.

(2) Shall not abandon such source material. Source material may be disposed of as follows:

(a) A cumulative total of 0.5 kg (1.1 lb) of source material in a solid, non-dispersible form may be transferred each calendar year, by a person authorized to receive, possess, use, and transfer source material under this general license to persons receiving the material for permanent disposal. The recipient of source material transferred under the provisions of 105 CMR 120.121(B)(2)(a) is exempt from the requirements to obtain a license under 105 CMR 120.100 to the extent the source material is permanently disposed. 105 CMR 120.121(B)(2)(a) does not apply to any person who is in possession of source material under a specific license issued under 105 CMR 120.100; or

(b) In accordance with 105 CMR 120.251.

(3) Is subject to the provisions in 105 CMR 120.001 through 120.019, 120.101(A), 120.131(A) through (C), 120.140, 120.142, and 120.150.

(4) Shall respond to written requests from the Agency to provide information relating to the general license within 30 calendar days of the date of the request, or other time specified in the request. If the person cannot provide the requested information within the allotted time, the person shall, within that same time period, request a longer period to supply the information by providing the Agency, using an appropriate method listed in 105 CMR 120.013, a written justification for the request;

(5) Shall not export such source material except in accordance with 10 CFR Part 110.

(C) Any person who receives, possesses, uses, or transfers source material in accordance with 105 CMR 120.121(A) shall conduct activities so as to minimize contamination of the facility and the environment. When activities involving such source material are permanently ceased at any site, if evidence of significant contamination is identified, the general licensee shall notify the Agency by an appropriate method listed in 105 CMR 120.013 about such contamination and may consult with the Agency as to the appropriateness of sampling and restoration activities to ensure that any contamination or residual source material remaining at the site where source material was used under this general license is not likely to result in exposures that exceed the limits in 105 CMR 120.245.

(D) A general license is hereby issued authorizing the receipt of title to source material without regard to quantity. This general license does not authorize any person to receive, possess, use, or transfer source material.

120.121: continued

(E) Depleted Uranium in Industrial Products and Devices.

(1) A general license is hereby issued to receive, acquire, possess, use, or transfer, in accordance with the provisions of 105 CMR 120.121(E)(2) through (5), depleted uranium contained in industrial products or devices for the purpose of providing a concentrated mass in a small volume of the product or device.

(2) The general license in 105 CMR 120.121(E)(1) applies only to industrial products or devices which have been manufactured either in accordance with a specific license issued to the manufacturer of the products or devices pursuant to 105 CMR 120.128(M) or in accordance with a specific license issued to the manufacturer by the U.S. Nuclear Regulatory Commission or an Agreement State which authorizes manufacture of the products or devices for distribution to persons generally licensed by the U.S. Nuclear Regulatory Commission or an Agreement State.

(3) (a) Persons who receive, acquire, possess, or use depleted uranium pursuant to the general license established by 105 CMR 120.121(E)(1) shall file form MRCP 120.100-1 "Certificate - Use of Depleted Uranium Under General License", with the Agency. The form shall be submitted within 30 days after the first receipt or acquisition of such depleted uranium. The general licensee shall furnish on form MRCP 120.100-1 the following information and such other information as may be required by that form:

1. name and address of the general licensee;

2. a statement that the general licensee has developed and will maintain procedures designed to establish physical control over the depleted uranium described in 105 CMR 120.121(E)(1) and designed to prevent transfer of such depleted uranium in any form, including metal scrap, to persons not authorized to receive the depleted uranium; and

3. name and title, address, and telephone number of the individual duly authorized to act for and on behalf of the general licensee in supervising the procedures identified in 105 CMR 120.121(E)(3)(a)2.

(b) The general licensee possessing or using depleted uranium under the general license established by 105 CMR 120.121(E)(1) shall report in writing to the Agency any changes in information furnished by him in form MRCP 120.100-1 "Certificate - Use of Depleted Uranium Under General License". The report shall be submitted within 30 days after the effective date of such change.

(4) A person who receives, acquires, possesses, or uses depleted uranium pursuant to the general license established by 105 CMR 120.121(E)(1):

(a) shall not introduce such depleted uranium, in any form, into a chemical, physical, or metallurgical treatment or process, except a treatment or process for repair or restoration of any plating or other covering of the depleted uranium;

(b) shall not abandon such depleted uranium;

(c) shall transfer or dispose of such depleted uranium only by transfer in accordance with the provisions of 105 CMR 120.140. In the case where the transferee receives the depleted uranium pursuant to the general license established by 105 CMR 120.121(E)(1), the transferor shall furnish the transferee a copy of 105 CMR 120.100 and a copy of form MRCP 120.100-1. In the case where the transferee receives the depleted uranium pursuant to a general license contained in the U.S. Nuclear Regulatory Commission's or Agreement State's regulation equivalent to 105 CMR 120.121(E)(1), the transferor shall furnish the transferee a copy of 105 CMR 120.100 and a copy of form MRCP 120.100-1 accompanied by a note explaining that use of the product or device is regulated by the U.S. Nuclear Regulatory Commission or Agreement State under requirements substantially the same as those in 105 CMR 120.100;

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(d) within 30 days of any transfer, shall report in writing to the Agency the name and address of the person receiving the depleted uranium pursuant to such transfer; and

(e) shall not export such depleted uranium except in accordance with a license issued by the U.S. Nuclear Regulatory Commission pursuant to 10 CFR Part 110.

(5) Any person receiving, acquiring, possessing, using, or transferring depleted uranium pursuant to the general license established by 105 CMR 120.121(E)(1) is exempt from the requirements of 105 CMR 120.200 and 120.750 with respect to the depleted uranium covered by that general license.

(F) Any person who receives, possesses, uses, or transfers source material in accordance with the general license granted in 105 CMR 120.121(A) is exempt from the provisions of 105 CMR 120.200 and 120.750 to the extent that such receipt, possession, use, and transfer are within the terms of this general license, except that such person shall comply with the provisions of 105 CMR 120.245 and 120.251 to the extent necessary to meet the provisions of 105 CMR 120.121(B)(2) and 120.121(C). However, this exemption does not apply to any person who also holds a specific license issued under 105 CMR 120.100.

(G) No person may initially transfer or distribute source material to persons generally licensed under 105 CMR 120.121(A)(1) or (2), or equivalent regulations of the NRC or an Agreement State, unless authorized by a specific license issued in accordance with 105 CMR 120.128(B) or equivalent provisions of the NRC or an Agreement State. This prohibition does not apply to analytical laboratories returning processed samples to the client who initially provided the sample.

120.122: General Licenses - Radioactive Material Other than Source Material

(A) Requirements for Other General Licenses (Reserved).

(B) Luminous Safety Devices for Aircraft.

(1) A general license is hereby issued to own, receive, acquire, possess, and use tritium or promethium-147 contained in luminous safety devices for use in aircraft, provided:

(a) each device contains not more than 10 curies (370 GBq) of tritium or 300 millicuries (11.1 GBq) of promethium-147; and

(b) each device has been manufactured, assembled or imported in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission, or each device has been manufactured or assembled in accordance with the specifications contained in a specific license issued by the Agency or any Agreement State to the manufacturer or assembler of such device pursuant to licensing requirements equivalent to those in 10 CFR Part 32, § 32.53.

(2) Persons who own, receive, acquire, possess, or use luminous safety devices pursuant to the general license in 105 CMR 120.122(B)(1) are exempt from the requirements of 105 CMR 120.200 through 120.299 and 120.750 through 120.760 except that they shall comply with the provisions of 105 CMR 120.281 and 120.282.

(3) This general license does not authorize the manufacture, assembly, or repair of luminous safety devices containing tritium or promethium-147.

(4) This general license does not authorize the ownership, receipt, acquisition, possession or use of promethium-147 contained in instrument dials.

(5) This general license is subject to the provisions of 105 CMR 120.005 through 120.016, 120.131, 120.140, 120.150, and 120.770 through 120.798.

(C) Requirements for Other General Licenses (Reserved).

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(D) Certain Detecting, Measuring, Gauging, or Controlling Devices and Certain Devices for Producing Light or an Ionized Atmosphere.

(1) A general license is hereby issued to commercial and industrial firms and research, educational and medical institutions, individuals in the conduct of their business, and State or local government agencies to acquire, receive, possess, use or transfer in accordance with the provisions of 105 CMR 120.122(D)(2) through (4), radioactive material, excluding special nuclear material, contained in devices designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing light or an ionized atmosphere.

(2)(a) The general license in 105 CMR 120.122(D)(1) applies only to radioactive material contained in devices which have been manufactured or initially transferred and labeled in accordance with the specifications contained in:

1. a specific license issued by the Agency pursuant to 105 CMR 120.128(D); or

2. an equivalent specific license issued by the U.S. Nuclear Regulatory Commission, an Agreement State, or an equivalent specific license issued by a State with provisions comparable to 105 CMR 120.128(D).

(b) The devices must have been received from one of the specific licensees described in 105 CMR 120.122(D)(2)(a) or through a transfer made under 105 CMR 120.122(D)(3)(i).

(3) Any person who owns, receives, acquires, possesses, uses, or transfers radioactive material in a device pursuant to the general license in 105 CMR 120.122(D)(1):

(a) shall assure that all labels affixed to the device at the time of receipt, and bearing a statement that removal of the label is prohibited, are maintained thereon and shall comply with all instructions and precautions provided by such labels;

(b) shall assure that the device is tested for leakage of radioactive material and proper operation of the "on-off" mechanism and indicator, if any, at no longer than six-month intervals or at such other intervals as are specified in the label, however,

1. devices containing only krypton need not be tested for leakage of radioactive material; and

2. devices containing only tritium or not more than 100 microcuries (3.7 MBq) of other beta and/or gamma-emitting material or ten microcuries (0.37 MBq) of alpha-emitting material and devices held in storage in the original shipping container prior to initial installation need not be tested for any purpose;

(c) shall assure that the tests required under 105 CMR 120.122(D)(3)(b) and other testing, installation, servicing, and removal from installation involving the radioactive material, its shielding or containment, are performed:

1. in accordance with the instructions provided by the labels; or

2. by a person holding an applicable specific license from the Agency, the U.S. Nuclear Regulatory Commission, or an Agreement State to perform such activities;

(d) shall maintain records showing compliance with the requirements of 105 CMR 120.122(D)(3)(b) and (c). The records shall show the results of tests. The records also shall show the dates of performance of, and the names of persons performing, testing, installation, servicing, and removal from installation concerning the radioactive material, its shielding or containment. The licensee shall retain these records as follows:

1. each record of a test for leakage of radioactive material required by 105 CMR 120.122(D)(3)(b) shall be retained for three years after the next required leak test is performed or until the sealed source is transferred or disposed of;

2. each record of a test of the "on-off" mechanism and indicator required by 105 CMR 120.122(D)(3)(b) shall be retained for three years after the next required test of the "on-off" mechanism and indicator is performed or until the sealed source is transferred or disposed of; and

3. each record that is required by 105 CMR 120.122(D)(3)(c) shall be maintained for a period of three years from the date of the recorded event or until the device is transferred or disposed of;

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(5) The physician, veterinarian, clinical laboratory or hospital possessing or using radioactive material under the general license of 105 CMR 120.122(I)(1) shall report in writing to the Agency, any changes in the information furnished by him in the "Certificate - *In Vitro* Testing with Radioactive Material Under General License", form MRCP 120.100-2. The report shall be furnished within 30 days after the effective date of such change.

(6) Any person using radioactive material pursuant to the general license of 105 CMR 120.122(I)(1) is exempt from the requirements of 105 CMR 120.200 and 120.750 with respect to radioactive material covered by that general license, except that such persons using the Mock Iodine-125 described in 105 CMR 120.122(I)(1)(e) shall comply with the provisions of 105 CMR 120.251, 120.281 and 120.282.

(J) Ice Detection Devices.

(1) A general license is hereby issued to own, receive, acquire, possess, use, and transfer strontium-90 contained in ice detection devices, provided each device contains not more than 50 microcuries (1.85 MBq) of strontium-90 and each device has been manufactured or imported in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission or each device has been manufactured in accordance with the specifications contained in a specific license issued by the Agency or an Agreement State to the manufacturer of such device pursuant to licensing requirements equivalent to those in 10 CFR Part 32, § 32.61.

(2) Persons who own, receive, acquire, possess, use, or transfer strontium-90 contained in ice detection devices pursuant to the general license in 105 CMR 120.122(J)(1),

(a) shall, upon occurrence of visually observable damage, such as a bend or crack or discoloration from overheating to the device, discontinue use of the device until it has been inspected, tested for leakage and repaired by a person holding a specific license from the U.S. Nuclear Regulatory Commission or an Agreement State to manufacture or service such devices; or shall dispose of the device pursuant to the provisions of 105 CMR 120.251;

(b) shall assure that all labels affixed to the device at the time of receipt, and which bear a statement which prohibits removal of the labels, are maintained thereon; and,

(c) are exempt from the requirements of 105 CMR 120.200 and 120.750 except that such persons shall comply with the provisions of 105 CMR 120.251, 120.281 and 120.282.

(3) This general license does not authorize the manufacture, assembly, disassembly or repair of strontium-90 in ice detection devices.

(4) This general license is subject to the provisions of 105 CMR 120.001 through 120.019, 120.131, 120.140, 120.150, and 120.770.

120.124: Filing Application for Specific Licenses

(A) Applications for specific licenses shall be filed in duplicate on form MRCP 120.100-4 as prescribed by the Agency.

(B) The Agency may at any time after the filing of the original application, and before the expiration of the license, require further statements in order to enable the Agency to determine whether the application should be granted or denied or whether a license should be modified or revoked.

(C) Each application shall be signed by the applicant or licensee or a person duly authorized to act for and on his or her behalf.

(D) An application for a license may include a request for a license authorizing one or more activities. The Agency will not grant the request if the proposed activities are not under the control of the same facility, administrator and radiation safety officer. In addition, when evaluating the request, the Agency will consider complexity, similarity and proximity of the proposed activities.

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(E) In the application, the applicant may incorporate by reference information contained in previous applications, statements, or reports filed with the Agency provided such references are clear and specific.

(F) Applications and documents submitted to the Agency may be made available for public inspection except that the Agency may withhold any document or part thereof from public inspection if disclosure of its content is not required in the public interest and would adversely affect the interest of a person concerned.

(G)(1) Except as provided in 105 CMR 120.124(G)(2), (3), and (4), an application for a specific license to authorize receipt, possession or use of radioactive material in the form of a sealed source or in a device that contains a sealed source shall either:

(a) identify the sealed source or device that contains a sealed source by manufacturer and model number as registered with the Agency under 105 CMR 120.128(N), with the NRC or an Agreement State, or for a source or a device containing radium-226 or accelerator-produced radioactive material with a State under provisions comparable to 105 CMR 120.128(N); or

(b) contain the information identified in 105 CMR 120.128(N)(3).

(2) for sources or devices manufactured prior to October 23, 2012 that are not registered with the Agency under 105 CMR 120.128(N) or with the NRC or an Agreement State, and for which the applicant is unable to provide all categories of information specified in 105 CMR 120.128(N)(3), the applicant must provide:

(a) All available information identified in 105 CMR 120.128(N)(3) concerning the source, and, if applicable, the device; and

(b) Sufficient additional information to demonstrate that there is reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property. Such information must include a description of the source or device, a description of radiation safety features, the intended use and associated operating experience, and the results of a recent leak test.

(3) For sealed sources and devices allowed to be distributed without registration of safety information in accordance with 105 CMR 120.128(N)(7)(a), the applicant may supply only the manufacturer, model number, and radionuclide and quantity.

(4) If it is not feasible to identify each sealed source and device individually, the applicant may propose constraints on the number and type of sealed sources and devices to be used and the conditions under which they will be used, in *lieu* of identifying each sealed source and device.

120.125: General Requirements for the Issuance of Specific Licenses

(A) A license application will be approved only if the Agency determines that:

(1) the applicant is qualified by reason of training and experience to use the material in question for the purpose requested in accordance with 105 CMR 120.000 in such a manner as to minimize danger to public health and safety or property;

(2) the applicant's proposed equipment, facilities, and procedures are adequate to minimize danger to public health and safety or property;

(3) the issuance of the license will not be inimical to the health and safety of the public; and,

(4) the applicant satisfies any applicable special requirements in 105 CMR 120.050 through 120.080, 120.126, 120.127, 120.128, 120.300, 120.500, 120.620 120.800, 120.890 and 120.900.

(B) Environmental Report, Commencement of Construction.

(1) In the case of an application for a license to receive and possess radioactive material for commercial waste disposal, or for the conduct of any other activity which the Agency determines will significantly affect the quality of the environment, a license application shall be reviewed and approved by the Agency before commencement of construction of the plant or facility in which the activity will be conducted. Issuance of the license shall be based upon a consideration by the Agency of the environmental, economic, technical and other benefits in comparison with the environmental costs and available alternatives and a determination that the action called for is the issuance of the proposed license, with any appropriate conditions to protect environmental values;

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(2) Commencement of construction prior to such conclusion shall be grounds for denial of a license to receive and possess radioactive material in such plant or facility.

(C) Financial Surety Arrangements and Recordkeeping for Decommissioning.

(1) Unless exempted by 105 CMR 120.125(C)(3), issuance, renewal or amendment of a license shall be dependent upon satisfactory financial surety arrangements to ensure the protection of the public health and safety in the event of abandonment, default or other inability of the licensee to meet the requirements of M.G.L. c. 111H, § 9 and 105 CMR 120.000.

(2) Each applicant for a specific license authorizing the possession and use of unsealed radioactive material with a half-life greater than 120 days and in quantities exceeding 10^5 times the applicable quantities set forth in 105 CMR 120.196: *Appendix B*, Table II shall submit a decommissioning funding plan as described in 105 CMR 120.125(C)(6). The decommissioning funding plan must also be submitted when a combination of isotopes is involved if R divided by 10^5 is greater than 1 (unity rule), where R is defined as the sum of the ratios of the quantity of each isotope to the applicable value in 105 CMR 120.196: *Appendix B*, Table II.

(3) Each applicant for a specific license authorizing possession and use of radioactive material of half-life greater than 120 days and in quantities specified in 105 CMR 120.125(C)(5) shall either:

(a) submit a decommissioning funding plan as described in 105 CMR 120.125(C)(6); or

(b) submit a certification that financial assurance for decommissioning has been provided in the amount prescribed by 105 CMR 120.125(C)(5) using one of the methods described in 105 120.125(C)(7). For an applicant, this certification may state that the appropriate assurance will be obtained after the application has been approved and the license issued, but prior to the receipt of licensed material. As part of the certification, a copy of the financial instrument obtained to satisfy the requirements of 105 CMR 120.125(C)(7) is to be submitted to the Agency.

(4) (a) Each holder of a specific license issued on or after March 11, 1994, which is of a type described in 105 CMR 120.125(C)(2) or (3), shall provide financial assurance for decommissioning in accordance with the criteria set forth in 105 CMR 120.125(C)(1) through (8).

(b) Each holder of a specific license issued before March 11, 1994, and of a type described in 105 CMR 120.125(C)(2) shall submit, on or before March 11, 1995, a decommissioning funding plan or a certification of financial assurance for decommissioning in an amount at least equal to $1,125,000, in accordance with the criteria set forth in this part. If the licensee submits the certification of financial assurance rather than a decommissioning funding plan at this time, the licensee shall include a decommissioning funding plan in any application for license renewal.

(c) Each holder of a specific license issued before March 11, 1994, and of a type described in 105 CMR 120.125(C)(3) shall submit, on or before March 11, 1995, a certification of financial assurance for decommissioning or a decommissioning funding plan in accordance with the criteria set forth in 105 CMR 120.125(C)(1) through (8).

(d) Waste collectors and waste processors, as defined in 10 CFR part 20, Appendix G must establish an Agency-approved decommissioning funding plan to assure the availability of funds for decommissioning activities conducted over the life of the licensed facility. The decommissioning funding plan must include the cost of disposal of the maximum radioactivity (curies) of radioactive material permitted by the license, and the cost of disposal of the maximum quantity, by volume, of radioactive material that could be present at the licensee's facility at any time, in addition to the cost to remediate the licensee's site to meet the license termination criteria of 105 CMR 120.200. The decommissioning funding plan must be submitted by April 6, 2007.

(e) If, in surveys made under 105 CMR 120.225(A), residual radioactivity in the facility and environment, including the subsurface, is detected at levels that would, if left uncorrected, prevent the site from meeting the 105 CMR 120.245 criteria for unrestricted use, the licensee must submit a decommissioning funding plan within one year of when the survey is completed.

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(5) Table of Required Amounts of Financial Assurance for Decommissioning by Quantity of Material:

-1	Greater than 10^4 but less than or equal to 10^5 times the applicable quantities in 105 CMR 120.196: *Appendix B*, Table II in unsealed form. (For a combination of isotopes, if R, as defined in 105 CMR 120.125(C)(2), divided by 10^4 is greater than 1 but R divided by 10^5 is less than or equal to 1.)	$1,125,000
-2a	Greater than 10^3 but less than or equal to 10^4 times the applicable quantities in 105 CMR 120.196: *Appendix B*, Table II in unsealed form. (For a combination of isotopes, if R, as defined in 105 CMR 120.125(C)(2), divided by 10^3 is greater than 1 but R divided by 10^4 is less than or equal to 1.)	$225,000
-2b	Greater than 10 mCi but less than 100 mCi of source material	$225,000
-3	Greater than 10^{10} times the applicable quantities in 105 CMR 120.196: *Appendix B*, Table II in sealed sources or plated foils. (For a combination of isotopes, if R, as defined in 105 CMR 120.125(C)(2), divided by 10^{10} is greater than 1.)	$113,000

(a) Licensees required to submit the $1,125,000 amount must do so by October 6, 2006.

(b) Licensees required to submit the $113,000 or $225,000 amount must do so by April 6, 2007.

(6) (a) Each decommissioning funding plan must be submitted for review and approval and must contain:

1. A detailed cost estimate for decommissioning, in an amount reflecting:

a. The cost of an independent contractor to perform all decommissioning activities;

b. The cost of meeting the 105 CMR 120.245 criteria for unrestricted use, provided that, if the applicant or licensee can demonstrate its ability to meet the provisions of 105 CMR 120.246, the cost estimate may be based on meeting the 105 CMR 120.246 criteria;

c. The volume of onsite subsurface material containing residual radioactivity that will require remediation to meet the criteria for license termination; and

d. An adequate contingency factor.

2. Identification of and justification for using the key assumptions contained in the cost estimate for decommissioning;

3. A description of the method of assuring funds for decommissioning from 105 CMR 120.125(C)(7), including means for adjusting cost estimates and associated funding levels periodically over the life of the facility;

4. A certification by the licensee that financial assurance for decommissioning has been provided in the amount of the cost estimate for decommissioning; and

5. A signed original of the financial instrument obtained to satisfy the requirements of 105 CMR 120.125(C)(7) (unless a previously submitted and accepted financial instrument continues to cover the cost estimate for decommissioning).

(b) At the time of license renewal and at intervals not to exceed three years, the decommissioning funding plan must be resubmitted with adjustments as necessary to account for changes in costs and the extent of contamination. If the amount of financial assurance will be adjusted downward, this cannot be done until the updated decommissioning funding plan is approved. The decommissioning funding plan must update the information submitted with the original or prior approved plan, and must specifically consider the effect of the following events on decommissioning costs:

1. Spills of radioactive material producing additional residual radioactivity in on-site subsurface material;

2. Waste inventory increasing above the amount previously estimated;

3. Waste disposal costs increasing above the amount previously estimated;

4. Facility modifications;

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5. Changes in authorized possession limits;
6. Actual remediation costs that exceed the previous cost estimate;
7. On-site disposal; and
8. Use of a settling pond.

(7) The financial instrument must include the licensee's name, license number, and docket number, and the name, address, and other contact information of the issuer, and, if a trust is used, the trustee. When any of the foregoing information changes, the licensee must, within 30 days, submit financial instruments reflecting such changes. The financial instrument submitted must be a signed original or signed original duplicate, except where a copy of the signed original is specifically permitted. Financial assurance for decommissioning must be provided by one or more of the following methods:

(a) Prepayment. Prepayment is the deposit prior to the start of operation into an account segregated from licensee assets and outside the licensee's administrative control of cash or liquid assets such that the amount of funds would be sufficient to pay decommissioning costs. Prepayment must be made into a trust account, and the trust must be acceptable to the Agency.

(b) A Surety Method, Insurance or Other Guarantee Method. These methods guarantee that decommissioning costs will be paid should the licensee default.

1. A surety method may be in the form of a surety bond, issued by a corporate surety company authorized to transact business in the Commonwealth; or an irrevocable letter of credit.

2. A parent company guarantee of funds for decommissioning costs may be used if the guarantee and test are as contained in 105 CMR 120.198: *Appendix D*. A parent company guarantee may not be used in combination with other financial methods to satisfy the requirements of 105 CMR 120.125(C).

3. For commercial corporations that issue bonds, a guarantee of funds by the applicant or licensee for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in 105 CMR 120.198: *Appendix E*.

4. For commercial companies that do not issue bonds, a guarantee of funds by the applicant or licensee for decommissioning costs may be used if the guarantee and test are as contained in 105 CMR 120.198: *Appendix F*.

5. For nonprofit entities, such as colleges, universities, and nonprofit hospitals, a guarantee of funds by the applicant or licensee may be used if the guarantee and test are as contained in 105 CMR 120.198: *Appendix G*.

6. Any surety method or insurance used to provide financial assurance for decommissioning must contain the following conditions:

a. The surety method or insurance must be open-ended or, if written for a specified term, such as five years, must be renewed automatically unless 90 days or more prior to the renewal date, the issuer notifies the Agency, the beneficiary, and the licensee of its intention not to renew. The surety method or insurance must also provide that the full face amount be paid to the beneficiary automatically prior to the expiration without proof of forfeiture if the licensee fails to provide a replacement acceptable to the Agency within 30 days after receipt of notification of cancellation.

b. The surety method or insurance must be payable to a trust established for decommissioning costs. The trustee and trust must be acceptable to the Agency. An acceptable trustee includes an appropriate state or federal government agency or an entity that has the authority to act as a trustee and whose trust operations are regulated and examined by a federal or state agency.

c. The surety method or insurance must remain in effect until the Agency has terminated the license.

(c) An External Sinking Fund. An external sinking fund in which deposits are made at least annually, coupled with a surety method or insurance, the value of which may decrease by the amount being accumulated in the sinking fund. An external sinking fund is a fund established and maintained by setting aside funds periodically in an account segregated from licensee assets and outside the licensee's administrative control in which the total amount of funds would be sufficient to pay decommissioning costs at the time termination of operation is expected. An external sinking fund must be in the form of a trust. If the other guarantee method is used, no surety or insurance may be combined with the external sinking fund. The surety or insurance provisions must be as stated in 105 CMR 120.125(C)(7)(b).

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(d) Statement of Intent. In the case of federal, state, or local government licensees, a statement of intent containing a cost estimate for decommissioning or an amount pursuant to 105 CMR 120.125(C)(5), and indicating that funds for decommissioning will be obtained when necessary.

(8) Each person licensed under 105 CMR 120.100 shall keep records of information important to the safe and effective decommissioning of the facility in an identified location until the license is terminated by the Agency. If records of relevant information are kept for other purposes, reference to these records and their locations may be used. Information the Agency considers important to decommissioning consists of:

(a) Records of spills or other unusual occurrences involving the spread of contamination in and around the facility, equipment, or site. These records may be limited to instances when contamination remains after any cleanup procedures or when there is reasonable likelihood that contaminants may have spread to inaccessible areas, as in the case of possible seepage into porous materials such as concrete. These records must include any known information on identification of involved nuclides, quantities, forms, and concentrations.

(b) As-built drawings and modifications of structures and equipment in restricted areas where radioactive materials are used and/or stored, and of locations of possible inaccessible contamination such as buried pipes that may be subject to contamination. If required drawings are referenced, each relevant document need not be indexed individually. If drawings are not available, the licensee shall substitute appropriate records of available information concerning these areas and locations.

(c) Except for areas containing only sealed sources (provided the sources have not leaked or no contamination remains after any leak) or radioactive materials having only half-lives of less than 65 days, a list contained in a single document and updated every two years, of the following:

1. all areas designated and formerly designated restricted areas as defined in 105 CMR 120.005;

2. all areas outside of restricted areas that require documentation under 105 CMR 120.125(C)(8)(a);

3. all areas outside of restricted areas where current and previous wastes have been buried as documented under 105 CMR 120.269; and

4. all areas outside of restricted areas which contain material such that, if the license expired, the licensee would be required to either decontaminate the area to unrestricted release levels or apply for approval for disposal under 105 CMR 120.252.

(d) Records of the cost estimate performed for the decommissioning funding plan or of the amount certified for decommissioning, and records of the funding method used for assuring funds if either a funding plan or certification is used.

(9) The following specific licensees are required to make financial surety arrangements:

(a) major processors;

(b) waste handling licensees;

(c) former U.S. Atomic Energy Commission or NRC licensed facilities; and

(d) all others except persons exempt pursuant to 105 CMR 120.125(C)(10).

(10) The following persons are exempt from the requirements of 105 CMR 120.125(C)(1):

(a) persons authorized to possess no more than 1,000 times the quantity specified in 105 CMR 120.196: *Appendix B*, Table 1 or combination of radioactive material listed therein as given in 105 CMR 120.196: *Appendix B*, Table 1, Note 1;

(b) persons authorized to possess radioactive noble gases in sealed sources with no radioactive daughter product with half-life greater than 30 days.

120.126: Special Requirements for Issuance of Certain Specific Licenses for Radioactive Material

Uses of Sealed Sources in Industrial Radiography. In addition to the requirements set forth in 105 CMR 120.125, a specific license for use of sealed sources in industrial radiography will be issued if:

(1) the applicant will have an adequate program for training radiographic personnel and submits to the Agency a schedule or description of such program which specifies the:

(a) initial training;

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(b) periodic training;
(c) on-the-job training; and
(d) means to be used by the licensee to determine the radiographic personnel's knowledge and understanding of and ability to comply with Agency regulations and licensing requirements, and the operating and emergency procedures of the applicant.

(2) the applicant has established and submits to the Agency satisfactory written operating and emergency procedures described in 105 CMR 120.325;

(3) the applicant will have an internal inspection system adequate to assure that 105 CMR 120.001, 120.020, 120.200, 120.300, 120.750, 120.770, license provisions, and the applicant's operating and emergency procedures are followed by radiographic personnel; the inspection system shall include the performance of internal inspections at intervals not to exceed three months and the retention of records of such inspections for five years;

(4) the applicant submits to the Agency a description of the overall organizational structure pertaining to the industrial radiography program, including specified delegations of authority and responsibility for operation of the program;

(5) the applicant who desires to conduct his own leak tests has established adequate procedures to be followed in testing sealed sources for possible leakage and contamination and submits to the Agency a description of such procedures including:
(a) instrumentation to be used;
(b) method of performing tests; and
(c) pertinent experience of the individual who will perform the test.

(6) the licensee shall conduct a program for inspection and maintenance of radiographic exposure devices and storage containers to assure proper functioning of components important to safety.

120.127: Special Requirements for Specific Licenses of Broad Scope

105 CMR 120.127 prescribes requirements for the issuance of specific licenses of broad scope for radioactive material and certain regulations governing holders of such licenses.

(A) The different types of broad scope licenses are set forth in 105 CMR 120.127(A):

(1) A "Type A specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of the radioactive material specified in the license, but not exceeding quantities specified in the license, for any authorized purpose. The quantities specified are usually in the multicurie range.

(2) A "Type B specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of radioactive material specified in 105 CMR 120.197: *Appendix C*, for any authorized purpose. The possession limit for a Type B license of broad scope, if only one radionuclide is possessed thereunder, is the quantity specified for that radionuclide in 105 CMR 120.197: *Appendix C*, Column I. If two or more radionuclides are possessed thereunder, the possession limit for each is determined as follows: For each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in 105 CMR 120.197: *Appendix C*, Column I, for that radionuclide. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity.

(3) A "Type C specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use, and transfer of any chemical or physical form of radioactive material specified in 105 CMR 120.197: *Appendix C*, for any authorized purpose. The possession limit for a Type C license of broad scope, if only one radionuclide is possessed thereunder, is the quantity specified for that radionuclide in 105 CMR 120.197: *Appendix C*, Column II. If two or more radionuclides are possessed thereunder, the possession limit is determined for each as follows: For each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in 105 CMR 120.197: *Appendix C*, Column II, for that radionuclide. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity.

(B) An application for a Type A specific license of broad scope will be approved if:

(1) the applicant satisfies the general requirements specified in 105 CMR 120.125;

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(2) the applicant has engaged in a reasonable number of activities involving the use of radioactive material; and

(3) the applicant has established administrative controls and provisions relating to organization and management, procedures, record keeping, material control and accounting, and management review that are necessary to assure safe operations, including:

(a) the establishment of a radiation safety committee composed of such persons as a radiation safety officer, a representative of management, and persons trained and experienced in the safe use of radioactive material;

(b) the appointment of a radiation safety officer who is qualified by training and experience in radiation protection, and who is available for advice and assistance on radiation safety matters; and

(c) the establishment of appropriate administrative procedures to assure:

1. control of procurement and use of radioactive material;

2. completion of safety evaluations of proposed uses of radioactive material which take into consideration such matters as the adequacy of facilities and equipment, training and experience of the user, and the operating or handling procedures; and

3. review, approval, and recording by the radiation safety committee of safety evaluations of proposed uses prepared in accordance with 105 CMR 120.127(B)(3)(c)2. prior to use of the radioactive material.

(C) An application for a Type B specific license of broad scope will be approved if:

(1) the applicant satisfies the general requirements specified in 105 CMR 120.125; and,

(2) the applicant has established administrative controls and provisions relating to organization and management, procedures, record keeping, material control and accounting, and management review that are necessary to assure safe operations, including:

(a) the appointment of a radiation safety officer who is qualified by training and experience in radiation protection, and who is available for advice and assistance on radiation safety matters; and

(b) the establishment of appropriate administrative procedures to assure;

1. control of procurement and use of radioactive material;

2. completion of safety evaluations of proposed uses of radioactive material which take into consideration such matters as the adequacy of facilities and equipment, training and experience of the user, and the operating or handling procedures; and,

3. review, approval, and recording by the radiation safety officer of safety evaluations of proposed uses prepared in accordance with 105 CMR 120.127(C)(2)(b)2. prior to use of the radioactive material.

(D) An application for a Type C specific license of broad scope will be approved if:

(1) the applicant satisfies the general requirements specified in 105 CMR 120.125;

(2) the applicant submits a statement that radioactive material will be used only by, or under the direct supervision of, individuals who have received:

(a) a college degree at the bachelor level, or equivalent training and experience, in the physical or biological sciences or in engineering; and

(b) at least 40 hours of training and experience in the safe handling of radioactive material, and in the characteristics of ionizing radiation, units of radiation dose and quantities, radiation detection instrumentation, and biological hazards of exposure to radiation appropriate to the type and forms of radioactive material to be used; and

(3) the applicant has established administrative controls and provisions relating to procurement of radioactive material, procedures, record keeping, material control and accounting, and management review necessary to assure safe operations.

(E) Specific licenses of broad scope are subject to the following conditions:

(1) Unless specifically authorized, persons licensed pursuant to 105 CMR 120.127 shall not:

(a) conduct tracer studies in the environment involving direct release of radioactive material;

(b) receive, acquire, own, possess, use, or transfer devices containing 100,000 curies (3.7 PBq) or more of radioactive material in sealed sources used for irradiation of materials;

(c) conduct activities for which a specific license issued by the Agency under 105 CMR 120.126, 120.128 or 120.500, and 120.800 is required; or

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(d) add or cause the addition of radioactive material to any food, beverage, cosmetic, drug, or other product designed for ingestion or inhalation by, or application to, a human being.

(2) Each Type A specific license of broad scope issued under 105 CMR 120.127 shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals approved by the licensee's radiation safety committee.

(3) Each Type B specific license of broad scope issued under 105 CMR 120.127 shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals approved by the licensee's radiation safety officer.

(4) Each Type C specific license of broad scope issued under 105 CMR 120.127 shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals who satisfy the requirements of 105 CMR 120.127(D).

120.128: Special Requirements for a Specific License to Manufacture, Assemble, Repair, or Distribute Commodities, Products, or Devices Which Contain Radioactive Material

(A) Licensing Requirements to Produce for Noncommercial Transfer Positron Emission Tomography (PET) Radioactive Drugs. An application from a medical facility, educational institution, or Federal facility to produce Positron Emission Tomography (PET) radioactive drugs for noncommercial transfer to licensees in its consortium authorized for medical use under 105 CMR 120.500, or equivalent Nuclear Regulatory Commission, or Agreement State requirements shall include:

(1) A request for authorization for the production of PET radionuclides or evidence of an existing license issued under 105 CMR 120.100 or equivalent Nuclear Regulatory Commission, or Agreement State requirements for a PET radionuclide production facility within its consortium from which it receives PET radionuclides.

(2) Evidence that the applicant is qualified to produce radioactive drugs for medical use by meeting one of the criteria in 105 CMR 120.128(J)(1)(b).

(3) Identification of individual(s) authorized to prepare the PET radioactive drugs if the applicant is a pharmacy, and documentation that each individual meets the requirements of an authorized nuclear pharmacist as specified in 105 CMR 120.128(J)(2)(b).

(4) Information identified in 105 CMR 120.128(J)(1)(c) on the PET drugs to be noncommercially transferred to members of its consortium.

(B) Licensing Requirements to Initially Transfer Source Material to Persons Generally Licensed under 105 CMR 120.121(A).

(1) An application for a specific license to initially transfer source material for use under 105 CMR 120.121(A), or equivalent regulations of the NRC or an Agreement State, will be approved if:

(a) The applicant satisfies the general requirements specified in 105 CMR 120.125; and

(b) The applicant submits adequate information on, and the Agency approves the methods to be used for quality control, labeling, and providing safety instructions to recipients.

(2) Each person licensed under 105 CMR 120.128(B) shall label the immediate container of each quantity of source material with the type of source material and quantity of material and the words, "'radioactive material".

(3) Each person licensed under 105 CMR 120.128(B) shall ensure that the quantities and concentrations of source material are as labeled and indicated in any transfer records.

(4) Each person licensed under 105 CMR 120.128(B) shall provide the information specified in 105 CMR 120.128(B)(4) to each person to whom source material is transferred for use under 105 CMR 120.121(A) or equivalent provisions in the NRC or Agreement State regulations. This information must be transferred before the source material is transferred for the first time in each calendar year to the particular recipient. The required information includes:

(a) A copy of 105 CMR 120.121(A) through (C), (F), and (G) and 105 CMR 120.140, or relevant equivalent regulations of the NRC or Agreement State.

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(b) Appropriate radiation safety precautions and instructions relating to handling, use, storage, and disposal of the material.

(5) Each person licensed under 105 CMR 120.128(B) shall report transfers as follows:

(a) File a report with the Agency by an appropriate method listed in 105 CMR 120.013. The report shall include the following information:

1. The name, address, and license number of the person who transferred the source material;

2. For each general licensee under 105 CMR 120.121(A) or equivalent NRC or Agreement State provisions to whom greater than 50 grams (0.11 lb) of source material has been transferred in a single calendar quarter, the name and address of the general licensee to whom source material is distributed; a responsible agent, by name and/or position and phone number, of the general licensee to whom the material was sent; and the type, physical form, and quantity of source material transferred; and

3. The total quantity of each type and physical form of source material transferred in the reporting period to all such generally licensed recipients.

(b) File a report with each responsible NRC or Agreement State agency that identifies all persons, operating under provisions equivalent to 105 CMR 120.121(A), to whom greater than 50 grams (0.11 lb) of source material has been transferred within a single calendar quarter. The report shall include the following information specific to those transfers made to the NRC or Agreement State being reported to:

1. The name, address, and license number of the person who transferred the source material; and

2. The name and address of the general licensee to whom source material was distributed; a responsible agent, by name and/or position and phone number, of the general licensee to whom the material was sent; and the type, physical form, and quantity of source material transferred.

3. The total quantity of each type and physical form of source material transferred in the reporting period to all such generally licensed recipients within the NRC's jurisdiction or the Agreement State.

(c) Submit each report by January 31st of each year covering all transfers for the previous calendar year. If no transfers were made to persons generally licensed under 105 CMR 120.121(A) or equivalent NRC or Agreement State provisions during the current period, a report shall be submitted to the Agency indicating so. If no transfers have been made to general licensees within a particular Agreement State during the reporting period, this information shall be reported to the responsible Agreement State agency upon request of that agency. If no transfers have been made to NRC general licensees during the reporting period, this information shall be reported to the NRC.

(6) Each person licensed under 105 CMR 120.128(B) shall maintain all information that supports the reports required by this section concerning each transfer to a general licensee for a period of one year after the event is included in a report to the NRC or to an Agreement State agency.

(C) Requirements for Other Specific Licenses (Reserved).

(D) Licensing Requirements to Manufacture or Initially Transfer Devices Containing Radioactive Material to Persons Generally Licensed under 105 CMR 120.122(D).

(1) An application for a specific license to manufacture or distribute devices containing radioactive material, excluding special nuclear material, to persons generally licensed under 105 CMR 120.122(D) or equivalent regulations of the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State will be approved if:

(a) the applicant satisfies the general requirements of 105 CMR 120.125;

(b) the applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control, labels, proposed uses, installation, servicing, leak testing, operating and safety instructions, and potential hazards of the device to provide reasonable assurance that:

1. the device can be safely operated by persons not having training in radiological protection;

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2. under ordinary conditions of handling, storage, and use of the device, the radioactive material contained in the device will not be released or inadvertently removed from the device, and it is unlikely that any person will receive in one year a dose in excess of 10% of the annual limits specified in 105 CMR 120.211(A), and

3. under accident conditions such as fire and explosion associated with handling, storage, and use of the device, it is unlikely that any person would receive an external radiation dose or dose commitment in excess of the following organ doses:

a. Whole body; head and trunk; active blood-forming organs; gonads; or lens of eye . . . . . 15 rems (150 mSv)

b. Hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than one square centimeter . . . . . 200 rems (2 Sv)

c. Other organs . . . . . 50 rems (500 mSv); and

(c) each device bears a durable, legible, clearly visible label or labels approved by the Agency, which contain in a clearly identified and separate statement:

1. instructions and precautions necessary to assure safe installation, operation, and servicing of the device; documents such as operating and service manuals may be identified in the label and used to provide this information;

2. the requirement, or lack of requirement, for leak testing, or for testing any "on-off" mechanism and indicator, including the maximum time interval for such testing, and the identification of radioactive material by isotope, quantity of radioactivity, and date of determination of the quantity; and

3. the information called for in one of the following statements, as appropriate, in the same or substantially similar form:

The receipt, possession, use, and transfer of this device, Model _____, Serial No. _____ , are subject to a general license or the equivalent and the regulations of the U.S. Nuclear Regulatory Commission or a State with which the U.S. Nuclear Regulatory Commission has entered into an agreement for the exercise of regulatory authority. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited. [The model, serial number, and name of the manufacturer or distributor may be omitted from the label provided the information is elsewhere specified in labeling affixed to the device.]

CAUTION - RADIOACTIVE MATERIAL

_____

Name of Manufacturer or Distributor

[Note: Devices licensed under 10 CFR 32.53 prior to January 19, 1975 may bear labels authorized by the regulations in effect on January 1, 1975.]

(d) each device having a separable source housing that provides the primary shielding for the source also bears, on the source housing, a durable label containing the device model number and serial number, the isotope and quantity, the words, “Caution-Radioactive Material”, the radiation symbol described in 105 CMR 120.237, and the name of the manufacturer or initial distributor.

(e) each device meeting the criteria of 105 CMR 120 122(D)(3)(m)1., bears a permanent (*e.g.*, embossed, etched, stamped, or engraved) label affixed to the source housing if separable, or the device if the source housing is not separable, that includes the words, “Caution-Radioactive Material”, and, if practicable, the radiation symbol described in 105 CMR 120.237.

(f) the device has been registered in the Sealed Source and Device Registry.

(2) In the event the applicant desires that the device be required to be tested at intervals longer than six months, either for proper operation of the "on-off" mechanism and indicator, if any, or for leakage of radioactive material or for both, the applicant shall include in the application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the device or similar devices and by design features which have a significant bearing on the probability or consequences of leakage of radioactive material from the device or failure of the "on-off" mechanism and indicator. In determining the acceptable interval for the test for leakage of radioactive material, the Agency will consider information which includes, but is not limited to:

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(a) primary containment or source capsule;
(b) protection of primary containment;
(c) method of sealing containment;
(d) containment construction materials;
(e) form of contained radioactive material;
(f) maximum temperature withstood during prototype tests;
(g) maximum pressure withstood during prototype tests;
(h) maximum quantity of contained radioactive material;
(i) radiotoxicity of contained radioactive material; and
(j) operating experience with identical devices or similarly designed and constructed devices.

(3) In the event the applicant desires that the general licensee under 105 CMR 120.122(D), or under equivalent regulations of the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State be authorized to install the device, collect the sample to be analyzed by a specific licensee for leakage of radioactive material, service the device, test the "on-off" mechanism and indicator, or remove the device from installation, the applicant shall include in the application written instructions to be followed by the general licensee, estimated calendar quarter doses associated with such activity or activities, and basis for such estimates. The submitted information shall demonstrate that performance of such activity or activities by an individual untrained in radiological protection, in addition to other handling, storage, and use of devices under the general license, is unlikely to cause that individual to receive a dose in excess of 10% of the annual limits specified in 105 CMR 120.211(A).

(4) Each person licensed under 105 CMR 120.128(D) to initially transfer devices to generally licensed persons shall:

(a) if a device containing radioactive material is to be transferred for use under the general license contained in 105 CMR 120.122(D), each person that is licensed under 105 CMR 120.128(D) shall provide the information specified in 120.128(D)(4) to each person to whom a device is to be transferred. This information must be provided before the device may be transferred. In the case of a transfer through an intermediate person, the information must also be provided to the intended user prior to initial transfer to the intermediate person. The required information includes:

1. a copy of the general license contained in 105 CMR 120.122(D); if 105 CMR 120.122(D)(3)(b) through (d) do not apply to the particular device, those paragraphs may be omitted;
2. a copy of 105 CMR 120.122, 120.009(A), 120.281, and 120.282;
3. a list of the services that can only be performed by a specific licensee; and,
4. information on acceptable disposal options including estimated costs of disposal;

(b) if radioactive material is to be transferred in a device for use under an equivalent general license of the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State each person that is licensed under 105 CMR 120.128(D) shall provide the information specified in 105 CMR 120.128(D)(4)(b) to each person to whom a device is to be transferred. This information must be provided before the device may be transferred. In the case of a transfer through an intermediate person, the information must also be provided to the intended user prior to initial transfer to the intermediate person. The required information includes:

1. a copy of NRC or Agreement State regulations equivalent to 105 CMR 120.122(D), 120.009(A), 120.281, and 120.282. If a copy of the 105 CMR 120.000 is provided to a prospective general licensee in *lieu* of the U.S. Nuclear Regulatory Commission's, Agreement State's, or Licensing State's regulations, it shall be accompanied by a note explaining that use of the device is regulated by the U.S. Nuclear Regulatory Commission, the Agreement State; or Licensing State; if certain paragraphs of the regulations do not apply to the particular device, those paragraphs may be omitted;
2. a list of the services that can only be performed by a specific licensee;
3. information on acceptable disposal options including estimated costs of disposal; and,
4 the name or title, address, and phone number of the contact at the U.S. Nuclear Regulatory Commission, the Agreement State, or Licensing State from which additional information may be obtained;

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(c) an alternative approach to informing customers may be proposed by the licensee for approval by the Agency;

(d) each device that is transferred after February 19, 2002 must meet the labeling requirements in 105 CMR 120.128(D)(1)(c) through (e);

(e) if a notification of bankruptcy has been made under 105 CMR 120.131(E) or the license is to be terminated, each person licensed under 105 CMR 120.128(D) shall provide, upon request, to the Agency and to any appropriate Agreement State or NRC, records of final disposition required under 105 CMR 120.128(D)(5)(c).

(5) Each person licensed under 105 CMR 120.128(D) to initially transfer devices to generally licensed persons shall comply with the requirements of 105 CMR 120.128(D)(5).

(a) The person shall report to the Agency all transfers of devices to persons for use under the general license in 105 CMR 120.122(D) and all receipts of devices from persons licensed under 105 CMR 120.122(D). The report must be submitted on a quarterly basis on NRC Form 653 - "Transfers of Industrial Devices Report" or in a clear and legible report containing all of the data required by the form.

1. The required information for transfers to general licensees includes:

a. the identity of each general licensee by name and mailing address for the location of use; if there is no mailing address for the location of use, an alternate address for the general licensee shall be submitted along with information on the actual location of use;

b. the name, title, and phone number of the person identified by the general licensee as having knowledge of and authority to take required actions to ensure compliance with the appropriate regulations and requirements;

c. the date of transfer;

d. the type, model number, and serial number of the device transferred; and

e. the quantity and type of byproduct material contained in the device.

2. If one or more intermediate persons will temporarily possess the device at the intended place of use before its possession by the user, the report must include the same information for both the intended user and each intermediate person, and clearly designate the intermediate person(s).

3. For devices received from a 105 CMR 120.122(D) general licensee, the report must include the identity of the general licensee by name and address, the type, model number, and serial number of the device received, the date of receipt, and, in the case of devices not initially transferred by the reporting licensee, the name of the manufacturer or initial transferor.

4. If the licensee makes changes to a device possessed by a 105 CMR 120.122(D) general licensee, such that the label must be changed to update required information, the report must identify the general licensee, the device, and the changes to information on the device label.

5. The report must cover each calendar quarter, must be filed within 30 days of the end of the calendar quarter, and must clearly indicate the period covered by the report.

6. The report must clearly identify the specific licensee submitting the report and include the license number of the specific licensee.

7. If no transfers have been made to U.S. Nuclear Regulatory Commission Licensees during the reporting period, this information shall be reported to the U.S. Nuclear Regulatory Commission.

8. If no transfers have been made to general licensees within a particular State during the reporting period, this information shall be reported to the responsible State agency upon request of that agency.

(b) The person shall report all transfers of devices to persons for use under a general license in the U.S. Nuclear Regulatory Commission's, an Agreement State's, or a Licensing State's regulations that are equivalent to 105 CMR 120.122(D) and all receipts of devices from general licensees in the U.S. Nuclear Regulatory Commission's, an Agreement State's, or a Licensing State's jurisdiction to the responsible agency. The report must be submitted on Form 653 - "Transfers of Industrial Devices Report" or in a clear and legible report containing all of the data required by the form.

1. The required information for transfers to general licensees includes:

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a. the identity of each general licensee by name and mailing address for the location of use; if there is no mailing address for the location of use, an alternate address for the general licensee shall be submitted along with information on the actual location of use;

b. the name, title, and phone number of the person identified by the general licensee as having knowledge of and authority to take required actions to ensure compliance with the appropriate regulations and requirements;

c. the date of transfer;

d. the type, model number, and serial number of the device transferred; and

e. the quantity and type of byproduct material contained in the device.

2. If one or more intermediate persons will temporarily possess the device at the intended place of use before its possession by the user, the report must include the same information for both the intended user and each intermediate person, and clearly designate the intermediate person(s).

3. For devices received from a general licensee, the report must include the identity of the general licensee by name and address, the type, model number, and serial number of the device received, the date of receipt, and, in the case of devices not initially transferred by the reporting licensee, the name of the manufacturer or initial transferor.

4. If the licensee makes changes to a device possessed by a general licensee, such that the label must be changed to update required information, the report must identify the general licensee, the device, and the changes to information on the device label.

5. The report must cover each calendar quarter, must be filed within 30 days of the end of the calendar quarter, and must clearly indicate the period covered by the report.

6. The report must clearly identify the specific licensee submitting the report and must include the license number of the specific licensee.

7. If no transfers have been made to U.S. Nuclear Regulatory Commission Licensees during the reporting period, this information shall be reported to the U.S. Nuclear Regulatory Commission.

8. If no transfers have been made to general licensees within a particular State during the reporting period, this information shall be reported to the responsible State agency upon request of that agency.

(c) The person shall maintain all information concerning transfers and receipts of devices that supports the reports required by 105 CMR 120.128(D)(5). Records required by 105 CMR 120.128(D)(5)(c) must be maintained for a period of three years following the date of the recorded event.

(E) Special Requirements for the Manufacture, Assembly, or Repair of Luminous Safety Devices for Use in Aircraft. An application for a specific license to manufacture, assemble, or repair luminous safety devices containing tritium or promethium-147 for use in aircraft, for distribution to persons generally licensed under 105 CMR 120.122(B) will be approved if:

(1) the applicant satisfies the general requirements specified in 105 CMR 120.125; and

(2) the applicant satisfies the requirements of 10 CFR Part 32 §§ 32.53 through 32.56.

(F) Special Requirements for License to Manufacture or Initially Transfer Calibration or Reference Sources Containing Americium-241, or Radium-226 for Distribution to Persons Generally Licensed under 105 CMR 120.122(G). An application for a specific license to manufacture or initially transfer calibration or reference sources containing americium-241, or radium-226, for distribution to persons generally licensed under 105 CMR 120.122(G), will be approved if:

(1) the applicant satisfies the general requirement of 105 CMR 120.125; and

(2) The applicant submits sufficient information regarding each type of calibration or reference source pertinent to evaluation of the potential radiation exposure, including:

(a) Chemical and physical form and maximum quantity of americium-241 or radium-226 in the source;

(b) Details of construction and design;

(c) Details of the method of incorporation and binding of the americium-241 or radium-226 in the source;

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(d) Procedures for and results of prototype testing of sources, which are designed to contain more than 0.005 microcurie of americium-241 or radium-226, to demonstrate that the americium-241 or radium-226 contained in each source will not be released or be removed from the source under normal conditions of use;

(e) Details of quality control procedures to be followed in manufacture of the source;

(f) Description of labeling to be affixed to the source or the storage container for the source;

(g) Any additional information, including experimental studies and tests, required by the Commission to facilitate a determination of the safety of the source.

(3) Each source will contain no more than 5 microcuries of americium-241 or radium-226.

(4) The Agency determines, with respect to any type of source containing more than 0.005 microcurie of americium-241 or radium-226, that:

(a) The method of incorporation and binding of the americium-241 or radium-226 in the source is such that the americium-241 will not be released or be removed from the source under normal conditions of use and handling of the source; and

(b) The source has been subjected to and has satisfactorily passed the prototype tests prescribed by 10 CFR 32.57(e).

(5) Each person licensed under 105 CMR 120.128(F) shall affix to each source, or storage container for the source, a label which shall contain sufficient information relative to safe use and storage of the source and shall include the following statement or a substantially similar statement which contains the information called for in the following statement:

The receipt, possession, use, and transfer of this source, Model _____, Serial No. _____, are subject to a general license or the equivalent and the regulations of the U.S. Nuclear Regulatory Commission or a State with which the U.S. Nuclear Regulatory Commission has entered into an agreement for the exercise of regulatory authority. Do not remove this label.

CAUTION - RADIOACTIVE MATERIAL-THIS SOURCE CONTAINS AMERICIUM-241 (OR RADIUM-226). DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

_____

Name of manufacturer or initial transferor

(6) Each person licensed under 105 CMR 120.128(F) shall perform a dry wipe test upon each source containing more than 3.7 kilobecquerels (0.1 microcurie) of americium-241 or radium-226 before transferring the source to a general licensee under 105 CMR 120.122(G) or under equivalent regulations of NRC or an Agreement State. This test shall be performed by wiping the entire radioactive surface of the source with a filter paper with the application of moderate finger pressure. The radioactivity on the filter paper shall be measured using methods capable of detecting 0.185 kilobecquerel (0.005 microcurie) of americium-241 or radium-226. If a source has been shown to be leaking or losing more than 0.185 kilobecquerel (0.005 microcurie) of americium-241 or radium-226 by the methods described in 105 CMR 120.128(F)(6), the source shall be rejected and shall not be transferred to a general licensee under 105 CMR 120.122(G) or equivalent regulations of NRC or an Agreement State.

(G) Requirements for Other Specific Licenses (Reserved).

(H) Manufacture and Distribution of Radioactive Material for Certain *In Vitro* Clinical or Laboratory Testing Under General License. An application for a specific license to manufacture or distribute radioactive material for use under the general license of 105 CMR 120.122(I) will be approved if:

(1) the applicant satisfies the general requirements specified in 105 CMR 120.125.

(2) the radioactive material is to be prepared for distribution in prepackaged units of:

(a) carbon-14 in units not exceeding ten microcuries (370 kBq) each.

(b) cobalt-57 in units not exceeding ten microcuries (370 kBq) each.

(c) hydrogen-3 (tritium) in units not exceeding 50 microcuries (1.85 MBq) each.

(d) iodine-125 in units not exceeding ten microcuries (370 kBq) each.

(e) Mock Iodine-125 in units not exceeding 0.05 microcurie (1.85 kBq) of iodine-129 and 0.005 microcurie (185 Bq) of americium-241 each.

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(f) iodine-131 in units not exceeding ten microcuries (370 kBq) each.
(g) iron-59 in units not exceeding 20 microcuries (740 kBq) each.
(h) selenium-75 in units not exceeding ten microcuries (370 kBq) each.

(3) each prepackaged unit bears a durable, clearly visible label:

(a) identifying the radioactive contents as to chemical form and radionuclide, and indicating that the amount of radioactivity does not exceed ten microcuries (370 kBq) of iodine-125, iodine-131, carbon-14, cobalt-57, or selenium-75; 50 microcuries (1.85 MBq) of hydrogen-3 (tritium); 20 microcuries (740 kBq) of iron-59; or Mock Iodine-125 in units not exceeding 0.05 microcurie (1.85 kBq) of iodine-129 and 0.005 microcurie (185 Bq) of americium-241 each; or cobalt-57 in units not exceeding 0.37 megabecquerel (10 microcuries); and

(b) displaying the radiation caution symbol described in 105 CMR 120.237(A) and the words, "CAUTION, RADIOACTIVE MATERIAL", and "Not for Internal or External Use in Humans or Animals".

(4) the following statement or a substantially similar statement which contains the information called for in the following statement, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:

This radioactive material may be received, acquired, possessed, and used only by physicians, veterinarians, clinical laboratories or hospitals and only for *in vitro* clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of the U.S. Nuclear Regulatory Commission or of a State with which the U.S. Nuclear Regulatory Commission has entered into an agreement for the exercise of regulatory authority.

_____
Name of Manufacturer

(5) the label affixed to the unit, or the leaflet or brochure which accompanies the package, contains adequate information as to the precautions to be observed in handling and storing such radioactive material. In the case of the Mock Iodine-125 reference or calibration source, the information accompanying the source must also contain directions to the licensee regarding the waste disposal requirements set out in 105 CMR 120.251.

(I) Licensing the Manufacture and Distribution of Ice Detection Devices. An application for a specific license to manufacture and distribute ice detection devices to persons generally licensed under 105 CMR 120.122(J) will be approved if:

(1) the applicant satisfies the general requirements of 105 CMR 120.125; and
(2) the criteria of 10 CFR Part 32, §§ 32.61 and 32.62 are met.

(J) Manufacture, Preparation, or Transfer for Commercial Distribution of Drugs Containing Radioactive Material for Medical Use under 105 CMR 120.500.

(1) An application for a specific license to manufacture, prepare, or transfer for commercial distribution radioactive drugs containing radioactive material for use by persons authorized pursuant to 105 CMR 120.500 will be approved if:

(a) the applicant satisfies the general requirements specified in 105 CMR 120.125;
(b) the applicant submits evidence that the applicant is at least one of the following:

1. registered or licensed with the U.S. Food and Drug Administration (FDA) as the owner or operator of a drug establishment that engages in the manufacture, preparation, propagation, compounding, or processing of a drug under 21 CFR 207.20(a);
2. registered or licensed with a State agency as a drug manufacturer;
3. licensed as a pharmacy by a State Board of Pharmacy;
4. operating as a nuclear pharmacy pursuant to 247 CMR 13.00: *Registration Requirements and Minimal Professional Standards for Nuclear Pharmacies*;
5. operating as a nuclear pharmacy within a Federal medical institution; or
6. a Positron Emission Tomography (PET) drug production facility registered with a State agency.

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(c) the applicant submits information on the radionuclide; the chemical and physical form; the maximum activity per vial, syringe, generator, or other container of the radioactive drug; and the shielding provided by the packaging to show it is appropriate for safe handling and storage of the radioactive drugs by medical use licensees; and

(d) the applicant satisfies the following labeling requirements:

1. a label is affixed to each transport radiation shield, whether it is constructed of lead, glass, plastic, or other material of a radioactive drug to be transferred for commercial distribution. The label must include the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL", the name of the radioactive drug or its abbreviation, and the quantity of radioactivity at a specified date and time. For radioactive drugs with a half life greater than 100 days the time may be omitted.

2. a label is affixed to each syringe, vial, or other container used to hold a radioactive drug to be transferred for commercial distribution. The label must include the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or " DANGER, RADIOACTIVE MATERIAL" and an identifier that ensures that the syringe, vial, or other container can be correlated with the information on the transport radiation shield label.

(2) A licensee pursuant to 105 CMR 120.128(J)(1)(b)3. or (b)4. or (b)5.:

(a) may prepare radioactive drugs for medical use, as defined in 105 CMR 120.502, provided that the radioactive drug is prepared by either an authorized nuclear pharmacist, as specified in 105 CMR 120.128(J)(2)(b) and (d), or an individual under the supervision of an authorized nuclear pharmacist as specified in 105 CMR 120.519.

(b) may allow a pharmacist to work as an authorized nuclear pharmacist if:

1. this individual qualifies as an authorized nuclear pharmacist as defined in 105 CMR 120.502; or

2. this individual meets the requirements specified in 105 CMR 120.526(B) and 120.529 and the licensee has received an approved license amendment identifying this individual as an authorized nuclear pharmacist; or

3. this individual is designated as an authorized nuclear pharmacist in accordance with 105 CMR 120.128(J)(2)(d).

(c) the actions authorized in 105 CMR 120.128(J)(2)(a) and (b) are permitted in spite of more restrictive language in license conditions.

(d) may designate a pharmacist, as defined in 105 CMR 120.005, as an authorized nuclear pharmacist if:

1. The individual was a nuclear pharmacist preparing only radioactive drugs containing accelerator-produced radioactive material; and

2. The individual practiced at a pharmacy at a Government agency or Federally recognized Indian Tribe before November 30, 2007 or at all other pharmacies before August 8, 2009, or an earlier date as noticed by the NRC.

(e) shall provide to the Agency:

1. A copy of each individual's certification by a specialty board whose certification process has been recognized by the Commission or an Agreement State as specified in 105 CMR 120.526(A) with the written attestation signed by a preceptor as required by 105 CMR 120.526(B);

2. Agreement State or Nuclear Regulatory Commission license;

3. Nuclear Regulatory Commission master materials licensee permit;

4. The permit issued by a licensee or Nuclear Regulatory Commission master materials permittee of broad scope or the authorization from a commercial nuclear pharmacy authorized to list its own authorized nuclear pharmacist;

5. Documentation that only accelerator-produced radioactive materials were used in the practice of nuclear pharmacy at a Government agency or Federally recognized Indian Tribe before November 30, 2007 or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC; and

6. A copy of the State pharmacy licensure or registration, no later than 30 days after the date that the licensee allows, under 105 CMR 120.128(J)(2)(b)1. and 3. of 105 CMR 120.128(J), the individual to work as an authorized nuclear pharmacist.

(3) A licensee shall possess and use instrumentation to measure the radioactivity of radioactive drugs. The licensee shall have procedures for use of the instrumentation. The licensee shall measure, by direct measurement or by combination of measurements and calculations, the amount of radioactivity in dosages of alpha-, beta-, or photon-emitting radioactive drugs prior to transfer for commercial distribution. In addition, the licensee shall:

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(a) perform tests before initial use, periodically, and following repair, on each instrument for accuracy, linearity, and geometry dependence, as appropriate for the use of the instrument; and make adjustments when necessary; and

(b) check each instrument for constancy and proper operation at the beginning of each day of use.

(4) Nothing in 105 CMR 120.128(J) relieves the licensee from complying with applicable FDA, other Federal, and State requirements governing radioactive drugs.

(K) Manufacture and Distribution of Generators or Reagent Kits for Preparation of Radiopharmaceuticals Containing Radioactive Material[5]. An application for a specific license to manufacture and distribute generators or reagent kits containing radioactive material for preparation of radiopharmaceuticals by persons licensed pursuant to 105 CMR 120.100 for the uses listed in 105 CMR 120.547 will be approved if:

(1) the applicant satisfies the general requirements specified in 105 CMR 120.125;

(2) the applicant submits evidence that:

(a) the generator or reagent kit is to be manufactured, labeled and packaged in accordance with the Federal Food, Drug and Cosmetic Act or the Public Health Service Act, such as a new drug application (NDA) approved by the Food and Drug Administration (FDA), or a "Notice of Claimed Investigational Exemption for a New Drug" (IND) that has been accepted by the FDA; or

(b) the manufacture and distribution of the generator or reagent kit are not subject to the Federal Food, Drug and Cosmetic Act and the Public Health Service Act.

(3) the applicant submits information on the radionuclide, chemical and physical form, packaging including maximum activity per package, and shielding provided by the packaging of the radioactive material contained in the generator or reagent kit;

(4) the label affixed to the generator or reagent kit contains information on the radionuclide, quantity, and date of assay; and

(5) the label affixed to the generator or reagent kit, or the leaflet or brochure which accompanies the generator or reagent kit, contains:

(a) adequate information, from a radiation safety standpoint, on the procedures to be followed and the equipment and shielding to be used in eluting the generator or processing radioactive material with the reagent kit; and

(b) a statement that this generator or reagent kit, as appropriate, is approved for use by persons licensed by the Agency pursuant to 105 CMR 120.547 or under equivalent licenses of the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State. The labels, leaflets, or brochures required by 105 CMR 120.128(K) are in addition to the labeling required by the Food and Drug Administration (FDA) and they may be separate from or, with the approval of FDA, may be combined with the labeling required by FDA.

(L) Manufacture and Distribution of Sources or Devices Containing Radioactive Material for Medical Use. An application for a specific license to manufacture and distribute sources and devices containing radioactive material to persons licensed pursuant to 105 CMR 120.500 for use as a calibration, transmission, or reference source or for the uses listed in 105 CMR 120.559, 120.568, 120.570 and 120.589 will be approved if:

(1) the applicant satisfies the general requirements in 105 CMR 120.125;

(2) the applicant submits sufficient information regarding each type of source or device pertinent to an evaluation of its radiation safety, including:

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[5] Although the Agency does not regulate the manufacture and distribution of reagent kits that do not contain radioacitve material, it does regulate the use of such reagent kits for the preparation of radiopharmaceuticals containing radioactive material as part of its licensing and regulation of the users of radioactive material. Any manufacturer of reagent kits that do not contain radioactive material who desires to have his reagent kits approved by the Agency for use by persons licensed pursuant to 105 CMR 120.547 may submit the pertinent information specified in 105 CMR 120.128(K).

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(a) the radioactive material contained, its chemical and physical form, and amount;
(b) details of design and construction of the source or device;
(c) procedures for, and results of, prototype tests to demonstrate that the source or device will maintain its integrity under stresses likely to be encountered in normal use and accidents;
(d) for devices containing radioactive material, the radiation profile of a prototype device;
(e) details of quality control procedures to assure that production sources and devices meet the standards of the design and prototype tests;
(f) procedures and standards for calibrating sources and devices;
(g) legend and methods for labeling sources and devices as to their radioactive content; and
(h) instructions for handling and storing the source or device from the radiation safety standpoint; these instructions are to be included on a durable label attached to the source or device or attached to a permanent storage container for the source or device; provided, that instructions which are too lengthy for such label may be summarized on the label and printed in detail on a brochure which is referenced on the label.

(3) the label affixed to the source or device, or to the permanent storage container for the source or device, contains information on the radionuclide, quantity, and date of assay, and a statement that the Agency has approved the distribution of the (name of source or device) to persons licensed to use radioactive material identified in 105 CMR 120.535, 120.559, 120.568, and 120.570 or under equivalent licenses of the U.S. Nuclear Regulatory Commission or an Agreement State;
(4) the source or device has been registered in the Sealed Source and Device Registry;
(5) in the event the applicant desires that the source or device be required to be tested for leakage of radioactive material at intervals longer than six months, he or she shall include in his or her application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the source or device or similar sources or devices and by design features that have a significant bearing on the probability or consequences of leakage of radioactive material from the source; and
(6) in determining the acceptable interval for test of leakage of radioactive material, the Agency will consider information that includes, but is not limited to:
(a) primary containment or source capsule;
(b) protection of primary containment;
(c) method of sealing containment;
(d) containment construction materials;
(e) form of contained radioactive material;
(f) maximum temperature withstood during prototype tests;
(g) maximum pressure withstood during prototype tests;
(h) maximum quantity of contained radioactive material;
(i) radiotoxicity of contained radioactive material; and
(j) operating experience with identical sources or devices or similarly designed and constructed sources or devices.

(M) Requirements for License to Manufacture and Distribute Industrial Products Containing Depleted Uranium for Mass-volume Applications.

(1) An application for a specific license to manufacture industrial products and devices containing depleted uranium for use pursuant to 105 CMR 120.121(E) or equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State will be approved if:
(a) the applicant satisfies the general requirements specified in 105 CMR 120.125;
(b) the applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling or marking, proposed uses, and potential hazards of the industrial product or device to provide reasonable assurance that possession, use, or transfer of the depleted uranium in the product or device is not likely to cause any individual to receive a radiation dose in excess of 10% of the annual limits specified in 105 CMR 120.211(A); and

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(c) the applicant submits sufficient information regarding the industrial product or device and the presence of depleted uranium for a mass-volume application in the product or device to provide reasonable assurance that unique benefits will accrue to the public because of the usefulness of the product or device.

(2) In the case of an industrial product or device whose unique benefits are questionable, the Agency will approve an application for a specific license under 105 CMR 120.128(M) only if the product or device is found to combine a high degree of utility and low probability of uncontrolled disposal and dispersal of significant quantities of depleted uranium into the environment.

(3) The Agency may deny any application for a specific license under 105 CMR 120.128(M) if the end use(s) of the industrial product or device cannot be reasonably foreseen.

(4) Each person licensed pursuant to 105 CMR 120.128(M)(1) shall:

(a) maintain the level of quality control required by the license in the manufacture of the industrial product or device, and in the installation of the depleted uranium into the product or device;

(b) label or mark each unit to:

1. identify the manufacturer of the product or device and the number of the license under which the product or device was manufactured, the fact that the product or device contains depleted uranium, and the quantity of depleted uranium in each product or device; and

2. state that the receipt, possession, use, and transfer of the product or device are subject to a general license or the equivalent and the regulations of the U.S. Nuclear Regulatory Commission or an Agreement State.

(c) assure that the depleted uranium before being installed in each product or device has been impressed with the following legend clearly legible through any plating or other covering: "Depleted Uranium";

(d) 1. furnish a copy of the general license contained in 105 CMR 120.121(E) and a copy of form MRCP 120.100-1 to each person to whom he or she transfers depleted uranium in a product or device for use pursuant to the general license contained in 105 CMR 120.121(E); or

2. furnish a copy of the general license contained in the U.S. Nuclear Regulatory Commission's or Agreement State's regulation equivalent to 105 CMR 120.121(E) and a copy of the U.S. Nuclear Regulatory Commission's or Agreement State's certificate, or alternatively, furnish a copy of the general license contained in 105 CMR 120.121(E) and a copy of form MRCP 120.100-1 to each person to whom he or she transfers depleted uranium in a product or device for use pursuant to the general license of the U.S. Nuclear Regulatory Commission or an Agreement State, with a note explaining that use of the product or device is regulated by the U.S. Nuclear Regulatory Commission or an Agreement State under requirements substantially the same as those in 105 CMR 120.121(E).

(e) report to the Agency all transfers of industrial products or devices to persons for use under the general license in 105 CMR 120.121(E). Such report shall identify each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the Agency and the general licensee, the type and model number of device transferred, and the quantity of depleted uranium contained in the product or device. The report shall be submitted within 30 days after the end of each calendar quarter in which such a product or device is transferred to the generally licensed person. If no transfers have been made to persons generally licensed under 105 CMR 120.121(E) during the reporting period, the report shall so indicate;

(f) 1. report to the U.S. Nuclear Regulatory Commission all transfers of industrial products or devices to persons for use under the U.S. Nuclear Regulatory Commission general license in 10 CFR Part 40, § 40.25;

2. report to the responsible State agency all transfers of devices manufactured and distributed pursuant to 105 CMR 120.128(M) for use under a general license in that State's regulations equivalent to 105 CMR 120.121(E);

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3. such report shall identify each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the Agency and the general licensee, the type and model number of the device transferred, and the quantity of depleted uranium contained in the product or device. The report shall be submitted within 30 days after the end of each calendar quarter in which such product or device is transferred to the generally licensed person;

4. if no transfers have been made to U.S. Nuclear Regulatory Commission licensees during the reporting period, this information shall be reported to the U.S. Nuclear Regulatory Commission; and

5. if no transfers have been made to general licensees within a particular Agreement State during the reporting period, this information shall be reported to the responsible Agreement State agency upon the request of that agency.

(g) keep records showing the name, address, and point of contact for each general licensee to whom he or she transfers depleted uranium in industrial products or devices for use pursuant to the general license provided in 105 CMR 120.121(E) or equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State. The records shall be maintained for a period of two years and shall show the date of each transfer, the quantity of depleted uranium in each product or device transferred, and compliance with the report requirements of 105 CMR 120.100.

(N) Sealed Source and Device Registration - Registration of Product Information and Inactivation of Certificates of Registration of Sealed Sources and Devices.

(1) Any manufacturer or initial distributor of a sealed source or device containing a sealed source may submit a request to the Agency for evaluation of radiation safety information about its product and for its registration.

(2) The request for review must be sent to the Agency in duplicate by an appropriate method listed in 105 CMR 120.013.

(3) The request for review of a sealed source or a device must include sufficient information about the design, manufacture, prototype testing, quality control program, labeling, proposed uses and leak testing and, for a device, the request must also include sufficient information about installation, service and maintenance, operating and safety instructions, and its potential hazards, to provide reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property.

(4) The Agency normally evaluates a sealed source or a device using radiation safety criteria in accepted industry standards. If these standards and criteria do not readily apply to a particular case, the Agency formulates reasonable standards and criteria with the help of the manufacturer or distributor. The Agency shall use criteria and standards sufficient to ensure that the radiation safety properties of the device or sealed source are adequate to protect health and minimize danger to life and property.

(5) After completing the evaluation and determining that requirements for registration have been met, the Agency shall issue a certificate of registration to the person making the request. The certificate of registration acknowledges the availability of the submitted information for inclusion in an application for a specific license proposing use of the product, or concerning use under an exemption from licensing or general license as applicable for the category of certificate.

(6) The person submitting the request for evaluation and registration of safety information about the product shall manufacture and distribute the product in accordance with:

(a) The statements and representations, including quality control program, contained in the request; and

(b) The provisions of the registration certificate.

(7) Authority to manufacture or initially distribute a sealed source or device to specific licensees may be provided in the license without the issuance of a certificate of registration in the following cases:

(a) Calibration and reference sources containing no more than:

1. 37 MBq (1 mCi), for beta and/or gamma emitting radionuclides; or

2. 0.37 MBq (10 μCi), for alpha emitting radionuclides; or

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(b) The intended recipients are qualified by training and experience and have sufficient facilities and equipment to safely use and handle the requested quantity of radioactive material in any form in the case of unregistered sources or, for registered sealed sources contained in unregistered devices, are qualified by training and experience and have sufficient facilities and equipment to safely use and handle the requested quantity of radioactive material in unshielded form, as specified in their licenses; and

1. The intended recipients are licensed under 105 CMR 120.127 or comparable provisions of NRC or an Agreement State;
2. The recipients are authorized for research and development; or
3. The sources and devices are to be built to the unique specifications of the particular recipient and contain no more than 740 GBq (20 Ci) of tritium or 7.4 GBq (200 mCi) of any other radionuclide.

(8) After the certificate is issued, the Agency may conduct an additional review as it determines is necessary to ensure compliance with current regulatory standards. In conducting its review, the Agency will complete its evaluation in accordance with criteria specified in 105 CMR 120.128(N). The Agency may request such additional information as it considers necessary to conduct its review and the certificate holder shall provide the information as requested.

(9) A certificate holder who no longer manufactures or initially transfers any of the sealed source(s) or device(s) covered by a particular certificate issued by the Agency shall request inactivation of the registration certificate. Such a request must be made to the Agency by an appropriate method listed in 105 CMR 120.013 and must normally be made no later than two years after initial distribution of all of the source(s) or device(s) covered by the certificate has ceased. However, if the certificate holder determines that an initial transfer was in fact the last initial transfer more than two years after that transfer, the certificate holder shall request inactivation of the certificate within 90 days of this determination and briefly describe the circumstances of the delay.

(10) If a distribution license is to be terminated in accordance with 105 CMR 120.132, the licensee shall request inactivation of its registration certificates associated with that distribution license before the Agency will terminate the license. Such a request for inactivation of certificate(s) must indicate that the license is being terminated and include the associated specific license number.

(11) A specific license to manufacture or initially transfer a source or device covered only by an inactivated certificate no longer authorizes the licensee to initially transfer such sources or devices for use. Servicing of devices must be in accordance with any conditions in the certificate, including in the case of an inactive certificate.

120.130: Issuance of Specific Licenses

(A)(1) Upon a determination that an application meets the requirements of M.G.L. c. 111, §§ 3, 5M through 5P and 105 CMR 120.000 and upon payment of the required fee as specified in 105 CMR 120.130(A)(2), the Agency will issue a specific license authorizing the proposed activity in such form and containing such conditions and limitations as it deems appropriate or necessary.

(2) Each initial application for a license or a certificate of registration for which a fee is established in 801 CMR 4.00: *Rates* shall be accompanied by a nonrefundable fee, payable to the Commonwealth of Massachusetts, in the amount specified for the corresponding annual fee. Thereafter, the Radiation Control Program will issue an annual fee invoice based on the applicable annual fee specified in 801 CMR 4.00. Fees are payable within 30 days after receipt of a fee invoice.

(B) The Agency may incorporate in any license at the time of issuance, or thereafter by appropriate rule, regulation, or order, such additional requirements and conditions with respect to the licensee's receipt, possession, use, and transfer of radioactive material subject to 105 CMR 120.100 as it deems appropriate or necessary in order to:

(1) minimize danger to public health and safety or property;

(2) require such reports and the keeping of such records, and to provide for such inspections of activities under the license as may be appropriate or necessary; and

(3) prevent loss or theft of material subject to 105 CMR 120.100.

120.131: Specific Terms and Conditions of Licenses

(A) Each license issued pursuant to 105 CMR 120.000 shall be subject to all the provisions of M.G.L. c. 111, §§ 3, 5M through 5P, and to all rules, regulations, orders of the Agency and license conditions as provided for in 105 CMR 120.130(B).

(B) (1) No license issued or granted under 105 CMR 120.000 and no right to possess or utilize radioactive material granted by any license issued pursuant to 105 CMR 120.131 shall be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person unless the Agency shall, after securing full information find that the transfer is in accordance with the provisions of M.G.L. c. 111, §§ 3, 5M through 5P, and to all valid rules, regulations, and orders of the Agency, and shall give its consent in writing.

(2) An application for transfer of license must include:

1. The identity, technical and financial qualifications of the proposed transferee; and
2. Financial assurance for decommissioning information required by 105 CMR 120.125(C), as applicable.

(C) Each person licensed by the Agency pursuant to 105 CMR 120.100 shall confine use and possession of the material licensed to the locations and purposes authorized in the license. Preparation for shipment and transport of byproduct material shall be in accordance with the provisions of 10 CFR Part 71 and 105 CMR 120.770.

(D) Each licensee shall notify the Agency in writing when the licensee decides to permanently discontinue all activities involving materials authorized under the license.

(E) Each licensee shall notify the Agency in writing immediately following the filing of a voluntary or involuntary petition for bankruptcy under any Chapter of Title 11 (Bankruptcy) of the United States Code by or against:

(1) the licensee;

(2) an entity (as that term is defined in 11 U.S.C. 101(15)) controlling the licensee or listing the license or licensee as property of the estate; or

(3) an affiliate (as that term is defined in 11 U.S.C. 101(2)) of the licensee.

(F) The notification specified in 105 CMR 120.131(E) shall indicate the bankruptcy court in which the petition for bankruptcy was filed and the date of the filing of the petition.

(G) Each portable gauge licensee shall use a minimum of two independent physical controls that form tangible barriers to secure portable gauges from unauthorized removal, whenever portable gauges are not under the control and constant surveillance of the licensee.

(H) Each licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators or rubidium-82 from strontium-82/rubidium-82 generators shall test the generator eluates for molybdenum-99 breakthrough or strontium-82 and strontium-85 contamination, respectively, in accordance with 105 CMR 120.548. The licensee shall record the results of each test and retain each record for three years after the record is made.

(I) (1) Authorization under 105 CMR 120.128(A) to produce Positron Emission Tomography (PET) radioactive drugs for noncommercial transfer to medical use licensees in its consortium does not relieve the licensee from complying with applicable FDA, other Federal, and State requirements governing radioactive drugs.

(2) Each licensee authorized under 105 CMR 120.128(A) to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall:

1. Satisfy the labeling requirements in 105 CMR 120.128(J)(1)(d) for each PET radioactive drug transport radiation shield and each syringe, vial, or other container used to hold a PET radioactive drug intended for noncommercial distribution to members of its consortium.
2. Possess and use instrumentation to measure the radioactivity of the PET radioactive drugs intended for noncommercial distribution to members of its consortium and meet the procedural, radioactivity measurement, instrument test, instrument check, and instrument adjustment requirements in 105 CMR 120.128(J)(3).

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(3) A licensee that is a pharmacy authorized under 105 CMR 120.128(A) to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall require that any individual that prepares PET radioactive drugs shall be:

1. an authorized nuclear pharmacist that meets the requirements in 105 CMR 120.128(J)(2)(b); or

2. an individual under the supervision of an authorized nuclear pharmacist as specified in 105 CMR 120.519.

(4) A pharmacy, authorized under 105 CMR 120.128(A) to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium that allows an individual to work as an authorized nuclear pharmacist, shall meet the requirements of 105 CMR 120.128(J)(2)(e).

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(5) other site-specific factors which the Agency may consider appropriate on a case-by-case basis, such as the regulatory requirements of other government agencies, lawsuits, ground-water treatment activities, monitored natural ground-water restoration, actions that could result in more environmental harm than deferred cleanup, and other factors beyond the control of the licensee.

(J) As the final step in decommissioning, the licensee shall:

(1) Certify the disposition of all licensed material including accumulated wastes, by submitting a completed Agency Form MRCP 120.100-3 or equivalent information; and,

(2) Conduct a radiation survey of the premises where the licensed activities were carried out and submit a report of the results of this survey unless the licensee demonstrates that the premises are suitable for release in some other manner. The licensee shall, as appropriate:

(a) Report levels of gamma radiation in units of millisieverts (microroentgen) per hour at one meter from surfaces, and report levels of radioactivity, including alpha and beta, in units of megabecquerels (disintegrations per minute or microcuries) per 100 square centimeters - removable and fixed - for surfaces, megabecquerels (microcuries) per milliliter for water, and becquerels (picocuries) per gram for solids such as soils or concrete; and

(b) Specify the survey instrument(s) used and certify that each instrument is properly calibrated and tested.

(K) Specific licenses, including expired licenses, will be terminated by written notice to the licensee when the Agency determines that:

(1) radioactive material has been properly disposed;

(2) reasonable effort has been made to eliminate residual radioactive contamination, if present; and

(3) (a) a radiation survey has been performed which demonstrates that the premises are suitable for release in accordance with Agency requirements; or

(b) other information submitted by the licensee is sufficient to demonstrate that the premises are suitable for release in accordance with Agency requirements.

120.133: Renewal of Licenses

(A) Applications for renewal of specific licenses shall be filed in accordance with 105 CMR 120.124.

(B) In any case in which a licensee, not less than 30 days prior to expiration of his existing license, has filed an application in proper form for renewal or for a new license authorizing the same activities, such existing license shall not expire until final action by the Agency.

120.134: Amendment of Licenses and Registration Certificates at Request of Licensee

(A) Applications for amendment of a license shall be filed in accordance with 105 CMR 120.124 and shall specify the respects in which the licensee desires the license to be amended and the grounds for such amendment. Applications for amendment of sealed source and device registration certificates must be filed in accordance with 105 CMR 120.128(N) and any other applicable provisions and must specify the respects in which the certificate holder desires its certificate to be amended and the grounds for the amendment.

(B) An invoice for an amendment fee will be issued on receipt of a request to amend a license. The amendment will not be issued until after the invoiced amount has been paid.

120.135: Agency Action on Applications to Renew or Amend

In considering an application by a licensee to renew or amend the license or to amend a sealed source or device registration certificate, the Agency will apply the criteria set forth in 105 CMR 120.125, 120.126, 120.127, and 120.128 and in 120.300, 120.500, 120.800 or 120.900, as applicable.

120.136: Persons Possessing a License for Source, Byproduct, or Special Nuclear Material in Quantities Not Sufficient to Form a Critical Mass on March 21, 1997

Any person who, on March 21, 1997, date of the Agreement between the Commonwealth and the NRC pursuant to section 274b of the Atomic Energy Act of 1954, as amended (42 USC 2021), possesses a general or specific license for source, byproduct, or special nuclear material in quantities not sufficient to form a critical mass, issued by the U.S. Nuclear Regulatory Commission, shall be deemed to possess a like license issued under 105 CMR 120.136 and M.G.L. c. 111, §§ 3, 5M, 5N, 5O and 5P, such license to expire either 90 days after receipt from the Agency of a notice of expiration of such license, or on the date or expiration specified in the U.S. Nuclear Regulatory Commission license, whichever is earlier.

120.137: Persons Possessing Naturally Occurring and Accelerator-produced Radioactive Material (NARM) on March 21, 1997

Any person who, on October 6, 2006, possesses NARM for which a specific license is required by M.G.L. c. 111, §§ 3, 5M, 5N, 5O and 5P or 105 CMR 120.137 shall be deemed to possess such a license issued under M.G.L. c. 111, §§ 3, 5M, 5N, 5O and 5P and 105 CMR 120.137. Such license shall expire on January 6, 2007; provided, however, that if within the 90 days the person possessing such material files an application in proper form for a license, such existing license shall not expire until the application has been finally determined by the Agency.

120.140: Transfer of Material

(A) No licensee shall transfer radioactive material except as authorized pursuant to 105 CMR 120.140.

(B) Except as otherwise provided in his license and subject to the provisions of 105 CMR 120.140(C) and (D), any licensee may transfer radioactive material:

(1) to the Agency (Only after receiving prior approval from the Agency.);

(2) to the U.S. Department of Energy;

(3) to any person exempt from 105 CMR 120.000 to the extent permitted under such exemption;

(4) to any person authorized to receive such material under terms of a general license or its equivalent, or a specific license or equivalent licensing document, issued by the Agency, the U.S. Nuclear Regulatory Commission, any Agreement State or any Licensing State, or to any person otherwise authorized to receive such material by the Federal Government or any agency thereof, the Agency, an Agreement State, or a Licensing State; or,

(5) as otherwise authorized by the Agency in writing.

(C) Before transferring radioactive material to a specific licensee of the Agency, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State, or to a general licensee who is required to register with the Agency, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State prior to receipt of the radioactive material, the licensee transferring the material shall verify that the transferee's license authorizes the receipt of the type, form, and quantity of radioactive material to be transferred.

(D) Any of the following methods for the verification required by 105 CMR 120.140(C) is acceptable:

(1) The transferor may possess and read a current copy of the transferee's specific license or registration certificate.

(2) The transferor may possess a written certification by the transferee that the transferee is authorized by license or registration certificate to receive the type, form, and quantity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency, and expiration date.

(3) For emergency shipments, the transferor may accept oral certification by the transferee that the transferee is authorized by license or registration certificate to receive the type, form, and quantity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency, and expiration date; provided, that the oral certification is confirmed in writing within ten days.

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RADIOACTIVE MATERIAL	COLUMN I CURIES	COLUMN II CURIES
Zirconium-97	1.0	0.01
Any Radioactive material other than source material, special nuclear material, or alpha emitting radioactive material not listed above.	0.1	0.001

Note 1: To convert curies (Ci) to SI units of gigabecquerels (GBq), multiply the above values by 37.

Example: Zirconium-97 (Col. II) (0.01 Ci multiplied by 37 is equivalent to 0.37 GBq)

120.198: Appendix D: Criteria Relating to Use of Financial Tests and Parent Company Guarantees for Providing Reasonable Assurance of Funds for Decommissioning

I. Introduction. An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based on obtaining a parent company guarantee that funds will be available for decommissioning costs and on a demonstration that the parent company passes a financial test. 105 CMR 120.198: *Appendix D* establishes criteria for passing the financial test and for obtaining the parent company guarantee.

II. Financial Test.

(A) To pass the financial test, the parent company must meet the criteria of either II.A.1 or II.A.2:

(1) The parent company must have:

(a) Two of the following three ratios: A ratio of total liabilities to net worth less than 2.0; a ratio of the sum of net income plus depreciation, depletion, and amortization to total liabilities greater than 0.1; and a ratio of current assets to current liabilities greater than 1.5;

(b) Net working capital and tangible net worth each at least six times the current decommissioning cost estimates (or prescribed amount if a certification is used);

(c) Tangible net worth of at least $21 million; and

(d) Assets located in the United States amounting to at least 90% of total assets or at least six times the current decommissioning cost estimates (or prescribed amount if a certification is used).

(2) The parent company must have:

(a) A current rating for its most recent uninsured, uncollateralized, and unencumbered bond issuance of AAA, AA, A, or BBB (including adjustments of + and -) as issued by Standard and Poor's or Aaa, Aa, A, or Baa (including adjustments of 1, 2, or 3) as issued by Moody's;

(b) Tangible net worth at least six times the current decommissioning cost estimate (or prescribed amount if a certification is used);

(c) Tangible net worth of at least $21 million; and

(d) Assets located in the United States amounting to at least 90% of total assets or at least six times the current decommissioning cost estimates (or prescribed amount if certification is used).

(B) The parent company's independent certified public accountant must have compared the data used by the parent company in the financial test, which is derived from the independently audited, year-end financial statement. In connection with that procedure, the licensee shall inform the Agency within 90 days of any matters coming to the auditor's attention that cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test.

(C) (1) After the initial financial test, the parent company must repeat the passage of the test within 90 days after the close of each succeeding fiscal year.

(2) If the parent company no longer meets the requirements of II.A, the licensee must send notice to the Agency of intent to establish alternate financial assurance as specified in the Agency's regulations. The notice must be sent by certified mail within 90 days after the end of the fiscal year for which the year end financial data show that the parent company no longer meets the financial test requirements. The licensee must provide alternate financial assurance within 120 days after the end of such fiscal year.

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III. Parent Company Guarantee. The terms of a parent company guarantee that an applicant or licensee obtains must provide that:

(A) The parent company guarantee will remain in force unless the guarantor sends notice of cancellation by certified mail to the licensee and the Agency. Cancellation may not occur, however, during the 120 days beginning on the date of receipt of the notice of cancellation by both the licensee and the Agency, as evidenced by the return receipts.

(B) If the licensee fails to provide alternate financial assurance as specified in the Agency's regulations within 90 days after receipt by the licensee and the Agency of a notice of cancellation of the parent company guarantee from the guarantor, the guarantor will provide such alternative financial assurance in the name of the licensee.

(C) The parent company guarantee and financial test provisions must remain in effect until the Agency has terminated the license.

(D) If a trust is established for decommissioning costs, the trustee and trust must be acceptable to the Agency. An acceptable trustee includes an appropriate state or federal government agency or an entity that has the authority to act as a trustee and whose trust operations are regulated and examined by a federal or state agency.

120.198: Appendix E: Criteria Relating to Use of Financial Tests and Self Guarantees for Providing Reasonable Assurance of Funds for Decommissioning

I. Introduction. An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based on furnishing its own guarantee that funds will be available for decommissioning costs and on a demonstration that the company passes the financial test of 105 CMR 120.198: *Appendix E*, Section II. The terms of the self-guarantee are in 105 CMR 120.198: *Appendix E*, Section III. 105 CMR 120.198: *Appendix E* establishes criteria for passing the financial test for the self-guarantee and establishes the terms for a self-guarantee.

II. Financial Test.

(A) To pass the financial test, a company must meet all of the following criteria:

(1) Tangible net worth of at least $21 million, and at least ten times the total current decommissioning cost estimate (or the current amount required if certification is used) for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor.

(2) Assets located in the United States amounting to at least 90% of total assets or at least ten times the total current decommissioning cost estimate (or the current amount required if certification is used) for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor.

(3) A current rating for its most recent uninsured, uncollateralized, and unencumbered bond issuance of AAA, AA, or A (including adjustments of + and -) as issued by Standard and Poors (S&P), Aaa, Aa, or A (including adjustments of 1, 2, or 3) as issued by Moody's.

(B) To pass the financial test, a company must meet all of the following additional requirements:

(1) The company must have at least one class of equity securities registered under the Securities Exchange Act of 1934.

(2) The company's independent certified public accountant must have compared the data used by the company in the financial test which is derived from the independently audited, year-end financial statements for the latest fiscal year, with the amounts in such financial statement. In connection with that procedure, the licensee shall inform the Agency within 90 days of any matters coming to the attention of the auditor that cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test.

(3) After the initial financial test, the company must repeat passage of the test within 90 days after the close of each succeeding fiscal year.

(C) If the licensee no longer meets the requirements of 105 CMR 120.198: *Appendix E*, Section II.(A), the licensee must send immediate notice to the Agency of its intent to establish alternate financial assurance as specified in the Agency's regulations within 120 days of such notice.

III. Company Self-Guarantee. The terms of a self-guarantee which an applicant or licensee furnishes must provide that:

(A) The guarantee will remain in force unless the licensee sends notice of cancellation by certified mail to the Agency. Cancellation may not occur, however, during the 120 days beginning on the date of receipt of the notice of cancellation by the Agency, as evidenced by the return receipts.

(B) The licensee shall provide alternative financial assurance as specified in the Agency's regulations within 90 days following receipt by the Agency of a notice of cancellation of the guarantee.

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(C) The guarantee and financial test provisions must remain in effect until the Agency has terminated the license or until another financial assurance method acceptable to the Agency has been put in effect by the licensee.

(D) The licensee will promptly forward to the Agency and the licensee's independent auditor all reports covering the latest fiscal year filed by the licensee with the Securities and Exchange Commission pursuant to the requirements of section 13 of the Securities and Exchange Act of 1934.

(E) If, at any time, the licensee's most recent bond issuance ceases to be rated in any category of "A" or above by either Standard and Poors or Moodys, the licensee will provide notice in writing of such fact to the Agency within 20 days after publication of the change by the rating service. If the licensee's most recent bond issuance ceases to be rated in any category of A or above by both Standard and Poors and Moodys, the licensee no longer meets the requirements of 105 CMR 120 198: *Appendix E*, Section II.(A).

(F) The applicant or licensee must provide to the Agency a written guarantee (a written commitment by a corporate officer) which states that the licensee will fund and carry out the required decommissioning activities or, upon issuance of an order by the Agency, the licensee will set up and fund a trust in the amount of the current cost estimates for decommissioning.

120.198: Appendix F: Criteria Relating to Use of Financial Tests and Self Guarantees for Providing Reasonable Assurance of Funds for Decommissioning by Commercial Companies That Have No Outstanding Rated Bonds

I. Introduction. An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based on furnishing its own guarantee that funds will be available for decommissioning costs and on a demonstration that the company passes the financial test of 105 CMR 120.198: *Appendix F*, Section II. The terms of the self-guarantee are in 105 CMR 120.198: *Appendix F*, Section III. 105 CMR 120.198: *Appendix F* establishes criteria for passing the financial test for the self-guarantee and establishes the terms for a self-guarantee.

II. Financial Test.

(A) To pass the financial test, a company must meet all of the following criteria:

(1) Tangible net worth greater than $21 million, or at least ten times the total current decommissioning cost estimate (or the current amount required if certification is used) whichever is greater, for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor.

(2) Assets located in the United States amounting to at least 90% of total assets or at least ten times the total current decommissioning cost estimate (or the current amount required if certification is used) for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor.

(3) A ratio of cash flow divided by total liabilities greater than 0.15 and a ratio of total liabilities divided by net worth less than 1.5.

(B) In addition, to pass the financial test, a company must meet all of the following additional requirements:

(1) The company's independent certified public accountant must have compared the data used by the company in the financial test, which is required to be derived from the independently audited year end financial statement based on United States generally accepted accounting practices for the latest fiscal year, with the amounts in such financial statement. In connection with that procedure, the licensee shall inform the Agency within 90 days of any matters that may cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test.

(2) After the initial financial test, the company must repeat passage of the test within 90 days after the close of each succeeding fiscal year.

(3) If the licensee no longer meets the requirements of 105 CMR 120.198: *Appendix F*, Section II.(A), the licensee must send immediate notice to the Agency of its intent to establish alternate financial assurance as specified in 105 CMR 120.125(C). The notice must be sent by certified mail, return receipt requested, within 90 days after the end of the fiscal year for which the year end financial data show that the licensee no longer meets the financial test requirements. The licensee must provide alternative financial assurance within 120 days after the end of such fiscal year.

III. Company Self-guarantee. The terms of a self-guarantee which an applicant or licensee furnishes must provide that:

(A) The guarantee shall remain in force unless the licensee sends notice of cancellation by certified mail, return receipt requested, to the Agency. Cancellation may not occur until an alternative financial assurance mechanism is in place.

(B) The licensee shall provide alternative financial assurance as specified in the Agency's regulations within 90 days following receipt by the Agency of a notice of cancellation of the guarantee.

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(C) The guarantee and financial test provisions must remain in effect until the Agency has terminated the license or until another financial assurance method acceptable to the Agency has been put in effect by the licensee.

(D) The applicant or licensee must provide to the Agency a written guarantee (a written commitment by a corporate officer) which states that the licensee will fund and carry out the required decommissioning activities or, upon issuance of an order by the Agency, the licensee will set up and fund a trust in the amount of the current cost estimates for decommissioning.

120.198: Appendix G: Criteria Relating to Use of Financial Tests and Self Guarantee for Providing Reasonable Assurance of Funds for Decommissioning by Nonprofit Colleges, Universities, and Hospitals

I. Introduction. An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based on furnishing its own guarantee that funds will be available for decommissioning costs and on a demonstration that the applicant or licensee passes the financial test of 105 CMR 120.198: *Appendix G*, Section II. The terms of the self-guarantee are in 105 CMR 120.198: *Appendix G*, Section III. 105 CMR 120.198: *Appendix G* establishes criteria for passing the financial test for the self-guarantee and establishes the terms for a self-guarantee.

II. Financial Test.

(A) For colleges and universities, to pass the financial test a college or university must meet either the criteria in 105 CMR 120.198: *Appendix G*, Section II.(A)(1) or the criteria in 105 CMR 120.198: *Appendix G*, Section II.(A)(2).

(1) For applicants or licensees that issue bonds, a current rating for its most recent uninsured, uncollateralized, and unencumbered bond issuance of AAA, AA, or A (including adjustments of + or -) as issued by Standard and Poor's (S&P) or Aaa, Aa, or A (including adjustments of 1, 2, or 3) as issued by Moody's.

(2) For applicants or licensees that do not issue bonds, unrestricted endowment consisting of assets located in the United States of at least $50 million, or at least 30 times the total current decommissioning cost estimate (or the current amount required if certification is used), whichever is greater, for all decommissioning activities for which the college or university is responsible as a self-guaranteeing licensee.

(B) For hospitals, to pass the financial test a hospital must meet either the criteria in 105 CMR 120.198: *Appendix G*, Section II.(B)(1) or the criteria in 105 CMR 120.198: *Appendix G*, Section II.(B)(2):

(1) For applicants or licensees that issue bonds, a current rating for its most recent uninsured, uncollateralized, and unencumbered bond issuance of AAA, AA, or A (including adjustments of + or -) as issued by Standard and Poor's (S&P) or Aaa, Aa, or A (including adjustments of 1, 2, or 3) as issued by Moody's.

(2) For applicants or licensees that do not issue bonds, all the following tests must be met:

(a) (Total Revenues less total expenditures) divided by total revenues must be equal to or greater than 0.04.

(b) Long term debt divided by net fixed assets must be less than or equal to 0.67.

(c) (Current assets and depreciation fund) divided by current liabilities must be greater than or equal to 2.55.

(d) Operating revenues must be at least 100 times the total current decommissioning cost estimate (or the current amount required if certification is used) for all decommissioning activities for which the hospital is responsible as a self-guaranteeing license.

(C) In addition, to pass the financial test, a licensee must meet the following requirements: (for institutions using 105 CMR 120.198: *Appendix G*: Section II, (A)(2) method of qualifying; for a self-guarantee 105 CMR 120.198: *Appendix G*: Sections II(C)(1) and II(C)(2) will apply.

(1) The licensee's independent certified public accountant must have compared the data used by the licensee in the financial test, which is required to be derived from the independently audited year end financial statements, based on United States generally accepted accounting practices, for the latest fiscal year, with the amounts in such financial statement. In connection with that procedure, the licensee shall inform the Agency within 90 days of any matters coming to the attention of the auditor that cause the auditor to believe that the data specified in the financial test should be adjusted and that the licensee no longer passes the test.

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(2) After the initial financial test, the licensee must repeat passage of the test within 90 days after the close of each succeeding fiscal year.

(3) If the licensee no longer meets the requirements of 105 CMR 120.198: *Appendix G*: Section I, the licensee must send notice to the Agency of its intent to establish alternative financial assurance as specified in Agency regulations. The notice must be sent by certified mail, return receipt requested, within 90 days after the end of the fiscal year for which the year end financial data show that the licensee no longer meets the financial test requirements. The licensee must provide alternate financial assurance within 120 days after the end of such fiscal year.

III. Self-guarantee. The terms of a self-guarantee which an applicant or licensee furnishes must provide that:

(A) The guarantee shall remain in force unless the licensee sends notice of cancellation by certified mail, and/or return receipt requested, to the Agency. Cancellation may not occur unless an alternative financial assurance mechanism is in place.

(B) The licensee shall provide alternative financial assurance as specified in 105 CMR 120.125(C) within 90 days following receipt by the Agency of a notice of cancellation of the guarantee.

(C) The guarantee and financial test provisions must remain in effect until the Agency has terminated the license or until another financial assurance method acceptable to the Agency has been put in effect by the licensee.

(D) The applicant or licensee must provide to the Agency a written guarantee (a written commitment by a corporate officer or officer of the institution) which states that the licensee will fund and carry out the required decommissioning activities or, upon issuance of an order by the Agency, the licensee will set up and fund a trust in the amount of the current cost estimates for decommissioning.

(E) If, at any time, the licensee's most recent bond issuance ceases to be rated in any category of "A" or above by either Standard and Poor's or Moody's, the licensee shall provide notice in writing of such fact to the Agency within 20 days after publication of the change by the rating service.

(F) If, at any time, the licensee's most recent bond issuance ceases to be rated in any category of "A" or above by either Standard and Poor's or Moody's, the licensee will provide notice in writing of such fact to the Agency within 20 days after publication of the change by the rating service. If the licensee's most recent bond issuance ceases to be rated in any category of A or above by both Standard and Poor's and Moody's, the licensee no longer meets the requirements of 105 CMR 120 199: *Appendix E*, Section II.(A).

120.200: STANDARDS FOR PROTECTION AGAINST RADIATION

120.201: Purpose

(A) 105 CMR 120.200 establishes standards for protection against ionizing radiation resulting from activities conducted pursuant to licenses or registrations issued by the Agency. The requirements of 105 CMR 120.200 are designed to control the receipt, possession, use, transfer, and disposal of sources of radiation by any licensee or registrant so the total dose to an individual, including doses resulting from all sources of radiation other than background radiation, does not exceed the standards for protection against radiation prescribed in 105 CMR 120.200. However, nothing in 105 CMR 120.200 shall be construed as limiting actions that may be necessary to protect health and safety.

(B) 105 CMR 120.200 is issued pursuant to M.G.L. c. 111, §§ 3, 5M, 5N, 5O, 5P.

120.202: Scope

Except as otherwise specifically provided in other Parts of 105 CMR 120.000, 105 CMR 120.200 applies to persons licensed or registered by the Department to receive, possess, use, transfer, or dispose of sources of radiation. The limits in 105 CMR 120.200 do not apply to doses due to background radiation, to exposure of patients to radiation for the purpose of medical diagnosis or therapy, to exposure from individuals administered radioactive material and released in accordance with 105 CMR 120.540 or to voluntary participation in medical research programs.

120.203: Definitions

As used in 105 CMR 120.200, the following definitions apply:

Annual Limit on Intake (ALI) means the derived limit for the amount of radioactive material taken into the body of an adult worker by inhalation or ingestion in one year. ALI is the smaller value of intake of a given radionuclide in one year by Reference Man that would result in a committed effective dose equivalent of 0.05 sievert (5 rem) or a committed dose equivalent of 0.5 sievert (50 rems) to any individual organ or tissue. ALI values for intake by ingestion and by inhalation of selected radionuclides are given in 105 CMR 120.296: *Appendix B*, Table I, Columns 1 and 2.

Class means a classification scheme for inhaled material according to its rate of clearance from the pulmonary region of the lung. Materials are classified as D, W, or Y, which applies to a range of clearance half-times: for Class D, Days, of less than ten days, for Class W, Weeks, from ten to 100 days, and for Class Y, Years, of greater than 100 days. For purposes of 105 CMR 120.000, "lung class" and "inhalation class" are equivalent terms.

Declared Pregnant Woman means a woman who has voluntarily informed the licensee or registrant, in writing, of her pregnancy and the estimated date of conception. The declaration remains in effect until the declared pregnant woman withdraws the declaration in writing or is no longer pregnant.

Derived Air Concentration (DAC) means the concentration of a given radionuclide in air which, if breathed by Reference Man for a working year of 2,000 hours under conditions of light work, results in an intake of one ALI. For purposes of 105 CMR 120.000, the condition of light work is an inhalation rate of 1.2 cubic meters of air per hour for 2,000 hours in a year. DAC values are given in 105 CMR 120.296: *Appendix B*, Table I, Column 3.

Derived Air Concentration-hour (DAC-hour) means the product of the concentration of radioactive material in air, expressed as a fraction or multiple of the derived air concentration for each radionuclide, and the time of exposure to that radionuclide, in hours. A licensee may take 2,000 DAC-hours to represent one ALI, equivalent to a committed effective dose equivalent of 0.05 sievert (5 rems).

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(3) The presence of removable contamination resulting from the decay of 185 Bq (0.005 μCi) or more of radium.

(F) The licensee or registrant shall immediately withdraw a leaking sealed source from use and shall take action to prevent the spread of contamination. The leaking sealed source shall be repaired or disposed of in accordance with this 105 CMR 120.200.

(G) Reports of test results for leaking or contaminated sealed sources shall be made pursuant to 105 CMR 120.288.

SURVEYS AND MONITORING

120.225: General

(A) Each licensee or registrant shall make, or cause to be made, surveys of areas, including the subsurface, that:

(1) are necessary for the licensee or registrant to comply with 105 CMR 120.200; and

(2) are necessary under the circumstances to evaluate:

(a) the magnitude and extent of radiation levels;

(b) concentrations or quantities of radioactive material residual radioactivity; and

(c) the potential radiological hazards of the radiation levels and residual radioactivity detected.

(B) Notwithstanding the provisions in 105 CMR 120.263(A), records from surveys describing the location and amount of subsurface residual radioactivity identified at the site must be kept with records important for decommissioning, and such records must be retained in accordance with 105 CMR 120.125(C)(8), as applicable.

(C) The licensee or registrant shall ensure that instruments and equipment used for quantitative radiation measurements, for example, dose rate and effluent monitoring, are calibrated at intervals not to exceed 12 months for the radiation measured except when a more frequent interval is specified in another applicable section of 105 CMR 120.000 or license condition.

(D) All personnel dosimeters, except for direct and indirect reading pocket ionization chambers and those dosimeters used to measure the dose to any extremity, that require processing to determine the radiation dose and that are used by licensees and registrants to comply with 105 CMR 120.211, with other applicable provisions of 105 CMR 120.000, or with conditions specified in a license or certificate of registration, shall be processed and evaluated by a dosimetry processor:

(1) holding current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Institute of Standards and Technology; and

(2) approved in this accreditation process for the type of radiation or radiations included in the NVLAP program that most closely approximates the type of radiation or radiations for which the individual wearing the dosimeter is monitored.

(E) The licensee or registrant shall ensure that adequate precautions are taken to prevent a deceptive exposure of an individual monitoring device.

120.226: Conditions Requiring Individual Monitoring of External and Internal Occupational Dose

Each licensee or registrant shall monitor exposures from sources of radiation at levels sufficient to demonstrate compliance with the occupational dose limits of 105 CMR 120.200. As a minimum:

(A) Each licensee or registrant shall monitor occupational exposure to radiation from licensed and unlicensed radiation sources under its control and shall supply and require the use of individual monitoring devices by:

(1) adults likely to receive, in one year from sources external to the body, a dose in excess of 10% of the limits in 105 CMR 120.211(A);

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(2) minors likely to receive, in one year from sources external to the body, a deep dose equivalent in excess of one millisievert (0.1 rem) a lens dose equivalent in excess of 1.5 millisievert (0.15 rem), or a shallow dose equivalent to the skin or to the extremities in excess of five millisieverts (0.5 rem);

(3) Declared pregnant women likely to receive during the entire pregnancy, from radiation sources external to the body, a deep dose equivalent in excess of one millisievert (0.1 rem). [Note: All of the occupational doses in 105 CMR 120.211 continue to be applicable to the declared pregnant worker as long as the embryo/fetus dose limit is not exceeded];

(4) individuals entering a high or very high radiation area;

(5) individuals working medical fluoroscopic equipment.

(a) An individual monitoring device used for the dose to an embryo/fetus of a declared pregnant woman, pursuant to 105 CMR 120.218(A), shall be located under the protective apron at the waist.

(b) An individual monitoring device used for lens dose equivalent shall be located at the neck (collar), or an unshielded location closer to the eye, outside the protective apron.

(c) When only one individual monitoring device is used to determine the effective dose equivalent for external radiation pursuant to 105 CMR 120.211(C)(2), it shall be located at the neck (collar) outside the protective apron. When a second individual monitoring device is used, for the same purpose, it shall be located under the protective apron at the waist. The second individual monitoring device is required for a declared pregnant woman.

(B) Each licensee shall monitor, to determine compliance with 105 CMR 120.214, the occupational intake of radioactive material by and assess the committed effective dose equivalent to:

(1) adults likely to receive, in one year, an intake in excess of 10% of the applicable ALI in 105 CMR 120.296: *Appendix B*, Table I, Columns 1 and 2; and

(2) minors likely to receive, in one year, a committed effective dose equivalent in excess of 0.1 millisievert (0.01 rem).

(3) declared pregnant women likely to receive, during the entire pregnancy, a committed effective dose equivalent in excess of 1m Sv (0.1 rem).

(C) Each licensee or registrant shall ensure that individuals who are required to monitor occupational doses in accordance with 105 CMR 120.226(A) wear individual monitoring devices as follows:

(1) An individual monitoring device used for monitoring the dose to whole body shall be worn at the unshielded location of the whole body likely to receive the highest exposure. When a protective apron is worn, the location of the individual monitoring device is typically at the neck (collar).

(2) An individual monitoring device used for monitoring the dose to an embryo/fetus of a declared pregnant woman, pursuant to 105 CMR 120.218(A), shall be located at the waist under any protective apron being worn by the woman.

(3) An individual monitoring device used for monitoring lens dose equivalent, to demonstrate compliance with 105 CMR 120.211(A)(2)(a), shall be located at the neck (collar), outside any protective apron being worn by the monitored individual, or at an unshielded location closer to the eye.

(4) An individual monitoring device used for monitoring the dose to the extremities, to demonstrate compliance with 105 CMR 120.211(A)(2)(b), shall be worn on the extremity most likely to receive the highest exposure. Each individual monitoring device shall be oriented to measure the highest dose to the extremity being monitored.

120.227: Control of Access to High Radiation Areas

(A) The licensee or registrant shall ensure that each entrance or access point to a high radiation area has one or more of the following features:

(1) a control device that, upon entry into the area, causes the level of radiation to be reduced below that level at which an individual might receive a deep dose equivalent of 0.1 rem (one millisievert) in one hour at 30 centimeters from the source of radiation or from any surface that the radiation penetrates;

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(2) a control device that energizes a conspicuous visible or audible alarm signal so that the individual entering the high radiation area and the supervisor of the activity are made aware of the entry; or,

(3) entryways that are locked, except during periods when access to the areas is required, with positive control over each individual entry.

NON-TEXT PAGE

120.239: Exceptions to Posting Requirements

(A) A licensee or registrant is not required to post caution signs in areas or rooms containing radioactive materials for periods of less than eight hours, if each of the following conditions is met:

(1) the radioactive materials are constantly attended during these periods by an individual who takes the precautions necessary to prevent the exposure of individuals to radioactive materials in excess of the limits established in 105 CMR 120.200; and,

(2) the area or room is subject to the licensee's or registrant's control.

(B) Rooms or other areas in hospitals that are occupied by patients are not required to be posted with caution signs pursuant to 105 CMR 120.242 provided that patient could be released from confinement pursuant to 105 CMR 120.540.

(C) Rooms or other areas in hospitals that are occupied by patients are not required to be posted with caution signs, provided that:

(1) A patient being treated with a permanent implant could be released from confinement pursuant 105 CMR 120.540; or

(2) A patient being treated with a therapeutic radiopharmaceutical could be released from confinement pursuant 105 CMR 120.540.

(D) A room or area is not required to be posted with a caution sign because of the presence of a sealed source provided the radiation level at 30 centimeters from the surface of the sealed source container or housing does not exceed 0.05 mSv (0.005 rem) per hour.

(E) A room or area is not required to be posted with a caution sign because of the presence of radiation machines used solely for diagnosis in the healing arts.

(F) Rooms in hospitals or clinics that are used for teletherapy are exempt from the requirement to post caution signs under 105 CMR 120.238 if:

(1) Access to the room is controlled pursuant to 105 CMR 120.573; and,

(2) Personnel in attendance take necessary precautions to prevent the inadvertent exposure of workers, other patients, and members of the public to radiation in excess of the limits established in 105 CMR 120.200.

120.240: Labeling Containers and Radiation Machines

(A) The licensee shall ensure that each container of licensed material bears a durable, clearly visible label bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL." The label shall also provide information, such as the radionuclides present, an estimate of the quantity of radioactivity, the date for which the activity is estimated, radiation levels, kinds of materials, and mass enrichment, to permit individuals handling or using the containers, or working in the vicinity of the containers, to take precautions to avoid or minimize exposures.

(B) Each licensee shall, prior to removal or disposal of empty uncontaminated containers to unrestricted areas, remove or deface the radioactive material label or otherwise clearly indicate that the container no longer contains radioactive materials.

(C) Each registrant shall ensure that each radiation machine is labeled in a conspicuous manner which cautions individuals that radiation is produced when it is energized.

120.241: Exemptions to Labeling Requirements

A licensee is not required to label:

(A) containers holding licensed material in quantities less than the quantities listed in 105 CMR 120.297: *Appendix C*; or

(B) containers holding licensed material in concentrations less than those specified in 105 CMR 120.296: *Appendix B*, Table III; or

120.241: continued

(C) containers attended by an individual who takes the precautions necessary to prevent the exposure of individuals in excess of the limits established by 105 CMR 120.200;

(D) containers when they are in transport and packaged and labeled in accordance with the regulations of the U.S. Department of Transportation[1];

(E) containers that are accessible only to individuals authorized to handle or use them, or to work in the vicinity of the containers, if the contents are identified to these individuals by a readily available written record. Examples of containers of this type are containers in locations such as water-filled canals, storage vaults, or hot cells. The record shall be retained as long as the containers are in use for the purpose indicated on the record; or

(F) installed manufacturing or process equipment, such as piping and tanks.

120.242: Procedures for Receiving and Opening Packages

(A) Each licensee or registrant who expects to receive a package containing quantities of radioactive material in excess of a Type A quantity, as defined in 105 CMR 120.772 and 105 CMR 120.798: *Appendix A*, shall make arrangements to receive:

(1) the package when the carrier offers it for delivery; or

(2) the notification of the arrival of the package at the carrier's terminal and to take possession of the package expeditiously.

(B) Each licensee or registrant shall:

(1) monitor the external surfaces of a labeled package for radioactive contamination unless the package contains only radioactive material in the form of gas or in special form as defined in 105 CMR 120.005;

(2) monitor the external surfaces of a labeled[2] package for radiation levels unless the package contains quantities of radioactive material that are less than or equal to the Type A quantity, as defined in 105 CMR 120.772 and 105 CMR 120.798: *Appendix A*; and

(3) monitor all packages known to contain radioactive material for radioactive contamination and radiation levels if there is evidence of degradation of package integrity, such as packages that are crushed, wet, or damaged.

(C) The licensee or registrant shall perform the monitoring required by 105 CMR 120.242 as soon as practicable after receipt of the package, but not later than three hours after the package is received at the licensee's facility if it is received during the licensee's normal working hours, or if there is evidence of degradation of package integrity, such as a package that is crushed, wet, or damaged. If a package is received after working hours, and has no evidence of degradation of package integrity, the package shall be monitored no later than three hours from the beginning of the next working day.

(D) The licensee or registrant shall immediately notify the final delivery carrier and, by telephone and telegram, mailgram, or facsimile, the Agency when:

(1) removable radioactive surface contamination exceeds the limits of 105 CMR 120.786(I); or

(2) External radiation levels exceed the limit of 105 CMR 120.783.

(E) Each licensee or registrant shall:

(1) establish, maintain, and retain written procedures for safely opening packages in which radioactive material is received; and

(2) ensure that the procedures are followed and that due consideration is given to special instructions for the type of package being opened.

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[1] Labeling of packages containing radioactive materials is required by the U.S. Department of Transportation if the amount and type of radioactive material exceeds the limits for an excepted quantity or article as defined and limited by U.S. Department of Transportation regulations 49 CFR 173.403(m) and (w) and 173.424.

[2] Labeled with a Radioactive White I, Yellow II, or Yellow III label as specified in U.S. Department of Transportation regulations 49 CFR 172.403 and 172.436 through 172.440.

120.242: continued

(F) Licensees or registrants transferring special form sources in vehicles owned or operated by the licensee to and from a work site are exempt from the contamination monitoring requirements of 105 CMR 120.246(B), but are not exempt from the monitoring requirement in 105 CMR 120.246(B) for measuring radiation levels that ensures that the source is still properly lodged in its shield.

120.243: Vacating Premises

Each licensee, registrant, or person possessing non-exempt sources of radiation shall, no less than 30 days before vacating or relinquishing possession or control of premises which may have been contaminated with radioactive material as a result of his activity, notify the Agency, in writing, of the intent to vacate. When deemed necessary by the Agency, the licensee, registrant, or person possessing non-exempt sources of radiation shall decontaminate the premises in such a manner as the Agency may specify.

RADIOLOGICAL CRITERIA FOR LICENSE TERMINATION

120.244: General Provisions and Scope

The criteria in 105 CMR 120.244 apply to the decommissioning of facilities licensed under 105 CMR 120.100,120.300, 120.500, 120.800 and 120.900.

(A) The criteria in 105 CMR 120.244 does not apply to sites, which have been decommissioned prior to October 6, 2006.

(B) After a site has been decommissioned and the license terminated in accordance with the criteria in 105 CMR 120.244, the Agency will require additional cleanup only if, based on new information, it determines that the criteria of 105 CMR 120.244 were not met and residual radioactivity remaining at the site could result in significant threat to public health and safety.

(C) When calculating TEDE to the average member of the critical group the licensee shall determine the peak annual TEDE dose expected within the first 1000 years after decommissioning.

(D) Specific time limits for completion of the decommissioning process are as specified in 105 CMR 120.132(G).

(1) Licensees shall complete decommissioning of the site or separate building or outdoor area as soon as practicable but not later than 24 months following the initiation of decommissioning.

(2) When decommissioning involves the entire site, the licensee shall request license termination as soon as practicable but not later than 24 months following the initiation of decommissioning.

(E) The Agency may approve a request for an alternative schedule for completion of the decommissioning of the site or separate building or outdoor area, and license termination is appropriate, if the Agency determines that the alternative is warranted.

120.245: Radiological Criteria for Unrestricted Use

A site will be considered acceptable for unrestricted use if the residual radioactivity that is distinguishable from background radiation results in a TEDE to an average member of the critical group that shall not exceed 0.10 mSv (10 mrem) per year, including that from groundwater sources of drinking water and the residual radioactivity has been reduced to levels that are as low as reasonably achievable (ALARA). Determination of the levels, which are ALARA, must take into account consideration of any detriments, such as deaths from transportation accidents, expected to potentially result from decontamination and waste disposal.

120.246: Criteria for License Termination Under Restricted Conditions

A site will be considered acceptable for license termination under restricted conditions if:

120.246: continued

(A) The licensee can demonstrate that further reductions in residual radioactivity necessary to comply with the provisions of 105 CMR 120.245 would result in net public or environmental harm or were not being made because the residual levels associated with restricted conditions are ALARA. Determination of the levels, which are ALARA must take into account consideration of any detriments, such as deaths from transportation accidents, expected to potentially result from decontamination and waste disposal;

(B) The licensee has made provisions for legally enforceable institutional controls that provide reasonable assurance that TEDE from residual radioactivity distinguishable from background to the average member of the critical group will not exceed 0.10 mSv (10 mrem) per year;

(C) The licensee has provided sufficient financial assurance to enable an independent third party, including a governmental custodian of a site, to assume and carry out responsibilities for any necessary control and maintenance of the site. Acceptable financial assurance mechanisms are:

(1) Funds placed into a trust segregated from the licensee's assets and outside the licensee's administrative control, and in which the adequacy of the trust funds is to be assessed based on an assumed annual 1% real rate of return on investment;

(2) A statement of intent in the case of State, or local Government licensees, as described in 105 CMR 120.125(C)(7)(d); or

(3) When a governmental entity is assuming custody and ownership of a site, an arrangement that is deemed acceptable by such governmental entity.

(D) The licensee has submitted a decommissioning plan or License Termination Plan (LTP) to the Agency indicating the licensee's intent to decommission in accordance with 105 CMR 120.132(D), and specifying that the licensee intends to decommission by restricting use of the site. The licensee shall document in the LTP or decommissioning plan how the advice of individuals and institutions in the community who may be affected by the decommissioning has been sought and incorporated, as appropriate, following analysis of that advice.

(1) Licensees proposing to decommission by restricting use of the site shall seek advice from such affected parties regarding the following matters concerning the proposed decommissioning:

(a) Whether provisions for institutional controls proposed by the licensee:

1. Will provide reasonable assurance that the TEDE from residual radioactivity distinguishable from background to the average member of the critical group will not exceed 0.10 mSv (10 mrem) TEDE per year;

2. Will be enforceable; and

3. Will not impose undue burdens on the local community or other affected parties.

(b) Whether the licensee has provided sufficient financial assurance to enable a third party, including a governmental custodian of a site, to assume and carry out responsibilities for any necessary control and maintenance of the site;

(2) In seeking advice on the issues identified in 105 CMR 120.246D(1), the licensee shall provide for:

(a) Participation by representatives of a broad cross section of community interests who may be affected by the decommissioning;

(b) An opportunity for a comprehensive, collective discussion on the issues by the participants represented; and

(c) A publicly available summary of the results of all such discussions, including a description of the individual viewpoints of the participants on the issues and the extent of agreement and disagreement among the participants on the issues.

(E) Residual radioactivity at the site has been reduced so that if the institutional controls were no longer in effect, there is reasonable assurance that the TEDE from residual radioactivity distinguishable from background to the average member of the critical group is as low as reasonably achievable and would not exceed either:

(1) 1mSv (100 mrem) per year; or

(2) 5mSv (500 mrem) per year provided the licensee:

(a) Demonstrates that further reductions in residual radioactivity necessary to comply with the one mSv/yr (100 mrem/yr) value of 105 CMR 120.246(E)(1) are not technically achievable, would be prohibitively expensive, or would result in net public or environmental harm;

120.246: continued

(b) Makes provisions for durable institutional controls;
(c) Provides sufficient financial assurance to enable a responsible government entity or independent third party, including a governmental custodian of a site, both to carry out periodic rechecks of the site no less frequently than every three years to assure that the institutional controls remain in place as necessary to meet the criteria of 105 CMR 120.246(B) and to assume and carry out responsibilities for any necessary control and maintenance of those controls. Acceptable financial assurance mechanisms are those in 105 CMR 120.246(C).

120.247: Alternate Criteria for License Termination

(A) The Agency may terminate a license using alternate criteria greater than the dose criterion of 105 CMR 120.245, 120.246(B), and 120.246(D)(1)(a)1., if the licensee:
(1) Provides assurance that public health and safety would continue to be protected, and that it is unlikely that the dose from all man-made sources combined, other than medical, would be more than the one mSv/yr (100 mrem/yr) limit, by submitting an analysis of possible sources of exposure;
(2) Has employed to the extent practical restrictions on the site use according to the provisions of 105 CMR 120.246 in minimizing exposures at the site; and
(3) Reduces doses to ALARA levels, taking into consideration any detriments such as traffic accidents expected to potentially result from decontamination and waste disposal.
(4) Has submitted a decommissioning plan or License Termination Plan (LTP) to the Agency indicating the licensee's intent to decommission in accordance with 105 CMR 120.132(D), and specifying that the licensee proposes to decommission by use of alternate criteria. The licensee shall document in the decommissioning plan or LTP how the advice of individuals and institutions in the community who may be affected by the decommissioning has been sought and addressed, as appropriate, following analysis of that advice. In seeking such advice, the license shall provide for:
(a) Participation by representatives of a broad cross section of community interests who may be affected by the decommissioning;
(b) An opportunity for a comprehensive, collective discussion on the issues by the participants represented; and
(c) A publicly available summary of the results of all such discussions, including a description of the individual viewpoints of the participants on the issues and the extent of agreement and disagreement among the participants on the issues.
(5) Has provided sufficient financial assurance in the form of a trust fund to enable an independent third party, including a governmental custodian of a site, to assume and carry out responsibilities for any necessary control and maintenance of the site.

(B) The use of alternate criteria to terminate a license requires the approval of the Agency after consideration of the Agency's staff's recommendations that will address any comments by other appropriate agencies and any public comments submitted pursuant to 105 CMR 120.248.

120.248: Public Notification and Public Participation

Upon the receipt of an LTP or decommissioning plan from the licensee, or a proposal by the licensee for release of a site pursuant to 105 CMR 120.246 and 120.247, or whenever the Agency deems such notice to be in the public interest, the Agency shall:

(A) Notify and solicit comments from:
(1) Local governments in the vicinity of the site and any Indian Nation or other indigenous people that have treaty or statutory rights that could be affected by the decommissioning; and
(2) Other appropriate agencies for cases where the licensee proposes to release a site pursuant to 105 CMR 120.247.

(B) Publish a notice in a forum, such as local newspapers, letters to State or local organizations, or other appropriate forum, that is readily accessible to individuals in the vicinity of the site, and solicit comments from affected parties.

120.249: Minimization of Contamination

(A) Applicants for licenses, after July 1, 1999, shall describe in the application how facility design and procedures for operation will minimize, to the extent practicable, contamination of the facility and the environment, facilitate eventual decommissioning, and minimize, to the extent practicable, the generation of radioactive waste.

(B) Licensees shall, to the extent practical, conduct operations to minimize the introduction of residual radioactivity into the site, including the subsurface, in accordance with the existing radiation protection requirements in 105 CMR 120.210 and radiological criteria for license termination in 105 CMR 120.244 through 120.249.

120.251: General Requirements

(A) Unless otherwise exempted, a licensee shall transfer waste containing licensed material for disposal, discharge or decay only:
(1) by transfer to an authorized recipient as provided in 105 CMR 120.256 or in 105 CMR 120.100, or 105 CMR 120.800, or to the U.S. Department of Energy;
(2) by decay in storage;
(3) by release in effluents within the limits in 105 CMR 120.221; or
(4) as authorized pursuant to 105 CMR 120.253 or 120.254.

(B) A person shall be specifically licensed to receive waste containing licensed material from other persons for:
(1) treatment prior to disposal;
(2) treatment by incineration;
(3) decay in storage;
(4) disposal at a land disposal facility licensed pursuant to 105 CMR 120.800; or
(5) storage until transferred to a storage or disposal facility authorized to receive the waste.

120.252: Method for Obtaining Approval of Proposed Disposal Procedures

A licensee or registrant or applicant for a license or registration may apply to the Agency for approval of proposed procedures, not otherwise authorized in 105 CMR 120.000, to dispose of licensed or registered material generated in the licensee's or registrant's operations. Each application shall include:

(A) A description of the waste containing licensed or registered material to be disposed of, including the physical and chemical properties that have an impact on risk evaluation, and the proposed manner and conditions of waste disposal;

(B) An analysis and evaluation of pertinent information on the nature of the environment;

(C) The nature and location of other potentially affected facilities; and

(D) Analyses and procedures to ensure that doses are maintained ALARA and within the dose limits in 105 CMR 120.200.

120.253: Discharge by Release into Sanitary Sewerage

(A) A licensee may discharge licensed material into sanitary sewerage if each of the following conditions is satisfied:
(1) the material is readily soluble, or is readily dispersible biological material, in water;
(2) the quantity of licensed radioactive material that the licensee releases into the sewer in one month divided by the average monthly volume of water released into the sewer by the licensee does not exceed the concentration listed in 105 CMR 120.296: *Appendix B*, Table III; and
(3) if more than one radionuclide is released, the following conditions must also be satisfied:
(a) the licensee shall determine the fraction of the limit in 105 CMR 120.296: *Appendix B*, Table III represented by discharges into sanitary sewerage by dividing the actual monthly average concentration of each radionuclide released by the licensee into the sewer by the concentration of that radionuclide listed in 105 CMR 120.296: *Appendix B*, Table III; and

120.253: continued

(b) the sum of the fractions for each radionuclide required by 105 CMR 120.253(A)(3)(a) does not exceed unity; and

(4) the total quantity of licensed or other radioactive material that the licensee releases into the sanitary sewerage in a year does not exceed five curies (185 gigabecquerels) of hydrogen-3, one curie (37 gigabecquerels) of carbon-14, and one curie (37 gigabecquerels) of all other radioactive materials combined.

(B) Excreta from individuals undergoing medical diagnosis or therapy with radioactive material are not subject to the limitations contained in 105 CMR 120.253(A).

120.254: Treatment or Disposal by Incineration

A licensee may treat licensed material by incineration only in the form and concentration specified in 105 CMR 120.255 or as specifically approved by the Agency pursuant to 105 CMR 120.252.

120.255: Disposal of Specific Wastes

(A) A licensee or registrant may dispose of the following licensed or registered material as if it were not radioactive:

(1) 1.85 kBq (0.05 μCi), or less, of hydrogen-3 or carbon-14 per gram of medium used for liquid scintillation counting; and

(2) 1.85 kBq (0.05 μCi), or less, of hydrogen-3 or carbon-14 per gram of animal tissue, averaged over the weight of the entire animal.

(B) A licensee or registrant shall not dispose of tissue pursuant to 105 CMR 120.255(A)(2) in a manner that would permit its use either as food for humans or as animal feed.

(C) The licensee or registrant shall maintain records in accordance with 105 CMR 120.269.

120.256: Transfer for Disposal and Manifests

(A) The requirements of 105 CMR 120.256 and 10 CFR 20: *Appendix G*, herein incorporated into 105 CMR120.256 by reference are designed to:

(1) Control transfers of low-level waste by any waste generator, waste collector, or waste processor licensee, as defined in 10 CFR 20: *Appendix G*, who ships low-level waste either directly, or indirectly through a waste collector or waste processor, to a licensed low-level waste land disposal facility as defined in 105 CMR 120.803;

(2) Establish a manifest tracking system; and

(3) Supplement existing requirements concerning transfers and recordkeeping for those wastes.

(B) (1) Any licensee shipping radioactive waste intended for ultimate disposal at a licensed land disposal facility must document the information required on the U.S. Nuclear Regulatory Commission's Uniform Low-level Radioactive Waste Manifest and transfer this recorded information to the intended consignee in accordance with 10 CFR 20: *Appendix G*.

(2) Any licensee shipping by-product material as defined in 105 CMR 120.005: By-product Material(2) and (3) intended for ultimate disposal at a land disposal facility licensed under 105 CMR 120.800 or equivalent NRC or Agreement State regulations must document the information required on the NRC's Uniform Low-level Radioactive Waste Manifest and transfer this recorded manifest information to the intended consignee in accordance with 10 CFR Part 20: *Appendix G*.

(C) Each shipment manifest shall include a certification by the waste generator as specified in 10 CFR 20: *Appendix G*.

(D) Each person involved in the transfer of waste for disposal or in the disposal of waste, including the waste generator, waste collector, and waste processor, shall comply with the requirements specified in 105 CMR 120.256 and 10 CFR 20: *Appendix G*.

120.256: continued

(E) Reports and notifications required to be made to the nearest NRC regional administrator by 10 CFR 20: *Appendix G* shall, instead, be made to the Agency.

120.257: Compliance with Environmental and Health Protection Regulations

Nothing in 105 CMR 120.251, 120.253, 20.254, or 120.256 relieves the licensee from complying with other applicable federal, state and local regulations governing any other toxic or hazardous properties of materials that may be disposed of in accordance with 105 CMR 120.251, 120.253, 120.254, or 120.256.

120.258: Disposal of Certain Byproduct Material

(A) Licensed material as defined in 105 CMR 120.005: By-product Material(2) and (3) may be disposed of in accordance with 105 CMR 120.800, even though it is not defined as low-level radioactive waste. Therefore, any licensed by-product material being disposed of at a facility, or transferred for ultimate disposal at a facility licensed under 105 CMR 120.800 or equivalent Nuclear Regulatory Commission or Agreement State requirements, must meet the requirements of 105 CMR 120.256.

(B) A licensee may dispose of byproduct material, as defined in 105 CMR 120.005: By-product Material(2) and (3), at a disposal facility authorized to dispose of such material in accordance with any Federal or State solid or hazardous waste law, including the Solid Waste Disposal Act, as authorized under the Energy Policy Act of 2005.

RECORDS

120.261: General Provisions

(A) Each licensee or registrant shall use the SI units becquerel, gray, sievert and coulomb per kilogram, or the special units curie, rad, rem and roentgen, including multiples and subdivisions, and shall clearly indicate the units of all quantities on records required by 105 CMR 120.261.

(B) Not withstanding the requirements of 105 CMR 120.261(A), when recording information on shipment manifests, as required in 105 CMR 120.256, information must be recorded in SI units or in SI units and special units as specified in 105 CMR 120.261(A).

(C) The licensee or registrant shall make a clear distinction among the quantities entered on the records required by 105 CMR 120.200, such as, total effective dose equivalent, total organ dose equivalent, shallow dose equivalent, lens dose equivalent, deep dose equivalent, or committed effective dose equivalent.

120.262: Records of Radiation Protection Programs

(A) Each licensee or registrant shall maintain records of the radiation protection program, including:

(1) the provisions of the program; and

(2) audits and other reviews of program content and implementation.

(B) The licensee or registrant shall retain the records required by 105 CMR 120.262(A)(1) until the Agency terminates each pertinent license or registration requiring the record. The licensee or registrant shall retain the records required by 105 CMR 120.262(A)(2) for three years after the record is made.

120.263: Records of Surveys

(A) Each licensee or registrant shall maintain records showing the results of surveys and calibrations required by 105 CMR 120.225 and 120.242(B). The licensee or registrant shall retain these records for three years after the record is made.

120.263: continued

(B) The licensee or registrant shall retain each of the following records until the Agency terminates each pertinent license or registration requiring the record:

(1) records of the results of surveys to determine the dose from external sources of radiation used, in the absence of or in combination with individual monitoring data, in the assessment of individual dose equivalents;

(2) records of the results of measurements and calculations used to determine individual intakes of radioactive material and used in the assessment of internal dose;

(3) records showing the results of air sampling, surveys, and bioassays required pursuant to 105 CMR 120.233(A)(3)(a) and (b); and

(4) records of the results of measurements and calculations used to evaluate the release of radioactive effluents to the environment.

120.264: Records of Tests for Leakage or Contamination of Sealed Sources

Records of tests for leakage or contamination of sealed sources required by 105 CMR 120.223 shall be kept in units of becquerel or microcurie and maintained for inspection by the Agency for five years after the records are made.

120.265: Determination and Records of Prior Occupational Dose

(A) For each individual who is likely to receive, in a year, an occupational dose requiring monitoring pursuant to 105 CMR 120.226, the licensee or registrant shall:

(1) Determine the occupational radiation dose received during the current year; and

(2) Attempt to obtain the records of cumulative occupational radiation dose.

(B) Prior to permitting an individual to participate in a planned special exposure, the licensee or registrant shall determine:

(1) The internal and external doses from all previous planned special exposures;

(2) All doses in excess of the limits, including doses received during accidents; and emergencies, received during the lifetime of the individual.

NON-TEXT PAGE

120.270: Records of Testing Entry Control Devices for Very High Radiation Areas

(A) Each licensee or registrant shall maintain records of tests made pursuant to 105 CMR 120.229(B)(9) on entry control devices for very high radiation areas. These records must include the date, time, and results of each such test of function.

(B) The licensee or registrant shall retain the records required by 105 CMR 120.270(A) for three years after the record is made.

120.271: Form of Records

Each record required by 105 CMR 120.200 shall be legible throughout the specified retention period. The record shall be the original or a reproduced copy or a microform, provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period or the record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records, such as letters, drawings, and specifications, shall include all pertinent information, such as stamps, initials, and signatures. The licensee or registrant shall maintain adequate safeguards against tampering with and loss of records.

REPORTS

120.281: Reports of Stolen, Lost, or Missing Licensed or Registered Sources of Radiation

(A) Telephone Reports. Each licensee or registrant shall report to the Agency by telephone as follows:

(1) immediately after its occurrence becomes known to the licensee, stolen, lost, or missing licensed radioactive material in an aggregate quantity equal to or greater than 1,000 times the quantity specified in 105 CMR 120.297: *Appendix C*, under such circumstances that it appears to the licensee that an exposure could result to individuals in unrestricted areas;

(2) within 30 days after its occurrence becomes known to the licensee, lost, stolen, or missing licensed radioactive material in an aggregate quantity greater than ten times the quantity specified in 105 CMR 120.297: *Appendix C* that is still missing;

(3) immediately after its occurrence becomes known to the registrant, a stolen, lost, or missing radiation machine.

(B) Written Reports. Each licensee or registrant required to make a report pursuant to 105 CMR 120.281(A) shall, within 30 days after making the telephone report, make a written report to the Agency setting forth the following information:

(1) a description of the licensed or registered source of radiation involved, including, for radioactive material, the kind, quantity, and chemical and physical form; and, for radiation machines, the manufacturer, model and serial number, type and maximum energy of radiation emitted;

(2) a description of the circumstances under which the loss or theft occurred;

(3) a statement of disposition, or probable disposition, of the licensed or registered source of radiation involved;

(4) exposures of individuals to radiation, circumstances under which the exposures occurred, and the possible total effective dose equivalent to persons in unrestricted areas;

(5) actions that have been taken, or will be taken, to recover the source of radiation; and

(6) procedures or measures that have been, or will be, adopted to ensure against a recurrence of the loss or theft of licensed or registered sources of radiation.

(C) Subsequent to filing the written report, the licensee or registrant shall also report additional substantive information on the loss or theft within 30 days after the licensee or registrant learns of such information.

120.281: continued

(D) The licensee or registrant shall prepare any report filed with the Agency pursuant to 105 CMR 120.281 so that names of individuals who may have received exposure to radiation are stated in a separate and detachable portion of the report.

120.282: Notification of Incidents

(A) Immediate Notification. Notwithstanding any other requirements for notification, each licensee or registrant shall immediately report each event involving a source of radiation possessed by the licensee or registrant that may have caused or threatens to cause any of the following conditions:

(1) An individual to receive:
(a) a total effective dose equivalent of 0.25 sievert (25 rems) or more;
(b) a lens dose equivalent of 0.75 sievert (75 rems) or more;
(c) a shallow dose equivalent to the skin or extremities or a total organ dose equivalent of 2.5 grays (250 rads) or more; or

(2) The release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for 24 hours, the individual could have received an intake five times the occupational ALI. This provision does not apply to locations where personnel are not normally stationed during routine operations, such as hot-cells or process enclosures.

(B) 24 Hour Notification. Each licensee or registrant shall, within 24 hours of discovery of the event, report to the Agency each event involving loss of control of a licensed or registered source of radiation possessed by the licensee or registrant that may have caused, or threatens to cause, any of the following conditions:

(1) An individual to receive, in a period of 24 hours:
(a) a total effective dose equivalent exceeding 0.05 sievert (five rems);
(b) a lens dose equivalent exceeding 0.15 sievert (15 rems);
(c) a shallow dose equivalent to the skin or extremities or a total organ dose equivalent exceeding 0.5 sievert (50 rems); or

(2) The release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for 24 hours, the individual could have received an intake in excess of one occupational ALI. This provision does not apply to locations where personnel are not normally stationed during routine operations, such as hot-cells or process enclosures.

(C) Licensees or registrants shall make the reports required by 105 CMR 120.282(A) and (B) by initial contact by telephone to the Agency and shall confirm the initial contact by telegram, mailgram, or facsimile to the Agency.

(D) The licensee or registrant shall prepare each report filed with the Agency pursuant to 105 CMR 120.282 so that names of individuals who have received exposure to sources of radiation are stated in a separate and detachable portion of the report.

(E) The provisions of 105 CMR 120.282 do not apply to doses that result from planned special exposures, provided such doses are within the limits for planned special exposures and are reported pursuant to 105 CMR 120.284.

120.283: Reports of Exposures, Radiation Levels, and Concentrations of Radioactive Material Exceeding the Constraints or the Limits

(A) Reportable Events. In addition to the notification required by 105 CMR 120.282, each licensee or registrant shall submit a written report within 30 days after learning of any of the following occurrences:

(1) incidents for which notification is required by 105 CMR 120.282; or
(2) doses in excess of any of the following:
(a) the occupational dose limits for adults in 105 CMR 120.211;
(b) the occupational dose limits for a minor in 105 CMR 120.217;
(c) the limits for an embryo/fetus of a declared pregnant woman in 105 CMR 120.218;
(d) the limits for an individual member of the public in 105 CMR 120.221;
(e) any applicable limit in the license or registration;
(f) the ALARA constraints for air emissions established under 105 CMR 120.210(D); or

120.755: continued

(E) Different representatives of licensees or registrants and workers may accompany the inspectors during different phases of an inspection if there is no resulting interference with the conduct of the inspection. However, only one workers' representative at a time may accompany the inspectors.

(F) With the approval of the licensee or registrant and the workers' representative, an individual who is not routinely engaged in work under control of the licensee or registrant, for example, a consultant to the licensee or registrant or to the workers' representative, shall be afforded the opportunity to accompany Agency inspectors during the inspection of physical working conditions.

(G) Notwithstanding the other provisions of 105 CMR 120.755, Agency inspectors are authorized to refuse to permit accompaniment by any individual who deliberately interferes with a fair and orderly inspection. With regard to areas containing information classified by an agency of the U.S. Government in the interest of national security, an individual who accompanies an inspector may have access to such information only if authorized to do so. With regard to any area containing proprietary information, the workers' representative for that area shall be an individual previously authorized by the licensee or registrant to enter that area.

120.756: Consultation with Workers During Inspections

(A) Agency inspectors may consult privately with workers concerning matters of occupational radiation protection and other matters related to applicable provisions of 105 CMR 120.000 and licenses to the extent the inspectors deem necessary for the conduct of an effective and thorough inspection.

(B) During the course of an inspection, any worker may bring privately to the attention of the inspectors, either orally or in writing, any past or present condition which the worker has reason to believe may have contributed to or caused any violation of M.G.L. c. 111, §§, 5N, and 5P, 105 CMR 120.000, or license condition, or any unnecessary exposure of an individual to sources of radiation under the licensee's or registrant's control. Any such notice in writing shall comply with the requirements of 105 CMR 120.757(A).

(C) The provisions of 105 CMR 120.756(B) shall not be interpreted as authorization to disregard instructions pursuant to 105 CMR 120.753.

120.757: Requests by Workers for Inspections

(A) Any worker or representative of workers believing that a violation of the Act, 105 CMR 120.000, or license conditions exists or has occurred in work under a license or registration with regard to radiological working conditions in which the worker is engaged may request an inspection by giving notice of the alleged violation to the Agency. Any such notice shall be in writing, shall set forth the specific grounds for the notice, and shall be signed by the worker or representative of the workers. A copy shall be provided to the licensee or registrant by the Agency no later than at the time of inspection except that, upon the request of the worker giving such notice, his name and the name of individuals referred to therein shall not appear in such copy or on any record published, released, or made available by the Agency, except for good cause shown.

(B) If, upon receipt of such notice, the Agency determines that the complaint meets the requirements set forth in 105 CMR 120.757(A), and that there are reasonable grounds to believe that the alleged violation exists or has occurred, an inspection shall be made as soon as practicable to determine if such alleged violation exists or has occurred. Inspections pursuant to 105 CMR 120.757 need not be limited to matters referred to in the complaint.

(C) No licensee, registrant, or contractor or subcontractor of a licensee or registrant shall discharge or in any manner discriminate against any worker because such worker has filed any complaint or instituted or caused to be instituted any proceeding under 105 CMR 120.000 or has testified or is about to testify in any such proceeding or because of the exercise by such worker on behalf of himself or others of any option afforded by 105 CMR 120.750.

120.758: Inspections not Warranted; Informal Review

(A) (1) If the Agency determines, with respect to a complaint under 105 CMR 120.757, that an inspection is not warranted because there are no reasonable grounds to believe that a violation exists or has occurred, the Agency shall notify the complainant in writing of such determination. The complainant may obtain review of such determination by submitting a written statement of position with the Department. The Department will provide the licensee or registrant with a copy of such statement by certified mail, excluding, at the request of the complainant, the name of the complainant. The licensee or registrant may submit an opposing written statement of position with the Department. The Department will provide the complainant with a copy of such statement by certified mail.

(2) Upon the request of the complainant, the Department may hold an informal conference in which the complainant and the licensee or registrant may, orally present their views. An informal conference may also be held at the request of the licensee or registrant, but disclosure of the identity of the complainant will be made only following receipt of written authorization from the complainant. After considering all written and oral views presented, the Department shall affirm, modify, or reverse the determination of the Agency and furnish the complainant and the licensee or registrant a written notification of the decision and the reason therefor.

(B) If the Agency determines that an inspection is not warranted because the requirements of 105 CMR 120.757(A) have not been met, the complainant shall be notified in writing of such determination. Such determination shall be without prejudice to the filing of a new complaint meeting the requirements of 105 CMR 120.757(A).

120.760: Emergency Plans

The user should formulate suitable emergency plans as may be indicated to protect his employees and the public against potential hazards due to his specific source(s), and should make known the details and existence of such plans to the Agency and such other public agencies having a concern; including, but not limited to, boards of health, fire departments and police departments.

120.770: TRANSPORTATION OF RADIOACTIVE MATERIAL

120.771: Purpose and Scope

(A) 105 CMR 120.770 establishes requirements for packaging, preparation for shipment, and transportation of licensed material.

(B) The packaging and transport of licensed material are also subject to other sections of 105 CMR 120.000 and to the regulations of other agencies (such as the United States Department of Transportation, the United States Postal Service and the United States Nuclear Regulatory Commission) having jurisdiction over means of transport. The requirements of 105 CMR 120.770 are in addition to, and not in substitution for, other requirements

(C) 105 CMR 120.770 applies to any licensee authorized by specific or general license issued by the Agency to receive, possess, use, or transfer licensed material, if the licensee delivers that material to a carrier for transport, transports the material outside the site of usage as specified in the Agency license, or transports that material on public highways. No provision of 105 CMR 120.770 authorizes possession of licensed material.

(D) Exemptions from the requirement for license in 105 CMR 120.773 are specified in 105 CMR 120.775. General licenses for which no NRC package approval is required are issued in 105 CMR 120.780 through 120.782. The general license in 105 CMR 120.777 requires that an NRC certificate of compliance or other package approval be issued for the package to be used under this general license. The transport of licensed material or delivery of licensed material to a carrier for transport is subject to the operating control and procedures requirements of 105 CMR 120.784 through 120.790, to the quality assurance requirements of 105 CMR 120.791 through 120.797, and to the general provisions of 105 CMR 120.771 through 120.774, including referenced United States Department of Transportation regulations.

120.771: continued

(E) 105 CMR 120.770 applies to any person required to obtaina certificate of compliance or an approved compliance plan from the NRC pursuant to 10 CFR 76 if the person delivers radioactive material to a common or contract carrier for transport or transports the material outside the confines of the person's plant or other authorized place of use.

120.772: Definitions

The following terms are as defined here for the purpose of 105 CMR 120.770. To ensure compatibility with international transportation standards, all limits in this part are given in terms of dual units: The International System of Units (SI) followed or preceded by U.S. standard or customary units. The U.S. customary units are not exact equivalents but are rounded to a convenient value, providing a functionally equivalent unit. For the purpose of 105 CMR 120.770, either unit may be used.

A_1 means the maximum activity of special form radioactive material permitted in a Type A package. This value is either listed in 105 CMR 120.798: *Appendix A*, Table A-1, or may be derived in accordance with the procedures prescribed in 105 CMR 120.798: *Appendix A*.

A_2 means the maximum activity of radioactive material, other than special form material, LSA, and SCO material, permitted in a Type A package. This value is either listed in 105 CMR 120.798: *Appendix A*, Table A-1, or may be derived in accordance with the procedures prescribed in 105 CMR 120.798: *Appendix A*.

Carrier means a person engaged in the transportation of passengers or property by land or water as a common, contract, or private carrier, or by civil aircraft.

Certificate Holder means a person who has been issued a certificate of compliance or other package approval by the Commission.

Certificate of Compliance (CoC) means the certificate issued by the Commission under 10 CFR 71 Subpart D which approves the design of a package for the transportation of radioactive material.

Consignment means each shipment of a package or groups of packages or load of radioactive material offered by a shipper for transport.

Contamination means the presence of a radioactive substance on a surface in quantities in excess of 0.4 Bq/cm^2 (1 x 10^{-5} $\mu Ci/cm^2$) for beta and gamma emitters and low toxicity alpha emitters, or 0.04 Bq/cm^2 (1 x 10^{-6} $\mu Ci/cm^2$) for all other alpha emitters.

(1) Fixed Contamination means contamination that cannot be removed from a surface during normal conditions of transport.

(2) Non-fixed Contamination means contamination that can be removed from a surface during normal conditions of transport.

Conveyance means:

(1) For transport by public highway or rail any transport vehicle or large freight container;

(2) For transport by water any vessel, or any hold, compartment, or defined deck area of a vessel including any transport vehicle on board the vessel; and

(3) For transport by any aircraft.

Criticality Safety Index (CSI) means the dimensionless number (rounded up to the next tenth) assigned to and placed on the label of a fissile material package, to designate the degree of control of accumulation of packages, overpacks or freight containers containing fissile material during transportation. Determination of the criticality safety index is described in 105 CMR 120.781 and 120.782, and 10 CFR 71.59. The criticality safety index for an overpack, freight container, consignment or conveyance containing fissile material packages is the arithmetic sum of the criticality safety indices of all the fissile material packages contained within the overpack, freight container, consignment or conveyance.

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Deuterium means, for the purposes of 10 CFR 71.15 and 71.22, deuterium and any deuterium compounds, including heavy water, in which the ratio of deuterium atoms to hydrogen atoms exceeds 1:5000.

DOT means the U.S. Department of Transportation.

Exclusive Use means the sole use by a single consignor of a conveyance for which all initial, intermediate, and final loading and unloading are carried out in accordance with the direction of the consignor or consignee. The consignor and the carrier must ensure that any loading or unloading is performed by personnel having radiological training and resources appropriate for safe handling of the consignment. The consignor must issue specific instructions, in writing, for maintenance of exclusive use shipment controls, and include them with the shipping paper information provided to the carrier by the consignor.

Fissile Material means the radionuclides uranium-233, uranium-235, plutonium-239, and plutonium-241, or any combination of these radionuclides. Fissile material means the fissile nuclides themselves, not material containing fissile nuclides. Unirradiated natural uranium and depleted uranium, and natural uranium or depleted uranium that has been irradiated in thermal reactors only are not included in 105 CMR 120.772: Fissile Material.[1] Certain exclusions from fissile material controls are provided in 105 CMR 120.775.

Graphite means, for the purposes of 105 CMR 120.775 and 120.781, graphite with a boron equivalent content less than five parts per million and density greater than 1.5 grams per cubic centimeter.

Indian Tribe means an Indian or Alaska Native Tribe, band, nation, pueblo, village, or community that the Secretary of the Interior acknowledges to exist as an Indian Tribe pursuant to the Federally Recognized Indian Tribe List Act of 1994, 25 U.S.C. 479a.

Low Specific Activity (LSA) Material means radioactive material with limited specific activity which is nonfissile or is excepted under 105 CMR 120.775(D), and which satisfies the descriptions and limits set forth in 105 CMR 120.772: Low Specific Activity (LSA) Material(1) through (3). Shielding materials surrounding the LSA material may not be considered in determining the estimated average specific activity of the package contents. The LSA material must be in one of three groups:

(1) LSA-I.

(a) Uranium and thorium ores, concentrates of uranium and thorium ores, and other ores containing naturally occurring radionuclides that are intended to be processed for the use of these radionuclides;

(b) Natural uranium, depleted uranium, natural thorium or their compounds or mixtures, provided they are unirradiated and in solid or liquid form;

(c) Radioactive material, other than fissile material, for which the A_2 value is unlimited; or

(d) Other radioactive material in which the activity is distributed throughout and the estimated average specific activity does not exceed 30 times the value for exempt material activity concentration determined in accordance with 105 CMR 120.798: *Appendix A*.

(2) LSA-II.

(a) Water with tritium concentration up to 0.8 TBq/liter (20.0 Ci/liter); or

(b) Other radioactive material in which the activity is distributed throughout and the estimated average specific activity does not exceed $10^{-4} A_2/g$ for solids and gases, and $10^{-5} A_2/g$ for liquids.

(3) LSA-III. Solids (*e.g.*, consolidated wastes, activated materials), excluding powders, that satisfy the requirements of 10 CFR 71.77, in which:

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[1] Agency jurisdiction extends only to "special nuclear material in quantities not sufficient to form a critical mass" as defined in 105 CMR 120.005.

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(a) The radioactive material is distributed throughout a solid or a collection of solid objects, or is essentially uniformly distributed in a solid compact binding agent (such as concrete, bitumen, ceramic, *etc*.);
(b) The radioactive material is relatively insoluble, or it is intrinsically contained in a relatively insoluble material, so that, even under loss of packaging, the loss of radioactive material per package by leaching, when placed in water for seven days, will not exceed 0.1 A_2; and
(c) The estimated average specific activity of the solid, excluding any shielding material, does not exceed 2 x 10^{-3} A_2/g.

Low Toxicity Alpha Emitters means natural uranium, depleted uranium, natural thorium; uranium-235, uranium-238, thorium-232, thorium-228 or thorium-230 when contained in ores or physical or chemical concentrates; or alpha emitters with a half-life of less than ten days.

Maximun Normal Operating Pressure means the maximum gauge pressure that would develop in the containment system in a period of one year under the heat condition specified in 10 CFR 71.71(c)(1), in the absence of venting, external cooling by an ancillary system, or operational controls during transport.

Natural Thorium means thorium with the naturally occurring distribution of thorium isotopes (essentially 100 weight percent thorium-232).

Normal Form Radioactive Material means radioactive material which has not been demonstrated to qualify as special form radioactive material.

Nuclear Waste means a quantity of source, byproduct or special nuclear material required to be in US Nuclear Regulatory Commission-approved specification packaging while transported to, through or across a state boundary to a disposal site, or to a collection point for transport to a disposal site.

Package means the packaging together with its radioactive contents as presented for transport.
(1) Fissile material package or Type AF package, Type BF package, Type B(U)F package, or Type B(M)F package means a fissile material packaging together with its fissile material contents.
(2) Type A package means a Type A packaging together with its radioactive contents. A Type A package is defined and must comply with the DOT regulations in 49 CFR Part 173.
(3) Type B package means a Type B packaging together with its radioactive contents. On approval, a Type B package design is designated by NRC as B(U) unless the package has a maximum normal operating pressure of more than 700 kPa (100 lbs./in^2) gauge or a pressure relief device that would allow the release of radioactive material to the environment under the tests specified in 10 CFR 71.73 (hypothetical accident conditions), in which case it will receive a designation B(M). B(U) refers to the need for unilateral approval of international shipments; B(M) refers to the need for multilateral approval of international shipments. There is no distinction made in how packages with these designations may be used in domestic transportation. To determine their distinction for international transportation, see DOT regulations in 49 CFR Part 173. A Type B package approved before September 6, 1983, was designated only as Type B. Limitations on its use are specified in 10 CFR 71.19.

Packaging means the assembly of components necessary to ensure compliance with the packaging requirements of 49 CFR Part 173. It may consist of one or more receptacles, absorbent materials, spacing structures, thermal insulation, radiation shielding, and devices for cooling or absorbing mechanical shocks. The vehicle, tie-down system, and auxiliary equipment may be designated as part of the packaging.

Regulations of the U.S. Department of Transportation (DOT) means the regulations in 49 CFR Parts 100 through 189 and Parts 390 through 397.

Regulations of the U.S. Nuclear Regulatory Commission (NRC) means the regulations in 10 CFR 71 for purposes of 105 CMR 120.770.

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Specific Activity of a radionuclide means the activity of a radionuclide per unit mass of that nuclide. The specific activity of a material in which the radionuclide is essentially uniformly distributed is the activity per unit mass of the material.

Surface Contaminated Object (SCO) means a solid object that is not itself classed as radioactive material, but which has radioactive material distributed on any of its surfaces. SCO must be in one of two groups with surface activity not exceeding the following limits:

(1) SCO-I: A solid object on which:

(a) The non-fixed contamination on the accessible surface averaged over 300 cm^2 (or the area of the surface if less than 300 cm^2) does not exceed four Bq/cm^2 (10^{-4} microcurie/cm^2) for beta and gamma and low toxicity alpha emitters, or 0.4 Bq/cm^2 (10^{-5} microcurie/cm^2) for all other alpha emitters;

(b) The fixed contamination on the accessible surface averaged over 300 cm^2 (or the area of the surface if less than 300 cm^2) does not exceed $4x10^4$ Bq/cm^2 (1.0 microcurie/cm^2) for beta and gamma and low toxicity alpha emitters, or $4x10^3$ Bq/cm^2 (0.1 microcurie/cm^2) for all other alpha emitters; and

(c) The non-fixed contamination plus the fixed contamination on the inaccessible surface averaged over 300 cm^2 (or the area of the surface if less than 300 cm^2) does not exceed $4x10^4$ Bq/cm^2 (one microcurie/cm^2) for beta and gamma and low toxicity alpha emitters, or $4x10^3$ Bq/cm^2 (0.1 microcurie/cm^2) for all other alpha emitters.

(2) SCO-II: A solid object on which the limits for SCO-I are exceeded and on which:

(a) The non-fixed contamination on the accessible surface averaged over 300 cm^2 (or the area of the surface if less than 300 cm^2) does not exceed 400 Bq/cm^2 (10^{-2} microcurie/cm^2) for beta and gamma and low toxicity alpha emitters or 40 Bq/cm^2 (10^{-3} microcurie/cm^2) for all other alpha emitters;

(b) The fixed contamination on the accessible surface averaged over 300 cm^2 (or the area of the surface if less than 300 cm^2) does not exceed $8x10^5$ Bq/cm^2 (20 microcuries/cm^2) for beta and gamma and low toxicity alpha emitters, or $8x10^4$ Bq/cm^2 (two microcuries/cm^2) for all other alpha emitters; and

(c) The non-fixed contamination plus the fixed contamination on the inaccessible surface averaged over 300 cm^2 (or the area of the surface if less than 300 cm^2) does not exceed $8x10^5$ Bq/cm^2 (20 microcuries/cm^2) for beta and gamma and low toxicity alpha emitters, or $8x10^4$ Bq/cm^2 (two microcuries/cm^2) for all other alpha emitters.

Transport Index means the dimensionless number (rounded up to the next tenth) placed on the label of a package to designate the degree of control to be exercised by the carrier during transportation. The transport index is the number determined by multiplying the maximum radiation level in millisievert (mSv) per hour at one meter (3.3 ft.) from the external surface of the package by 100 (equivalent to the maximum radiation level in millirem per hour at one meter (3.3 ft.).

Tribal Official means the highest ranking individual that represents Tribal leadership, such as the Chief, President, or Tribal Council leadership.

Type A Quantity means a quantity of radioactive material, the aggregate radioactivity of which does not exceed A_1 for special form radioactive material or A_2 for normal form radioactive material, where A_1 and A_2 are given in 105 CMR 120.798: *Appendix A* or may be determined by procedures described in 105 CMR 120.798: *Appendix A*.

Type B Quantity means a quantity of radioactive material greater than a Type A quantity.

Unirradiated Uranium means uranium containing not more than 2×10^3 Bq of plutonium per gram of uranium-235, not more than 9×10^6 Bq of fission products per gram of uranium-235, and not more than 5×10^{-3} g of uranium-236 per gram of uranium-235.

Uranium - Natural, Depleted, Enriched.

(1) Natural Uranium means uranium (which may be chemically separated) with the naturally occurring distribution of uranium isotopes (approximately 0.711 weight percent uranium-235, and the remainder by weight essentially uranium-238).

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(2) Depleted Uranium means uranium containing less uranium-235 than the naturally occurring distribution of uranium isotopes.
(3) Enriched Uranium means uranium containing more uranium-235 than the naturally occurring distribution of uranium isotopes.

GENERAL REGULATORY PROVISIONS

120.773: Requirement for License

Except as authorized in a general license or a specific license issued by the Agency, or as exempted in 105 CMR 120.775, no licensee may:

(A) Deliver licensed material to a carrier for transport; or

(B) Transport licensed material.

120.774: Transportation of Licensed Material

(A) Each licensee who transports licensed material outside the site of usage, as specified in the Agency license, or where transport is on public highways, or who delivers licensed material to a carrier for transport, shall comply with the applicable requirements of the U.S. Department of Transportation regulations in 49 CFR Parts 107, 171 through 180, and 390 through 397, appropriate to the mode of transport.

(1) The licensee shall particularly note DOT regulations in the following areas:
(a) Packaging - 49 CFR Part 173: Subparts A and B and I.
(b) Marking and labeling - 49 CFR Part 172: Subpart D, §§ 172.400 through 172.407, §§ 172.436 through 172.441, and Subpart E.
(c) Placarding - 49 CFR Part 172: Subpart F, especially §§ 172.500 through 172.519, 172.556, and Appendices B and C.
(d) Accident reporting - 49 CFR Part 171: §§ 171.15 and 171.16.
(e) Shipping papers and emergency information - 49 CFR Part 172: Subparts C and G.
(f) Hazardous material employee training - 49 CFR Part 172: Subpart H.
(g) Security plans - 49 CFR Part 172: Subpart I.
(h) Hazardous material shipper/carrier registration - 49 CFR Part 107: Subpart G.

(2) The licensee shall also note DOT regulations pertaining to the following modes of transportation:
(a) Rail - 49 CFR Part 174: Subparts A through D, and K.
(b) Air - 49 CFR Part 175.
(c) Vessel - 49 CFR Part 176: Subparts A through F and M.
(d) Public Highway - 49 CFR Part 177 and Parts 390 through 397.

(3) Assure that any special instructions needed to safely open the package are sent to or have been made available to the consignee in accordance with 105 CMR 120.242(E).

(B) If, for any reason, the regulations of the U.S. Department of Transportation are not applicable to a shipment of licensed material, the licensee shall conform to the standards and requirements of 49 CFR Parts 107, 171 through 180 and 390 through 397 appropriate to the mode of transport to the same extent as if the shipment was subject to the regulations. A request for modification, waiver, or exemption from those requirements, and any notification referred to in those requirements, must be filed with, or made to, the Director, Radiation Control Program.

120.775: Exemptions

(A) Any physician licensed by a State to dispense drugs in the practice of medicine is exempt from 105 CMR 120.774 with respect to transport by the physician of licensed material for use in the practice of medicine. However, any physician operating under 105 CMR 120.775 must be licensed under 10 CFR Part 35 or the equivalent Agreement State regulations.

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(B) Common and contract carriers, freight forwarders, and warehouse workers who are subject to the requirements of the U.S. Department of Transportation in 49 CFR 170 through 189 or the U.S. Postal Service in the Postal Service Manual (Domestic Mail Manual), Section 124.3 incorporated by reference, 39 CFR 111.11 (1974), and the U.S. Postal Service are exempt from the requirements of 105 CMR 120.770 to the extent that they transport or store radioactive material in the regular course of their carriage for others or storage incident thereto. Common and contract carriers who are not subject to the requirements of the U.S. Department of Transportation or U.S. Postal Service are subject to 105 CMR 120.773 and other applicable requirements of 105 CMR 120.000.

(C) A licensee is exempt from all requirements of 105 CMR 120.770, with respect to shipment or carriage of the following low-level materials:

(1) Natural material and ores containing naturally occurring radionuclides that are either in their natural state, or have only been processed for purposes other than for the extraction of the radionuclides, and which are not intended to be processed for the use of these radionuclides, provided the activity concentration of the material does not exceed ten times the applicable radionuclide activity concentration values specified in 105 CMR 120.798: *Appendix A*, Table A-2, or *Table A-3*.

(2) Materials for which the activity concentration is not greater than the activity concentration values specified in 105 CMR 120.798: *Appendix A*, Table A-2, or *Table A-3*, or for which the consignment activity is not greater than the limit for an exempt consignment found in 105 CMR 120.798: *Appendix A*, Table A-2, or *Table A-3*.

(3) Non-radioactive solid objects with radioactive substances present on any surfaces in quantities not in excess of the levels cited in the definition of contamination in 105 CMR 120.772.

(D) Fissile materials meeting one of the following requirements are exempt from the classification as fissile material and from the fissile material package standards of 10 CFR 71.55 and 10 CFR 71.59, but are subject to all other requirements of 10 CFR 71, except as noted.

(1) Individual package containing two grams or less fissile material.

(2) Individual or bulk packaging containing 15 grams or less of fissile material provided the package has at least 200 grams of solid nonfissile material for every gram of fissile material. Lead, beryllium, graphite, and hydrogenous material enriched in deuterium may be present in the package but must not be included in determining the required mass for solid nonfissile material.

(3) (a) Low concentrations of solid fissile material commingled with solid nonfissile material, provided that:

1. There is at least 2000 grams of solid nonfissile material for every gram of fissile material, and

2. There is no more than 180 grams of fissile material distributed within 360 kg of contiguous nonfissile material.

(b) Lead, beryllium, graphite, and hydrogenous material enriched in deuterium may be present in the package but must not be included in determining the required mass of solid nonfissile material.

(4) Uranium enriched in uranium-235 to a maximum of 1% by weight, and with total plutonium and uranium-233 content of up to 1% of the mass of uranium-235, provided that the mass of any beryllium, graphite, and hydrogenous material enriched in deuterium constitutes less than 5% of the uranium mass, and that the fissile material is distributed homogeneously and does not form a lattice arrangement within the package.

(5) Liquid solutions of uranyl nitrate enriched in uranium-235 to a maximum of 2% by mass, with a total plutonium and uranium-233 content not exceeding 0.002% of the mass of uranium, and with a minimum nitrogen to uranium atomic ratio (N/U) of two. The material must be contained in at least a DOT Type A package.

(6) Packages containing, individually, a total plutonium mass of not more than 1000 grams, of which not more than 20% by mass may consist of plutonium-239, plutonium-241, or any combination of these radionuclides.

120.776: General Licenses for Carriers

(A) A general license is hereby issued to any common or contract carrier not exempt under 105 CMR 120.775 to receive, possess, transport, and store radioactive material in the regular course of their carriage for others or storage incident thereto, provided the transportation and storage is in accordance with the applicable requirements, appropriate to the mode of transport, of the U.S. Department of Transportation insofar as such requirements relate to the loading and storage of packages, placarding of the transporting vehicle, and incident reporting.[3]

(B) A general license is hereby issued to any private carrier to transport radioactive material, provided the transportation is in accordance with the applicable requirements, appropriate to the mode of transport, of the U.S. Department of Transportation insofar as such requirements relate to the loading and storage of packages, placarding of the transporting vehicle, and incident reporting.[3]

(C) Persons who transport radioactive material pursuant to the general licenses in 105 CMR 120.776(A) or (B) are exempt from the requirements of 105 CMR 120.200 and 120.750 to the extent that they transport radioactive material.

120.777: General License: Nuclear Regulatory Commission - Approved Packages

(A) A general license is hereby issued to any licensee of the Agency to transport, or to deliver to a carrier for transport, licensed material in a package for which a license, certificate of compliance, or other approval has been issued by the Nuclear Regulatory Commission.

(B) This general license applies only to a licensee who has a quality assurance program approved by the Agency as satisfying the provisions of 105 CMR 120.791 through 120.797.

(C) Each licensee issued a general license under 105 CMR 120.777(A) shall:

(1) Maintain a copy of the NRC issued certificate of compliance, or other approval by the Nuclear Regulatory Commission of the package, and the drawings and other documents referenced in the approval relating to the use and maintenance of the packaging and to the actions to be taken prior to shipment;

(2) Comply with the terms and conditions of the license, certificate, or other approval by the Nuclear Regulatory Commission, as applicable, and the applicable requirements of 105 CMR 120.771 through 120.774 and 105 CMR 120.784 through 120.797; and

(3) Submit in writing before the first use of the package to: ATTN: Document Control Desk, Director, Division of Spent Fuel Storage and Transportation, Office of Nuclear Material Safety and Safeguards, using an appropriate method listed in 10 CFR 71.1(a), the licensee's name and license number and the package identification number specified in the package approval.

(D) The general license in 105 CMR 120.777(A) applies only when the package approval authorizes use of the package under this general license.

(E) For a Type B or fissile material package, the design of which was approved by the Nuclear Regulatory Commission before April 1, 1996, the general license is subject to the additional restrictions of 10 CFR 71.19.

120.779: General License: U.S. Department of Transportation Specification Container

(A) A general license is issued to any licensee to transport, or to deliver to a carrier for transport, licensed material in a specification container for fissile material or for a Type B quantity of radioactive material as specified in 49 CFR Parts 173 and 178.

(B) This general license applies only to a licensee who:

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[3] Notification of an incident shall be filed with, or made to, the Agency as prescribed in 49 CFR, regardless of, and in addition to, notification made to U.S. Department of Transportation or other agencies.

120.779: continued

(1) Has a copy of the specification;
(2) Complies with the terms and conditions of the specification and the applicable requirements of 105 CMR 120.770; and
(3) Has a quality assurance program as required by 105 CMR 120.791.

(C) This general license in 105 CMR 120.779(A) is subject to the limitation that the specification container may not be used for a shipment to a location outside the United States except by multilateral approval as defined in 49 CFR 173.403.

(D) The general license specified in 105 CMR 120.779 expires on October 1, 2008.

120.780: General License - Use of Foreign Approved Package

(A) A general license is issued to any licensee of the Agency to transport, or to deliver to a carrier for transport, licensed material in a package, the design of which has been approved in a foreign national competent authority certificate which has been revalidated by the U.S. Department of Transportation as meeting the applicable requirements of 49 CFR 171.23.

(B) This general license applies only to shipments made to or from locations outside the United States.

(C) Except as otherwise provided in 105 CMR 120.780, the general license applies only to a licensee who has a quality assurance program approved by the Agency as satisfying the applicable provisions of 105 CMR 120.791 through 120.797.

(D) Each licensee issued a general license under 105 CMR 120.780(A) shall:
(1) Maintain a copy of the applicable certificate, the revalidation, and the drawings and other documents referenced in the certificate, relating to the use and maintenance of the packaging and to the actions to be taken before shipment; and
(2) Comply with the terms and conditions of the certificate and revalidation, and with the applicable requirements of 105 CMR 120.771 through 120.774 and 105 CMR 120.784 through 120.797.

120.781: General License: Fissile Material, Limited Quantity per Package

(A) A general license is hereby issued to any licensee to transport fissile material, or to deliver fissile material to a carrier for transport, if the material is shipped in accordance with 105 CMR 120.781. The fissile material need not be contained in a package which meets the standards of 10 CFR 71 Subparts E and F; however, the material must be contained in a Type A package. The Type A package must also meet the DOT requirements of 49 CFR 173.417(a).

(B) The general license applies only to a licensee who has a quality assurance program approved by the Agency as satisfying the provisions of 105 CMR 120.791 through 120.797.

(C) The general license applies only when a package's contents:
(1) Contain less than a Type A quantity of fissile material; and
(2) Contain less than 500 total grams of beryllium, graphite, or hydrogenous material enriched in deuterium.

(D) The general license applies only to packages containing fissile material that are labeled with a CSI which:
(1) Has been determined in accordance with 105 CMR 120.781(E);
(2) Has a value less than or equal to ten; and
(3) For a shipment of multiple packages containing fissile material, the sum of the CSIs must be less than or equal to 50 (for shipment on a nonexclusive use conveyance) and less than or equal to 100 (for shipment on an exclusive use conveyance).

120.781: continued

(E)(1) The value for the CSI must be greater than or equal to the number calculated by the following equation:

$$CSI = 10\left[\frac{\text{grams of } {}^{235}U}{X} + \frac{\text{grams of } {}^{233}U}{Y} + \frac{\text{grams of Pu}}{Z}\right]$$

(2) The calculated CSI must be rounded up to the first decimal place;

(3) The values of X, Y, and Z used in the CSI equation must be taken from Tables I or II, as appropriate;

(4) If Table II is used to obtain the value of X, then the values for the terms in the equation for uranium-233 and plutonium must be assumed to be zero; and

(5) Table I values for X, Y, and Z must be used to determine the CSI if:

(a) Uranium-233 is present in the package;

(b) The mass of plutonium exceeds 1% of the mass of uranium-235;

(c) The uranium is of unknown uranium-235 enrichment or greater than 24 weight percent enrichment; or

(d) Substances having a moderating effectiveness (*i.e.*, an average hydrogen density greater than H^2O) (*e.g.*, certain hydrocarbon oils or plastics) are present in any form, except as polyethylene used for packing or wrapping.

TABLE I – Mass Limits for General License Packages Containing Mixed Quantities of Fissile Material or Uranium-235 of Unknown Enrichment per 105 CMR 120.781(E)

Fissile Materials	Fissile material mass mixed with moderating substances having an average hydrogen density less than or equal to H_2O (grams)	Fissile material mass mixed with moderating substances having an average hydrogen density greater than H_2O[a] (grams)
^{235}U (X)	60	38
^{233}U (Y)	43	27
^{239}Pu or ^{241}Pu (Z)	37	24

[a] When mixtures of moderating substances are present, the lower mass limits shall be used if more than 15% of the moderating substance has an average hydrogen density greater than H2O.

120.781: continued

Table II – Mass Limits for General License Packages Containing Uranium-235 of Known Enrichment per 105 CMR 120.781(E)

Uranium Enrichment in Weight Percent of ^{235}U Not Exceeding	Fissile Material Mass of ^{235}U (X) (grams)
24	60
20	63
15	67
11	72
10	76
9.5	78
9	81
8.5	82
8	85
7.5	88
7	90
6.5	93
6	97
5.5	102
5	108
4.5	114
4	120
3.5	132
3	150
2.5	180
2	246
1.5	408
1.35	480
1	1,020
0.92	1,800

120.782: General License: Plutonium Beryllium Special Form Material

(A) A general license is issued to any licensee to transport fissile material in the form of plutonium beryllium (Pu Be) special form sealed sources, or to deliver Pu Be sealed sources to a carrier for transport, if the material is shipped in accordance with 105 CMR 120.782. This material need not be contained in a package which meets the standards of subparts E and F of 10 CFR 71; however, the material must be contained in a Type A package. The Type A package must also meet the DOT requirements of 49 CFR 173.417(a).

(B) The general license applies only to a licensee who has a quality assurance program approved by the Agency as satisfying the provisions of 105 CMR 120.791 through 120.797.

(C) The general license applies only when a package's contents:
(1) Contain no more than a Type A quantity of radioactive material; and,
(2) Contain less than 1000 g of plutonium, provided that: plutonium-239, plutonium-241, or any combination of these radionuclides, constitutes less than 240 g of the total quantity of plutonium in the package.

(D) The general license applies only to packages labeled with a CSI which:
(1) Has been determined in accordance with 105 CMR 120.782(E);
(2) Has a value less than or equal to 100; and,
(3) For a shipment of multiple packages containing Pu Be sealed sources, the sum of the CSIs must be less than or equal to 50 (for shipment on a nonexclusive use conveyance) and less than or equal to 100 (for shipment on an exclusive use conveyance).

(E)(1) The value for the CSI must be greater than or equal to the number calculated by the following equation:

$$CSI = 10\left[\frac{\text{grams of } {}^{239}\text{Pu} + \text{grams of } {}^{241}\text{Pu}}{24}\right];$$

(2) The calculated CSI must be rounded up to the first decimal place.

PACKAGE APPROVAL STANDARDS

120.783: External Radiation Standards for All Packages

(A) Except as provided in 105 CMR 120.783(B), each package of radioactive materials offered for transportation must be designed and prepared for shipment so that under conditions normally incident to transportation the radiation level does not exceed 2 mSv/hr (200 mrem/hr) at any point on the external surface of the package, and the transport index does not exceed ten.

(B) A package that exceeds the radiation level limits specified in 105 CMR 120.783(A) must be transported by exclusive use shipment only, and the radiation levels for such shipment must not exceed the following during transportation:
(1) 2 mSv/h (200 mrem/h) on the external surface of the package, unless the following conditions are met, in which case the limit is 10 mSv/h (1000 mrem/h):
(a) The shipment is made in a closed transport vehicle;
(b) The package is secured within the vehicle so that its position remains fixed during transportation; and,
(c) There are no loading or unloading operations between the beginning and end of the transportation;
(2) 2 mSv/h (200 mrem/h) at any point on the outer surface of the vehicle, including the top and underside of the vehicle; or in the case of a flat-bed style vehicle, at any point on the vertical planes projected from the outer edges of the vehicle, on the upper surface of the load or enclosure, if used, and on the lower external surface of the vehicle; and
(3) 0.1 mSv/h (10 mrem/h) at any point two meters (80 in.) from the outer lateral surfaces of the vehicle (excluding the top and underside of the vehicle); or in the case of a flat-bed style vehicle, at any point two meters (6.6 ft.) from the vertical planes projected by the outer edges of the vehicle (excluding the top and underside of the vehicle); and

120.783: continued

(4) 0.02 mSv/h (2 mrem/h) in any normally occupied space, except that this provision does not apply to private carriers, if exposed personnel under their control wear radiation dosimetry devices in conformance with 105 CMR 120.226.

(C) For shipments made under the provisions of 105 CMR 120.783(B), the shipper shall provide specific written instructions to the carrier for maintenance of the exclusive use shipment controls. The instructions must be included with the shipping paper information.

(D) The written instructions required for exclusive use shipments must be sufficient so that, when followed, they will cause the carrier to avoid actions that will unnecessarily delay delivery or unnecessarily result in increased radiation levels or radiation exposures to transport workers or members of the general public.

OPERATING CONTROLS AND PROCEDURES

120.784: Assumptions as to Unknown Properties of Fissile Material

When the isotopic abundance, mass, concentration, degree of irradiation, degree of moderation, or other pertinent property of fissile material in any package is not known, the licensee shall package the fissile material as if the unknown properties have credible values that will cause the maximum neutron multiplication.

120.785: Preliminary Determinations

Prior to the first use of any packaging for the shipment of licensed material, the licensee shall ascertain that the determinations in 10 CFR 71.85(a) through (c) have been made.

120.786: Routine Determinations

Prior to each shipment of licensed material, the licensee shall ensure that the package with its contents satisfies applicable requirements of 10 CFR 71 and of the license. The licensee shall determine that:

(A) The package is proper for the contents to be shipped;

(B) The package is in unimpaired physical condition except for superficial defects such as marks or dents;

(C) Each closure device of the packaging, including any required gasket, is properly installed and secured and free of defects;

(D) Any system for containing liquid is adequately sealed and has adequate space or other specified provision for expansion of the liquid;

(E) Any pressure relief device is operable and set in accordance with written procedures;

(F) The package has been loaded and closed in accordance with written procedures;

(G) For fissile material, any moderator or neutron absorber, if required, is present and in proper condition;

(H) Any structural part of the package which could be used to lift or tie down the package during transport is rendered inoperable for that purpose unless it satisfies design requirements specified in 10 CFR 71.45;

(I) The level of non-fixed (removable) radioactive contamination on the external surfaces of each package offered for shipment is as low as reasonably achievable, and within the limits specified in DOT regulations in 49 CFR 173.443;

(J) External radiation levels around the package and around the vehicle, if applicable, will not exceed the limits specified in 10 CFR 71.47 at any time during transportation; and

120.786: continued

(K) Accessible package surface temperatures will not exceed the limits specified in 10 CFR 71.43(g) at any time during transportation.

120.787: Air Transport of Plutonium

Notwithstanding the provisions of any general licenses and notwithstanding any exemptions stated directly in 105 CMR 120.770 or included indirectly by citation of the U.S. Department of Transportation regulations, as may be applicable, the licensee shall assure that plutonium in any form, whether for import, export, or domestic shipment, is not transported by air, or delivered to a carrier for air transport, unless:

(A) The plutonium is contained in a medical device designed for individual human application;

(B) The plutonium is contained in a material in which the specific activity is not greater than or equal to the activity concentration values for plutonium specified in 105 CMR 120.798: *Appendix A*, Table A-2, and in which the radioactivity is essentially uniformly distributed;

(C) The plutonium is shipped in a single package containing no more than an A_2 quantity of plutonium in any isotope or form and is shipped in accordance with 105 CMR 120.774;

(D) The plutonium is shipped in a package specifically authorized (in the Certificate of Compliance issued by the Nuclear Regulatory Commission for that package) for the shipment of plutonium by air; or

(E) For a shipment of plutonium by air which is subject to105 CMR 120.787(D), the licensee shall, through special arrangement with the carrier, require compliance with 49 CFR 175.704, U.S. Department of Transportation regulations applicable to the air transport of plutonium.

(F) Nothing in 105 CMR 120.787 is to be interpreted as removing or diminishing the requirements of 10 CFR 73.24.

120.788: Opening Instructions

Before delivery of a package to a carrier for transport, the licensee shall ensure that any special instructions needed to safely open the package have been sent to, or otherwise made available to, the consignee for the consignee's use in accordance with 105 CMR 120.242(E).

120.789: Records

(A) Each licensee shall maintain, for a period of three years after shipment, a record of each shipment of licensed material not exempt under 105 CMR 120.775(C), showing where applicable:

(1) Identification of the packaging by model number and serial number;
(2) Verification that there are no significant defects in the packaging, as shipped;
(3) Volume and identification of coolant;
(4) Type and quantity of licensed material in each package, and the total quantity of each shipment;
(5) For each item of irradiated fissile material:
  (a) Identification by model number and serial number;
  (b) Irradiation and decay history to the extent appropriate to demonstrate that its nuclear and thermal characteristics comply with license conditions; and
  (c) Any abnormal or unusual condition relevant to radiation safety;
(6) Date of the shipment;
(7) For fissile packages and for Type B packages, any special controls exercised;
(8) Name and address of the transferee;
(9) Address to which the shipment was made; and
(10) Results of the determinations required by 105 CMR 120.786 and by the conditions of the package approval.

120.789: continued

(B) The licensee shall make available to the Agency for inspection, upon reasonable notice, all records required by 105 CMR 120.770 through 120.798. Records are only valid if stamped, initialed, or signed and dated by authorized personnel, or otherwise authenticated.

(C) The licensee shall maintain sufficient written records to furnish evidence of the quality of packaging. The records to be maintained include: results of the determinations required by 105 CMR 120.785; design, fabrication, and assembly records; results of reviews, inspections, tests, and audits; results of monitoring work performance and materials analyses; and results of maintenance, modification, and repair activities. Inspection, test, and audit records must identify the inspector or data recorder, the type of observation, the results, the acceptability, and the action taken in connection with any deficiencies noted. These records must be retained for three years after the life of the packaging to which they apply.

120.790: Advance Notification of Shipment of Nuclear Waste

(A)(1) As specified in 105 CMR 120.790(B) through (D), each licensee shall provide advance notification to the governor of a State, or the governor's designee, of the shipment of licensed material, within or across the boundary of the State, before the transport, or delivery to a carrier, for transport, of licensed material outside the confines of the licensee's plant or other place of use or storage.

(2) As specified in 105 CMR 120.790(B) through (D) each licensee shall provide advance notification to the Tribal official of participating Tribes referenced in 105 CMR 120.790(C)(3)(c), or the official's designee, of the shipment of licensed material, within or across the boundary of the Tribe's reservation, before the transport, or delivery to a carrier, for transport, of licensed material outside the confines of the licensee's plant or other place of use or storage.

(B) Advance notification is required under 105 CMR 120.790 for shipment of licensed material meeting the following three conditions:

(1) The licensed material is required by 10 CFR 71 to be in Type B packaging for transportation;

(2) The licensed material is being transported into, within, or through a state en route to a disposal facility or to a collection point for transport to a disposal facility; and

(3) The quantity of licensed material in a single package exceeds the least of the following:

(a) 3000 times the A_1 value of the radionuclides as specified in 105 CMR 120.798: *Appendix A*, Table A-1 for special form radioactive material;

(b) 3000 times the A_2 value of the radionuclides as specified in 105 CMR 120.798: *Appendix A*, Table A-1 for normal form radioactive material; or

(c) 1000 TBq (27,000 Ci).

(C) Procedures for Submitting Advance Notification.

(1) The notification must be made in writing to the office of each appropriate governor or governor's designee, the office of each appropriate Tribal official or Tribal official's designee, and to the Director of the Agency.

(2) A notification delivered by mail must be postmarked at least seven days before the beginning of the seven-day period during which departure of the shipment is estimated to occur.

(3) A notification delivered by any other means than mail must reach the office of the governor or of the governor's designee or the Tribal official or Tribal official's designee at least four days before the beginning of the seven-day period during which departure of the shipment is estimated to occur.

(a) A list of the names and mailing addresses of the governors' designees receiving advance notification of transportation of nuclear waste was published in the *Federal Register* on June 30, 1995 (60 FR 34306).

(b) Contact information for each State, including telephone and mailing addresses of governors and governors' designees, and participating Tribes, including telephone and mailing addresses of Tribal officials and Tribal official's designees, is available on the NRC website at: https://scp.nrc.gov/special/designee.pdf.

120.790: continued

(c) A list of the names and mailing addresses of the governors' designees and Tribal officials' designees of participating Tribes is available on request from the Director, Division of Material Safety, State, Tribal, and Rulemaking Programs, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

(4) The licensee shall retain a copy of the notification as a record for three years.

(D) Information to Be Furnished in Advance Notification of Shipment. Each advance notification of shipment of nuclear waste must contain the following information:

(1) The name, address, and telephone number of the shipper, carrier, and receiver of the nuclear waste shipment;

(2) A description of the nuclear waste contained in the shipment, as specified in the regulations of DOT in 49 CFR 172.202 and 172.203(d);

(3) The point of origin of the shipment and the seven-day period during which departure of the shipment is estimated to occur;

(4) The seven-day period during which arrival of the shipment at State boundaries or Tribal reservation boundaries is estimated to occur;

(5) The destination of the shipment, and the seven-day period during which arrival of the shipment is estimated to occur; and

(6) A point of contact, with a telephone number, for current shipment information.

(E) Revision Notice. A licensee who finds that schedule information previously furnished to a governor or governor's designee or a Tribal official or Tribal official's designee, in accordance with 105 CMR 120.790, will not be met, shall telephone a responsible individual in the office of the governor of the State or of the governor's designee or the Tribal official or the Tribal official's designee and inform that individual of the extent of the delay beyond the schedule originally reported. The licensee shall maintain a record of the name of the individual contacted for three years.

(F) Cancellation Notice.

(1) Each licensee who cancels a nuclear waste shipment for which advance notification has been sent shall send a cancellation notice to the governor of each State or to the governor's designee previously notified, each Tribal official or to the Tribal official's designee previously notified, and to the Director of the Agency.

(2) The licensee shall state in the notice that it is a cancellation and identify the advance notification that is being canceled. The licensee shall retain a copy of the notice as a record for three years.

QUALITY ASSURANCE

120.791: Quality Assurance Requirements

(A) Purpose. 105 CMR 120.791 through 120.797 describes quality assurance requirements applying to design, purchase, fabrication, handling, shipping, storing, cleaning, assembly, inspection, testing, operation, maintenance, repair, and modification of components of packaging that are important to safety. As used in 105 CMR 120.791 through 120.797, "quality assurance" comprises all those planned and systematic actions necessary to provide adequate confidence that a system or component will perform satisfactorily in service. Quality assurance includes quality control, which comprises those quality assurance actions related to control of the physical characteristics and quality of the material or component to predetermined requirements. Each licensee is responsible for the quality assurance requirements that apply to its use of a packaging for the shipment of licensed material subject to 105 CMR 120.791 through 120.797.

(B) Establishment of Program. Each licensee shall establish, maintain, and execute a quality assurance program satisfying each of the applicable criteria of 105 CMR 120.791 through 120.797 and satisfying any specific provisions that are applicable to the licensee's activities including procurement of packaging. The licensee shall execute the applicable criteria in a graded approach to an extent that is commensurate with the quality assurance requirement's importance to safety.

120.791: continued

(C) Approval of Program. Before the use of any package for the shipment of licensed material subject to 105 CMR 120.791 through 120.797, each licensee shall obtain Agency approval of its quality assurance program. Using an appropriate method listed in 105 CMR 120.013, each licensee shall file a description of its quality assurance program, including a discussion of which requirements of 105 CMR 120.791 through 120.797 are applicable and how they will be satisfied, by submitting the description to the Agency.

(D) Radiography Containers. A program for transport container inspection and maintenance limited to radiographic exposure devices, source changers, or packages transporting these devices and meeting the requirements of 10 CFR 34.31(b) or equivalent Agreement State requirement, is deemed to satisfy the requirements of 105 CMR 120.777(B) and 120.791(B).

120.792: Quality Assurance Organization

(A) The licensee shall be responsible for the establishment and execution of the quality assurance program. The licensee may delegate to others, such as contractors, agents, or consultants, the work of establishing and executing the quality assurance program, or any part of the quality assurance program, but shall retain responsibility for the program. These activities include performing the functions associated with attaining quality objectives and the quality assurance functions.

(B) The quality assurance functions are:

(1) Assuring that an appropriate quality assurance program is established and effectively executed; and

(2) Verifying, by procedures such as checking, auditing, and inspection, that activities affecting the functions that are important to safety have been correctly performed.

120.793: Quality Assurance Program

(A) The licensee shall establish, at the earliest practicable time consistent with the schedule for accomplishing the activities, a quality assurance program that complies with the requirements of 105 CMR 120.791 through 120.797. The licensee shall document the quality assurance program by written procedures or instructions and shall carry out the program in accordance with those procedures throughout the period during which the packaging is used. The licensee shall identify the material and components to be covered by the quality assurance program, the major organizations participating in the program, and the designated functions of these organizations.

(B) The licensee shall base the requirements and procedures of its quality assurance program on the following considerations concerning the complexity and proposed use of the package and its components:

(1) The impact of malfunction or failure of the item to safety;

(2) The design and fabrication complexity or uniqueness of the item;

(3) The need for special controls and surveillance over processes and equipment;

(4) The degree to which functional compliance can be demonstrated by inspection or test; and

(5) The quality history and degree of standardization of the item.

(C) The licensee shall provide for indoctrination and training of personnel performing activities affecting quality, as necessary to assure that suitable proficiency is achieved and maintained. The licensee shall review the status and adequacy of the quality assurance program at established intervals. Management of other organizations participating in the quality assurance program shall review regularly the status and adequacy of that part of the quality assurance program they are executing.

120.794: Changes to Quality Assurance Program

(A) Each quality assurance program approval holder shall submit, in accordance with 105 CMR 120.013, a description of a proposed change to its Agency-approved quality assurance program that will reduce commitments in the program description as approved by the Agency. The quality assurance program approval holder shall not implement the change before receiving Agency approval. The description of a proposed change to the Agency-approved quality assurance program must identify the change, the reason for the change, and the basis for concluding that the revised program incorporating the change continues to satisfy the applicable requirements of 105 CMR 120.791 through 120.797.

(B) Each quality assurance program approval holder may change a previously approved quality assurance program without prior Agency approval, if the change does not reduce the commitments in the quality assurance program previously approved by the Agency. Changes to the quality assurance program that do not reduce the commitments shall be submitted to the Agency every 24 months, in accordance with 105 CMR 120.013. In addition to quality assurance program changes involving administrative improvements and clarifications, spelling corrections, and non-substantive changes to punctuation or editorial items, the following changes are not considered reductions in commitment:

(1) The use of a quality assurance standard approved by the Agency that is more recent than the quality assurance standard in the applicant's current quality assurance program at the time of the change;

(2) The use of generic organizational position titles that clearly denote the position function, supplemented as necessary by descriptive text, rather than specific titles, provided that there is no substantive change to either the functions of the position or reporting responsibilities;

(3) The use of generic organizational charts to indicate functional relationships, authorities, and responsibilities, or alternatively, the use of descriptive text, provided that there is no substantive change to the functional relationships, authorities, or responsibilities;

(4) The elimination of quality assurance program information that duplicates language in quality assurance regulatory guides and quality assurance standards to which the quality assurance program approval holder has committed to on record; and

(5) Organizational revisions that ensure that persons and organizations performing quality assurance functions continue to have the requisite authority and organizational freedom, including sufficient independence from cost and schedule when opposed to safety considerations.

(C) Each quality assurance program approval holder shall maintain records of quality assurance program changes.

120.795: Corrective Action

The licensee shall establish measures to assure that conditions adverse to quality, such as deficiencies, deviations, defective material and equipment, and nonconformances, are promptly identified and corrected. In the case of a significant condition adverse to quality, the measures must assure that the cause of the condition is determined and corrective action taken to preclude repetition. The identification of the significant condition adverse to quality, the cause of the condition, and the corrective action taken must be documented and reported to appropriate levels of management.

120.796: Quality Assurance Records

The licensee shall maintain sufficient written records to describe the activities affecting quality. These records must include changes to the quality assurance program as required by 105 CMR 120.794. The records must include the instructions or procedures that establish a records retention program that is consistent with applicable regulations and designates factors such as duration, location, and assigned responsibility. The licensee shall retain these records for three years beyond the date when the licensee last engaged in the activity for which the quality assurance program was developed. If any portion of the quality assurance program, written procedures or instructions is superseded, the licensee shall retain the superseded material for three years after it is superseded.

120.797: Audits

The licensee shall carry out a comprehensive system of planned and periodic audits to verify compliance with all aspects of the quality assurance program and to determine the effectiveness of the program. The audits must be performed in accordance with written procedures or checklists by appropriately trained personnel not having direct responsibilities in the areas being audited. Audited results must be documented and reviewed by management having responsibility in the area audited. Follow-up action, including reaudit of deficient areas, must be taken where indicated.

120.798: Appendix A – Determination of A_1 and A_2

I. Values of A_1 and A_2 for individual radionuclides, which are the bases for many activity limits elsewhere in 105 CMR 120.000 are given in Table A-1. The curie (Ci) values specified are obtained by converting from the Terabecquerel (TBq) figure. The Terabecquerel values are the regulatory standard. The curie values are for information only and are not intended to be the regulatory standard. Where values of A_1 or A_2 are unlimited, it is for radiation control purposes only. For nuclear criticality safety, some materials are subject to controls placed on fissile material.

II. (a) For individual radionuclides whose identities are known, but which are not listed in Table A-1, the A_1 and A_2 values contained in Table A-3 may be used. Otherwise, the licensee shall obtain prior Agency approval of the A_1 and A_2 values for radionuclides not listed in Table A-1, before shipping the material.
(b) For individual radionuclides whose identities are known, but which are not listed in Table A-2, the exempt material activity concentration and exempt consignment activity values contained in Table A-3 may be used. Otherwise, the licensee shall obtain prior Agency approval of the exempt material activity concentration and exempt consignment activity values for radionuclides not listed in Table A-2, before shipping the material.
(c) The licensee shall submit requests for prior approval, described in Appendix AII(a) and II(b), to the Agency, in accordance with 105 CMR 120.013.

III. In the calculations of A_1 and A_2 for a radionuclide not in Table A-1, a single radioactive decay chain, in which radionuclides are present in their naturally occurring proportions, and in which no daughter nuclide has a half-life either longer than ten days, or longer than that of the parent nuclide, shall be considered as a single radionuclide, and the activity to be taken into account, and the A_1 or A_2 value to be applied, shall be those corresponding to the parent nuclide of that chain. In the case of radioactive decay chains in which any daughter nuclide has a half-life either longer than ten days, or greater than that of the parent nuclide, the parent and those daughter nuclides shall be considered as mixtures of different nuclides.

IV. For mixtures of radionuclides whose identities and respective activities are known, the following conditions apply:

(a) For special form radioactive material, the maximum quantity transported in a Type A package is as follows:

$$\sum_i \frac{B(i)}{A_1(i)} \leq 1$$

where B(i) is the activity of radionuclide i in special form, and $A_1(i)$ is the A_1 value for radionuclide i.

(b) For normal form radioactive material, the maximum quantity transported in a Type A package is as follows:

$$\sum_i \frac{B(i)}{A_2(i)} \leq 1$$

where B(i) is the activity of radionuclide i in normal form, and $A_2(i)$ is the A_2 value for radionuclide i.

Appendix A: continued

(c) If the package contains both special and normal form radioactive material, the activity that may be transported in a Type A package is as follows:

$$\sum_i \frac{B(i)}{A_1(i)} + \sum_j \frac{C(j)}{A_2(j)} \leq 1$$

where B(i) is the activity of radionuclide i as special form radioactive material, $A_1(i)$ is the A_1 value for radionuclide i, C(j) is the activity of radionuclide j as normal form radioactive material, and $A_2(j)$ is the A_2 value for radionuclide j.

(d) Alternatively, the A_1 value for mixtures of special form material may be determined as follows:

$$A_1 \text{ for mixture} = \frac{1}{\sum_i \frac{f(i)}{A_1(i)}}$$

where f(i) is the fraction of activity for radionuclide i in the mixture and $A_1(i)$ is the appropriate A_1 value for radionuclide i.

(e) Alternatively, the A_2 value for mixtures of normal form material may be determined as follows:

$$A_2 \text{ for mixture} = \frac{1}{\sum_i \frac{f(i)}{A_2(i)}}$$

where f(i) is the fraction for radioactivity for radionuclide i in the mixture and $A_2(i)$ is the appropriate A_2 value for radioradionuclide i.

(f) The exempt activity concentration for mixtures of nuclides may be determined as follows:

$$\text{Exempt activity concentration for mixture} = \frac{1}{\sum_i \frac{f(i)}{[A](i)}}$$

where f(i) is the fraction of activity of radionuclide i in the mixture, and [A](i) is the activity concentration for exempt material containing radionuclide i.

(g) The activity limit for an exempt consignment for mixtures of radionuclides may be determined as follows:

$$\text{Exempt consignment activity limit for mixture} = \frac{1}{\sum_i \frac{f(i)}{A(i)}}$$

where f(i) is the fraction of activity of radionuclide i in the mixture, and A(i) is the activity limit for exempt consignments for radionuclide i.

V. (a) When the identity of each radionuclide is known, but the individual activities of some of the radionuclides are not known, the radionuclides may be grouped, and the lowest A_1 or A_2 value, as appropriate, for the radionuclides in each group may be used in applying the formulas in paragraph IV. Groups may be based on the total alpha activity and the total beta/gamma activity when these are known, using the lowest A_1 or A_2 values for the alpha emitters and beta/gamma emitters.

Appendix A: continued

(b) When the identity of each radionuclide is known but the individual activities of some of the radionuclides are not known, the radionuclides may be grouped and the lowest [A] (activity concentration for exempt material) or A (activity limit for exempt consignment) value, as appropriate, for the radionuclides in each group may be used in applying the formulas in paragraph IV of this appendix. Groups may be based on the total alpha activity and the total beta/gamma activity when these are known, using the lowest [A] or A values for the alpha emitters and beta/gamma emitters, respectively.

Table A - 1: A_1 and A_2 VALUES FOR RADIONUCLIDES

						Specific activity	
Symbol of radionuclides	Element and atomic number	A_1 (TBq)	A_1 (Ci)[b]	A_2 (TBq)	A_2 (Ci)[b]	(TBq/g)	(Ci/g)
Ac-225 (a)	Actinium (89)	$8.0X10^{-1}$	$2.2X10^{1}$	$6.0X10^{-3}$	$1.6X10^{-1}$	$2.1X10^{3}$	$5.8X10^{4}$
Ac-227 (a)		$9.0X10^{-1}$	$2.4X10^{1}$	$9.0X10^{-5}$	$2.4X10^{-3}$	$2.7X10^{0}$	$7.2X10^{1}$
Ac-228		$6.0X10^{-1}$	$1.6X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$8.4X10^{4}$	$2.2X10^{6}$
Ag-105	Silver (47)	$2X10^{0}$	$5.4X10^{1}$	$2X10^{0}$	$5.4X10^{1}$	$1.1X10^{3}$	$3.0X10^{4}$
Ag-108m (a)		$7.0X10^{-1}$	$1.9X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$9.7X10^{-1}$	$2.6X10^{1}$
Ag-110m (a)		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$1.8X10^{2}$	$4.7X10^{3}$
Ag-111		$2.0X10^{0}$	$5.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$5.8X10^{3}$	$1.6X10^{5}$
Al-26	Aluminum (13)	$1.0X10^{-1}$	$2.7X10^{0}$	$1.0X10^{-1}$	$2.7X10^{0}$	$7.0X10^{-4}$	$1.9X10^{-2}$
Am-241	Americium (95)	$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$1.3X10^{-1}$	$3.4X10^{0}$
Am-242m (a)		$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$3.6X10^{-1}$	$1.0X10^{1}$
Am-243 (a)		$5.0X10^{0}$	$1.4X10^{2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$7.4X10^{-3}$	$2.0X10^{-1}$
Ar-37	Argon (18)	$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$3.7X10^{3}$	$9.9X10^{4}$
Ar-39		$4.0X10^{1}$	$1.1X10^{3}$	$2.0X10^{1}$	$5.4X10^{2}$	$1.3X10^{0}$	$3.4X10^{1}$
Ar-41		$3.0X10^{-1}$	$8.1X10^{0}$	$3.0X10^{-1}$	$8.1X10^{0}$	$1.5X10^{6}$	$4.2X10^{7}$
As-72	Arsenic (33)	$3.0X10^{-1}$	$8.1X10^{0}$	$3.0X10^{-1}$	$8.1X10^{0}$	$6.2X10^{4}$	$1.7X10^{6}$
As-73		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$8.2X10^{2}$	$2.2X10^{4}$
As-74		$1.0X10^{0}$	$2.7X10^{1}$	$9.0X10^{-1}$	$2.4X10^{1}$	$3.7X10^{3}$	$9.9X10^{4}$
As-76		$3.0X10^{-1}$	$8.1X10^{0}$	$3.0X10^{-1}$	$8.1X10^{0}$	$5.8X10^{4}$	$1.6X10^{6}$
As-77		$2.0X10^{1}$	$5.4X10^{2}$	$7.0X10^{-1}$	$1.9X10^{1}$	$3.9X10^{4}$	$1.0X10^{6}$
At-211 (a)	Astatine (85)	$2.0X10^{1}$	$5.4X10^{2}$	$5.0X10^{-1}$	$1.4X10^{1}$	$7.6X10^{4}$	$2.1X10^{6}$
Au-193	Gold (79)	$7.0X10^{0}$	$1.9X10^{2}$	$2.0X10^{0}$	$5.4X10^{1}$	$3.4X10^{4}$	$9.2X10^{5}$
Au-194		$1.0X10^{0}$	$2.7X10^{1}$	$1.0X10^{0}$	$2.7X10^{1}$	$1.5X10^{4}$	$4.1X10^{5}$
Au-195	Gold (79)	$1.0X10^{1}$	$2.7X10^{2}$	$6.0X10^{0}$	$1.6X10^{2}$	$1.4X10^{2}$	$3.7X10^{3}$
Au-198		$1.0X10^{0}$	$2.7X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$9.0X10^{3}$	$2.4X10^{5}$
Au-199		$1.0X10^{1}$	$2.7X10^{2}$	$6.0X10^{-1}$	$1.6X10^{1}$	$7.7X10^{3}$	$2.1X10^{5}$
Ba-131 (a)	Barium (56)	$2.0X10^{0}$	$5.4X10^{1}$	$2.0X10^{0}$	$5.4X10^{1}$	$3.1X10^{3}$	$8.4X10^{4}$
Ba-133		$3.0X10^{0}$	$8.1X10^{1}$	$3.0X10^{0}$	$8.1X10^{1}$	$9.4X10^{0}$	$2.6X10^{2}$
Ba-133m		$2.0X10^{1}$	$5.4X10^{2}$	$6.0X10^{-1}$	$1.6X10^{1}$	$2.2X10^{4}$	$6.1X10^{5}$
Ba-140 (a)		$5.0X10^{-1}$	$1.4X10^{1}$	$3.0X10^{-1}$	$8.1X10^{0}$	$2.7X10^{3}$	$7.3X10^{4}$
Be-7	Beryllium (4)	$2.0X10^{1}$	$5.4X10^{2}$	$2.0X10^{1}$	$5.4X10^{2}$	$1.3X10^{4}$	$3.5X10^{5}$
Be-10		$4.0X10^{1}$	$1.1X10^{3}$	$6.0X10^{-1}$	$1.6X10^{1}$	$8.3X10^{-4}$	$2.2X10^{-2}$
Bi-205	Bismuth (83)	$7.0X10^{-1}$	$1.9X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$1.5X10^{3}$	$4.2X10^{4}$
Bi-206		$3.0X10^{-1}$	$8.1X10^{0}$	$3.0X10^{-1}$	$8.1X10^{0}$	$3.8X10^{3}$	$1.0X10^{5}$
Bi-207		$7.0X10^{-1}$	$1.9X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$1.9X10^{0}$	$5.2X10^{1}$
Bi-210		$1.0X10^{0}$	$2.7X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$4.6X10^{3}$	$1.2X10^{5}$
Bi-210m(a)		$6.0X10^{-1}$	$1.6X10^{1}$	$2.0X10^{-2}$	$5.4X10^{-1}$	$2.1X10^{-5}$	$5.7X10^{-4}$
Bi-212 (a)		$7.0X10^{-1}$	$1.9X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$5.4X10^{5}$	$1.5X10^{7}$
Bk-247	Berkelium (97)	$8.0X10^{0}$	$2.2X10^{2}$	$8.0X10^{-4}$	$2.2X10^{-2}$	$3.8X10^{-2}$	$1.0X10^{0}$
Bk-249 (a)		$4.0X10^{1}$	$1.1X10^{3}$	$3.0X10^{-1}$	$8.1X10^{0}$	$6.1X10^{1}$	$1.6X10^{3}$

Appendix A: continued

Table A - 1: A_1 and A_2 VALUES FOR RADIONUCLIDES (continued)

						Specific activity	
Symbol of radionuclides	Element and atomic number	A_1 (TBq)	A_1 (Ci)[b]	A_2 (TBq)	A_2 (Ci)[b]	(TBq/g)	(Ci/g)
Br-76	Bromine (35)	$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$9.4X10^{4}$	$2.5X10^{6}$
Br-77		$3.0X10^{0}$	$8.1X10^{1}$	$3.0X10^{0}$	$8.1X10^{1}$	$2.6X10^{4}$	$7.1X10^{5}$
Br-82		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{4}$	$1.1X10^{6}$
C-11	Carbon (6)	$1.0X10^{0}$	$2.7X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$3.1X10^{7}$	$8.4X10^{8}$
C-14		$4.0X10^{1}$	$1.1X10^{3}$	$3.0X10^{0}$	$8.1X10^{1}$	$1.6X10^{-1}$	$4.5X10^{0}$
Ca-41	Calcium (20)	Unlimited	Unlimited	Unlimited	Unlimited	$3.1X10^{-3}$	$8.5X10^{-2}$
Ca-45		$4.0X10^{1}$	$1.1X10^{3}$	$1.0X10^{0}$	$2.7X10^{1}$	$6.6X10^{2}$	$1.8X10^{4}$
Ca-47 (a)		$3.0X10^{0}$	$8.1X10^{1}$	$3.0X10^{-1}$	$8.1X10^{0}$	$2.3X10^{4}$	$6.1X10^{5}$
Cd-109	Cadmium (48)	$3.0X10^{1}$	$8.1X10^{2}$	$2.0X10^{0}$	$5.4X10^{1}$	$9.6X10^{1}$	$2.6X10^{3}$
Cd-113m		$4.0X10^{1}$	$1.1X10^{3}$	$5.0X10^{-1}$	$1.4X10^{1}$	$8.3X10^{0}$	$2.2X10^{2}$
Cd-115 (a)		$3.0X10^{0}$	$8.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$1.9X10^{4}$	$5.1X10^{5}$
Cd-115m		$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$9.4X10^{2}$	$2.5X10^{4}$
Ce-139	Cerium (58)	$7.0X10^{0}$	$1.9X10^{2}$	$2.0X10^{0}$	$5.4X10^{1}$	$2.5X10^{2}$	$6.8X10^{3}$
Ce-141		$2.0X10^{1}$	$5.4X10^{2}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.1X10^{3}$	$2.8X10^{4}$
Ce-143		$9.0X10^{-1}$	$2.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$2.5X10^{4}$	$6.6X10^{5}$
Ce-144 (a)		$2.0X10^{-1}$	$5.4X10^{0}$	$2.0X10^{-1}$	$5.4X10^{0}$	$1.2X10^{2}$	$3.2X10^{3}$
Cf-248	Californium (98)	$4.0X10^{1}$	$1.1X10^{3}$	$6.0X10^{-3}$	$1.6X10^{-1}$	$5.8X10^{1}$	$1.6X10^{3}$
Cf-249		$3.0X10^{0}$	$8.1X10^{1}$	$8.0X10^{-4}$	$2.2X10^{-2}$	$1.5X10^{-1}$	$4.1X10^{0}$
Cf-250		$2.0X10^{1}$	$5.4X10^{2}$	$2.0X10^{-3}$	$5.4X10^{-2}$	$4.0X10^{0}$	$1.1X10^{2}$
Cf-251		$7.0X10^{0}$	$1.9X10^{2}$	$7.0X10^{-4}$	$1.9X10^{-2}$	$5.9X10^{-2}$	$1.6X10^{0}$
Cf-252		$1.0X10^{-1}$	$2.7X10^{0}$	$3.0X10^{-3}$	$8.1X10^{-2}$	$2.0X10^{1}$	$5.4X10^{2}$
Cf-253 (a)		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{-2}$	$1.1X10^{0}$	$1.1X10^{3}$	$2.9X10^{4}$
Cf-254		$1.0X10^{-3}$	$2.7X10^{-2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$3.1X10^{2}$	$8.5X10^{3}$
Cl-36	Chlorine (17)	$1.0X10^{1}$	$2.7X10^{2}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.2X10^{-3}$	$3.3X10^{-2}$
Cl-38		$2.0X10^{-1}$	$5.4X10^{0}$	$2.0X10^{-1}$	$5.4X10^{0}$	$4.9X10^{6}$	$1.3X10^{8}$
Cm-240	Curium (96)	$4.0X10^{1}$	$1.1X10^{3}$	$2.0X10^{-2}$	$5.4X10^{-1}$	$7.5X10^{2}$	$2.0X10^{4}$
Cm-241		$2.0X10^{0}$	$5.4X10^{1}$	$1.0X10^{0}$	$2.7X10^{1}$	$6.1X10^{2}$	$1.7X10^{4}$
Cm-242	Curium (96)	$4.0X10^{1}$	$1.1X10^{3}$	$1.0X10^{-2}$	$2.7X10^{-1}$	$1.2X10^{2}$	$3.3X10^{3}$
Cm-243		$9.0X10^{0}$	$2.4X10^{2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$1.9X10^{-3}$	$5.2X10^{1}$
Cm-244		$2.0X10^{1}$	$5.4X10^{2}$	$2.0X10^{-3}$	$5.4X10^{-2}$	$3.0X10^{0}$	$8.1X10^{1}$
Cm-245		$9.0X10^{0}$	$2.4X10^{2}$	$9.0X10^{-4}$	$2.4X10^{-2}$	$6.4X10^{-3}$	$1.7X10^{-1}$
Cm-246		$9.0X10^{0}$	$2.4X10^{2}$	$9.0X10^{-4}$	$2.4X10^{-2}$	$1.1X10^{-2}$	$3.1X10^{-1}$
Cm-247 (a)		$3.0X10^{0}$	$8.1X10^{1}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$3.4X10^{-6}$	$9.3X10^{-5}$
Cm-248		$2.0X10^{-2}$	$5.4X10^{-1}$	$3.0X10^{-4}$	$8.1X10^{-3}$	$1.6X10^{-4}$	$4.2X10^{-3}$
Co-55	Cobalt (27)	$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$1.1X10^{5}$	$3.1X10^{6}$
Co-56		$3.0X10^{-1}$	$8.1X10^{0}$	$3.0X10^{-1}$	$8.1X10^{0}$	$1.1X10^{3}$	$3.0X10^{4}$
Co-57		$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{1}$	$2.7X10^{2}$	$3.1X10^{2}$	$8.4X10^{3}$
Co-58		$1.0X10^{0}$	$2.7X10^{1}$	$1.0X10^{0}$	$2.7X10^{1}$	$1.2X10^{3}$	$3.2X10^{4}$
Co-58m		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$2.2X10^{5}$	$5.9X10^{6}$
Co-60		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$4.2X10^{1}$	$1.1X10^{3}$
Cr-51	Chromium (24)	$3.0X10^{1}$	$8.1X10^{2}$	$3.0X10^{1}$	$8.1X10^{2}$	$3.4X10^{3}$	$9.2X10^{4}$
Cs-129	Cesium (55)	$4.0X10^{0}$	$1.1X10^{2}$	$4.0X10^{0}$	$1.1X10^{2}$	$2.8X10^{4}$	$7.6X10^{5}$
Cs-131		$3.0X10^{1}$	$8.1X10^{2}$	$3.0X10^{1}$	$8.1X10^{2}$	$3.8X10^{3}$	$1.0X10^{5}$
Cs-132		$1.0X10^{0}$	$2.7X10^{1}$	$1.0X10^{0}$	$2.7X10^{1}$	$5.7X10^{3}$	$1.5X10^{5}$
Cs-134		$7.0X10^{-1}$	$1.9X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$4.8X10^{1}$	$1.3X10^{3}$
Cs-134m		$4.0X10^{1}$	$1.1X10^{3}$	$6.0X10^{-1}$	$1.6X10^{1}$	$3.0X10^{5}$	$8.0X10^{6}$
Cs-135		$4.0X10^{1}$	$1.1X10^{3}$	$1.0X10^{0}$	$2.7X10^{1}$	$4.3X10^{-5}$	$1.2X10^{-3}$
Cs-136		$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$2.7X10^{3}$	$7.3X10^{4}$
Cs-137 (a)		$2.0X10^{0}$	$5.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$3.2X10^{0}$	$8.7X10^{1}$
Cu-64	Copper (29)	$6.0X10^{0}$	$1.6X10^{2}$	$1.0X10^{0}$	$2.7X10^{1}$	$1.4X10^{5}$	$3.9X10^{6}$
Cu-67		$1.0X10^{1}$	$2.7X10^{2}$	$7.0X10^{-1}$	$1.9X10^{1}$	$2.8X10^{4}$	$7.6X10^{5}$

Appendix A: continued

Table A - 1: A_1 and A_2 VALUES FOR RADIONUCLIDES (continued)

						Specific activity	
Symbol of radionuclides	Element and atomic number	A_1 (TBq)	A_1 (Ci)[b]	A_2 (TBq)	A_2 (Ci)[b]	(TBq/g)	(Ci/g)
Dy-159	Dysprosium (66)	$2.0X10^{1}$	$5.4X10^{2}$	$2.0X10^{1}$	$5.4X10^{2}$	$2.1X10^{2}$	$5.7X10^{3}$
Dy-165		$9.0X10^{-1}$	$2.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$3.0X10^{5}$	$8.2X10^{6}$
Dy-166 (a)		$9.0X10^{-1}$	$2.4X10^{1}$	$3.0X10^{-1}$	$8.1X10^{0}$	$8.6X10^{3}$	$2.3X10^{5}$
Er-169	Erbium (68)	$4.0X10^{1}$	$1.1X10^{3}$	$1.0X10^{0}$	$2.7X10^{1}$	$3.1X10^{3}$	$8.3X10^{4}$
Er-171		$8.0X10^{-1}$	$2.2X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$9.0X10^{4}$	$2.4X10^{6}$
Eu-147	Europium (63)	$2.0X10^{0}$	$5.4X10^{1}$	$2.0X10^{0}$	$5.4X10^{1}$	$1.4X10^{3}$	$3.7X10^{4}$
Eu-148		$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$6.0X10^{2}$	$1.6X10^{4}$
Eu-149		$2.0X10^{1}$	$5.4X10^{2}$	$2.0X10^{1}$	$5.4X10^{2}$	$3.5X10^{2}$	$9.4X10^{3}$
Eu-150 (short-lived)		$2.0X10^{0}$	$5.4X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$6.1X10^{4}$	$1.6X10^{6}$
Eu-150 (long-lived)		$7.0X10^{-1}$	$1.9X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$6.1X10^{4}$	$1.6X10^{6}$
Eu-152		$1.0X10^{0}$	$2.7X10^{1}$	$1.0X10^{0}$	$2.7X10^{1}$	$6.5X10^{0}$	$1.8X10^{2}$
Eu-152m		$8.0X10^{-1}$	$2.2X10^{1}$	$8.0X10^{-1}$	$2.2X10^{1}$	$8.2X10^{4}$	$2.2X10^{6}$
Eu-154		$9.0X10^{-1}$	$2.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$9.8X10^{0}$	$2.6X10^{2}$
Eu-155		$2.0X10^{1}$	$5.4X10^{2}$	$3.0X10^{0}$	$8.1X10^{1}$	$1.8X10^{1}$	$4.9X10^{2}$
Eu-156		$7.0X10^{-1}$	$1.9X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$2.0X10^{3}$	$5.5X10^{4}$
F-18	Fluorine (9)	$1.0X10^{0}$	$2.7X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$3.5X10^{6}$	$9.5X10^{7}$
Fe-52 (a)	Iron (26)	$3.0X10^{-1}$	$8.1X10^{0}$	$3.0X10^{-1}$	$8.1X10^{0}$	$2.7X10^{5}$	$7.3X10^{6}$
Fe-55		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$8.8X10^{1}$	$2.4X10^{3}$
Fe-59		$9.0X10^{-1}$	$2.4X10^{1}$	$9.0X10^{-1}$	$2.4X10^{1}$	$1.8X10^{3}$	$5.0X10^{4}$
Fe-60 (a)		$4.0X10^{1}$	$1.1X10^{3}$	$2.0X10^{-1}$	$5.4X10^{0}$	$7.4X10^{-4}$	$2.0X10^{-2}$
Ga-67	Gallium (31)	$7.0X10^{0}$	$1.9X10^{2}$	$3.0X10^{0}$	$8.1X10^{1}$	$2.2X10^{4}$	$6.0X10^{5}$
Ga-68		$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$1.5X10^{6}$	$4.1X10^{7}$
Ga-72		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$1.1X10^{5}$	$3.1X10^{6}$
Gd-146 (a)	Gadolinium (64)	$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$6.9X10^{2}$	$1.9X10^{4}$
Gd-148		$2.0X10^{1}$	$5.4X10^{2}$	$2.0X10^{-3}$	$5.4X10^{-2}$	$1.2X10^{0}$	$3.2X10^{1}$
Gd-153		$1.0X10^{1}$	$2.7X10^{2}$	$9.0X10^{0}$	$2.4X10^{2}$	$1.3X10^{2}$	$3.5X10^{3}$
Gd-159		$3.0X10^{0}$	$8.1X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$3.9X10^{4}$	$1.1X10^{6}$
Ge-68 (a)	Germanium (32)	$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$2.6X10^{2}$	$7.1X10^{3}$
Ge-71		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$5.8X10^{3}$	$1.6X10^{5}$
Ge-77		$3.0X10^{-1}$	$8.1X10^{0}$	$3.0X10^{-1}$	$8.1X10^{0}$	$1.3X10^{5}$	$3.6X10^{6}$
Hf-172 (a)	Hafnium (72)	$6.0X10^{-1}$	$1.6X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$4.1X10^{1}$	$1.1X10^{3}$
Hf-175		$3.0X10^{0}$	$8.1X10^{1}$	$3.0X10^{0}$	$8.1X10^{1}$	$3.9X10^{2}$	$1.1X10^{4}$
Hf-181		$2.0X10^{0}$	$5.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$6.3X10^{2}$	$1.7X10^{4}$
Hf-182		Unlimited	Unlimited	Unlimited	Unlimited	$8.1X10^{-6}$	$2.2X10^{-4}$
Hg-194 (a)	Mercury (80)	$1.0X10^{0}$	$2.7X10^{1}$	$1.0X10^{0}$	$2.7X10^{1}$	$1.3X10^{-1}$	$3.5X10^{0}$
Hg-195m (a)		$3.0X10^{0}$	$8.1X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$1.5X10^{4}$	$4.0X10^{5}$
Hg-197		$2.0X10^{1}$	$5.4X10^{2}$	$1.0X10^{1}$	$2.7X10^{2}$	$9.2X10^{3}$	$2.5X10^{5}$
Hg-197m		$1.0X10^{1}$	$2.7X10^{2}$	$4.0X10^{-1}$	$1.1X10^{1}$	$2.5X10^{4}$	$6.7X10^{5}$
Hg-203		$5.0X10^{0}$	$1.4X10^{2}$	1	$2.7X10^{1}$	$5.1X10^{2}$	$1.4X10^{4}$
Ho-166	Holmium (67)	$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$2.6X10^{4}$	$7.0X10^{5}$
Ho-166m		$6.0X10^{-1}$	$1.6X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$6.6X10^{-2}$	$1.8X10^{0}$
I-123	Iodine (53)	$6.0X10^{0}$	$1.6X10^{2}$	$3.0X10^{0}$	$8.1X10^{1}$	$7.1X10^{4}$	$1.9X10^{6}$
I-124		$1.0X10^{0}$	$2.7X10^{1}$	$1.0X10^{0}$	$2.7X10^{1}$	$9.3X10^{3}$	$2.5X10^{5}$
I-125		$2.0X10^{1}$	$5.4X10^{2}$	$3.0X10^{0}$	$8.1X10^{1}$	$6.4X10^{2}$	$1.7X10^{4}$
I-126		$2.0X10^{0}$	$5.4X10^{1}$	$1.0X10^{0}$	$2.7X10^{1}$	$2.9X10^{3}$	$8.0X10^{4}$
I-129		Unlimited	Unlimited	Unlimited	Unlimited	$6.5X10^{-6}$	$1.8X10^{-4}$
I-131		$3.0X10^{0}$	$8.1X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$4.6X10^{3}$	$1.2X10^{5}$
I-132		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$3.8X10^{5}$	$1.0X10^{7}$
I-133		$7.0X10^{-1}$	$1.9X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$4.2X10^{4}$	$1.1X10^{6}$

Appendix A: continued

Table A - 1: A_1 and A_2 VALUES FOR RADIONUCLIDES (continued)

						Specific activity	
Symbol of radionuclides	Element and atomic number	A_1 (TBq)	A_1 (Ci)[b]	A_2 (TBq)	A_2 (Ci)[b]	(TBq/g)	(Ci/g)
I-134		$3.0X10^{-1}$	$8.1X10^{0}$	$3.0X10^{-1}$	$8.1X10^{0}$	$9.9X10^{5}$	$2.7X10^{7}$
I-135 (a)		$6.0X10^{-1}$	$1.6X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.3X10^{5}$	$3.5X10^{6}$
In-111	Indium (49)	$3.0X10^{0}$	$8.1X10^{1}$	$3.0X10^{0}$	$8.1X10^{1}$	$1.5X10^{4}$	$4.2X10^{5}$
In-113m		$4.0X10^{0}$	$1.1X10^{2}$	$2.0X10^{0}$	$5.4X10^{1}$	$6.2X10^{5}$	$1.7X10^{7}$
In-114m (a)		$1.0X10^{1}$	$2.7X10^{2}$	$5.0X10^{-1}$	$1.4X10^{1}$	$8.6X10^{2}$	$2.3X10^{4}$
In-115m		$7.0X10^{0}$	$1.9X10^{2}$	$1.0X10^{0}$	$2.7X10^{1}$	$2.2X10^{5}$	$6.1X10^{6}$
Ir-189 (a)	Iridium (77)	$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{1}$	$2.7X10^{2}$	$1.9X10^{3}$	$5.2X10^{4}$
Ir-190		$7.0X10^{-1}$	$1.9X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$2.3X10^{3}$	$6.2X10^{4}$
Ir-192		[c]$1.0X10^{0}$	[c]$2.7X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$3.4X10^{2}$	$9.2X10^{3}$
Ir-194		$3.0X10^{-1}$	$8.1X10^{0}$	$3.0X10^{-1}$	$8.1X10^{0}$	$3.1X10^{4}$	$8.4X10^{5}$
K-40	Potassium (19)	$9.0X10^{-1}$	$2.4X10^{1}$	$9.0X10^{-1}$	$2.4X10^{1}$	$2.4X10^{-7}$	$6.4X10^{-6}$
K-42		$2.0X10^{-1}$	$5.4X10^{0}$	$2.0X10^{-1}$	$5.4X10^{0}$	$2.2X10^{5}$	$6.0X10^{6}$
K-43		$7.0X10^{-1}$	$1.9X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.2X10^{5}$	$3.3X10^{6}$
Kr-79	Krypton (36)	$4.0X10^{0}$	$1.1X10^{2}$	$2.0X10^{0}$	$5.4X10^{1}$	$4.2X10^{4}$	$1.1X10^{6}$
Kr-81		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$7.8X10^{-4}$	$2.1X10^{-2}$
Kr-85		$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{1}$	$2.7X10^{2}$	$1.5X10^{1}$	$3.9X10^{2}$
Kr-85m		$8.0X10^{0}$	$2.2X10^{2}$	$3.0X10^{0}$	$8.1X10^{1}$	$3.0X10^{5}$	$8.2X10^{6}$
Kr-87		$2.0X10^{-1}$	$5.4X10^{0}$	$2.0X10^{-1}$	$5.4X10^{0}$	$1.0X10^{6}$	$2.8X10^{7}$
La-137	Lanthanum (57)	$3.0X10^{1}$	$8.1X10^{2}$	$6.0X10^{0}$	$1.6X10^{2}$	$1.6X10^{-3}$	$4.4X10^{-2}$
La-140		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$2.1X10^{4}$	$5.6X10^{5}$
Lu-172	Lutetium (71)	$6.0X10^{-1}$	$1.6X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$4.2X10^{3}$	$1.1X10^{5}$
Lu-173		$8.0X10^{0}$	$2.2X10^{2}$	$8.0X10^{0}$	$2.2X10^{2}$	$5.6X10^{1}$	$1.5X10^{3}$
Lu-174		$9.0X10^{0}$	$2.4X10^{2}$	$9.0X10^{0}$	$2.4X10^{2}$	$2.3X10^{1}$	$6.2X10^{2}$
Lu-174m		$2.0X10^{1}$	$5.4X10^{2}$	$1.0X10^{1}$	$2.7X10^{2}$	$2.0X10^{2}$	$5.3X10^{3}$
Lu-177		$3.0X10^{1}$	$8.1X10^{2}$	$7.0X10^{-1}$	$1.9X10^{1}$	$4.1X10^{3}$	$1.1X10^{5}$
Mg-28 (a)	Magnesium (12)	$3.0X10^{-1}$	$8.1X10^{0}$	$3.0X10^{-1}$	$8.1X10^{0}$	$2.0X10^{5}$	$5.4X10^{6}$
Mn-52	Manganese (25)	$3.0X10^{-1}$	$8.1X10^{0}$	$3.0X10^{-1}$	$8.1X10^{0}$	$1.6X10^{4}$	$4.4X10^{5}$
Mn-53		Unlimited	Unlimited	Unlimited	Unlimited	$6.8X10^{-5}$	$1.8X10^{-3}$
Mn-54		$1.0X10^{0}$	$2.7X10^{1}$	$1.0X10^{0}$	$2.7X10^{1}$	$2.9X10^{2}$	$7.7X10^{3}$
Mn-56		$3.0X10^{-1}$	$8.1X10^{0}$	$3.0X10^{-1}$	$8.1X10^{0}$	$8.0X10^{5}$	$2.2X10^{7}$
Mo-93	Molybdenum (42)	$4.0X10^{1}$	$1.1X10^{3}$	$2.0X10^{1}$	$5.4X10^{2}$	$4.1X10^{-2}$	$1.1X10^{0}$
Mo-99 (a) (h)		$1.0X10^{0}$	$2.7X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.8X10^{4}$	$4.8X10^{5}$
N-13	Nitrogen (7)	$9.0X10^{-1}$	$2.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$5.4X10^{7}$	$1.5X10^{9}$
Na-22	Sodium (11)	$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$2.3X10^{2}$	$6.3X10^{3}$
Na-24		$2.0X10^{-1}$	$5.4X10^{0}$	$2.0X10^{-1}$	$5.4X10^{0}$	$3.2X10^{5}$	$8.7X10^{6}$
Nb-93m	Niobium (41)	$4.0X10^{1}$	$1.1X10^{3}$	$3.0X10^{1}$	$8.1X10^{2}$	$8.8X10^{0}$	$2.4X10^{2}$
Nb-94		$7.0X10^{-1}$	$1.9X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$6.9X10^{-3}$	$1.9X10^{-1}$
Nb-95		$1.0X10^{0}$	$2.7X10^{1}$	$1.0X10^{0}$	$2.7X10^{1}$	$1.5X10^{3}$	$3.9X10^{4}$
Nb-97		$9.0X10^{-1}$	$2.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$9.9X10^{5}$	$2.7X10^{7}$
Nd-147	Neodymium (60)	$6.0X10^{0}$	$1.6X10^{2}$	$6.0X10^{-1}$	$1.6X10^{1}$	$3.0X10^{3}$	$8.1X10^{4}$
Nd-149		$6.0X10^{-1}$	$1.6X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$4.5X10^{5}$	$1.2X10^{7}$
Ni-59	Nickel (28)	Unlimited	Unlimited	Unlimited	Unlimited	$3.0X10^{-3}$	$8.0X10^{-2}$
Ni-63		$4.0X10^{1}$	$1.1X10^{3}$	$3.0X10^{1}$	$8.1X10^{2}$	$2.1X10^{0}$	$5.7X10^{1}$
Ni-65		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$7.1X10^{5}$	$1.9X10^{7}$
Np-235	Neptunium (93)	$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$5.2X10^{1}$	$1.4X10^{3}$
Np-236 (short-lived)		$2.0X10^{1}$	$5.4X10^{2}$	$2.0X10^{0}$	$5.4X10^{1}$	$4.7X10^{-4}$	$1.3X10^{-2}$
Np-236 (long-lived)		$9.0X10^{0}$	$2.4X10^{2}$	$2.0X10^{2}$	$5.4X10^{-1}$	$4.7X10^{-4}$	$1.3X10^{-2}$
Np-237		$2.0X10^{1}$	$5.4X10^{2}$	$2.0X10^{-3}$	$5.4X10^{-2}$	$2.6X10^{-5}$	$7.1X10^{-4}$
Np-239		$7.0X10^{0}$	$1.9X10^{2}$	$4.0X10^{-1}$	$1.1X10^{1}$	$8.6X10^{3}$	$2.3X10^{5}$

Appendix A: continued

Table A - 1: A_1 and A_2 VALUES FOR RADIONUCLIDES (continued)

						Specific activity	
Symbol of radionuclides	Element and atomic number	A_1 (TBq)	A_1 (Ci)[b]	A_2 (TBq)	A_2 (Ci)[b]	(TBq/g)	(Ci/g)
Os-185	Osmium (76)	$1.0X10^{0}$	$2.7X10^{1}$	$1.0X10^{0}$	$2.7X10^{1}$	$2.8X10^{2}$	$7.5X10^{3}$
Os-191		$1.0X10^{1}$	$2.7X10^{2}$	$2.0X10^{0}$	$5.4X10^{1}$	$1.6X10^{3}$	$4.4X10^{4}$
Os-191m		$4.0X10^{1}$	$1.1X10^{3}$	$3.0X10^{1}$	$8.1X10^{2}$	$4.6X10^{4}$	$1.3X10^{6}$
Os-193		$2.0X10^{0}$	$5.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$2.0X10^{4}$	$5.3X10^{5}$
Os-194 (a)		$3.0X10^{-1}$	$8.1X10^{0}$	$3.0X10^{-1}$	$8.1X10^{0}$	$1.1X10^{1}$	$3.1X10^{2}$
P-32	Phosphorus (15)	$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$1.1X10^{4}$	$2.9X10^{5}$
P-33		$4.0X10^{1}$	$1.1X10^{3}$	$1.0X10^{0}$	$2.7X10^{1}$	$5.8X10^{3}$	$1.6X10^{5}$
Pa-230 (a)	Protactinium (91)	$2.0X10^{0}$	$5.4X10^{1}$	$7.0X10^{-2}$	$1.9X10^{0}$	$1.2X10^{3}$	$3.3X10^{4}$
Pa-231		$4.0X10^{0}$	$1.1X10^{2}$	$4.0X10^{-4}$	$1.1X10^{-2}$	$1.7X10^{-3}$	$4.7X10^{-2}$
Pa-233		$5.0X10^{0}$	$1.4X10^{2}$	$7.0X10^{-1}$	$1.9X10^{1}$	$7.7X10^{2}$	$2.1X10^{4}$
Pb-201	Lead (82)	$1.0X10^{0}$	$2.7X10^{1}$	$1.0X10^{0}$	$2.7X10^{1}$	$6.2X10^{4}$	$1.7X10^{6}$
Pb-202		$4.0X10^{1}$	$1.1X10^{3}$	$2.0X10^{1}$	$5.4X10^{2}$	$1.2X10^{-4}$	$3.4X10^{-3}$
Pb-203		$4.0X10^{0}$	$1.1X10^{2}$	$3.0X10^{0}$	$8.1X10^{1}$	$1.1X10^{4}$	$3.0X10^{5}$
Pb-205		Unlimited	Unlimited	Unlimited	Unlimited	$4.5X10^{-6}$	$1.2X10^{-4}$
Pb-210 (a)		$1.0X10^{0}$	$2.7X10^{1}$	$5.0X10^{-2}$	$1.4X10^{0}$	$2.8X10^{0}$	$7.6X10^{1}$
Pb-212 (a)		$7.0X10^{-1}$	$1.9X10^{1}$	$2.0X10^{-1}$	$5.4X10^{0}$	$5.1X10^{4}$	$1.4X10^{6}$
Pd-103 (a)	Palladium (46)	$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$2.8X10^{3}$	$7.5X10^{4}$
Pd-107		Unlimited	Unlimited	Unlimited	Unlimited	$1.9X10^{-5}$	$5.1X10^{-4}$
Pd-109		$2.0X10^{0}$	$5.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$7.9X10^{4}$	$2.1X10^{6}$
Pm-143	Promethium (61)	$3.0X10^{0}$	$8.1X10^{1}$	$3.0X10^{0}$	$8.1X10^{1}$	$1.3X10^{2}$	$3.4X10^{3}$
Pm-144		$7.0X10^{-1}$	$1.9X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$9.2X10^{1}$	$2.5X10^{3}$
Pm-145		$3.0X10^{1}$	$8.1X10^{2}$	$1.0X10^{1}$	$2.7X10^{2}$	$5.2X10^{0}$	$1.4X10^{2}$
Pm-147		$4.0X10^{1}$	$1.1X10^{3}$	$2.0X10^{0}$	$5.4X10^{1}$	$3.4X10^{1}$	$9.3X10^{2}$
Pm-148m (a)		$8.0X10^{-1}$	$2.2X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$7.9X10^{2}$	$2.1X10^{4}$
Pm-149		$2.0X10^{0}$	$5.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.5X10^{4}$	$4.0X10^{5}$
Pm-151		$2.0X10^{0}$	$5.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$2.7X10^{4}$	$7.3X10^{5}$
Po-210	Polonium (84)	$4.0X10^{1}$	$1.1X10^{3}$	$2.0X10^{-2}$	$5.4X10^{-1}$	$1.7X10^{2}$	$4.5X10^{3}$
Pr-142	Praseodymium (59)	$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$4.3X10^{4}$	$1.2X10^{6}$
Pr-143		$3.0X10^{0}$	$8.1X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$2.5X10^{3}$	$6.7X10^{4}$
Pt-188 (a)	Platinum (78)	$1.0X10^{0}$	$2.7X10^{1}$	$8.0X10^{-1}$	$2.2X10^{1}$	$2.5X10^{3}$	$6.8X10^{4}$
Pt-191		$4.0X10^{0}$	$1.1X10^{2}$	$3.0X10^{0}$	$8.1X10^{1}$	$8.7X10^{3}$	$2.4X10^{5}$
Pt-193		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$1.4X10^{0}$	$3.7X10^{1}$
Pt-193m		$4.0X10^{1}$	$1.1X10^{3}$	$5.0X10^{-1}$	$1.4X10^{1}$	$5.8X10^{3}$	$1.6X10^{5}$
Pt-195m		$1.0X10^{1}$	$2.7X10^{2}$	$5.0X10^{-1}$	$1.4X10^{1}$	$6.2X10^{3}$	$1.7X10^{5}$
Pt-197		$2.0X10^{1}$	$5.4X10^{2}$	$6.0X10^{-1}$	$1.6X10^{1}$	$3.2X10^{4}$	$8.7X10^{5}$
Pt-197m		$1.0X10^{1}$	$2.7X10^{2}$	$6.0X10^{-1}$	$1.6X10^{1}$	$3.7X10^{5}$	$1.0X10^{7}$
Pu-236	Plutonium (94)	$3.0X10^{1}$	$8.1X10^{2}$	$3.0X10^{-3}$	$8.1X10^{-2}$	$2.0X10^{1}$	$5.3X10^{2}$
Pu-237		$2.0X10^{1}$	$5.4X10^{2}$	$2.0X10^{1}$	$5.4X10^{2}$	$4.5X10^{2}$	$1.2X10^{4}$
Pu-238		$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$6.3X10^{-1}$	$1.7X10^{1}$
Pu-239		$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$2.3X10^{-3}$	$6.2X10^{-2}$
Pu-240		$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$8.4X10^{-3}$	$2.3X10^{-1}$
Pu-241 (a)		$4.0X10^{1}$	$1.1X10^{3}$	$6.0X10^{-2}$	$1.6X10^{0}$	$3.8X10^{0}$	$1.0X10^{2}$
Pu-242		$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$1.5X10^{-4}$	$3.9X10^{-3}$
Pu-244 (a)		$4.0X10^{-1}$	$1.1X10^{1}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$6.7X10^{-7}$	$1.8X10^{-5}$
Ra-223 (a)	Radium (88)	$4.0X10^{-1}$	$1.1X10^{1}$	$7.0X10^{-3}$	$1.9X10^{-1}$	$1.9X10^{3}$	$5.1X10^{4}$
Ra-224 (a)		$4.0X10^{-1}$	$1.1X10^{1}$	$2.0X10^{-2}$	$5.4X10^{-1}$	$5.9X10^{3}$	$1.6X10^{5}$
Ra-225 (a)		$2.0X10^{-1}$	$5.4X10^{0}$	$4.0X10^{-3}$	$1.1X10^{-1}$	$1.5X10^{3}$	$3.9X10^{4}$
Ra-226 (a)		$2.0X10^{-1}$	$5.4X10^{0}$	$3.0X10^{-3}$	$8.1X10^{-2}$	$3.7X10^{-2}$	$1.0X10^{0}$
Ra-228 (a)		$6.0X10^{-1}$	$1.6X10^{1}$	$2.0X10^{-2}$	$5.4X10^{-1}$	$1.0X10^{1}$	$2.7X10^{2}$

Appendix A: continued

Table A - 1: A_1 and A_2 VALUES FOR RADIONUCLIDES (continued)

						Specific activity	
Symbol of radionuclides	Element and atomic number	A_1 (TBq)	A_1 (Ci)[b]	A_2 (TBq)	A_2 (Ci)[b]	(TBq/g)	(Ci/g)
Rb-81	Rubidium (37)	$2.0X10^{0}$	$5.4X10^{1}$	$8.0X10^{-1}$	$2.2X10^{1}$	$3.1X10^{5}$	$8.4X10^{6}$
Rb-83 (a)		$2.0X10^{0}$	$5.4X10^{1}$	$2.0X10^{0}$	$5.4X10^{1}$	$6.8X10^{2}$	$1.8X10^{4}$
Rb-84		$1.0X10^{0}$	$2.7X10^{1}$	$1.0X10^{0}$	$2.7X10^{1}$	$1.8X10^{3}$	$4.7X10^{4}$
Rb-86		$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$3.0X10^{3}$	$8.1X10^{4}$
Rb-87		Unlimited	Unlimited	Unlimited	Unlimited	$3.2X10^{-9}$	$8.6X10^{-8}$
Rb(nat)		Unlimited	Unlimited	Unlimited	Unlimited	$6.7X10^{6}$	$1.8X10^{8}$
Re-184	Rhenium (75)	$1.0X10^{0}$	$2.7X10^{1}$	$1.0X10^{0}$	$2.7X10^{1}$	$6.9X10^{2}$	$1.9X10^{4}$
Re-184m		$3.0X10^{0}$	$8.1X10^{1}$	$1.0X10^{0}$	$2.7X10^{1}$	$1.6X10^{2}$	$4.3X10^{3}$
Re-186		$2.0X10^{0}$	$5.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$6.9X10^{3}$	$1.9X10^{5}$
Re-187		Unlimited	Unlimited	Unlimited	Unlimited	$1.4X10^{-9}$	$3.8X10^{-8}$
Re-188		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$3.6X10^{4}$	$9.8X10^{5}$
Re-189 (a)		$3.0X10^{0}$	$8.1X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$2.5X10^{4}$	$6.8X10^{5}$
Re(nat)		Unlimited	Unlimited	Unlimited	Unlimited	$0.0X10^{0}$	$2.4X10^{-8}$
Rh-99	Rhodium (45)	$2.0X10^{0}$	$5.4X10^{1}$	$2.0X10^{0}$	$5.4X10^{1}$	$3.0X10^{3}$	$8.2X10^{4}$
Rh-101		$4.0X10^{0}$	$1.1X10^{2}$	$3.0X10^{0}$	$8.1X10^{1}$	$4.1X10^{1}$	$1.1X10^{3}$
Rh-102		$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$4.5X10^{1}$	$1.2X10^{3}$
Rh-102m		$2.0X10^{0}$	$5.4X10^{1}$	$2.0X10^{0}$	$5.4X10^{1}$	$2.3X10^{2}$	$6.2X10^{3}$
Rh-103m		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$1.2X10^{6}$	$3.3X10^{7}$
Rh-105		$1.0X10^{1}$	$2.7X10^{2}$	$8.0X10^{-1}$	$2.2X10^{1}$	$3.1X10^{4}$	$8.4X10^{5}$
Rn-222 (a)	Radon (86)	$3.0X10^{-1}$	$8.1X10^{0}$	$4.0X10^{-3}$	$1.1X10^{-1}$	$5.7X10^{3}$	$1.5X10^{5}$
Ru-97	Ruthenium (44)	$5.0X10^{0}$	$1.4X10^{2}$	$5.0X10^{0}$	$1.4X10^{2}$	$1.7X10^{4}$	$4.6X10^{5}$
Ru-103 (a)		$2.0X10^{0}$	$5.4X10^{1}$	$2.0X10^{0}$	$5.4X10^{1}$	$1.2X10^{3}$	$3.2X10^{4}$
Ru-105		$1.0X10^{0}$	$2.7X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$2.5X10^{5}$	$6.7X10^{6}$
Ru-106 (a)		$2.0X10^{-1}$	$5.4X10^{0}$	$2.0X10^{-1}$	$5.4X10^{0}$	$1.2X10^{2}$	$3.3X10^{3}$
S-35	Sulphur (16)	$4.0X10^{1}$	$1.1X10^{3}$	$3.0X10^{0}$	$8.1X10^{1}$	$1.6X10^{3}$	$4.3X10^{4}$
Sb-122	Antimony (51)	$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$1.5X10^{4}$	$4.0X10^{5}$
Sb-124		$6.0X10^{-1}$	$1.6X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$6.5X10^{2}$	$1.7X10^{4}$
Sb-125		$2.0X10^{0}$	$5.4X10^{1}$	$1.0X10^{0}$	$2.7X10^{1}$	$3.9X10^{1}$	$1.0X10^{3}$
Sb-126		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$3.1X10^{3}$	$8.4X10^{4}$
Sc-44	Scandium (21)	$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$6.7X10^{5}$	$1.8X10^{7}$
Sc-46		$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$1.3X10^{3}$	$3.4X10^{4}$
Sc-47		$1.0X10^{1}$	$2.7X10^{2}$	$7.0X10^{-1}$	$1.9X10^{1}$	$3.1X10^{4}$	$8.3X10^{5}$
Sc-48		$3.0X10^{-1}$	$8.1X10^{0}$	$3.0X10^{-1}$	$8.1X10^{0}$	$5.5X10^{4}$	$1.5X10^{6}$
Se-75	Selenium (34)	$3.0X10^{0}$	$8.1X10^{1}$	$3.0X10^{0}$	$8.1X10^{1}$	$5.4X10^{2}$	$1.5X10^{4}$
Se-79		$4.0X10^{1}$	$1.1X10^{3}$	$2.0X10^{0}$	$5.4X10^{1}$	$2.6X10^{-3}$	$7.0X10^{-2}$
Si-31	Silicon (14)	$6.0X10^{-1}$	$1.6X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.4X10^{6}$	$3.9X10^{7}$
Si-32		$4.0X10^{1}$	$1.1X10^{3}$	$5.0X10^{-1}$	$1.4X10^{1}$	$3.9X10^{0}$	$1.1X10^{2}$
Sm-145	Samarium (62)	$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{1}$	$2.7X10^{2}$	$9.8X10^{1}$	$2.6X10^{3}$
Sm-147		Unlimited	Unlimited	Unlimited	Unlimited	$8.5X10^{-1}$	$2.3X10^{-8}$
Sm-151		$4.0X10^{1}$	$1.1X10^{3}$	$1.0X10^{1}$	$2.7X10^{2}$	$9.7X10^{-1}$	$2.6X10^{1}$
Sm-153		$9.0X10^{0}$	$2.4X10^{2}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.6X10^{4}$	$4.4X10^{5}$
Sn-113 (a)	Tin (50)	$4.0X10^{0}$	$1.1X10^{2}$	$2.0X10^{0}$	$5.4X10^{1}$	$3.7X10^{2}$	$1.0X10^{4}$
Sn-117m		$7.0X10^{0}$	$1.9X10^{2}$	$4.0X10^{-1}$	$1.1X10^{1}$	$3.0X10^{3}$	$8.2X10^{4}$
Sn-119m		$4.0X10^{1}$	$1.1X10^{3}$	$3.0X10^{1}$	$8.1X10^{2}$	$1.4X10^{2}$	$3.7X10^{3}$
Sn-121m (a)		$4.0X10^{1}$	$1.1X10^{3}$	$9.0X10^{-1}$	$2.4X10^{1}$	$2.0X10^{0}$	$5.4X10^{1}$
Sn-123		$8.0X10^{-1}$	$2.2X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$3.0X10^{2}$	$8.2X10^{3}$
Sn-125		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{3}$	$1.1X10^{5}$
Sn-126 (a)		$6.0X10^{-1}$	$1.6X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$1.0X10^{-3}$	$2.8X10^{-2}$
Sr-82 (a)	Strontium (38)	$2.0X10^{-1}$	$5.4X10^{0}$	$2.0X10^{-1}$	$5.4X10^{0}$	$2.3X10^{3}$	$6.2X10^{4}$

Appendix A: continued

Table A - 1: A_1 and A_2 VALUES FOR RADIONUCLIDES (continued)

						Specific activity	
Symbol of radionuclides	Element and atomic number	A_1 (TBq)	A_1 (Ci)[b]	A_2 (TBq)	A_2 (Ci)[b]	(TBq/g)	(Ci/g)
Sr-85		$2.0X10^{0}$	$5.4X10^{1}$	$2.0X10^{0}$	$5.4X10^{1}$	$8.8X10^{2}$	$2.4X10^{4}$
Sr-85m		$5.0X10^{0}$	$1.4X10^{2}$	$5.0X10^{0}$	$1.4X10^{2}$	$1.2X10^{6}$	$3.3X10^{7}$
Sr-87m		$3.0X10^{0}$	$8.1X10^{1}$	$3.0X10^{0}$	$8.1X10^{1}$	$4.8X10^{5}$	$1.3X10^{7}$
Sr-89		$6.0X10^{-1}$	$1.6X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.1X10^{3}$	$2.9X10^{4}$
Sr-90 (a)		$3.0X10^{-1}$	$8.1X10^{0}$	$3.0X10^{-1}$	$8.1X10^{0}$	$5.1X10^{0}$	$1.4X10^{2}$
Sr-91 (a)		$3.0X10^{-1}$	$8.1X10^{0}$	$3.0X10^{-1}$	$8.1X10^{0}$	$1.3X10^{5}$	$3.6X10^{6}$
Sr-92 (a)		$1.0X10^{0}$	$2.7X10^{1}$	$3.0X10^{-1}$	$8.1X10^{0}$	$4.7X10^{5}$	$1.3X10^{7}$
T(H-3)	Tritium (1)	$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$3.6X10^{2}$	$9.7X10^{3}$
Ta-178 (long-lived)	Tantalum (73)	$1.0X10^{0}$	$2.7X10^{1}$	$8.0X10^{-1}$	$2.2X10^{1}$	$4.2X10^{6}$	$1.1X10^{8}$
Ta-179		$3.0X10^{1}$	$8.1X10^{2}$	$3.0X10^{1}$	$8.1X10^{2}$	$4.1X10^{1}$	$1.1X10^{3}$
Ta-182		$9.0X10^{-1}$	$2.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$2.3X10^{2}$	$6.2X10^{3}$
Tb-157	Terbium (65)	$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$5.6X10^{-1}$	$1.5X10^{1}$
Tb-158		$1.0X10^{0}$	$2.7X10^{1}$	$1.0X10^{0}$	$2.7X10^{1}$	$5.6X10^{-1}$	$1.5X10^{1}$
Tb-160		$1.0X10^{0}$	$2.7X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$4.2X10^{2}$	$1.1X10^{4}$
Tc-95m (a)	Technetium (43)	$2.0X10^{0}$	$5.4X10^{1}$	$2.0X10^{0}$	$5.4X10^{1}$	$8.3X10^{2}$	$2.2X10^{4}$
Tc-96		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$1.2X10^{4}$	$3.2X10^{5}$
Tc-96m (a)		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$1.4X10^{6}$	$3.8X10^{7}$
Tc-97		Unlimited	Unlimited	Unlimited	Unlimited	$5.2X10^{-5}$	$1.4X10^{-3}$
Tc-97m		$4.0X10^{1}$	$1.1X10^{3}$	$1.0X10^{0}$	$2.7X10^{1}$	$5.6X10^{2}$	$1.5X10^{4}$
Tc-98		$8.0X10^{-1}$	$2.2X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$3.2X10^{-5}$	$8.7X10^{-4}$
Tc-99		$4.0X10^{1}$	$1.1X10^{3}$	$9.0X10^{-1}$	$2.4X10^{1}$	$6.3X10^{-4}$	$1.7X10^{-2}$
Tc-99m		$1.0X10^{1}$	$2.7X10^{2}$	$4.0X10^{0}$	$1.1X10^{2}$	$1.9X10^{5}$	$5.3X10^{6}$
Te-121	Tellurium (52)	$2.0X10^{0}$	$5.4X10^{1}$	$2.0X10^{0}$	$5.4X10^{1}$	$2.4X10^{3}$	$6.4X10^{4}$
Te-121m		$5.0X10^{0}$	$1.4X10^{2}$	$3.0X10^{0}$	$8.1X10^{1}$	$2.6X10^{2}$	$7.0X10^{3}$
Te-123m		$8.0X10^{0}$	$2.2X10^{2}$	$1.0X10^{0}$	$2.7X10^{1}$	$3.3X10^{2}$	$8.9X10^{3}$
Te-125m		$2.0X10^{1}$	$5.4X10^{2}$	$9.0X10^{-1}$	$2.4X10^{1}$	$6.7X10^{2}$	$1.8X10^{4}$
Te-127		$2.0X10^{1}$	$5.4X10^{2}$	$7.0X10^{-1}$	$1.9X10^{1}$	$9.8X10^{4}$	$2.6X10^{6}$
Te-127m (a)		$2.0X10^{1}$	$5.4X10^{2}$	$5.0X10^{-1}$	$1.4X10^{1}$	$3.5X10^{2}$	$9.4X10^{3}$
Te-129		$7.0X10^{-1}$	$1.9X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$7.7X10^{5}$	$2.1X10^{7}$
Te-129m (a)		$8.0X10^{-1}$	$2.2X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$1.1X10^{3}$	$3.0X10^{4}$
Te-131m (a)		$7.0X10^{-1}$	$1.9X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$3.0X10^{4}$	$8.0X10^{5}$
Te-132 (a)		$5.0X10^{-1}$	$1.4X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$1.1X10^{4}$	$3.0X10^{5}$
Th-227	Thorium (90)	$1.0X10^{1}$	$2.7X10^{2}$	$5.0X10^{-3}$	$1.4X10^{-1}$	$1.1X10^{3}$	$3.1X10^{4}$
Th-228 (a)		$5.0X10^{-1}$	$1.4X10^{1}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$3.0X10^{1}$	$8.2X10^{2}$
Th-229		$5.0X10^{0}$	$1.4X10^{2}$	$5.0X10^{-4}$	$1.4X10^{-2}$	$7.9X10^{-3}$	$2.1X10^{-1}$
Th-230		$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$7.6X10^{-4}$	$2.1X10^{-2}$
Th-231	Thorium (90)	$4.0X10^{1}$	$1.1X10^{3}$	$2.0X10^{-2}$	$5.4X10^{-1}$	$2.0X10^{4}$	$5.3X10^{5}$
Th-232		Unlimited	Unlimited	Unlimited	Unlimited	$4.0X10^{-9}$	$1.1X10^{-7}$
Th-234 (a)		$3.0X10^{-1}$	$8.1X10^{0}$	$3.0X10^{-1}$	$8.1X10^{0}$	$8.6X10^{2}$	$2.3X10^{4}$
Th(nat)		Unlimited	Unlimited	Unlimited	Unlimited	$8.1X10^{-9}$	$2.2X10^{-7}$
Ti-44 (a)	Titanium (22)	$5.0X10^{-1}$	$1.4X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$6.4X10^{0}$	$1.7X10^{2}$
Tl-200	Thallium (81)	$9.0X10^{-1}$	$2.4X10^{1}$	$9.0X10^{-1}$	$2.4X10^{1}$	$2.2X10^{4}$	$6.0X10^{5}$
Tl-201		$1.0X10^{1}$	$2.7X10^{2}$	$4.0X10^{0}$	$1.1X10^{2}$	$7.9X10^{3}$	$2.1X10^{5}$
Tl-202		$2.0X10^{0}$	$5.4X10^{1}$	$2.0X10^{0}$	$5.4X10^{1}$	$2.0X10^{3}$	$5.3X10^{4}$
Tl-204		$1.0X10^{1}$	$2.7X10^{2}$	$7.0X10^{-1}$	$1.9X10^{1}$	$1.7X10^{1}$	$4.6X10^{2}$
Tm-167	Thulium (69)	$7.0X10^{0}$	$1.9X10^{2}$	$8.0X10^{-1}$	$2.2X10^{1}$	$3.1X10^{3}$	$8.5X10^{4}$
Tm-170		$3.0X10^{0}$	$8.1X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$2.2X10^{2}$	$6.0X10^{3}$
Tm-171		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$

Appendix A: continued

Table A - 1: A_1 and A_2 VALUES FOR RADIONUCLIDES (continued)

						Specific activity	
Symbol of radionuclides	Element and atomic number	A_1 (TBq)	A_1 (Ci)[b]	A_2 (TBq)	A_2 (Ci)[b]	(TBq/g)	(Ci/g)
U-230 (fast lung absorption) (a)(d)	Uranium (92)	$4.0X10^{1}$	$1.1X10^{3}$	$1.0X10^{-1}$	$2.7X10^{0}$	$1.0X10^{3}$	$2.7X10^{4}$
U-230 (medium lung absorption) (a)(e)		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{-3}$	$1.1X10^{-1}$	$1.0X10^{3}$	$2.7X10^{4}$
U-230 (slow lung absorption) (a)(f)		$3.0X10^{1}$	$8.1X10^{2}$	$3.0X10^{-3}$	$8.1X10^{-2}$	$1.0X10^{3}$	$2.7X10^{4}$
U-232 (fast lung absorption) (d)		$4.0X10^{1}$	$1.1X10^{3}$	$1.0X10^{-2}$	$2.7X10^{-1}$	$8.3X10^{-1}$	$2.2X10^{1}$
U-232 (medium lung absorption) (e)		$4.0X10^{1}$	$1.1X10^{3}$	$7.0X10^{-3}$	$1.9X10^{-1}$	$8.3X10^{-1}$	$2.2X10^{1}$
U-232 (slow lung absorption) (f)		$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$8.3X10^{-1}$	$2.2X10^{1}$
U-233 (fast lung absorption) (d)	Uranium (92)	$4.0X10^{1}$	$1.1X10^{3}$	$9.0X10^{-2}$	$2.4X10^{0}$	$3.6X10^{-4}$	$9.7X10^{-3}$
U-233 (medium lung absorption) (e)		$4.0X10^{1}$	$1.1X10^{3}$	$2.0X10^{-2}$	$5.4X10^{-1}$	$3.6X10^{-4}$	$9.7X10^{-3}$
U-233 (slow lung absorption) (f)		$4.0X10^{1}$	$1.1X10^{3}$	$6.0X10^{-3}$	$1.6X10^{-1}$	$3.6X10^{-4}$	$9.7X10^{-3}$
U-234 (fast lung absorption) (d)		$4.0X10^{1}$	$1.1X10^{3}$	$9.0X10^{-2}$	$2.4X10^{0}$	$2.3X10^{-4}$	$6.2X10^{-3}$
U-234 (medium lung absorption) (e)		$4.0X10^{1}$	$1.1X10^{3}$	$2.0X10^{-2}$	$5.4X10^{-1}$	$2.3X10^{-4}$	$6.2X10^{-3}$
U-234 (slow lung absorption) (f)		$4.0X10^{1}$	$1.1X10^{3}$	$6.0X10^{-3}$	$1.6X10^{-1}$	$2.3X10^{-4}$	$6.2X10^{-3}$
U-235 (all lung absorption types) (a), (d), (e), (f)		Unlimited	Unlimited	Unlimited	Unlimited	$8.0X10^{-8}$	$2.2X10^{-6}$
U-236 (fast lung absorption) (d)		Unlimited	Unlimited	Unlimited	Unlimited	$2.4X10^{-6}$	$6.5X10^{-5}$
U-236 (medium lung absorption) (e)		$4.0X10^{1}$	$1.1X10^{3}$	$2.0X10^{-2}$	$5.4X10^{-1}$	$2.4X10^{-6}$	$6.5X10^{-5}$
U-236 (slow lung absorption) (f)		$4.0X10^{1}$	$1.1X10^{3}$	$6.0X10^{-3}$	$1.6X10^{-1}$	$2.4X10^{-6}$	$6.5X10^{-5}$
U-238 (all lung absorption types) (d), (e), (f)		Unlimited	Unlimited	Unlimited	Unlimited	$1.2X10^{-8}$	$3.4X10^{-7}$
U (nat)		Unlimited	Unlimited	Unlimited	Unlimited	$2.6X10^{-8}$	$7.1X10^{-7}$
U (enriched to 20% or less)(g)		Unlimited	Unlimited	Unlimited	Unlimited	N/A	N/A
U (dep)		Unlimited	Unlimited	Unlimited	Unlimited	$0.0X10^{0}$	*See* Table A-3
V-48	Vanadium (23)	$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$6.3X10^{3}$	$1.7X10^{5}$
V-49		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$3.0X10^{2}$	$8.1X10^{3}$
W-178 (a)	Tungsten (74)	$9.0X10^{0}$	$2.4X10^{2}$	$5.0X10^{0}$	$1.4X10^{2}$	$1.3X10^{3}$	$3.4X10^{4}$
W-181		$3.0X10^{1}$	$8.1X10^{2}$	$3.0X10^{1}$	$8.1X10^{2}$	$2.2X10^{2}$	$6.0X10^{3}$
W-185		$4.0X10^{1}$	$1.1X10^{3}$	$8.0X10^{-1}$	$2.2X10^{1}$	$3.5X10^{2}$	$9.4X10^{3}$
W-187		$2.0X10^{0}$	$5.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$2.6X10^{4}$	$7.0X10^{5}$
W-188 (a)		$4.0X10^{-1}$	$1.1X10^{1}$	$3.0X10^{-1}$	$8.1X10^{0}$	$3.7X10^{2}$	$1.0X10^{4}$
Xe-122 (a)	Xenon (54)	$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$4.8X10^{4}$	$1.3X10^{6}$
Xe-123		$2.0X10^{0}$	$5.4X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$4.4X10^{5}$	$1.2X10^{7}$
Xe-127		$4.0X10^{0}$	$1.1X10^{2}$	$2.0X10^{0}$	$5.4X10^{1}$	$1.0X10^{3}$	$2.8X10^{4}$
Xe-131m		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$3.1X10^{3}$	$8.4X10^{4}$
Xe-133		$2.0X10^{1}$	$5.4X10^{2}$	$1.0X10^{1}$	$2.7X10^{2}$	$6.9X10^{3}$	$1.9X10^{5}$
Xe-135		$3.0X10^{0}$	$8.1X10^{1}$	$2.0X10^{0}$	$5.4X10^{1}$	$9.5X10^{4}$	$2.6X10^{6}$
Y-87 (a)	Yttrium (39)	$1.0X10^{0}$	$2.7X10^{1}$	$1.0X10^{0}$	$2.7X10^{1}$	$1.7X10^{4}$	$4.5X10^{5}$
Y-88		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$5.2X10^{2}$	$1.4X10^{4}$
Y-90		$3.0X10^{-1}$	$8.1X10^{0}$	$3.0X10^{-1}$	$8.1X10^{0}$	$2.0X10^{4}$	$5.4X10^{5}$
Y-91		$6.0X10^{-1}$	$1.6X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$9.1X10^{2}$	$2.5X10^{4}$
Y-91m		$2.0X10^{0}$	$5.4X10^{1}$	$2.0X10^{0}$	$5.4X10^{1}$	$1.5X10^{6}$	$4.2X10^{7}$
Y-92		$2.0X10^{-1}$	$5.4X10^{0}$	$2.0X10^{-1}$	$5.4X10^{0}$	$3.6X10^{5}$	$9.6X10^{6}$
Y-93		$3.0X10^{-1}$	$8.1X10^{0}$	$3.0X10^{-1}$	$8.1X10^{0}$	$1.2X10^{5}$	$3.3X10^{6}$
Yb-169	Ytterbium (79)	$4.0X10^{0}$	$1.1X10^{2}$	$1.0X10^{0}$	$2.7X10^{1}$	$8.9X10^{2}$	$2.4X10^{4}$
Yb-175		$3.0X10^{1}$	$8.1X10^{2}$	$9.0X10^{-1}$	$2.4X10^{1}$	$6.6X10^{3}$	$1.8X10^{5}$
Zn-65	Zinc (30)	$2.0X10^{0}$	$5.4X10^{1}$	$2.0X10^{0}$	$5.4X10^{1}$	$3.0X10^{2}$	$8.2X10^{3}$
Zn-69		$3.0X10^{0}$	$8.1X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.8X10^{6}$	$4.9X10^{7}$

Appendix A: continued

Table A - 1: A_1 and A_2 VALUES FOR RADIONUCLIDES (continued)

						Specific activity	
Symbol of radionuclides	Element and atomic number	A_1 (TBq)	A_1 (Ci)[b]	A_2 (TBq)	A_2 (Ci)[b]	(TBq/g)	(Ci/g)
Zn-69m (a)		$3.0X10^{0}$	$8.1X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.2X10^{5}$	$3.3X10^{6}$
Zr-88	Zirconium (40)	$3.0X10^{0}$	$8.1X10^{1}$	$3.0X10^{0}$	$8.1X10^{1}$	$6.6X10^{2}$	$1.8X10^{4}$
Zr-93		Unlimited	Unlimited	Unlimited	Unlimited	$9.3X10^{-5}$	$2.5X10^{-3}$
Zr-95 (a)		$2.0X10^{0}$	$5.4X10^{1}$	$8.0X10^{-1}$	$2.2X10^{1}$	$7.9X10^{2}$	$2.1X10^{4}$
Zr-97 (a)		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$7.1X10^{4}$	$1.9X10^{6}$

[a] A_1 and/or A_2 values include contributions from daughter nuclides with half-lives less than ten days, as listed in the following:

Mg-28	Al-28
Ca-47	Sc-47
Ti-44	Sc-44
Fe-52	Mn-52m
Fe-60	Co-60m
Zn-69m	Zn-69
Ge-68	Ga-68
Rb-83	Kr-83m
Sr-82	Rb-82
Sr-90	Y-90
Sr-91	Y-91m
Sr-92	Y-92
Y-87	Sr-87m
Zr-95	Nb-95m
Zr-97	Nb-97m, Nb-97
Mo-99	Tc-99m
Tc-95m	Tc-95
Tc-96m	Tc-96
Ru-103	Rh-103m
Ru-106	Rh-106
Pd-103	Rh-103m
Ag-108m	Ag-108
Ag-110m	Ag-110
Cd-115	In-115m
In-114m	In-114
Sn-113	In-113m
Sn-121m	Sn-121
Sn-126	Sb-126m
Te-127m	Te-127
Te-129m	Te-129
Te-131m	Te-131
Te-132	I-132
I–135	Xe-135m
Xe-122	I-122
Cs-137	Ba-137m
Ba-131	Cs-131
Ba-140	La-140
Ce-144	Pr-144m, Pr-144
Pm-148m	Pm-148
Gd-146	Eu-146
Dy-166	Ho-166
Hf-172	Lu-172
W-178	Ta-178
W-188	Re-188
Re-189	Os-189m
Os-194	Ir-194
Ir-189	Os-189m
Pt-188	Ir-188

Appendix A: continued

Hg-194	Au-194
Hg-195m	Hg-195
Pb-210	Bi-210
Pb-212	Bi-212, Tl-208, Po-212
Bi-210m	Tl-206
Bi-212	Tl-208, Po-212
At-211	Po-211
Rn-222	Po-218, Pb-214, At-218, Bi-214, Po-214
Ra-223	Rn-219, Po-215, Pb-211, Bi-211, Po-211, Tl-207
Ra-224	Rn-220, Po-216, Pb-212, Bi-212, Tl-208, Po-212
Ra-225	Ac-225, Fr-221, At-217, Bi-213, Tl-209, Po-213, Pb-209
Ra-226	Rn-222, Po-218, Pb-214, At-218, Bi-214, Po-214
Ra-228	Ac-228
Ac-225	Fr-221, At-217, Bi-213, Tl-209, Po-213, Pb-209
Ac-227	Fr-223
Th-228	Ra-224, Rn-220, Po-216, Pb-212, Bi-212, Tl-208, Po-212
Th-234	Pa-234m, Pa-234
Pa-230	Ac-226, Th-226, Fr-222, Ra-222, Rn-218, Po-214
U-230	Th-226, Ra-222, Rn-218, Po-214
U-235	Th-231
Pu-241	U-237
Pu-244	U-240, Np-240m
Am-242m	Am-242, Np-238
Am-243	Np-239
Cm-247	Pu-243
Bk-249	Am-245
Cf-253	Cm-249

[b] The values of A_1 and A_2 in Curies (Ci) are approximate and for information only; the regulatory standard units are Terabecquerels (TBq) (*see* 105 CMR 120.798: *Appendix A – Determination of A_1 and A_2, subsection I*).
[c] The activity of Ir-192 in special form may be determined from a measurement of the rate of decay or a measurement of the radiation level at a prescribed distance from the source.
[d] These values apply only to compounds of uranium that take the chemical form of UF_6, UO_2F_2 and $UO_2(NO_3)_2$ in both normal and accident conditions of transport.
[e] These values apply only to compounds of uranium that take the chemical form of UO_3, UF_4, UCl_4 and hexavalent compounds in both normal and accident conditions of transport.
[f] These values apply to all compounds of uranium other than those specified in notes (d) and (e) of this table.
[g] These values apply to unirradiated uranium only.
[h] A_2 = 0.74 TBq (20 Ci) for Mo-99 for domestic use.

Appendix A: continued

Table A - 2: EXEMPT MATERIAL ACTIVITY CONCENTRATIONS AND EXEMPT CONSIGNMENT ACTIVITY LIMITS FOR RADIONUCLIDES

Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
Ac-225	Actinium (89)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Ac-227		$1.0X10^{-1}$	$2.7X10^{-12}$	$1.0X10^{3}$	$2.7X10^{-8}$
Ac-228		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ag-105	Silver (47)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ag-108m (b)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ag-110m		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ag-111		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Al-26	Aluminum (13)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Am-241	Americium (95)	$1.0X10^{0}$	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
Am-242m (b)		$1.0X10^{0}$	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
Am-243 (b)		$1.0X10^{0}$	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Ar-37	Argon (18)	$1.0X10^{6}$	$2.7X10^{-5}$	$1.0X10^{8}$	$2.7X10^{-3}$
Ar-39		$1.0X10^{7}$	$2.7X10^{-4}$	$1.0X10^{4}$	$2.7X10^{-7}$
Ar-41		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{9}$	$2.7X10^{-2}$
As-72	Arsenic (33)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
As-73		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
As-74		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
As-76		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
As-77		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
At-211	Astatine (85)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Au-193	Gold (79)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Au-194		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Au-195		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Au-198		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Au-199		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ba-131	Barium (56)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ba-133		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ba-133m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ba-140 (b)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Be-7	Beryllium (4)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Be-10		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{6}$	$2.7X10^{-5}$
Bi-205	Bismuth (83)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Bi-206		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Bi-207		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Bi-210		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Bi-210m		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Bi-212 (b)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Bk-247	Berkelium (97)	1	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
Bk-249		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Br-76	Bromine (35)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Br-77		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Br-82		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
C-11	Carbon (6)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
C-14		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Ca-41	Calcium (20)	$1.0X10^{5}$	$2.7X10^{-6}$	$1.0X10^{7}$	$2.7X10^{-4}$
Ca-45		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Ca-47		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$

Appendix A: continued

Table A - 2: EXEMPT MATERIAL ACTIVITY CONCENTRATIONS AND EXEMPT CONSIGNMENT ACTIVITY LIMITS FOR RADIONUCLIDES (continued)

Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
Cd-109	Cadmium (48)	$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{6}$	$2.7X10^{-5}$
Cd-113m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Cd-115		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Cd-115m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ce-139	Cerium (58)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ce-141		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Ce-143		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ce-144 (b)		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Cf-248	Californium (98)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Cf-249		1	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Cf-250		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Cf-251		1	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Cf-252		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Cf-253		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Cf-254		1	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Cl-36	Chlorine (17)	$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{6}$	$2.7X10^{-5}$
Cl-38		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Cm-240	Curium (96)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Cm-241		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Cm-242		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Cm-243		$1.0X10^{0}$	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
Cm-244		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Cm-245		1	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Cm-246		1	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Cm-247		1	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
Cm-248		1	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Co-55	Cobalt (27)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Co-56		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Co-57		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Co-58		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Co-58m		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Co-60		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Cr-51	Chromium (24)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Cs-129	Cesium (55)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Cs-131		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Cs-132		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Cs-134		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Cs-134m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{5}$	$2.7X10^{-6}$
Cs-135		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Cs-136		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Cs-137 (b)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Cu-64	Copper (29)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Cu-67		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Dy-159	Dysprosium (66)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Dy-165		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Dy-166 (a)		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Er-169	Erbium (68)	$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Er-171		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$

Appendix A: continued

Table A - 2: EXEMPT MATERIAL ACTIVITY CONCENTRATIONS AND EXEMPT CONSIGNMENT ACTIVITY LIMITS FOR RADIONUCLIDES (continued)

Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
Eu-147	Europium (63)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Eu-148		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Eu-149		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Eu-150 (short-lived)		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Eu-150 (long-lived)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Eu-152		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Eu-152 m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Eu-154		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Eu-155		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Eu-156		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
F-18	Fluorine (9)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Fe-52	Iron (26)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Fe-55		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{6}$	$2.7X10^{-5}$
Fe-59		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Fe-60		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Ga-67	Gallium (31)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ga-68		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Ga-72		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Gd-146	Gadolinium (64)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Gd-148		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Gd-153		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Gd-159		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ge-68	Germanium (32)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Ge-71		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{8}$	$2.7X10^{-3}$
Ge-77		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Hf-172	Hafnium (72)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Hf-175		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Hf-181		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Hf-182		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Hg-194	Mercury (80)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Hg-195m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Hg-197		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Hg-197m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Hg-203		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Ho-166	Holmium (67)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{5}$	$2.7X10^{-6}$
Ho-166m		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
I-123	Iodine (53)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
I-124		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
I-125		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
I-126		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
I-129		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
I-131		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
I-132		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
I-133		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
I-134		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
I-135		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
In-111	Indium (49)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
In-113m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$

Appendix A: continued

Table A - 2: EXEMPT MATERIAL ACTIVITY CONCENTRATIONS AND EXEMPT CONSIGNMENT ACTIVITY LIMITS FOR RADIONUCLIDES (continued)

Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
In-114m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
In-115m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ir-189	Iridium (77)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Ir-190		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ir-192		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Ir-194		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
K-40	Potassium (19)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
K-42		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
K-43		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Kr-79	Krypton (36)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{5}$	$2.7X10^{-6}$
Kr-81		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Kr-85		$1.0X10^{5}$	$2.7X10^{-6}$	$1.0X10^{4}$	$2.7X10^{-7}$
Kr-85m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{10}$	$2.7X10^{-1}$
Kr-87		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{9}$	$2.7X10^{-2}$
La-137	Lanthanum (57)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
La-140		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Lu-172	Lutetium (71)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Lu-173		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Lu-174		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Lu-174m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Lu-177		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Mg-28	Magnesium (12)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Mn-52	Manganese (25)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Mn-53		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{9}$	$2.7X10^{-2}$
Mn-54		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Mn-56		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Mo-93	Molybdenum (42)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{8}$	$2.7X10^{-3}$
Mo-99		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
N-13	Nitrogen (7)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{9}$	$2.7X10^{-2}$
Na-22	Sodium (11)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Na-24		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Nb-93m	Niobium (41)	$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Nb-94		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Nb-95		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Nb-97		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Nd-147	Neodymium (60)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Nd-149		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ni-59	Nickel (28)	$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{8}$	$2.7X10^{-3}$
Ni-63		$1.0X10^{5}$	$2.7X10^{-6}$	$1.0X10^{8}$	$2.7X10^{-3}$
Ni-65		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Np-235	Neptunium (93)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Np-236 (short-lived)		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Np-236 (long-lived)		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Np-237 (b)		1	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Np-239		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Os-185	Osmium (76)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Os-191		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Os-191m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Os-193		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Os-194 (a)		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$

Appendix A: continued

Table A - 2: EXEMPT MATERIAL ACTIVITY CONCENTRATIONS AND EXEMPT CONSIGNMENT ACTIVITY LIMITS FOR RADIONUCLIDES (continued)

Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
P-32	Phosphorus (15)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{5}$	$2.7X10^{-6}$
P-33		$1.0X10^{5}$	$2.7X10^{-6}$	$1.0X10^{8}$	$2.7X10^{-3}$
Pa-230 (a)	Protactinium (91)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pa-231		1	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Pa-233		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Pb-201	Lead (82)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pb-202		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pb-203		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pb-205		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Pb-210 (b)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Pb-212 (b)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Pd-103	Palladium (46)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{8}$	$2.7X10^{-3}$
Pd-107		$1.0X10^{5}$	$2.7X10^{-6}$	$1.0X10^{8}$	$2.7X10^{-3}$
Pd-109		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pm-143	Promethium (61)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pm-144		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pm-145		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Pm-147		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Pm-148m		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pm-149		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pm-151		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Po-210	Polonium (84)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Pr-142	Praseodymium (59)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Pr-143		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pt-188	Platinum (78)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pt-191		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pt-193		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Pt-193m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Pt-195m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pt-197		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pt-197m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pu-236	Plutonium (94)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Pu-237		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Pu-238		1	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
Pu-239		1	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
Pu-240		1	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Pu-241)		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Pu-242		1	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
Pu-244		1	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
Ra-223 (b)	Radium (88)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Ra-224 (b)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Ra-225		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Ra-226 (b)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Ra-228 (b)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Rb-81	Rubidium (37)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Rb-83		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Rb-84		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Rb-86		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Rb-87		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Rb(nat)		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$

Appendix A: continued

Table A - 2: EXEMPT MATERIAL ACTIVITY CONCENTRATIONS AND EXEMPT CONSIGNMENT ACTIVITY LIMITS FOR RADIONUCLIDES (continued)

Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
Re-184	Rhenium (75)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Re-184m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Re-186		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Re-187		$1.0X10^{6}$	$2.7X10^{-5}$	$1.0X10^{9}$	$2.7X10^{-2}$
Re-188		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Re-189		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Re(nat)		$1.0X10^{6}$	$2.7X10^{-5}$	$1.0X10^{9}$	$2.7X10^{-2}$
Rh-99	Rhodium (45)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Rh-101		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Rh-102		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Rh-102m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Rh-103m		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{8}$	$2.7X10^{-3}$
Rh-105		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Rn-222 (b)	Radon (86)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{8}$	$2.7X10^{-3}$
Ru-97	Ruthenium (44)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Ru-103		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ru-105		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ru-106 (b)		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
S-35	Sulphur (16)	$1.0X10^{5}$	$2.7X10^{-6}$	$1.0X10^{8}$	$2.7X10^{-3}$
Sb-122	Antimony (51)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{4}$	$2.7X10^{-7}$
Sb-124		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Sb-125		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Sb-126		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Sc-44	Scandium (21)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Sc-46		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Sc-47		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Sc-48		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Se-75	Selenium (34)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Se-79		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Si-31	Silicon (14)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Si-32		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Sm-145	Samarium (62)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Sm-147		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Sm-151		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{8}$	$2.7X10^{-3}$
Sm-153		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Sn-113	Tin (50)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Sn-117m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Sn-119m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Sn-121m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Sn-123		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Sn-125		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Sn-126		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Sr-82	Strontium (38)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Sr-85		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Sr-85m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Sr-87m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Sr-89		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Sr-90 (b)		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{4}$	$2.7X10^{-7}$
Sr-91		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Sr-92		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$

Appendix A: continued

Table A - 2: EXEMPT MATERIAL ACTIVITY CONCENTRATIONS AND EXEMPT CONSIGNMENT ACTIVITY LIMITS FOR RADIONUCLIDES (continued)

Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
T(H-3)	Tritium (1)	$1.0X10^{6}$	$2.7X10^{-5}$	$1.0X10^{9}$	$2.7X10^{-2}$
Ta-178 (long-lived)	Tantalum (73)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ta-179		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Ta-182		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Tb-157	Terbium (65)	$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Tb-158		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Tb-160		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Tc-95m	Technetium (43)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Tc-96		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Tc-96m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Tc-97		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{8}$	$2.7X10^{-3}$
Tc-97m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Tc-98		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Tc-99		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Tc-99m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Te-121	Tellurium (52)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Te-121m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Te-123m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Te-125m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Te-127		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Te-127m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Te-129		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Te-129m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Te-131m		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Te-132		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Th-227	Thorium (90)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Th-228 (b)		1	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
Th-229 (b)		1	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Th-230		1	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
Th-231		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Th-232		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Th-234 (b)		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{5}$	$2.7X10^{-6}$
Th (nat)(b)		1	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Ti-44	Titanium (22)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Tl-200	Thallium (81)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Tl-201		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Tl-202		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Tl-204		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{4}$	$2.7X10^{-7}$
Tm-167	Thulium (69)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Tm-170		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Tm-171		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{8}$	$2.7X10^{-3}$
U-230 (fast lung absorption) (b)(d)	Uranium (92)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
U-230 (medium lung absorption) (e)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
U-230 (slow lung absorption) (f)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
U-232 (fast lung absorption) (b), (d)	Uranium (92)	$1.0X10^{0}$	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
U-232 (medium lung absorption) (e)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
U-232 (slow lung absorption) (f)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$

Appendix A: continued

Table A - 2: EXEMPT MATERIAL ACTIVITY CONCENTRATIONS AND EXEMPT CONSIGNMENT ACTIVITY LIMITS FOR RADIONUCLIDES (continued)

Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
U-233 (fast lung absorption) (d)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
U-233 (medium lung absorption) (e)		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
U-233 (slow lung absorption) (f)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
U-234 (fast lung absorption) (d)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
U-234 (medium lung absorption) (e)		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
U-234 (slow lung absorption) (f)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
U-235 (all lung absorption types) (b), (d), (e), (f)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
U-236 (fast lung absorption) (d)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
U-236 (medium lung absorption) (e)	Uranium (92)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
U-236 (slow lung absorption) (f)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
U-238 (all lung absorption types) (b), (d), (e), (f)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
U (nat) (b)		$1.0X10^{0}$	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
U (enriched to 20% or less)(g)		$1.0X10^{0}$	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
U (dep)		$1.0X10^{0}$	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
V-48	Vanadium (23)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
V-49		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
W-178	Tungsten (74)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
W-181		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
W-185		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
W-187		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
W-188		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Xe-122	Xenon (54)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{9}$	$2.7X10^{-2}$
Xe-123		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{9}$	$2.7X10^{-2}$
Xe-127		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{5}$	$2.7X10^{-6}$
Xe-131m		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{4}$	$2.7X10^{-7}$
Xe-133		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{4}$	$2.7X10^{-7}$
Xe-135		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{10}$	$2.7X10^{-1}$
Y-87	Yttrium (39)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Y-88		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Y-90		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{5}$	$2.7X10^{-6}$
Y-91		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Y-91m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Y-92		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Y-93		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Yb-169	Ytterbium (79)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Yb-175		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Zn-65	Zinc (30)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Zn-69		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{6}$	$2.7X10^{-5}$
Zn-69m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Zr-88	Zirconium (40)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Zr-93 (b)		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Zr-95		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Zr-97 (b)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$

[a] [Reserved]

Appendix A: continued

[b] Parent nuclides and their progeny included in secular equilibrium are listed in the following:

Sr-90	Y-90
Zr-93	Nb-93m
Zr-97	Nb-97
Ru-106	Rh-106
Ag-108m	Ag-108
Cs-137	Ba-137m
Ce-144	Pr-144
Ba-140	La-140
Bi-212	Tl-208 (0.36), Po-212 (0.64)
Pb-210	Bi-210, Po-210
Pb-212	Bi-212, Tl-208 (0.36), Po-212 (0.64)
Rn-220	Po-216
Rn-222	Po-218, Pb-214, Bi-214, Po-214
Ra-223	Rn-219, Po-215, Pb-211, Bi-211, Tl-207
Ra-224	Rn-220, Po-216, Pb-212, Bi-212, Tl-208(0.36), Po-212 (0.64)
Ra-226	Rn-222, Po-218, Pb-214, Bi-214, Po-214, Pb-210, Bi-210, Po-210
Ra-228	Ac-228
Th-228	Ra-224, Rn-220, Po-216, Pb-212, Bi-212, Tl-208 (0.36), Po-212 (0.64)
Th-229	Ra-225, Ac-225, Fr-221, At-217, Bi-213, Po-213, Pb-209
Th-nat	Ra-228, Ac-228, Th-228, Ra-224, Rn-220, Po-216, Pb-212, Bi-212, Tl-208 (0.36), Po-212 (0.64)
Th-234	Pa-234m
U-230	Th-226, Ra-222, Rn-218, Po-214
U-232	Th-228, Ra-224, Rn-220, Po-216, Pb-212, Bi-212, Tl-208 (0.36), Po-212 (0.64)
U-235	Th-231
U-238	Th-234, Pa-234m
U-nat	Th-234, Pa-234m, U-234, Th-230, Ra-226, Rn-222, Po-218, Pb-214, Bi-214, Po-214, Pb-210, Bi-210, Po-210
Np-237	Pa-233
Am-242m	Am-242
Am-243	Np-239

[c] [Reserved]

[d] These values apply only to compounds of uranium that take the chemical form of UF_6, UO_2F_2 and $UO_2(NO_3)_2$ in both normal and accident conditions of transport.

[e] These values apply only to compounds of uranium that take the chemical form of UO_3, UF_4, UCl_4 and hexavalent compounds in both normal and accident conditions of transport.

[f] These values apply to all compounds of uranium other than those specified in notes (d) and (e) of this table.

[g] These values apply to unirradiated uranium only.

Appendix A: continued

Table A-3: General Values for A_1 and A_2)

Contents	A_1		A_2		Activity concentration for exempt material	Activity concentration for exempt material	Activity limits for exempt consignments	Activity limits for exempt consignments
	(TBq)	(Ci)	(TBq)	(Ci)	(Bq/g)	(Ci/g)	(Bq)	(Ci)
Only beta or gamma emitting radionuclides are known to be present	1×10^{-1}	2.7×10^{0}	2×10^{-2}	5.4×10^{-1}	1×10^{1}	2.7×10^{-10}	1×10^{4}	2.7×10^{-7}
Alpha emitting radionuclides, but no neutron emitters, are known to be present (a)	2×10^{-1}	5.4×10^{0}	9×10^{-5}	2.4×10^{-3}	1×10^{-1}	2.7×10^{-12}	1×10^{3}	2.7×10^{-8}
Neutron emitting radio-nuclides are known to be present or no relevant data is available	1×10^{-3}	2.7×10^{-2}	9×10^{-5}	2.4×10^{-3}	1×10^{-1}	2.7×10^{-12}	1×10^{3}	2.7×10^{-8}

[a] If beta or gamma emitting radionuclides are known to be present, the A_1 value of 0.1 TBq (2.7 Ci) should be used.

Table A-4: Activity-mass Relationships for Uranium

Uranium Enrichment[1] wt % U-235 present	Specific Activity	
	TBq/g	Ci/g
0.45	1.8×10^{-8}	5.0×10^{-7}
0.72	2.6×10^{-8}	7.1×10^{-7}
1	2.8×10^{-8}	7.6×10^{-7}
1.5	3.7×10^{-8}	1.0×10^{-6}
5	1.0×10^{-7}	2.7×10^{-6}
10	1.8×10^{-7}	4.8×10^{-6}
20	3.7×10^{-7}	1.0×10^{-5}
35	7.4×10^{-7}	2.0×10^{-5}
50	9.3×10^{-7}	2.5×10^{-5}
90	2.2×10^{-6}	5.8×10^{-5}
93	2.6×10^{-6}	7.0×10^{-5}
95	3.4×10^{-6}	9.1×10^{-5}

120.800: LICENSING AND OPERATIONAL REQUIREMENTS FOR LOW-LEVEL RADIOACTIVE WASTE FACILITIES

120.801: Purpose and Scope

(A) 105 CMR 120.800 establishes procedures, performance objectives, criteria, terms and conditions governing the issuance of licenses for the treatment, storage or disposal of low-level radioactive wastes received from other persons, as well as the development, operation, closure, post-closure observation and maintenance, and institutional control of a low-level radioactive waste treatment, storage or disposal facility. The requirements of 105 CMR 120.800 are in addition to, and not in substitution for, other applicable requirements of 105 CMR 120.000.

(B) 105 CMR 120.800 is applicable to any low-level radioactive waste facility for treatment, storage, or disposal of all classes of waste, which are not exempt from regulation pursuant to 105 CMR 120.200 as well as any wastes that the Board has required to be treated, stored or disposed of at a low-level radioactive waste facility.

120.801: continued

(C) 105 CMR 120.800 is applicable to any method of treatment, storage or disposal except shallow land burial, as defined in 105 CMR 120.803. Shallow land burial is prohibited.

(D) Class A, B, C, as defined in 105 CMR 120.200, and mixed waste may be accepted for storage, treatment or disposal at a facility, if the Board so determines. Waste received at a facility shall be handled in accordance with the operational requirements of 105 CMR 120.800.

Docket # 1,226

THE COMMONWEALTH OF MASSACHUSETTS
William Francis Galvin
Secretary of the Commonwealth

Regulation Filing *To be completed by filing agency*

CHAPTER NUMBER: **105 CMR 173.000**

CHAPTER TITLE: **Mobile Integrated Health Care and Community EMS Programs**

AGENCY: **Department of Public Health**

SUMMARY OF REGULATION: *State the general requirements and purposes of this regulation.*

This regulation establishes the eligibility, minimum requirements and the application process for entities seeking approval to operate Mobile Integrated Health Care (MIH) and Community EMS (CEMS) programs.

REGULATORY AUTHORITY: **M.G.L. c. 111O**

AGENCY CONTACT: **Sondra M. Korman** PHONE: **617-624-5215**

ADDRESS: **Department of Public Health, 250 Washington Street, Boston, MA 02108**

Compliance with M.G.L. c. 30A

EMERGENCY ADOPTION - *if this regulation is adopted as an emergency, state the nature of the emergency.*

PRIOR NOTIFICATION AND/OR APPROVAL - *If prior notification to and/or approval of the Governor, Legislature or others was required, list each notification, and/or approval and date, including notice to the Local Government Advisory Commission.*

Notice pursuant to Executive Order 145 sent on August 12, 2016

PUBLIC REVIEW - *M.G.L. c. 30A sections 2 and/or 3 requires notice of the hearing or comment period, including a small business impact statement, be filed with the Secretary of the Commonwealth, published in appropriate newspapers, and sent to persons to whom specific notice must be given at least 21 days prior to such hearing or comment period.*

Date of public hearing or comment period: **Public Hearing-September 22, 2016; Comment period closed-September 30, 2016**

FISCAL EFFECT - *Estimate the fiscal effect of the public and private sectors.*

For the first and second year: **Health care entities (including municipal ambulance services) may require startup costs for program development, training; minimal public costs.**

For the first five years: **Lower but ongoing industry costs; minimal public costs.**

No fiscal effect:

SMALL BUSINESS IMPACT - *M.G.L. c. 30A section 5 requires each agency to file an amended small business impact statement with the Secretary of the Commonwealth prior to the adoption of a proposed regulation. If the purpose of this regulation is to set rates for the state, this section does not apply.*

Date amended small business impact statement was filed: **August 8, 2018**

CODE OF MASSACHUSETTS REGULATIONS INDEX - *List key subjects that are relevant to this regulation:*
EMS, EMT, community paramedic, mobile integrated health care, community EMS, ambulance service, health care entity, ED Avoidance

PROMULGATION - *State the action taken by this regulation and its effect on existing provisions of the Code of Massachusetts Regulations (CMR) or repeal, replace or amend. List by CMR number:*

Promulgation of 105 CMR 173.000

ATTESTATION - *The regulation described herein and attached hereto is a true copy of the regulation adopted by this agency.* ATTEST:

SIGNATURE: SIGNATURE ON FILE DATE: **Aug 24 2018**

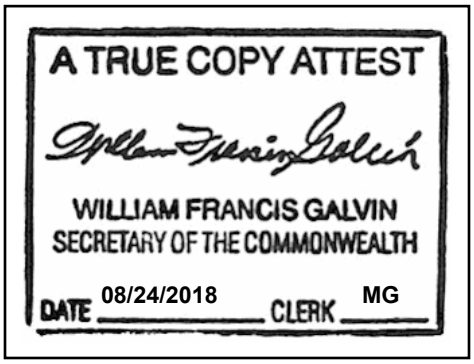
Publication - *To be completed by the Regulations Division*

MASSACHUSETTS REGISTER NUMBER: **1373** DATE: **09/07/2018**

EFFECTIVE DATE: **09/07/2018**

CODE OF MASSACHUSETTS REGULATIONS

Remove these pages:	*Insert these pages:*
1043, 1044	**1043 - 1050.6**



105 CMR 173.000: MOBILE INTEGRATED HEALTH CARE AND COMMUNITY EMS PROGRAMS

Section

173.010: Scope and Applicability

(A) Unless otherwise expressly permitted by the Department, no person or entity shall establish, maintain, or hold itself out as an MIH or Community EMS Program as defined in 105 CMR 173.020 without a valid Certificate of Approval issued by the Department in accordance with 105 CMR 173.000.

(B) 105 CMR 173.000 applies to:

(1) Every person who seeks a valid Certificate of Approval from the Department to establish an MIH or Community EMS Program; and

(2) Every person who operates an MIH or Community EMS Program.

173.020: Definitions

As used in 105 CMR 173.000, the following definitions shall apply unless the context requires otherwise:

911 EMS Patient. An individual who has activated a Primary Ambulance Response by dialing the emergency telephone access number 911, or its local equivalent.

Ambulance Service. An entity licensed by the Department pursuant to 105 CMR 170.000: *Emergency Medical Services System* to provide emergency medical services.

Applicant. A Community EMS Applicant or an MIH Applicant as further defined.

Authorization to Practice. The approval granted to EMS Personnel by the medical director of the MIH or Community EMS Program approved by the Department pursuant to 105 CMR 173.000.

Certificate of Approval. Written approval to operate an MIH or Community EMS Program pursuant to 105 CMR 173.000, subject to all terms and conditions contained in the Certificate of Approval.

Commissioner. The Commissioner of Public Health or his or her designee.

Community EMS Applicant. A local public health authority seeking an initial Certificate of Approval or renewal thereof to operate a Community EMS Program in partnership with the local jurisdiction's designated primary ambulance service.

173.020: continued

Community EMS Program. A program operated by the local public health authority and developed in coordination with the local jurisdiction's designated primary ambulance service(s) and which utilizes the primary ambulance service's EMS Personnel to provide community outreach and assistance in order to advance illness or injury prevention within the local jurisdiction(s) in accordance with 105 CMR 173.060. The Community EMS Program shall be approved by the local jurisdiction, in the manner required by such jurisdiction, and the ambulance service's affiliate hospital medical director.

Community Paramedic. A person who:

(1) is certified as a paramedic pursuant to M.G.L. c 111C and 105 CMR 170.000: *Emergency Medical Services System*;

(2) has successfully completed an education program developed or selected by the medical director of the MIH Program for which the community paramedic is employed, as well as any additional training required by Department guidelines; and

(3) is dispatched by an MIH Program to provide services or treatment to a patient within his or her scope of practice in accordance with Department-issued Statewide Treatment Protocols and clinical protocols of the program.

Department. The Department of Public Health, pursuant to M.G.L. c. 17, § 1.

Duplication of Services. A proposed service which does not address a gap in service delivery, pursuant to 105 CMR 173.040(A).

ED Avoidance. A component of an MIH Program pursuant to 173.050 that includes the applicable local jurisdiction(s)'s designated primary ambulance service(s) and, following primary ambulance response, assessment and consultation with on-line medical direction, utilizes paramedics with advanced training to manage the patient as an MIH patient in accordance with the provisions of 105 CMR 173.100(A) and Department guidelines.

Emergency Medical Technician (EMT). An EMT-Basic, Advanced EMT or Paramedic certified by the Department pursuant to 105 CMR 170.000: *Emergency Medical Services System.*

Emergency Service Program (ESP). A designated program under the direction of the Department of Mental Health and MassHealth Office of Behavioral Health that provides behavioral health crisis assessment, intervention and stabilization services through four service components:

(1) Mobile Crisis Intervention (MCI) services for youth;

(2) adult mobile services;

(3) ESP community based locations;

(4) and community crisis stabilization (CCS) services for 18 years of age and older.

EMS. Emergency medical services, as defined in 105 CMR 170.000: *Emergency Medical Services System.*

EMS First Responder (EFR). A person certified pursuant to 105 CMR 170.000: *Emergency Medical Services System* who has, at a minimum, successfully completed a course in emergency medical care approved by the Department pursuant to M.G.L. c. 111, § 201 and 105 CMR 171.000: *Massachusetts First Responder Training* and who provides emergency medical care through employment by, or in association with, a licensed EFR service at the first responder level.

EMS First Response Service (EFR Service). An entity licensed by the Department pursuant to 105 CMR 170.000: *Emergency Medical Services System* to provide rapid response and EMS.

EMS Personnel. EFRs and EMTs.

Entity or Person. An individual or his or her estate upon his or her death, or a corporation, a government agency, a partnership, a trust, an association, or an organized group of persons, whether incorporated or not, or any receiver, trustee, or other liquidating agent of any of the foregoing while acting in such capacity.

173.020: continued

Health Care Entity. A health care facility, health care provider, local public health authority, provider organization, carrier, or any combination thereof, including, but not limited to, an ambulance service licensed under M.G.L. c. 111C, a visiting nurse association, an accountable care organization, or a home health agency.

Health Care Facility. A licensed institution providing health care services or a health care setting, including, but not limited to, hospitals and other licensed inpatient centers, ambulatory, surgical or treatment centers, skilled nursing centers, residential treatment centers, diagnostic, laboratory and imaging centers, and rehabilitation and other therapeutic health settings.

Health Care Personnel or Personnel. An individual or individuals employed by or affiliated with a health care provider, who provide direct patient care. Health Care Personnel may include, but not be limited to, Community Paramedics, EMS Personnel, EMS First Responders, nurses, Nurse Practitioners, Physician Assistants, or social workers.

Health Care Provider. A provider of medical, behavioral or health services or any other person or organization that furnishes bills or is paid for health care services delivery in the normal course of business.

Injury. Harm that results in exacerbation, complication or other deterioration of a patient's condition.

Local Jurisdiction. A city or town or multiple cities or towns.

Local Public Health Authority. The appropriate and legally designated health authority of the city, town, or other legally constituted governmental unit within the Commonwealth having the usual powers and duties of the board of health or health department of a city or town.

Medical Control. The clinical oversight provided by a physician or existing primary care provider to all components of the MIH Program, including, but not limited to, medical direction, training, scope of practice and authorization to practice of EMS Personnel, which may include community paramedics, continuous quality assurance and improvement and clinical protocols.

Medical Direction. The authorization for treatment provided by a physician or existing primary care provider in accordance with clinical protocols, whether on-line through direct communication or telecommunication, or off-line through standing orders.

Medical Director. The physician or physicians appropriately trained to meet the unique social/cultural, linguistic, medical and population health needs of an MIH Program's patient population and designated by the MIH Program to carry out any supervisory medical control responsibilities for the MIH Program.

MIH Applicant. A health care entity or entities seeking an initial Certificate of Approval or renewal thereof to operate an MIH Program.

MIH Patient. An individual identified by a health care entity as warranting MIH Program services.

Mobile Integrated Health Care Program (MIH Program). A Department-approved program, including MIH Programs with an ED Avoidance Component, that utilizes EMS Personnel, which may include community paramedics to deliver healthcare services to patients in an out-of-hospital environment in coordination with health care facilities or other health care providers, which may include, but not be limited to, primary care providers, home care agencies, visiting nurse associations, or other in-home services; provided, that the medical care and services may include, but not be limited to, chronic disease management, behavioral health, preventative care, post-discharge follow-up visits, or transport or referral to facilities other than hospital emergency departments.

173.020: continued

Nurse Practitioner. A licensed registered nurse authorized by the Massachusetts Board of Registration in Nursing to practice in the Commonwealth of Massachusetts as an Advanced Practice Registered Nurse pursuant to 244 CMR 4.00: *Advanced Practice Registered Nursing* and whose scope of practice includes the provision of primary care services.

Physician. A physician duly licensed to practice medicine in the Commonwealth of Massachusetts by the Massachusetts Board of Registration in Medicine, pursuant to M.G.L. c. 112, § 2 and 243 CMR: *Board of Registration in Medicine*.

Physician Assistant. A person who is registered pursuant to 263 CMR: *Board of Registration of Physician Assistants* and who may provide medical services appropriate to his or her training, experience and skills under the supervision of a registered physician.

Primary Ambulance Response. First-line ambulance response, pre-hospital treatment and, if applicable, transportation by an ambulance service designated as a service zone provider or recognized in a service zone plan to provide first-line ambulance response, pre-hospital treatment and transportation pursuant to a provider contract.

Primary Ambulance Service. The business or regular activity, whether for profit or not, by an ambulance service licensed pursuant to 105 CMR 170.000: *Emergency Medical Services System*, designated under a service zone plan for the purpose of providing rapid response and pre-hospital EMS, including, without limitation, patient assessment, patient treatment, patient preparation for transport and patient transport to appropriate health care facilities, in conformance with the service zone plan.

Primary Care Provider. A physician, physician assistant or nurse practitioner qualified to provide general medical care who:

(1) supervises, coordinates, prescribes, or otherwise provides or proposes health care services;
(2) initiates referrals for specialist care; and
(3) maintains continuity of care within the scope of practice.

Provider Organization. Any corporation, partnership, business trust, association or organized group of persons, which is in the business of health care delivery or management, whether incorporated or not, that represents one or more health care providers in contracting with carriers or third-party administrators for the payment of health care services; provided that the definition shall include, but not be limited to, physician organizations, physician-hospital organizations, independent practice associations, provider networks, accountable care organizations, and any other organization that contracts with carriers or third-party administrators for payment for health care services.

Scope of Practice. The clinical skills or functions that:

(1) are defined by applicable state laws and regulations governing certification, licensure or registration of each individual providing services or treatment in the MIH or Community EMS Program approved by the Department pursuant to 105 CMR 173.000; and
(2) the clinical protocols developed by such programs.

Serious Incident. An incident that results in injury to a patient not ordinarily expected as a result of the patient's condition.

173.030: Application Process

(A) An applicant shall submit all required documents and non-refundable fees to the Department in a manner and form as determined by the Department. The Department may expedite review of applications with a focus on underserved populations. The Department may request additional documentation and materials as deemed appropriate.

(B) An applicant seeking renewal of a Certificate of Approval shall submit all required documentation and non-refundable fees at least 120 calendar days prior to the expiration of the program's current Certificate of Approval.

173.030: continued

(1) If all required documentation and fees are submitted to the Department in a complete and timely fashion, as determined by the Department, the Certificate of Approval shall not expire until the Department has made a determination on the application for renewal.
(2) If the required documentation and fees are not submitted to the Department in a timely fashion, as determined by the Department, the Certificate of Approval shall expire at the direction of the Department, and the MIH or Community EMS Program may not continue to operate without the express written permission of the Department.

173.040: Minimum Requirements for MIH Program Approval

(A) A complete application for MIH Program Approval shall, at a minimum:
(1) Identify and validate one or more gaps in service delivery using data and a corresponding community health needs assessment;
(2) Describe how the proposed MIH Program would address identified gaps in service delivery and provide improvements in quality, access, and cost effectiveness, an increase in patient satisfaction, improvement in patients' quality of life, and an increase in interventions that promote health equity, including cultural and linguistic competencies, through one or more of the following:
(a) A decrease in avoidable emergency department visits or hospital readmissions;
(b) A decrease in total medical expenditures;
(c) A decrease in cost to patient;
(d) A decrease in time to appropriate patient care in an appropriate health care setting;
(e) An increase in access to medical or follow-up care under the direction of the patient's Primary Care Provider; or
(f) Improvement in clinical care coordination, including, but not limited to the patient's adherence to medication and other therapies previously prescribed by the patient's Primary Care Provider.
(3) Pursuant to M.G.L. c. 111O, § 2(b)(iii), describe any proposed partnerships with existing health care entities; identify all partnerships, contracts, agreements, and affiliation agreements between the applicant and other health care entities; and propose a plan for coordination and use of existing personnel and resources without duplication of services;
(4) For proposed programs with a primary focus on MassHealth beneficiaries with behavioral health needs, identify partnership or coordination with an ESP;
(5) Demonstrate, through such information as financial and legal viability, sustainability and compliance history, sufficient capacity to develop and operate the proposed MIH Program in accordance with 105 CMR 173.000;
(6) Designate a medical director who shall be responsible for meeting the requirements of all clinical aspects of the proposed MIH Program, including, but not limited to, 105 CMR 173.100(A)(9);
(7) Provide a complete description of the proposed operational plan for medical control and medical direction including, but not limited to, lines of authority and responsibility, development and review of clinical protocols, training and assessment of skills, communication systems, and continuous quality assurance and improvement; and
(8) Provide a complete description of the proposed coordination and interaction with applicable 911 EMS systems in accordance with the provisions of 105 CMR 173.100.

(B) Upon receipt of a complete initial or renewal application for a Certificate of Approval to operate an MIH Program, the Department shall evaluate the application, and any other information requested by the Department, and determine approval based on the applicant's satisfaction of the minimum requirements set forth at 105 CMR 173.040(A).

173.050: Additional Eligibility and Minimum Requirements for MIH Applicant with ED Avoidance Component

(A) An MIH Applicant must include each designated primary ambulance service(s) in the applicable local jurisdiction(s) in order to be eligible to apply for a Certificate of Approval to operate an MIH Program that includes an ED Avoidance component.

(B) A complete application for MIH Program with ED Avoidance Component shall, at a minimum:

173.050: continued

(1) Meet the minimum requirements set forth at 105 CMR 173.040(A);
(2) Include appropriate clinical and triage protocols and advanced training for paramedics who will operate under the proposed ED Avoidance programming in accordance with 105 CMR 173.050 and protocols established by the Department pursuant to M.G.L. c. 111O; and
(3) Describe the coordination and management of any 911 EMS patient who the responding paramedic finds, after assessment and consultation with online medical direction, may be more appropriately managed as an MIH patient, in accordance with the provisions of 105 CMR 173.100(B) and Department guidelines.

(C) Upon receipt of a complete initial or renewal application for a Certificate of Approval to operate an MIH Program with ED Avoidance Component, the Department shall evaluate the application, and any other information requested by the Department, and determine approval based on the applicant's satisfaction of the minimum requirements set forth in 105 CMR 173.050(A).

173.060: Community EMS Program Approval

(A) Any Community EMS Applicant seeking a valid Certificate of Approval for public health service(s) as defined in Department guidelines issued pursuant to 105 CMR 173.060(B) shall be required to provide notification, in the form and manner as determined by the Department, at least 30 calendar days prior to anticipated commencement of Community EMS Program operations.

(B) The Department shall not issue a Certificate of Approval to authorize a Community EMS Program to provide any services other than those evidence-based illness and injury prevention services, such as falls prevention, concussion training, certain vaccinations under local public health authority direction, blood pressure screenings and health promotion screening programs, pursuant to 105 CMR 180.000: *The Operation, Approval and Licensing of Clinical Laboratories*, that are deemed high-value public health services with low-risk potential to patients as defined by the Department in guidelines and are consistent with identified community health needs. Persons may submit to the Commissioner for consideration by the Department a written request with appropriate supplemental evidence supporting the future inclusion in, or exclusion from, said guidelines of certain evidence-based illness and injury prevention service(s).

(C) All EMS Personnel training and activities related to the Community EMS Program must be approved by the local public health agency and the primary ambulance service's affiliate hospital medical director.

(D) The designated primary ambulance service's affiliate hospital medical director shall:
(1) Ensure all EMS Personnel providing services in a Community EMS Program successfully complete additional training tailored to meet the specific needs of the particular Community EMS Program;
(2) Review the quality of the EMS Personnel's delivery of services; and
(3) Ensure EMS Personnel provide services only within their scope of practice.

173.070: Certificate of Approval

(A) Following Department determination that the proposed MIH or Community EMS Program has met the minimum requirements of 105 CMR 173.000, the Department shall issue a Certificate of Approval to the applicant, subject to any terms and conditions specified by the Department.

(B) Unless otherwise expressly denied by the Department in writing, notification, as set forth in 105 CMR 173.060(A), shall constitute a valid Certificate of Approval for the purposes of a Community EMS Program pursuant to 105 CMR 173.060 and 173.070.

(C) A Certificate of Approval shall be valid for two years from the date of issue unless otherwise specified in the Certificate of Approval.

173.070: continued

(D) The Department may deny an application for a Certificate of Approval for any of the reasons set forth in 105 CMR 173.080.

(E) A Certificate of Approval may not be transferred or assigned to another service, program, agency, entity, or location.

(F) After receipt of a Certificate of Approval, an MIH or Community EMS Program may seek approval of modifications in accordance with processes and criteria established in Department guidance.

173.080: Grounds for Denial, Revocation, or Non-renewal of Approval

Each of the following, in and of itself, shall constitute full and adequate ground on which the Department may deny an application for a Certificate of Approval, provide the applicant with the option to resubmit, revoke or refuse to renew a Certificate of Approval to operate an MIH or Community EMS Program:

(A) Failure to meet applicable requirements for approval as specified in 105 CMR 173.000;

(B) Failure to meet the requirements of applicable federal or state law or regulations;

(C) Failure to provide information as required within 105 CMR 173.000;

(D) Any action or condition that endangers public health and safety, as determined by the Department;

(E) Obtaining or attempting to obtain a Certificate of Approval or renewal thereof by fraud, misrepresentation, or knowing omission(s) of material information, or by submission of incorrect, false or misleading information;

(F) Fraud, deceit or knowing omission(s) of material information or providing false or misleading statements, orally or in writing, to the Department;

(G) Conviction of an applicant, approved entity or person with significant financial or management interest in the MIH or Community EMS Program, whether proposed or in operation, of Medicare or Medicaid fraud, or other criminal offense related to the operation of the program or indicating that operation of the program may endanger public health or safety;

(H) Reasonable basis for the Department to conclude that a discrepancy exists between the representations by the applicant as to the MIH or Community EMS Program services to be afforded patients and the services actually rendered or to be rendered;

(I) Failure to meet the duties and responsibilities for MIH or Community EMS Programs as required by 105 CMR 173.000;

(J) Failure to comply with any term or condition prescribed by the Department within a Certificate of Approval;

(K) Failure to submit an acceptable plan of correction as required under 105 CMR 173.120;

(L) Failure to comply with a Department-approved plan of correction or correction order in accordance with 105 CMR 173.120;

(M) Denial of entry to Department agents to conduct site visits or inspections, or an attempt to impede the work of Department agents; or

(N) Any other violation of M.G.L. c. 111O, 105 CMR 173.000, or related Department guidelines.

Nothing in 105 CMR 173.080 shall limit the Department from adopting additional grounds through adjudication.

173.090: Process for Denial, Revocation or Refusal of a Certificate of Approval for an MIH or Community EMS Program

(A) If the Department initiates an action to deny, revoke, or refuse to renew a Certificate of Approval, the Department shall provide the MIH or Community EMS Program with written notice of the reasons and grounds for the Department's action, the provisions of law relied upon, and an opportunity to resubmit the application within 30 calendar days of receipt of the notice of agency action. If the Department denies the resubmitted application, the MIH or Community EMS Program may request an adjudicatory hearing within 14 calendar days of receipt of the notice of agency action.

(B) Upon receipt of a request for hearing within the time period prescribed by 105 CMR 173.090(A), the Department shall afford the aggrieved party an opportunity for an adjudicatory hearing to be conducted by a designated hearing officer.

(C) If a hearing is not requested within the time period prescribed by 105 CMR 173.090(A), the right to a hearing shall be waived and a final agency decision shall be issued.

(D) All adjudicatory proceedings shall be conducted in accordance with M.G.L. c. 30A and 801 CMR 1.01: *Formal Rules*.

173.100: Minimum Standards of Operation

(A) MIH Programs. An MIH Program shall meet the following minimum standards of operation:

(1) If an MIH Program's on-scene personnel, after assessment and in accordance with medical direction, determines that the patient is experiencing a medical emergency, the MIH Program's on-scene personnel shall activate the 911 EMS system and continue to assess and treat the patient in accordance with clinical protocols until transfer of care to the responding ambulance service in accordance with 105 CMR 170.355(B)(2) and (4) and the applicable service zone plan.

(2) When a primary ambulance service of a municipality, which is also part of a Department-approved MIH Program with ED Avoidance component, receives a 911 call to respond to a patient within its MIH program, the service shall respond in accordance 105 CMR 170.000: *Emergency Medical Services System*. If after assessment and consultation with on-line medical direction, the responding paramedic finds the patient may be more appropriately managed as an MIH patient or transported to a destination other than an emergency department, the EMS Personnel may initiate transfer of patient care to the MIH Program with the ED avoidance component in accordance with Department-established protocols and follow the process for timely coordination with the patient's primary care provider, or associated health care entity to establish a primary care relationship, pursuant to 105 CMR 173.100(A)(8)(h).

(3) If an MIH Program deploys or intends to deploy a vehicle when responding to an MIH call or for a scheduled home visit, such vehicle must be appropriate for the clinical encounter as approved by the Department.

(4) Each MIH Program shall file a written report with the Department within five calendar days of any serious incident involving its program, personnel or property. Such reportable serious incidents shall include, but are not limited to, any of the following covered by its Certificate of Approval:

(a) Death that is unanticipated, not related to the natural course of the patient's illness or underlying condition, or that is the result of an error or other incident, as specified in guidelines of the Department;

(b) Full or partial evacuation of the facility or residence to which the MIH program responds for any reason;

(c) Fire;

(d) Apparent suicide;

(e) Serious criminal acts;

(f) Pending or actual strike action by its employees, and contingency plans for operation of the MIH Program;

(g) Any anesthesia-related complications that result in serious morbidity or death of a patient;

173.100: continued

(h) A motor vehicle crash involving an MIH vehicle reportable under M.G.L. c. 90, § 26;
(i) Medication errors resulting in injury;
(j) Failure to provide treatment in accordance with clinical protocols resulting in injury;
(k) Major medical or communication device failure or other equipment failure or user error resulting in serious injury; or
(l) Death, injury, or illness occurring within 24 hours of an MIH with ED Avoidance encounter.

(5) Each MIH Program shall immediately report to the Department and appropriate authorities, for any patient treated by the MIH Program, any suspected instance(s) of abuse, neglect, mistreatment of that patient or misappropriation of that patient's property at or by a nursing home, rest home, home health, home maker, hospice, family member and/or others.

(6) Each MIH Program shall report to the Department any other serious incident or accident occurring on premises covered by the MIH Program's Certificate of Approval that seriously affects the health and safety of a patient or that causes serious physical injury to a patient within seven calendar days of the date of occurrence of the event.

(7) Each MIH Program shall comply with all guidelines established by the Department for submission of data required by 105 CMR 173.100(A)(8)(r).

(8) Each MIH Program shall have written policies and procedures consistent with the requirements established in 105 CMR 173.100, Department guidelines, accepted standards of care for the delivery of health care services and treatment, and applicable laws. All policies and procedures required under 105 CMR 173.100(A) shall be provided to personnel providing services or treatment on behalf of an MIH Program. In addition, such policies and procedures shall be made available to the Department upon request. At a minimum, the policies and procedures shall address:

(a) Documentation of organizational structure including medical control, affiliation agreements, lines of authority, responsibility, communication, personnel practices, and staff assignment;
(b) Statement of goals, objectives and types of services offered by the program;
(c) Capability of personnel providing services or treatment in the MIH Program, including confirmation that such personnel are currently certified, licensed or registered in accordance with applicable laws and regulations;
(d) Medical control and medical direction, including authorization to practice of EMS personnel;
(e) Process for development and periodic review of clinical protocols;
(f) Process for obtaining a patient's informed consent at each clinical encounter;
(g) Documentation of training and assessment standards for all personnel providing treatment and services;
(h) Process for coordinating care with a patient's primary care provider, or associated health care entity to establish a primary care relationship;
(i) Process for obtaining medications from a pharmacy in accordance with 105 CMR 700.000: *Implementation of M.G.L. c. 94C*;
(j) Compliance with applicable federal and state laws and regulations, including, but not limited to such laws and regulations governing possession and administration of controlled substances;
(k) Process for ensuring that each health care provider providing services and treatment in the MIH Program maintains an appropriate and current registration to possess controlled substances and instruments for administration of controlled substances in accordance with 105 CMR 700.000: *Implementation of M.G.L. c. 94C*;
(l) Compliance with the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and regulatory requirements in 42 CFR Part 493;
(m) Process for ensuring that each health care provider providing services or treatment in the MIH Program obtains CLIA certificates appropriate for the type of testing to be performed;
(n) Maintenance of equipment and medical devices in accordance with manufacturers' recommendations;
(o) Compliance with federal and state confidentiality laws and regulations;
(p) Security of and access to patient medical records and information;

173.100: continued

(q) Management of patients who experience a medical emergency and require activation of the 911 EMS system in accordance with the provision of 105 CMR 173.100(A);
(r) Management of 911 EMS Patients by a designated primary ambulance service that is part of an approved MIH Program with an ED avoidance component pursuant to 105 CMR 173.050 when the primary ambulance service's responding paramedic appropriately determines whether a patient may be more appropriately managed as an MIH patient or transported to a destination other than an emergency department in accordance with the provision of 105 CMR 173.100(B) and Department guidelines;
(s) Dispatch and communications;
(t) Infection control procedures;
(u) Continuous quality assurance and improvement program;
(v) Collection and maintenance of data relative to access, availability, quality, and cost associated with delivery of program services, to be submitted on a quarterly basis in accordance with Department guidelines;
(w) Non-discrimination; and
(x) Serious incident response and reports in accordance with 105 CMR 173.100(A)(4).

(9) An MIH Program's medical director's responsibilities shall include but not be limited to the following:
(a) Develop and update clinical protocols appropriate to:
1. the unique medical needs of the MIH Program's patient population; and
2. the particular personnel providing MIH services including, but not limited to, Community Paramedics, EMS Personnel, nurses, Nurse Practitioners, Physician Assistants and others;
(b) Grant authorization to practice to Community Paramedics and other EMS Personnel providing health care services on behalf of MIH Programs;
(c) Ensure that all MIH Program personnel are properly trained and provide health care services or treatment:
1. within the scope of their practice;
2. in accordance with the clinical protocols developed for the MIH Program; and,
3. in accordance with any additional training required by Department guidelines;
(d) Ensure that the MIH Program maintains a secure and effective telecommunication system and that all on-line medical direction is recorded;
(e) Make on-line medical direction available to MIH Program personnel during all hours of operation;
(f) Ensure that all physicians and other primary care providers who provide on-line medical direction to MIH Program personnel receive appropriate training in:
1. the scope of practice of each type of MIH Program personnel;
2. the specific clinical protocols developed for the MIH Program; and
3. any additional training required by Department guidelines.
(g) Coordinate the MIH Program's continuous quality assurance and improvement program.

(B) Community EMS Programs. A Community EMS Program shall meet the following minimum standards of operation:
(1) If a Community EMS Program's on-scene personnel, after assessment and in accordance with medical direction, determines that the patient is experiencing a medical emergency, the personnel shall activate the 911 EMS system and continue to assess and treat the patient in accordance with clinical protocols until transfer of care to the responding ambulance service in accordance with 105 CMR 170.355(B)(2) and (4) and the applicable service zone plan.
(2) If a Community EMS Program deploys or intends to deploy a vehicle when responding to a Community EMS call or a scheduled home visit, such vehicle must be appropriate for the clinical encounter as approved by the Department.
(3) Each Community EMS Program shall have written policies and procedures consistent with the requirements established in Department guidelines, accepted standards of care for the delivery of health care services and treatment, and applicable laws.

173.110: Complaints

(A) Upon receipt of any complaint or serious incident report, the Department shall take appropriate steps to investigate, as appropriate, whether the reported or alleged act or practice violates M.G.L. c. 111O, any provision of 105 CMR 173.000, any guidelines, or any condition imposed by the Department in its Certificate of Approval. The Department may also refer the complaint or serious incident report to the appropriate governmental authority responsible for licensure, certification, registration, approval, or oversight as deemed necessary.

(B) If, after investigation, the Department finds that the act or practice violates M.G.L. c. 111O, any provision of 105 CMR 173.000, Department guideline, or any condition imposed by the Department in its Certificate of Approval, the Department may issue a correction order in accordance with 105 CMR 173.120 or an agency action in accordance with 105 CMR 173.090.

173.120: Inspections, Statement of Deficiency, Order to Correct

(A) The Department, either announced or unannounced, may inspect any MIH or Community EMS Program for compliance with 105 CMR 173.000, Department guidelines, or conditions imposed by the Department in its Certificate of Approval.

(B) Whenever the Department finds upon inspection or through information in its possession that an MIH or Community EMS Program is not in compliance, it may issue an order to correct the deficiency. The correction order shall include a statement of the deficiencies found, the provision of law relied upon, and a reasonable prescribed period for correction.

(C) Within ten business days, an MIH or Community EMS Program shall submit to the Department a written plan of correction for each violation cited in the deficiency statement.

(D) Every plan of correction shall set forth, with respect to each deficiency, the specific corrective step(s) to be taken, a timetable for such steps, and the date by which compliance will be achieved. The timetable and the compliance dates shall be consistent with achievement of compliance in the most expeditious manner possible.

(E) The Department shall review the plan of correction for compliance and will notify the MIH or Community EMS Program whether the plan is accepted or rejected.

(F) Upon expiration of the time specified for correction, the Department may re-inspect the MIH or Community EMS Program in order to determine whether it is in compliance with the correction order.

173.130: Summary Suspension of Certificate of Approval

(A) In accordance with 105 CMR 173.090, the Commissioner may summarily suspend an MIH or Community EMS Program Certificate of Approval, pending further proceedings for revocation of or refusal to renew a Certificate of Approval, whenever the Commissioner finds that the continued operation of such program poses an imminent threat to public health and safety.

(B) The Department shall issue written notice of the suspension action which shall contain the reasons and grounds for immediate suspension, the provisions of law relied on, and an opportunity to request an adjudicatory hearing within 14 calendar days of receipt of the notice of the suspension action.

(C) Upon receipt of a request for hearing within the time period prescribed by 105 CMR 173.090, the Department shall promptly afford the aggrieved party an opportunity for an adjudicatory hearing to be conducted by a designated hearing officer. If a hearing is not requested within the required time period, the right to a hearing shall be waived and a final agency decision shall issue.

(D) Until the suspension is lifted or final agency determination is made, the MIH or Community EMS Program may not operate.

173.140: Waiver of Requirements

(A) The Commissioner may waive the applicability of one or more of the requirements imposed on a particular MIH or Community EMS program by 105 CMR 173.000 if the Commissioner finds that:

(1) Compliance would cause undue hardship;

(2) The MIH or Community EMS Program's non-compliance would not adversely affect the quality of patient care or patient safety;

(3) The MIH or Community EMS Program has instituted compensating features that are acceptable to the Department.

(B) The MIH or Community EMS Program shall provide to the Commissioner written documentation supporting its request for a waiver.

173.150: Severability

The provisions of 105 CMR 173.000 are severable. If a court of competent jurisdiction declares any section, subsection, paragraph, or provision unconstitutional or invalid, the validity of the remaining provisions shall not be affected.

REGULATORY AUTHORITY

105 CMR 173.000: M.G.L. c. 111O and c. 111, § 3.

(105 CMR 174.000 THROUGH 179.000: RESERVED)

NON-TEXT PAGE

Docket # 1,053

THE COMMONWEALTH OF MASSACHUSETTS
William Francis Galvin
Secretary of the Commonwealth

Regulation Filing *To be completed by filing agency*

CHAPTER NUMBER: **130 CMR 419.000**

CHAPTER TITLE: **Day Habilitation Center Services**

AGENCY: **Division of Medical Assistance**

SUMMARY OF REGULATION: *State the general requirements and purposes of this regulation.*

130 CMR 419.000 governs MassHealth providers of day habilitation services and provides program requirements and conditions of payment for the provision of day habilitation services to MassHealth members.

REGULATORY AUTHORITY: **130 CMR 419.000: M.G.L. c. 118E, §§. 7 and 12**

AGENCY CONTACT: **Deborah Briggs** PHONE: **617 847-3302**

ADDRESS: **100 Hancock Street, 6th Floor, Quincy, MA 02171**

Compliance with M.G.L. c. 30A

EMERGENCY ADOPTION - *if this regulation is adopted as an emergency, state the nature of the emergency.*

PRIOR NOTIFICATION AND/OR APPROVAL - *If prior notification to and/or approval of the Governor, Legislature or others was required, list each notification, and/or approval and date, including notice to the Local Government Advisory Commission.*

EO 145 notifications: November 14, 2017
EO 562: August 21, 2018

PUBLIC REVIEW - *M.G.L. c. 30A sections 2 and/or 3 requires notice of the hearing or comment period, including a small business impact statement, be filed with the Secretary of the Commonwealth, published in appropriate newspapers, and sent to persons to whom specific notice must be given at least 21 days prior to such hearing or comment period.*

Date of public hearing or comment period: **December 20, 2017**

FISCAL EFFECT - *Estimate the fiscal effect of the public and private sectors.*

For the first and second year: _____

For the first five years: _____

No fiscal effect: **No effect**

SMALL BUSINESS IMPACT - *M.G.L. c. 30A section 5 requires each agency to file an amended small business impact statement with the Secretary of the Commonwealth prior to the adoption of a proposed regulation. If the purpose of this regulation is to set rates for the state, this section does not apply.*

Date amended small business impact statement was filed: **August 8, 2018**

CODE OF MASSACHUSETTS REGULATIONS INDEX - *List key subjects that are relevant to this regulation:*

PROMULGATION - *State the action taken by this regulation and its effect on existing provisions of the Code of Massachusetts Regulations (CMR) or repeal, replace or amend. List by CMR number:*

130 CMR 419.000 has been amended.

ATTESTATION - *The regulation described herein and attached hereto is a true copy of the regulation adopted by this agency.* ATTEST:

SIGNATURE: SIGNATURE ON FILE DATE: **Aug 24 2018**

Publication - *To be completed by the Regulations Division*

MASSACHUSETTS REGISTER NUMBER: **1373** DATE: **09/07/2018**

EFFECTIVE DATE: **09/07/2018**

CODE OF MASSACHUSETTS REGULATIONS

Remove these pages:	*Insert these pages:*
8.1 & 8.2	**8.1 & 8.2**
301 - 312.4	**301 - 312.10**

A TRUE COPY ATTEST
WILLIAM FRANCIS GALVIN
SECRETARY OF THE COMMONWEALTH
DATE 08/24/2018 CLERK MG

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130 CMR 419.000: DAY HABILITATION CENTER SERVICES

Section

419.401: Introduction

130 CMR 419.000 establishes the requirements for the provision of services by day habilitation programs under MassHealth. All day habilitation providers must comply with the regulations governing MassHealth including, but not limited to, 130 CMR 419.000 and 450.000: *Administrative and Billing Regulations*.

419.402: Definitions

The following terms used in 130 CMR 419.000 have the meanings given in 130 CMR 419.402 unless the context clearly requires a different meaning.

Activities of Daily Living (ADLs) - fundamental personal care tasks performed daily as part of an individual's routine self-care. ADLs include, but are not limited to, eating, toileting, dressing, bathing, transferring, and mobility or ambulation.

Clinical Assessment - the screening process of cataloging a member's need for DH using a tool designated by the MassHealth agency and that forms the basis for prior authorization.

Day Habilitation (DH) - a service, for individuals with an intellectual disability (ID) or a developmental disability (DD), that is based on a day habilitation service plan that sets forth measurable goals and objectives, and prescribes an integrated program of activities and therapies necessary to reach the stated goals and objectives.

Day Habilitation Provider (DH Provider) - the entity with responsibility for the day-to-day operation of facilities and programs subject to 130 CMR 419.000.

Day Habilitation Service Plan (DHSP) - a written plan of care for each member that sets forth realistic and measurable behaviorally based goals that prescribe an integrated program of individually designed activities and/or therapies necessary to achieve these goals. The objective of the plan is to help the member reach his or her optimal level of physical, cognitive, psychosocial, occupational capabilities, and wellness.

Department of Developmental Services (DDS) - an agency of the Commonwealth of Massachusetts established under M.G.L. c. 19B.

419.402: continued

Department of Public Health (DPH) - an agency of the Commonwealth of Massachusetts, established under M.G.L. c. 17, § 1.

Developmental Disability - a severe, chronic disability that

(1) is attributable to other conditions found to be closely related to ID, apart from mental illness, which results in the impairment of general intellectual functioning or adaptive behavior similar to that of persons with ID, and which requires treatment or services similar to those required for such persons;
(2) is manifested before a person reaches 22 years of age;
(3) is likely to continue indefinitely; and
(4) results in substantial functional limitations in three or more of the following major areas:
    (a) self-care;
    (b) understanding and use of language;
    (c) learning;
    (d) mobility;
    (e) self-direction; or
    (f) capacity for independent living.

Developmental Skills Training - a series of planned, coordinated, goal-oriented services that are designed to improve the functional abilities of a person with an intellectual or developmental disability. Such services include, but are not limited to, self-help skills, sensorimotor skills, communication skills, independent living skills, affective development skills, social development skills, and behavioral skills.

EOHHS - the Executive Office of Health and Human Services established under M.G.L. c. 6A.

Full-time Equivalent (FTE) - a standardized measure of a program's personnel resources used by the EOHHS. One FTE equals coverage by one staff member for 40 hours per week.

Functional Level - the degree to which individuals can perform daily living activities and manage their lives independently. Functional level is measured through professional clinical assessments.

Hospital - a facility that is licensed or operated as a hospital by the Massachusetts department of public health or the Massachusetts department of mental health that provides diagnosis and treatment on an inpatient or outpatient basis for patients who have any of a variety of medical conditions.

Instrumental Activities of Daily Living (IADLs) - activities related to independent living that are incidental to the care of the member and that include, but are not limited to, household-management tasks, laundry, shopping, housekeeping, meal preparation and cleanup, transportation, care and maintenance of medical equipment and adaptive devices, medication management or any other need determined by the DH provider as being instrumental to the health care and general well-being of the member.

Intellectual Disability (ID) - significantly sub-average intellectual functioning existing concurrently with and related to significant limitations in adaptive functioning. ID originates before 18 years of age. The meaning of ID is consistent with the standard contained in the 11th edition of the *American Association on Intellectual and Developmental Disabilities's Intellectual Disability: Definition, Classification, and Systems of Supports* (2010) or any subsequent publication.

Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICF/ID) - a facility, or distinct part of a facility, that provides intermediate care facility services as defined under 42 CFR 440.150, and that meets federal conditions of participation, and is licensed by the Commonwealth primarily for the diagnosis, treatment, or rehabilitation for individuals with intellectual disabilities; and provides, in a protected residential setting, ongoing evaluation, planning, 24-hour supervision, coordination, and integration for health or rehabilitative services to help individuals function at their greatest ability.

419.402: continued

Level II Preadmission Screening and Resident Review (Level II PASRR) - a comprehensive evaluation and determination performed by DDS for any individual seeking admission or continued stay in a Medicaid nursing facility, in accordance with 42 CFR 483.100, to determine whether an individual suspected of having intellectual or other developmental disability has such a condition and if so, whether the individual requires the level of services provided by a nursing facility, and if so, whether specialized services are required.

MassHealth - the medical assistance and benefit programs administered by EOHHS pursuant to Title XIX of the Social Security Act (42 U.S.C. 1396), Title XXI of the Social Security Act (42 U.S.C. 1397), M.G.L. c. 118E, and other applicable laws and waivers to provide and pay for medical services to eligible members.

Member - a person determined by the MassHealth agency to be eligible for MassHealth.

Nursing Facility (NF) - an institution (or a distinct part of an institution) which is primarily engaged in providing skilled nursing care and related services for residents who require medical or nursing care, rehabilitation services for the rehabilitation of injured people, people with disabilities, or sick persons, or on a regular basis, health-related care and services to individuals who because of their mental or physical condition require care and services that the meets the requirements of Sections 1919(a), (b), (c), and (d) of the Social Security Act and is licensed under and certified by the Massachusetts Department of Public Health.

Primary Care Provider (PCP) - a physician, physician assistant, or nurse practitioner who operates under the supervision of a physician.

Rolland Integrated Service Plan (RISP) - a comprehensive service plan developed by an interdisciplinary team consisting of the DDS service coordinator where applicable, the member (or authorized representative), NF staff representatives, the specialized services provider, and other relevant professionals (such as physical therapists, speech pathologists, occupational therapists, dieticians, and medical staff). The purpose is to address care in all settings for persons with ID or DD who reside in NFs and receive specialized services.

Service Needs Assessment (SNA) - a compilation of evaluations by qualified professionals that determine a member's level of functioning, needs, and strengths, and makes specific recommendations for day habilitation to address identified needs.

Significant Change - a major change in the member's status that:
(1) impacts more than one area of the member's health status; and
(2) requires the professional interdisciplinary team's review or revision of the DHSP.

Specialized Services - services specified by EOHHS for an NF resident with ID or DD which, combined with services provided by the nursing facility or other service providers, result in treatment that meets the requirements of 42 CFR 483.440(a)(1).

419.403: Eligible Members

(A) MassHealth Members. MassHealth members, subject to the restrictions and limitations described in 130 CMR 450.105: *Coverage Types* that specifies for each MassHealth coverage type, which services are covered, and which members are eligible to receive those services.

(B) Recipients of the Emergency Aid to the Elderly, Disabled and Children Program. For information on covered services for recipients of Emergency Aid to the Elderly, Disabled and Children, *see* 130 CMR 450.106: *Emergency Aid to the Elderly, Disabled and Children*.

(C) For information on verifying member eligibility and coverage type, *see* 130 CMR 450.107: *Eligible Members and the MassHealth Card*.

419.404: Provider Eligibility

An organization seeking to participate in MassHealth as a day habilitation provider must

(A) be located in Massachusetts;

(B) enter into a contract with the MassHealth agency through submission of an application that includes all documentation specified by the MassHealth agency or its designee and be certified by the MassHealth agency or its designee in accordance with the requirements set forth in 419.000 and 450.000: *Administrative and Billing Regulations* to conduct a business in Massachusetts that delivers health and human services to individuals with ID/DD;

(C) accept the MassHealth agency payments as payment in full for DH;

(D) be in operation at least five business days a week, six hours per day;

(E) contract with DDS in accordance with EOHHS guidelines, to ensure coordination of services to DDS clients;

(F) be accredited by the Commission on Accreditation of Rehabilitation Facilities (CARF) or the Council on Quality and Leadership;

(G) meet all provider participation requirements described in 130 CMR 419.400 and 450.000: *Administrative and Billing Regulations*.

(H) participate in any DH provider orientation required by EOHHS;

(I) submit to the MassHealth agency or its designee a written description of DH offered by the DH provider and its service plan; and

(J) agree to periodic inspections by the MassHealth agency or its designee, that assess the quality of member care and ensure compliance with 130 CMR 419.000 and 130 CMR 450.000: *Administrative and Billing Regulations*.

419.405: Scope of Day Habilitation

(A) A DH provider must have the services described in 130 CMR 419.408 available on-site and sufficient to meet the needs of MassHealth members.

(B) A DH provider must provide the following services.

(1) Nursing Services and Health Care Supervision. The DH provider must provide nursing coverage on site. Nursing services must be provided to meet the needs of each member and must include the following:

(a) administration of medications and treatments prescribed by the member's PCP during the time the member is at the program;

(b) education in hygiene and health concerns;

(c) coordination of each member's DHSP with other health care professionals including the NF where the member resides, if applicable;

(d) monitoring each member's health status and documenting those findings in the member's medical record at least monthly and every six months as part of the interdisciplinary team review, and more often if the member's condition requires more frequent monitoring;

(e) reporting changes in the member's condition to the member's PCP;

(f) oversight of therapy treatment as recommended by a licensed therapist and, as applicable, PCP order; and

(g) coordinated implementation of the PCP's orders with the member, authorized representative, and DH provider staff.

(2) Developmental Skills Training. The DH provider must provide skills training in the following areas: self-help development, sensorimotor development, communication development, social development, independent living development, affective development skills, social development skills, and behavior development.

419.405: continued

(3) Therapy Services. The DH provider must provide therapy services when recommended through the service needs assessment. Therapy services include:

(a) speech/language therapy;
(b) occupational therapy;
(c) physical therapy; and
(d) behavior management.

(4) Assistance with Activities of Daily Living (ADL). The DH provider must have sufficient staff at its site to provide assistance with ADLs.

(5) Day Habilitation Service Management. The DH provider must undertake activities that ensure implementation of the member's day habilitation service plan including required reviews described in 130 CMR 419.419.

419.406: Clinical Eligibility Criteria

(A) All members, except those who are residents of an NF, must meet the following clinical eligibility criteria for receipt of DH:

(1) have ID or DD as defined in 130 CMR 419.402 and as certified by a PCP;

(2) need DH to acquire, improve, or retain their maximum skill level and independent functioning.

(B) In order for a member residing in an NF to be eligible for receipt of DH, DDS must have determined *via* a Level II PASRR that the member requires specialized services.

419.407: Clinical Assessment and Prior Authorization

(A) Clinical Assessment. As part of the prior authorization process, a DH provider must assess the member's clinical status, need for DH, and appropriate DH service level. Completed clinical assessment documentation must be submitted to the MassHealth agency, or its designee, in the form and format requested by the MassHealth agency. A new clinical assessment is required every two years or sooner if the member experiences a significant change.

(1) Assessment Period. Members newly seeking DH may receive DH for up to 45 business days, not subject to prior authorization, concurrent with the provider's completion of the member's initial clinical assessment for DH.

(2) Assessment Criteria. Providers must include the following as part of the clinical assessment or reassessment of a member:

(a) Confirm that the member had a physical examination by a PCP within 12 months prior to seeking authorization for services;

(b) Confirm that within 12 months prior to seeking authorization for services, the member has had a comprehensive evaluation by a referring entity that includes, at a minimum, the following:

1. a written assessment of the member's social skills; and
2. a written assessment of the member's medical, mental, functional, and developmental status.

(3) Obtain the written approval of the clinical assessment from the member, the member's clinical authorized representative, and PCP or medical clinic.

(4) For members residing in NFs for whom the Level II PASRR conducted by DDS concluded that the member requires specialized services, the DH provider must obtain a copy of the DDS Level II PASSR determination notice and maintain a copy of this notice in the member's record.

(B) Prior Authorization.

(1) A DH provider must obtain prior authorization from the MassHealth agency or its designee as a prerequisite to payment for the provision of DH provided to the member after the 45th business day of the member's receipt of DH from the DH provider, and every two years thereafter, and upon significant change.

(2) Prior authorization determines the medical necessity for DH as described under 130 CMR 419.406 and in accordance with 130 CMR 450.204: *Medical Necessity*.

419.407: continued

(3) Prior authorization specifies the level of payment for the service.
(a) The MassHealth agency pays DH providers for DH provided from the first date on which DH is provided to an eligible member through the date of prior authorization approval at the moderate rate of payment;
(b) After prior authorization the MassHealth agency pays DH providers for DH services provided to an eligible member at one of three levels of payment reflecting the member's assessed need for DH in accordance with the member's prior authorization for DH;
(4) Prior authorization does not establish or waive any other prerequisites for payment such as the member's financial eligibility described in 130 CMR 503.007: *Potential Sources of Health Care* and 517.008: *Potential Sources of Health Care*.
(5) When submitting a request for prior authorization for payment of DH to the MassHealth agency, or its designee, the DH provider must submit requests in the form and format as required by the MassHealth agency. The DH provider must include all required information including, but not limited to, documentation of the completed clinical assessment; other nursing, medical, or psychosocial evaluations or assessments; and any other documentation that the MassHealth agency, or its designee, requests in order to complete the review and determination of prior authorization.
(6) In making its prior authorization determination, the MassHealth agency or its designee may require additional assessments of the member or require other necessary information in support of the request for prior authorization.

(C) Notice of Determination of Prior Authorization.
(1) Notice of Approval. If the MassHealth agency or its designee approves a request for prior authorization, it will send written notice to the member and the DH provider.
(2) Notice of Denial or Service Modification. If the MassHealth agency or its designee denies, or modifies, a request for prior authorization of DH, the MassHealth agency or its designee will notify both the member and the DH provider. The notice will state the reason for the denial or service modification and contain information about the member's right to appeal and the appeal procedure.
(3) Right of Appeal. A member may appeal a service denial or modification by requesting a fair hearing in accordance with 130 CMR 610.000: *Fair Hearing Rules*.

(D) Review. The MassHealth agency, or its designee, may at any time review the medical necessity of the provision of DH to MassHealth members including, but not limited to, instances in which there has been a significant change in the member's status as defined in 130 CMR 419.402.

419.408: Quality Management

DH providers must participate in any quality management and program integrity processes established by the MassHealth agency including making any necessary data available and access to visit the provider's place of business upon request by the MassHealth agency or its designee.

419.409: Conditions of Payment

(A) The MassHealth agency pays for DH in accordance with the applicable payment methodology and rate schedule established by EOHHS, including supplemental staffing for those who reside in an NF and attend a community-based DH and for DH provided in NFs. Rates of payment for DH do not cover or include any room and board.

(B) Payment for services is subject to the conditions, exclusions, and limitations set forth in 130 CMR 419.000 and 450.000: *Administrative and Billing Regulations*.

(C) The MassHealth agency pays a DH provider for DH only if
(1) the member receiving DH is eligible under 130 CMR 419.403;
(2) the member meets the clinical eligibility criteria for DH in accordance with 130 CMR 419.406;
(3) the DH provider has obtained prior authorization for DH provided on or after the 46th business day following the initial date of service in accordance with 130 CMR 419.407;

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(4) the DH provider is not billing for days that are non-covered under 130 CMR 419.431; and

(5) for members who reside in a NF, the member's Level II PASRR conducted by DDS determines that the member requires specialized services.

(D) Transition between Two DH Providers. If a member changes from one DH provider to another DH provider, a new clinical assessment is required and the new DH provider must obtain a new prior authorization. The previous DH provider when possible may continue to provide and bill for DH to the member if the provision of such services is permissible under 130 CMR 419.407, while the new DH provider is obtaining prior authorization and until the member, if eligible for DH, is admitted and receiving services from the new DH provider. The previous DH provider must discharge the member from its day habilitation program before the new DH provider may bill the MassHealth agency for DH. The MassHealth agency will pay only one DH provider per day for the provision of DH to a member.

(E) The DH provider must review each member in its care to ensure that the clinical eligibility criteria for DH continue to be met. A DH provider may not bill and the MassHealth agency will not pay for any member who does not meet the clinical criteria for DH.

(F) The MassHealth agency's payment to a DH provider ends on the date on which a member no longer meets the clinical criteria for DH described in 130 CMR 419.406, is no longer receiving DH, or no longer has a prior authorization in effect, whichever comes first.

(G) The MassHealth agency pays for DH provided by a participating DH in an NF where the member resides if the conditions of 130 CMR 419.409 and 419.433 are met.

(H) The MassHealth agency pays for DH delivered at an approved site and census.

419.410: Early and Periodic Screening, Diagnosis and Treatment (EPSDT) Services

The MassHealth agency pays for all medically necessary day habilitation services for EPSDT-eligible members in accordance with 130 CMR 450.140: *Early and Periodic Screening, Diagnosis and Treatment (EPSDT) Services: Introduction*, without regard to service limitations described in 130 CMR 419.000, and with prior authorization.

419.416: Day Habilitation Provider Responsibilities

In addition to meeting all of the qualifications set forth in 130 CMR 419.000 and 450.000: *Administrative and Billing Regulations*, the DH provider must meet all of the following requirements.

(A) Policies and Procedures Manual. Each DH provider must develop, maintain, and periodically review and update policies and procedures governing the delivery of DH. The policy and procedures manual must at minimum include a mission statement; the goals and objectives of the program; an organizational chart describing the lines of authority and communication needed to manage the DH program including the lines of authority for delegation of responsibility down to the member care level; job descriptions that include titles, reporting authority, qualifications and responsibilities; a description of the governing body; and a description of the fiscal/business management system that clearly specifies the use of funds within budgetary constraints and fiscal restrictions and fiscal reporting by month, reflecting all sources of income and program expenses. All documentation must be kept on site or readily accessible. Additionally, each policy and procedure manual must contain written policies and procedures for the following:

(1) administrative policies and procedures including, but not limited to

(a) human resources and personnel;

(b) staff and staffing requirements;

(c) backup staff in the event coverage is required due to illness, vacation, or other reasons;

(d) staff education and training;

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(e) DH provider staff evaluation and monitoring;
(f) emergencies including fire, safety, and disasters, including notifying the fire department and police in emergencies and relocating members during an emergency;
(g) MassHealth basics and MassHealth member rights;
(h) human rights and nondiscrimination;
(i) incident and accident reporting;
(j) staff and member grievances;
(k) cultural competency;
(l) quality assurance and improvement;
(m) emergency services and plans;
(n) first aid and cardiopulmonary resuscitation requirements;
(o) Health Insurance Portability and Accountability Act (HIPAA);
(p) food storage and preparation areas;
(q) coordination of DH with other services the member is receiving; and
(r) procedures to be followed if a member is missing or lost.

(2) clinical policies and procedures including, but not limited to,
(a) evaluations and assessments;
(b) privacy and confidentiality;
(c) medication administration, management, and storage;
(d) universal precautions;
(e) infection control and communicable diseases;
(f) recognizing and reporting abuse (physical, sexual, emotional, psychological) neglect, self-neglect and financial exploitation;
(g) description and use of positive behavioral supports (PBS);
(h) admission criteria; and
(i) discharge planning and follow-up.

(B) Recordkeeping and Reporting Requirements.

(1) Recordkeeping. The DH provider must maintain records in compliance with the requirements set forth in 130 CMR 450.000: *Administrative and Billing Regulations* and all other applicable state and federal laws. All records including, but not limited to, the following must be accessible and made available on site for inspection by the MassHealth agency or its designee:

(a) Member Records. The record must contain information necessary to identify the member. Each member's record also must include all documentation pertaining to the DHSP and the design of an appropriate DHSP including, but not limited to, the following:

1. the member's name, member identification number, address, telephone number, sex, age, marital status, next of kin or authorized representative, school or employment status, the date of initial contact with the program, and the emergency fact sheet in accordance with 130 CMR 419.430(D);
2. a member profile that includes a brief history including diagnoses, and clinical and behavioral needs. If applicable the member profile must also include: specialized service needs, the reason for referral to DH, the name of the DHSM assigned to the member and, the name and contact information of the DDS service coordinator;
3. an educational, social, medical, and vocational history with assessment reports from qualified providers and an updated record of past and present immunizations and tuberculin tests;
4. a copy of the clinical assessment that was submitted as part of the prior authorization process, and copies of any reassessments;
5. a report of the member's most recent annual physical examination and the PCP's recommended service plan based on their review of this report;
6. the name, address, and telephone number of the PCP serving the member;
7. the written approval of the DHSP plan from the professional interdisciplinary team, the PCP, the member or the member's authorized representative;
8. documentation supporting the member's level of payment;
9. documentation by the DHSM of all conferences with the member, the member's authorized representatives, and with outside professionals;
10. daily attendance records;

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11. progress notes updated monthly by the DHSM, the health-care supervisor, and, when appropriate and available, by other people significantly involved in implementing the DHSP;

12. reports of all semiannual reviews conducted in accordance with 130 CMR 419.405(B)(1) and 419.419(D)(3) and any other reports generated in compliance with 130 CMR 419.000;

13. written authorization from the member or the member's authorized representative for the release of information;

14. the discharge notice, if the member is discharged; and

15. a copy of the Level II PASRR notice, if applicable.

(b) Administrative Records. The DH provider must maintain

1. payroll records;

2. personnel records, that include the requirements set forth in 130 CMR 419.421(A)(1), including evidence of completed staff orientation and training;

3. financial and billing records;

4. member utilization records, including the number of members being served and number of individuals on a waiting list;

5. records of staffing levels and staff qualifications;

6. records of complaints and grievances; and

7. contracts for subcontracted services.

(c) Incident and Accident Records. The DH provider must maintain an easily accessible record of member and staff incidents and accidents. The record may be kept within the individual member medical record or employee record or within a separate, accessible file.

(2) Reporting Requirements.

(a) Program Reporting.

1. The DH provider must submit all of following information in the format and time frames as requested by the MassHealth agency:

a. cost and expense information; and

b. any change in DH provider contact information.

2. The DH provider must make available to the MassHealth agency or its designee, the following:

a. copies of any and all accreditation correspondence with CARF or Council on Quality and Leadership; and

b. any additional information requested by MassHealth or its designee related to the provider's provision of DH, including information, such as clinical and statistical or cost and expense information, and other data necessary to measure the quality of the services delivered by the DH provider.

3. The DH provider must comply with all applicable reporting requirements of other state agencies such as DDS.

(b) Clinical Incident Reporting. The DH provider must immediately notify the MassHealth agency of any of the following incidents and follow-up in writing within three business days:

1. fire or other unnatural disaster at the program site;

2. a life threatening accident or serious physical injury to a member that requires medical treatment beyond basic first aid, including self-inflicted injury or when cause of origin of injury is unknown;

3. death of a member at, en route to, or en route from the program;

4. evidence of serious communicable disease contracted by program staff or members;

5. any allegation of abuse or neglect of or by the member; and

6. a member missing from a DH provider site or missing from any other location during the provision of DH.

(C) Staffing Ratios and Requirements. A DH provider must have sufficient qualified staff in accordance with 130 CMR 419.421 to deliver DH and have specific personnel policies, including procedures for monitoring current licensure or certification of professional staff, staff training, supervision, and evaluation.

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(1) A DH provider must have a full-time program director.
(2) A DH provider with 28 or fewer participants must include on its staff a professional interdisciplinary team of no fewer than four health care professionals as described in 130 CMR 419.421.
(3) A DH with more than 28 participants must have one additional full-time equivalent (FTE) health-care professional for every seven additional participants. The minimum professional FTE staff-to-member ratio is one-to-seven. The maximum professional FTE staff-to-member ratio is one-to-four. For every additional 28 participants, the additional staff members must form a team as described in 130 CMR 419.416(E).
(4) DH providers must have a nurse health care supervisor for at least 0.75 FTE comprised of a licensed registered nurse for 0.5 FTE allowing for the balance of coverage, 0.25 FTE, on-site to be provided by an LPN. RNs must provide supervision of LPNs for a minimum of six hours per week for 28 participants, with an additional two hours per week for every additional 14 participants.
(5) A DH provider may employ direct care staff (paraprofessionals) to help meet the needs of its members. The maximum FTE paraprofessional-to-member ratio is one-to-four.
(6) Staffing ratios will be based on the average daily census of members enrolled with the DH provider at the specific DH site during the rate year, calculated using data from the last quarter.
(7) The DH provider must designate one person as the administrator. The same person, if qualified, may serve as both the administrator and the program director.

(D) Referrals and Written Agreements. To ensure that members receive all the services required in their DHSPs, the DH provider must make prompt and appropriate referrals for those services not provided by the day habilitation program itself. The DH provider must document all referrals in the member's clinical record and coordinate such referrals with DDS in accordance with the requirements of the contract (*see* 130 CMR 419.404(A)(4)).

419.417: Service Needs Assessment

A Service Needs Assessment (SNA) determines a member's functional level, needs, and strengths, and makes specific recommendations to address acquisition, improvement, or maintenance of each identified need area for the member. Each SNA must

(A) be completed within 45 business days of a member's admission and every two years thereafter and upon a significant change in the member's condition;

(B) assess each of the following need areas: self-help skills, sensorimotor skills, communication skills, independent living skills, affective development skills, social development skills, behavioral development skills, and wellness; and

(C) identify which need areas will be addressed in the DHSP.

419.419: Day Habilitation Service Plan (DHSP)

(A) Interim DHSP. Within five business days after the member's admission, the DH provider's professional interdisciplinary team must design an interim DHSP. The plan must outline a temporary schedule of treatment and activities that will be used until the final DHSP is completed.

(B) Final Day Habilitation Service Plan. Together with the SNA, the final DHSP must be completed within 45 business days of the date of the member's admission and updated every two years or upon significant change and must be developed with participation of the member, the member's authorized representatives, where applicable and appropriate, and must be derived from the SNA for each member. The final DHSP describes each training program, measurable goals, and objectives that address the need areas identified in the SNA. The DHSP must be designed in a manner that integrates the various activities, tasks, and, if appropriate, therapies recommended to meet the member's areas of need. The final DHSP must include, but is not limited to, the following:

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(1) a medical plan of care;
(2) a service plan coversheet that outlines the development of the member's DHSP, based on the recommendations from the SNA;
(3) goals and objectives that are written in behavioral and measurable terms.
(a) Goals must
1. be written without the use of ambiguous action verbs;
2. provide for clear means for establishing attainment of the goal within the established time frames.
(b) Objectives must address specific skill acquisition and retention as it relates to a goal and must
1. be written without the use of ambiguous action verbs;
2. measure only one observable behavior; and
3. use performance and stability criterion.

(C) Reviews.
(1) The DHSM must review the member's goals and objectives every six months or upon significant change and must inform the staff, using staff meetings, of any changes in the member's status or DHSP.
(2) The health care supervisor must ensure that monthly progress notes are completed and reflect the member's plan of care. Any significant changes in the member's health status must be discussed with the DH staff.
(3) The core professional interdisciplinary team must conduct, at least two times per year, a review of the member's overall progress. Components of this review, at a minimum, must include
(a) a comprehensive review of the member's goals and objectives (if a change in goals and objectives is indicated by the review, the member's DHSP must be reformulated); and
(b) comprehensive medical review based on the member's DHSP.

419.420: Discharge

(A) Discharge Procedures. The DH provider must coordinate the discharge with the member, member's authorized representative, DDS, if applicable, and with the staff of the DH provider or other agency to which the member is transferred, if applicable.

(B) Discharge Plan. A discharge plan, dated and signed by the program director, must be kept in the member's record for at least four years after the date of discharge and must remain accessible to representatives from the MassHealth agency and other state and federal agencies that are authorized by law to have such information.

419.421: Day Habilitation Staff Qualifications, Responsibilities, and Training

(A) General Staffing Requirements.
(1) Prior to hiring or contracting with any staff, the DH provider must
(a) check the candidate's references and job history and ensure that the candidate meets all of the required experience, education, and qualifications before hiring;
(b) conduct a Criminal Offender Records Information (CORI) check and determine whether any offender records may disqualify the individual for employment;
(c) check the Office of Inspector General (OIG) List of Excluded Individuals and Entities (LEIE) to determine whether the candidate appears on the LEIE and is thus disqualified from employment;
(d) conduct a national criminal background check in accordance with the administrative procedures described at 115 CMR 12.00: *National Criminal Background Checks*;
(e) conduct license and certification checks and validate that the candidate has obtained all necessary licenses and certifications and that all licenses and certifications are current;
(f) ensure that each DH staff person is not providing direct care to any member whom that staff person is related to or legally responsible for; and
(g) ensure that each DH staff person has received a tuberculosis screening within the previous 12 months.

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(2) On an ongoing basis, the DH provider must

(a) ensure that all staff receive tuberculosis screenings in accordance with current guidelines issued by the Centers for Disease Control and Prevention (CDC) and DPH;

(b) conduct an OIG LEIE check for all staff each month;

(c) ensure that all staff are appropriately trained and managed which must include, but not be limited to, training in recognition and reporting of abuse;

(d) have available at all times a sufficient number of educated, experienced, trained, and competent personnel to provide DH individuals with ID or DD;

(e) evaluate staff annually using standardized evaluation measures;

(f) maintain a separate personnel file for each staff member with all applicable information including performance evaluations; and

(g) include in each staff member's personnel file any staff incident or accident reports.

(B) Professional Interdisciplinary Team.

(1) The DH provider must have a core professional interdisciplinary team that consists of the heath-care supervisor, developmental specialist, DHSM and program director. Responsibilities of the core professional interdisciplinary team include, but are not limited to

(a) completion or submission of member needs based on a clinical assessment using a tool in the form and format established by the MassHealth agency or its designee to the MassHealth agency or its designee.

(b) design implementation, supervision and continued review of the DH provider's provision of DH to members in accordance with members' individual DHSP.

(2) Additional Interdisciplinary Team members.

(a) For the purposes of completing each member's SNA, the interdisciplinary team must also include the following clinicians: physical therapist, speech and language pathologist, occupational therapist, and behavioral specialist as well as other health care professionals as applicable. Definitions and minimum qualifications relating to these disciplines are in 130 CMR 419.419. The composition of the team must be appropriate to the needs of the participants. These additional team members are also responsible for reassessing a member's areas of need in the event of a significant change in the member's condition.

(b) Circumstance for continued participation of interdisciplinary team reviews:

1. If based on a member's SNA the Interdisciplinary team determines that a member receive formal direct therapy, which would be implemented by the therapist, therapy aide, or pathologist, the recommending therapist or pathologist must continue to participate in the member's interdisciplinary team reviews;

2. If based on a member's SNA the Interdisciplinary team determines that a member does not require continued formal direct therapy, the applicable therapist or pathologist does not need to continue to participate in the member's interdisciplinary reviews;

3. If a significant change in the member's condition occurs, the appropriate clinician(s) must reevaluate the member's SNA and the recommendations.

(C) Administrator.

(1) Qualifications. The administrator must hold either a bachelor's degree in business management or a related field or have at least two years of experience in health-care management. One year of that experience must have been in a supervisory capacity.

(2) Responsibilities. The administrator must

(a) manage day-to-day activities, if acting as the program director;

(b) report to the MassHealth agency or its designee and other involved agencies;

(c) monitor compliance with all applicable laws and regulations governing DH; and

(d) implement the DH provider's policies and procedures.

(D) Program Director.

(1) Qualifications. The program director must hold a bachelor's degree in a health related field, with at least three years of relevant health care experience, of which at least two of those years must have been spent in a supervisory role. Six years of relevant health care experience, with three of those years serving in a supervisory role, may be substituted in *lieu* of a bachelor's degree.

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(2) Responsibilities. The program director must
(a) manage the day-to-day activities of the provision of DH;
(b) monitor compliance with all applicable laws and regulations governing the provision of DH;
(c) implement and oversee the DH provider's policies and procedures;
(d) hire, oversee training, supervise, evaluate, and when necessary fire staff members;
(e) oversee member services and participate on all interdisciplinary teams; and,
(f) report to the MassHealth agency and other involved agencies, as requested and required by the agency or agencies.

(E) Health Care Supervisor.
(1) Qualifications. The health care supervisor must be licensed as a registered nurse in the Commonwealth of Massachusetts with at least one year of relevant experience.
(2) Responsibilities. The health care supervisor is responsible for overseeing the indirect and direct nursing care, as defined in 244 CMR 4.00: *Advanced Practice Registered Nursing*, provided to members receiving DH from the DH provider and must
(a) supervise or provide direct care and training in relevant areas;
(b) coordinate medical services with each member's PCP or medical clinic;
(c) oversee all health care services provided to the member while at the program;
(d) complete nursing assessments;
(e) participate on all interdisciplinary teams;
(f) obtain reports and approval of medical care plans from PCPs;
(g) ensure that nurse progress notes are recorded monthly;
(h) ensure that the members' DHSP are documented accordingly;
(i) advise the program director and other DH provider staff of any medical problems that may hinder a member's participation in DH or in a specific activity; and
(j) supervise any other nursing staff.

(F) Developmental Specialist.
(1) Qualifications. Each developmental specialist must have a high school diploma or GED.
(2) Responsibilities. Each developmental specialist must
(a) participate in member interdisciplinary team reviews;
(b) ensure member training programs are implemented according to their DHSP; and
(c) provide assistance with activities of daily living.

(G) Day Habilitation Service Manager (DHSM). Each member must be assigned a DHSM. The DHSM can be the program director or developmental specialist or other personnel that meet the qualifications set forth in 130 CMR 419.421(G)(1).
(1) Qualifications. The DHSM must have experience with case managing and case reviews in a relevant health care setting.
(2) Responsibilities include
(a) supervising the implementation of the DHSP;
(b) reviewing members' DHSP;
(c) ensuring plan updates are made to the DHSP;
(d) participating in interdisciplinary team meetings; and
(e) maintaining member records.

(H) Other Licensed Nursing Staff.
(1) Qualifications. Other licensed nursing staff must be licensed in the Commonwealth of Massachusetts as either a practical nurse or registered nurse and have a minimum of at least one year of relevant work experience.
(2) Responsibilities. Under the direction of the health-care supervisor, other licensed nursing staff must
(a) provide direct care and training in relevant areas;
(b) coordinate medical services with each member's PCP or medical clinic;
(c) complete nursing assessments;
(d) obtain reports and approval of medical care plans from PCPs;
(e) complete all nursing documentation and monthly nursing notes; and

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(f) advise the program director and other DH staff of any medical problems that may hinder a member's participation in DH or in a specific activity.

(I) Other Direct Care Staff (Paraprofessionals).

(1) Qualifications. Have a minimum of at least one year of relevant work experience in a health care setting.

(2) Responsibilities include

(a) assisting with Activities of Daily Living;

(b) assisting with implementation member individual programs; and

(c) providing input for interdisciplinary team reviews.

(J) Behavioral Professionals.

(1) Qualifications.

(a) Behavioral Specialist. The behavioral specialist must have one year of relevant work experience in developing behavioral programming for individuals.

(b) Psychologist. The psychologist must be currently licensed by the Massachusetts Board of Registration of Psychologists, or have at least a master's degree in clinical psychology and at least three years of full-time, supervised, postgraduate experience.

(c) Behavioral Aide. A behavioral aide must have at least one year of experience with data collection and with implementing behavioral programming.

(2) Responsibilities.

(a) Behavioral Specialists. A behavioral specialist must

1. assess each individual's behavioral and affective development need areas, except for those individuals with no documented history of behaviors or who, at the time of assessment are not exhibiting behaviors noted in their history; and

2. make recommendations, based upon assessment, on the behavioral programming and habilitation services necessary to meet the members identified needs.

(b) Psychologist. If the DH provider includes psychological testing, a psychologist must perform such testing.

(c) Behavioral Aides. A behavioral aide must assist with assessment and implementation of behavioral programming to address identified need areas.

(K) Therapists.

(1) Physical Therapist.

(a) Qualifications.

1. A physical therapist must be licensed by the Massachusetts Board of Registration in Allied Health Professions and have one year of relevant work experience in a training program.

2. Any additional physical therapy personnel must be licensed by the Massachusetts Board of Registration in Allied Health Professions or must be graduates of an approved physical-therapy-assistant program and be licensed by the Massachusetts Board of Registration in Allied Health Professions. A physical therapy assistant must work under the direct supervision of the licensed physical therapist.

(b) Responsibilities of the physical therapist include

1. assessing each individual's therapy and developmental skill need areas; and

2. recommending, based upon the assessments, the DH necessary to meet the member's identified areas of need.

(2) Occupational Therapist.

(a) Qualifications.

1. Occupational therapists must be licensed by the Massachusetts Board of Registration in Allied Health Professions, and have one year of relevant work experience.

2. Any additional occupational therapy personnel must be licensed by the Massachusetts Board of Registration in Allied Health Professions or must be graduates of an approved occupational therapy assistant program and be licensed by the Massachusetts Board of Registration in Allied Health professions. An occupational therapy assistant must work under the direct supervision of the licensed occupational therapist.

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(b) Responsibilities of the occupational therapist include

1. assessing each member's therapy and developmental skill need areas; and

2. recommending, based upon the assessments, the DH necessary to meet the member's identified areas of need.

(3) Speech and Language Pathologist.

(a) Qualifications.

1. Speech and language pathologists must be licensed by the Massachusetts Board of Registration in Speech-language Pathology and Audiology and have either a Certificate of Clinical Competence (CCC) from the American Speech, Language, and Hearing Association (ASLHA) or a statement from ASLHA of certification equivalency.

2. Any additional speech and language pathology personnel must work under the direct supervision of the licensed pathologist as a speech therapy assistant (STA). STAs must be enrolled in a professional training program or must have obtained at least a bachelor's degree in speech pathology and audiology.

(b) Responsibilities of the speech and language pathologist include

1. assessing each member's communication needs; and

2. recommending, based upon the assessments, the DH necessary to meet the member's identified areas of need.

(L) DH Staff Training Requirements. The DH provider must provide initial and annual training to all staff members who are responsible for the care of a member. Records of completed training must be kept on file and updated regularly by the DH provider. The initial training must be completed for new staff within three months of hire and must include, but is not limited to, the following topics:

(1) delivery of DH by the DH provider;
(2) DH provider written policies and procedures;
(3) DH provider staff roles and responsibilities;
(4) caring for people with ID/DD, behavioral health issues, including positive behavioral supports (PBS), behavior acceptance, and accommodations;
(5) observation, reporting, and documentation of the member's status;
(6) emergency procedures
(7) universal precautions and infection control practices;
(8) advance directives;
(9) prevention of, and reporting of, abuse, neglect, mistreatment and misappropriation/ financial exploitation;
(10) techniques of providing safe personal care assistance: good body mechanics;
(11) human rights, non-discrimination and cultural sensitivity;
(12) recognizing, responding to, and reporting change in condition, emergencies, and knowledge of emergency procedures, including the DH provider's fire, safety, and disaster plans.
(13) the requirements of 130 CMR 419.000;
(14) information about local health, fire, safety, and building codes;
(15) privacy and confidentiality;
(16) interdisciplinary professional team approach;
(17) communication and interpersonal skills;
(18) completing and filing critical incident reports; and
(19) recognizing the physical, emotional, and developmental needs of the individuals in their care and working in a manner that respects them, their privacy, and their property.

419.430: Emergency Services and Plans

The DH provider must establish plans, policies, and procedures for medical and other emergencies developed with the assistance of local and state fire and safety experts, and posted in offices of staff and conspicuous locations throughout each DH provider site. These plans and procedures must include, at a minimum, the following:

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(A) Written emergency policies and procedures that must include

(1) an emergency evacuation plan that is in compliance with and coordinated with local fire department requirements and that must, at a minimum, require quarterly fire and evacuation drills for all staff members, and which must be documented in accordance with 130 CMR 419.416(B);

(2) a procedure to be followed if participant is missing or lost;

(3) procedures for handling medical emergencies at each DH provider site;

(4) persons and entities to be notified in case of an emergency;

(5) locations of alarm signals and fire extinguishers; and

(6) staff training in emergency procedures including, but not limited to, assignment of specific tasks and responsibilities to the personnel and documentation of such training.

(B) Written procedure for emergency transportation to an acute care hospital must be in accordance with the following requirements.

(1) In the event of a medical emergency, a DH provider must call the emergency access number 911 and arrange for the transport of a member to an acute care hospital for emergency medical care.

(2) The DH provider must provide all pertinent health information to the emergency medical technician(s) and to any hospital to which any member is transported, including the member's Comfort Care/Do Not Resuscitate Verification Form, Massachusetts Medical Orders for Life-sustaining Treatment (MOLST) Form, or other advance directive on file with the DH provider, as applicable.

(3) The DH provider must contact the member's PCP, authorized representative, and, if applicable, DDS service coordinator at the time of the emergency or immediately thereafter to advise of the emergency and all actions taken in response to the emergency.

(4) The DH provider must, immediately after such medical emergency, document in the member's clinical record the following:

(a) the nature of the emergency and actions taken in response to the emergency;

(b) the reason for the member's emergency transport to an acute care hospital, if applicable; and

(c) the name of the member's authorized representative who was notified of the medical emergency and the date and time the member's authorized representative was notified.

(C) A written Continuity of Operations Plan (COOP) in accordance with the resources available from the Massachusetts Department of Public Health's Office of Preparedness and Emergency Management;

(D) An emergency fact sheet on each member, updated biannually, that contains the following information:

(1) the name and telephone number of the member's PCP;

(2) the member's diagnosis;

(3) any special treatments or medications the member may need;

(4) the member's allergies;

(5) insurance information; and

(6) the name and telephone number of the identified contact person, the authorized representative to be notified in case of emergency and, if applicable, DDS service coordinator.

(E) A written policy on staffing that includes at least two staff members certified in first aid and cardiopulmonary resuscitation (CPR) be on duty at all times. The provider must maintain a current record of training and recertification of staff and post the names of certified individuals in a conspicuous location.

419.431: Noncoverage

The following are considered non-covered days and are ineligible for payment under 101 CMR 419.431:

419.431: continued

(A) Any portion of a day during which the member is absent from the DH program, unless the provider documents that the member was receiving services from the DH provider's staff in a community setting.

(B) Day Habilitation provided to a member when the member's needs can no longer be met by the DH as determined by the PCP and the professional interdisciplinary team in consultation, or by a qualified representative of the MassHealth agency, DDS, or DPH.

(C) Days or any portion of a day on which the following services are provided:
(1) vocational- and prevocational-training services, which include vocational-skills assessment, career counseling, job training, and job placement;
(2) work-related services, which provide participants with work skills and supervised employment for the production of saleable goods;
(3) educational services, which involve traditional classroom instruction of academic subjects, tutoring, and academic counseling; and
(4) social, vocational, and recreational services.

(D) Day Habilitation when provided to members residing in ICF/ID;

(E) Day Habilitation when provided to a member 21 years of age or older who is receiving hospice services;

(F) Day Habilitation when provided more than five days per week and six hours per day per member;

(G) Day Habilitation when provided at a site that has not been approved by the MassHealth agency or its designee or does not have a current approval on file;

(H) Day Habilitation when provided on or after the effective date of the discharge plan; and

(I) Claims billed above the census on file as approved by the MassHealth agency or its designee.

419.432: Physical Site

(A) Physical Site. The MassHealth agency or its designee approves each day habilitation site and census. A DH provider must provide DH at a site that meets all of the requirements in 130 CMR 419.432(A)(1) through (14). In the event of a site change, renovation, new construction, or change in census, the DH provider must forward a copy of all plans to the MassHealth agency or its designee for approval.
(1) The site must be designed with adequate space for the provision of all DH, with a minimum of 50 square feet of programming space per participant. This minimum does not include offices (except nurses' offices if used for member treatment), hallways, storage areas, reception areas, and other areas not used for the provision of DH. For sites with kitchens used for activities other than meal preparation, 100% of the kitchen floor area is counted as part of the participant space requirement.
(2) When located in a building or facility housing other services, the DH provider must provide DH solely within the space allocated for day habilitation.
(3) Within one year of September 7, 2018, the DH provider site must be in a location that complies with the Americans with Disabilities Act (ADA) and ADA Standards for Accessible Design that include but are not limited to:
(a) The site is on-ground level with at least two means of egress;
(b) The site is free of architectural barriers;
(c) The site is designed to meet the needs of people with disabilities; and
(d) The site is in compliance with local health, fire, and safety codes.
(4) For sites approved on or after September 7, 2018, that occupy multi-level space, the site must have at a minimum one elevator for egress, and evacuation plans must include specific procedures for evacuation of those in wheelchairs and comply with local and state evacuation requirements.

419.432: continued

(5) The site must include adequate outdoor space for members to safely arrive at and depart from the DH provider site.
(6) DH providers must provide a protected and secure environment for members, including members who wander or require increased supervision and security.
(7) The site must include sufficient parking capacity to satisfy the needs of members, staff, and the public.
(8) The site must include a clean and sanitary food preparation area equipped with a refrigerator, a sink, adequate counter space, and adequate storage space.
(9) Adequate artificial lighting must be available in all rooms, stairways, hallways, corridors, bathrooms, and offices.
(10) A DH provider site serving five or more unrelated participants must comply with 780 CMR 3.00: *Use and Occupancy Classification* (State Building Code).
(11) The MassHealth agency must approve each DH site. In the event of a site change, renovation, or new construction, the provider must forward a copy of all plans to the MassHealth agency for approval. Upon completion of renovations, moves, or new construction, the MassHealth agency or its designee must view the site to determine compliance with the requirements.
(12) The kitchen and bathrooms must be designed and equipped for teaching ADL skills to all participants.
(13) In at least one participant area, the site must have a fire extinguisher and a first aid kit, easily accessible to staff.
(14) The site must meet the requirements of all state and local building, sanitary, health, fire, and zoning codes, and all other requirements pertaining to health, safety, and sanitation.
(15) The participants must have access to hand sanitizer dispensers and to at least one handwashing station. Hand sanitizer dispensers and hand washing stations must be conveniently placed and accessible to staff. Hand sanitizer dispensers and handwashing stations must be placed with consideration for participant safety and accessibility.
(16) Participants must have access to natural light and outside views.
(17) Participants must have adequate lighting, heating, and ventilation so that participants are comfortable in all seasons of the year.

419.433: Day Habilitation for MassHealth Members with ID/DD Residing in NFs

For purposes of providing DH to MassHealth members with ID or DD residing in NFs, DH providers must comply with all of the requirements outlined in 130 CMR 419.433 as well as coordinate and communicate with the member, the DDS service coordinator, if applicable, and the NF, actively participate in the development of the RISP, and attend the NF plan of care meetings to ensure that the DHSP complements and reinforces the service plans referenced in the member's RISP.

(A) Admission Criteria. In addition to the criteria outlined in 130 CMR 419.406, a MassHealth member with ID or DDs residing in a NF may receive DH designed to improve the member's level of independent functioning.

(B) Service Needs Assessment (SNA). In addition to the requirements outlined in 130 CMR 419.417, the SNA for a MassHealth member with ID or DD residing in a NF who receives DH must:
(1) be completed by a qualified professional who must possess a master's degree in a human-services-related field or other professional license in a human or health services field;
(2) include any and all applicable therapy or nursing assessments completed by the NF. In *lieu* of utilizing assessments completed by the NF, the provider may complete specialized assessments that take into consideration the member's disabilities;
(3) assess all specialized service need areas to determine if specialized services are needed and if so what day habilitation services are appropriate to meet those needs; and
(4) be completed upon a significant change involving a change in the member's Level II PASRR or as the member's RISP dictates.

419.433: continued

(C) Day Habilitation Service Plan.

(1) The comprehensive DHSP must meet all of the requirements set forth in 130 CMR 419.416 and must

(a) be completed and forwarded to the DDS service coordinator if applicable, together with the SNA, within 90 days of the referral for specialized services;

(b) be completed in conjunction with the DDS service coordinator as applicable, and the NF;

(c) provide DH that is adequate in frequency and intensity to lead to progress; and

(d) ensure, in conjunction with the NF, that the DHSP interventions complement and reinforce the RISP.

(2) DH contained in the DHSP must be available and offered to the member.

(3) To ensure progress toward goals and objectives and to identify significant changes, the DHSP should be evaluated on the following schedule:

(a) Monthly Reviews. In addition to the requirements outlined in 130 CMR 419.417(C), the DHSM must notify the member's DDS service coordinator where applicable, within seven business days, if the monthly review demonstrates a significant change in the member's condition that may affect the Level II PASRR determinations.

(b) Quarterly Reviews. The quarterly review must:

1. include a reevaluation of continued need for in-facility DH; and
2. conduct quarterly reviews with the DDS service coordinator where applicable, in conjunction with the NF quarterly plan of care meeting, when applicable.

(D) Communication and Coordination Requirements. For each NF resident with ID or DD that receives DH, the DH provider staff must

(1) meet with the NF at least twice each year, in addition to the annual plan of care meeting, to coordinate the development and update of the DHSP;

(2) provide copies of the interim DHSP to the members of the RISP interdisciplinary team at least three days prior to the initial RISP meeting;

(3) submit the final DHSP, and any changes to the plan, for approval by the RISP interdisciplinary team;

(4) incorporate any changes recommended by the RISP interdisciplinary team into the final DHSP within 45 days of the initial RISP meeting;

(5) determine what other care plans have been, or are in the process of being, developed by other providers or agencies in an effort to avoid duplication;

(6) ensure that the goals and objectives of the DHSP are consistent with those in the other plans, and forward a copy to the DDS area office, and the NF; and

(7) immediately notify the DDS service coordinator, where applicable, in the event of a disruption of DH.

(E) Ongoing Documentation and Recordkeeping Requirements.

(1) Day Habilitation Providers. In addition to the requirements outlined at 130 CMR 419.416, DH providers must develop and maintain records that document the DH provided to members with ID or DD residing in a NF. Such documentation must include:

(a) the date the member was referred for specialized services in a day habilitation setting; and

(b) documentation that the RISP interdisciplinary team has approved the final DHSP and any subsequent plan revisions.

(2) Nursing Facilities. The DH provider must:

(a) provide to the NF copies of the DHSP and any revisions to it, the SNA, and quarterly progress notes;

(b) attend the annual NF Plan of Care meeting at the nursing facility to coordinate the development of the two plans; and

(c) accommodate requests from NFs regarding carry-over of the strategies employed in the provision of DH to a member.

(3) DDS Service Coordinators. DH providers must communicate with DDS service coordinators as follows:

(a) contact the DDS service coordinator for instruction in the event that the DH provider determines that it is not appropriate to provide DH to a member in the specialized services need areas;

419.433: continued

(b) communicate with the DDS service coordinator concerning all issues related to DH, including notification of any changes in the DHSP goals, objectives and/or strategies; and

(c) forward a copy of the DHSP and quarterly reviews to the DDS service coordinator for inclusion in the RISP at the NF.

(F) Provision of Day Habilitation in an NF (In-facility). DH may be provided in the NF to a member with ID or DD when

(1) the member is so medically fragile that transport to a DH provider site outside of the NF presents a significant risk to the health and safety of the resident;

(2) the member has declined to receive DH at the DH provider's community site; or

(3) as determined by the RISP interdisciplinary team, DH is the only service that is available to meet the member's specialized services needs.

419.434: Withdrawal of a Day Habilitation Provider from MassHealth

A DH provider that intends to withdraw from MassHealth must satisfy all of the following obligations.

(A) MassHealth Notification.

(1) A DH provider electing to withdraw from participation in MassHealth must send written notice to the MassHealth agency or its designee, and DDS, of the provider's intention to withdraw from participating as a MassHealth DH provider. The DH provider must send the withdrawal notice by certified or registered mail, return receipt requested, to the MassHealth agency or its designee, no fewer than 90 days before the effective date of withdrawal.

(2) The DH provider must forward to the MassHealth agency or its designee a list of all members currently receiving DH. The DH provider must notify the MassHealth agency in writing as members are placed in other programs or begin to receive alternative services, including the name of the new program or service and each member's start date in the new program or service.

(B) Notification to Member and Authorized Representatives.

(1) The DH provider must notify all members, authorized representatives of members and other funding sources in writing of the intended closing date no fewer than 90 days from the intended closing date, and specify the assistance to be provided to each member in identifying alternative services.

(2) On the same date on which the DH provider sends a withdrawal notice to the MassHealth agency or its designee, the provider must give notice, in hand, to all members to whom it is providing DH along with notice to the members' authorized representatives, including for those members who have been transferred to hospitals, or who are on medical or nonmedical leave of absence. The notice must advise that any member who is eligible for MassHealth on the effective date of the withdrawal must relocate to another DH provider participating in MassHealth to ensure continuation of MassHealth payment of services and must be determined eligible to continue to receive the services. A copy of this notice must be forwarded to the MassHealth agency or its designee.

(3) The notice must also state that the DH provider will work promptly and diligently to arrange for the relocation of members to MassHealth-participating DH providers or, if appropriate, to alternative community-service providers.

(C) Emergency Withdrawal. In the instance of alleged emergency withdrawal, the DH provider must contact the MassHealth agency, or its designee, within one business day of the emergency withdrawal and follow up, in writing, within the next three business days informing the MassHealth agency, or its designee, of the reasoning for such emergency withdrawal, and must provide proof in documentation or other form as the MassHealth agency may require. The DH provider must also notify all members, member representatives, the MassHealth agency, and DDS coordinator, if applicable, about the status of all members and any plans for relocation.

419.434: continued

(D) Admission and Relocation Requirements.

(1) A DH provider must not admit any new MassHealth members after the date on which the withdrawal notice was sent to the MassHealth agency or its designee. Members receiving DH from the DH provider, for whom prior authorization was sought prior to the withdrawal notice being sent, who are then authorized for DH after the notice of withdrawal, are not considered newly admitted members.

(2) Notwithstanding provision for emergency withdrawal, a DH provider that withdraws from participation in MassHealth must assist members to whom it has been providing DH to identify and locate another DH provider and must continue to provide its current level of DH until all members receiving services from the DH provider have been admitted with a new DH provider or another qualified MassHealth provider.

(3) A DH provider seeking to withdraw from the MassHealth program shall work promptly and diligently to arrange for the relocation of members to MassHealth participating DH provider or other qualified MassHealth providers.

REGULATORY AUTHORITY

130 CMR 419.000: M.G.L. c. 118E, §§ 7 and 12.

NON-TEXT PAGE

Docket # 1020

THE COMMONWEALTH OF MASSACHUSETTS
William Francis Galvin
Secretary of the Commonwealth

Notice of Correction

Regulation Filing *To be completed by filing agency*

CHAPTER NUMBER: **130 CMR 450.000**

CHAPTER TITLE: **Administrative and Billing Regulations**

AGENCY: **Division of Medical Assistance**

ORIGINAL PUBLICATION REFERENCE: **1376** *Date:* **10/19/2018**

SUMMARY OF CORRECTION:
The initial paragraph for 130 CMR 450.303 contains an errant link to the MassHealth Drug List (presently listed as "https://masshealthdruglist.ehs.state.ma.us/MHDL/." The present link should be deleted and replaced with the following: www.mass.gov/druglist

AGENCY CONTACT: **Deborah M. Briggs** PHONE: **(617) 847-3302**

ADDRESS: **100 Hancock Street, Quincy, MA 02171**

ATTESTATION - *The regulation described herein and attached hereto is a true copy of the regulation adopted by this agency.* ATTEST:

SIGNATURE: SIGNATURE ON FILE DATE: **Aug 24 2018**

Publication *To be completed by the Regulations Division*

MASSACHUSETTS REGISTER NUMBER: **1373** DATE: **09/07/2018**

EFFECTIVE DATE: **06/16/2017**

CODE OF MASSACHUSETTS REGULATIONS

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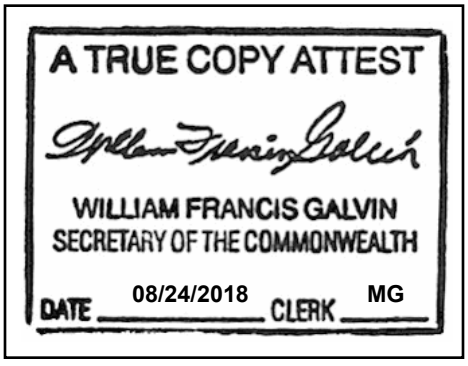

450.303: Prior Authorization

In certain instances, the MassHealth agency requires providers to obtain prior authorization to provide medical services. These instances are identified in the billing instructions, program regulations, associated lists of service codes and service descriptions, provider bulletins, and other written issuances from the MassHealth agency. Such information including, but not limited to, the MassHealth Drug List is available on the MassHealth website at www.mass.gov/druglist, and copies may be obtained upon request. The provider must submit all prior-authorization requests in accordance with the MassHealth agency instructions. Prior authorization determines only the medical necessity of the authorized service, and does not establish or waive any other prerequisites for payment, such as member eligibility or resort to health-insurance payment.

(A) The MassHealth agency acts on appropriately completed and submitted requests for prior authorization within the following time periods.

(1) For pharmacy services - by telephone or other telecommunication device within 24 hours of the request for prior authorization. The MassHealth agency will authorize at least a 72-hour supply of a prescription drug to the extent required by federal law. (*See* 42 U.S.C. 1396r-8(d)(5).)

(2) For transportation to medical services - within seven calendar days after a request for service, or the number of days, if less than seven, necessary to avoid any serious and imminent risk to the health or safety of the member that might arise if the MassHealth agency did not act before the full seven days have elapsed.

(3) For independent nurse services - within 14 calendar days after a request for service.

(4) For durable medical equipment - within 15 calendar days after a request for service.

(5) For all other MassHealth services - within 21 calendar days after a request for service.

(B) The following rules apply for prior-authorization requests.

(1) The date of any prior-authorization request is the date the request is received by the MassHealth agency, if the request conforms to all applicable submission requirements including, but not limited to, the form, the address to which the request is sent, and required documentation.

(2) If a provider submits a request that does not comply with all submission requirements, the MassHealth agency informs the provider

(a) of the relevant requirements, including any applicable program regulations;

(b) that the MassHealth agency will act on the request within the time limits specified in 130 CMR 450.303 if the required information is received by the MassHealth agency within four calendar days after the request; and

(c) that if the required information is not submitted within four calendar days, the MassHealth agency's decision may be delayed by the time elapsing between the four days and when the MassHealth agency receives the necessary information.

(3) A service is authorized on the date the MassHealth agency sends a notice of its decision to the member or someone acting on the member's behalf.

(C) The MassHealth agency does not act on requests for prior authorization for

(1) covered services that do not require prior authorization; or

(2) noncovered services, except to the extent that MassHealth regulations specifically allow for prior-authorization requests.

450.304: Claim Submission: Signature Requirement

Every CMS-1500 claim form submitted for payment must be signed by the provider that provided the service or the provider's agent on behalf of the provider that provided the service. A provider that accepts payment of a claim is presumed to have authorized the submission of the claim on his or her behalf.

450.307: Unacceptable Billing Practices

(A) No provider may claim payment in a way that may result in payment that exceeds the maximum allowable amount payable for such service under the applicable payment method.

450.307: continued

(B) Without limiting the generality of 130 CMR 450.307(A), the following billing practices are forbidden:

(1) duplicate billing, which includes the submission of multiple claims for the same service, for the same member, by the same provider or multiple providers;

(2) overstating or misrepresenting services, including submitting separate claims for services or procedures provided as components of a more-comprehensive service for which a single rate of payment is established; and

(3) submitting claims under an individual practitioner's provider ID/service location number for services for which the practitioner is otherwise entitled to compensation.

450.309: Time Limitation on Submission of Claims: General Requirements

(A) In accordance with M.G.L. c. 118E, § 38, all claims must be received by the MassHealth agency within 90 days from the date of service or the date of the explanation of benefits from another insurer. When a service is provided continuously on consecutive dates, the date from which the 90-day deadline is measured is the latest date of service.

(B) For claims that are not submitted within the 90-day period but that meet one of the exceptions specified below, a provider must request a waiver of the billing deadline (a 90-day waiver) pursuant to the billing instructions provided by the MassHealth agency. The exceptions are as follows:

(1) a medical service was provided to a person who was not a member on the date of service, but was later enrolled as a member for a period that includes the date of service; and

(2) a medical service was provided to a member who failed to inform the provider in a timely fashion of the member's eligibility for MassHealth.

(C) When a medical service was provided to a MassHealth member in another state by a provider that is not enrolled in MassHealth, the MassHealth agency will consider a claim for such service to have been timely submitted if all of the following apply:

(1) the medical service was provided in accordance with 130 CMR 450.109;

(2) the provider submits an application to the MassHealth agency to become a participating provider within 90 days after the date of service and the MassHealth agency approves the application; and

(3) the provider submits the claim for payment within 90 days after the date of the notice from the MassHealth agency approving the provider's application.

(D) All requests for waivers of the billing deadline submitted to the MassHealth agency for review must be submitted electronically in a format designated by the MassHealth agency, unless the provider has been approved for an electronic claim submission waiver as specified in 130 CMR 450.302(A)(3).

450.313: Time Limitation on Submission of Claims: Claims for Members with Health Insurance

If a provider delays submitting a claim in order to bill a member's health insurer (*see* 130 CMR 450.316 through 450.318), the claim will have been timely submitted if it is received:

(A) no later than the 90th day after the date of the notice of final disposition by the health insurer (if more than one insurer is involved, the submission period will be measured from the latest final disposition, and the period for making requests will be measured from the date of the notice of final disposition from the previous insurer); and

(B) no later than 18 months after the date of service.

450.314: Final Deadline for Submission of Claims

(A) If the MassHealth agency has denied a claim that was initially submitted within the 90-day deadline, the provider may resubmit the claim with appropriate corrections or supporting information.

Docket # 809

THE COMMONWEALTH OF MASSACHUSETTS
William Francis Galvin
Secretary of the Commonwealth

Notice of Compliance

Regulation Filing *To be completed by filing agency*

CHAPTER NUMBER: **780 CMR 26.00**

CHAPTER TITLE: **Plastic**

AGENCY: **State Board of Building Regulations and Standards**

THIS REGULATION WAS ORIGINALLY FILED AS AN EMERGENCY:

Published in Massachusetts Register Number: **1368** *Date:* **06/29/2018**

PRIOR NOTIFICATION AND/OR APPROVAL - *If prior notification to and/or approval of the Governor, Legislature or others was required, list each notification, and/or approval and date, including notice to the Local Government Advisory Commission.*

L.G.A.C. (E.O. 145) - June 7, 2018; Massachusetts Register Notice - July 27, 2018; Boston Globe and Springfield Republican Notices - July 20, 2018

PUBLIC REVIEW - *M.G.L. c. 30A sections 2 and/or 3 requires notice of the hearing or comment period, including a small business impact statement, be filed with the Secretary of the Commonwealth, published in appropriate newspapers, and sent to persons to whom specific notice must be given at least 21 days prior to such hearing or comment period.*

Date of public hearing or comment period: **August 14, 2018**

SMALL BUSINESS IMPACT - *M.G.L. c. 30A section 5 requires each agency to file an amended small business impact statement with the Secretary of the Commonwealth prior to the adoption of a proposed regulation. If the purpose of this regulation is to set rates for the state, this section does not apply.*

Date amended small business impact statement was filed: **August 23, 2018**

AGENCY CONTACT: **Charles Kilb** PHONE: **617-727-2707**

ADDRESS: **Div. of Prof. Licensure, 1000 Washington St., 7th Fl., Boston, MA 02118**

ATTESTATION - *The regulation described herein and attached hereto is a true copy of the regulation adopted by this agency.* ATTEST:

SIGNATURE: SIGNATURE ON FILE DATE: **Aug 24 2018**

Publication - *To be completed by the Regulations Division*

MASSACHUSETTS REGISTER NUMBER: **1373** DATE: **09/07/2018**

EFFECTIVE DATE: **06/06/2018**

CODE OF MASSACHUSETTS REGULATIONS

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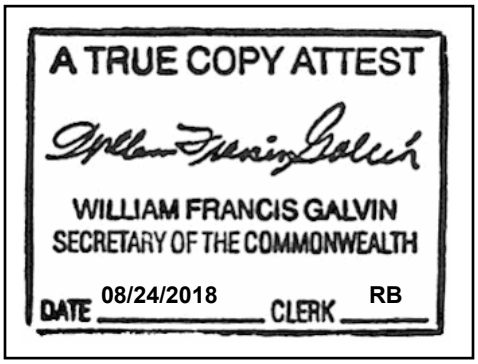

780 CMR: MASSACHUSETTS AMENDMENTS TO THE *INTERNATIONAL BUILDING CODE 2015*

CHAPTER 26: PLASTIC

2603.5.5 Revise subsection as follows:

2603.5.5 Vertical and Lateral Fire Propagation. The exterior wall assembly shall be tested in accordance with and comply with the acceptance criteria of NFPA 285.

Exceptions: Wall assemblies where the foam plastic insulation is covered on each face by not less than one inch (25 mm) thickness of masonry, concrete, terra cotta, stucco or ½ inch thick Type X gypsum board and meeting one of the following:

1. There is no airspace between the insulation and the masonry, concrete, terracotta, stucco, or ½ inch thick type X gypsum board.
2. The insulation has a flame spread index of not more than 25 as determined in accordance with ASTM E 84 or UL 723 and the maximum airspace between the insulation and the concrete or masonry is not more than one inch (25 mm).

NON-TEXT PAGE

Docket # 14

THE COMMONWEALTH OF MASSACHUSETTS
William Francis Galvin
Secretary of the Commonwealth

Regulation Filing *To be completed by filing agency*

CHAPTER NUMBER: **958 CMR 11.00**

CHAPTER TITLE: **Internal Appeals Process and External Review Process for Risk-bearing Provider Organizations and Accountable Care Organizations**

AGENCY: **Health Policy Commission**

SUMMARY OF REGULATION: *State the general requirements and purposes of this regulation.*

958 CMR 11.00 applies to all Risk-bearing Provider Organizations and Accountable Care Organizations subject to the requirements of M.G.L. c. 176O § 24, M.G.L. c. 6D §§ 15 and 16. 958 CMR 11.00 establishes requirements for administering internal appeals processes and establishes the requirements for external review of appeals submitted by or on behalf of Patients of Risk-bearing Provider Organizations and Accountable Care Organizations.

REGULATORY AUTHORITY: **M.G.L. c. 176O § 24, M.G.L. c. 6D §§ 15 and 16**

AGENCY CONTACT: **Lois Johnson** PHONE: **6179791405**

ADDRESS: **50 Milk Street, 8th Floor, Boston, MA**

Compliance with M.G.L. c. 30A

EMERGENCY ADOPTION - *if this regulation is adopted as an emergency, state the nature of the emergency.*

PRIOR NOTIFICATION AND/OR APPROVAL - *If prior notification to and/or approval of the Governor, Legislature or others was required, list each notification, and/or approval and date, including notice to the Local Government Advisory Commission.*

Notice to the Local Government Advisory Committee on 4/18/18

PUBLIC REVIEW - *M.G.L. c. 30A sections 2 and/or 3 requires notice of the hearing or comment period, including a small business impact statement, be filed with the Secretary of the Commonwealth, published in appropriate newspapers, and sent to persons to whom specific notice must be given at least 21 days prior to such hearing or comment period.*

Date of public hearing or comment period: **5/3/18-5/25/18, public hearing on 5/25/18**

FISCAL EFFECT - *Estimate the fiscal effect of the public and private sectors.*

For the first and second year: **minimal or no effect**

For the first five years: **minimal or no effect**

No fiscal effect: **minimal or no effect**

SMALL BUSINESS IMPACT - *M.G.L. c. 30A section 5 requires each agency to file an amended small business impact statement with the Secretary of the Commonwealth prior to the adoption of a proposed regulation. If the purpose of this regulation is to set rates for the state, this section does not apply.*

Date amended small business impact statement was filed: **7/17/18**

CODE OF MASSACHUSETTS REGULATIONS INDEX - *List key subjects that are relevant to this regulation:*

Risk-bearing Provider Organization
Accountable Care Organization
Internal Appeal
External Review

PROMULGATION - *State the action taken by this regulation and its effect on existing provisions of the Code of Massachusetts Regulations (CMR) or repeal, replace or amend. List by CMR number:*

New chapter, 958 CMR 11.00

ATTESTATION - *The regulation described herein and attached hereto is a true copy of the regulation adopted by this agency.* ATTEST:

SIGNATURE: SIGNATURE ON FILE DATE: **Aug 23 2018**

Publication - *To be completed by the Regulations Division*

MASSACHUSETTS REGISTER NUMBER: **1373** DATE: **09/07/2018**

EFFECTIVE DATE: **09/07/2018**

CODE OF MASSACHUSETTS REGULATIONS

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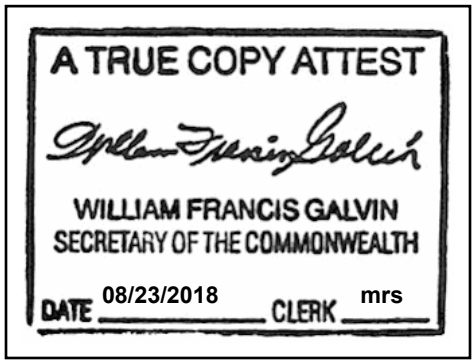

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958 CMR 11.00: INTERNAL APPEALS PROCESS AND EXTERNAL REVIEW PROCESS FOR RISK-BEARING PROVIDER ORGANIZATIONS AND ACCOUNTABLE CARE ORGANIZATIONS

Section

11.01: Scope and Purpose

958 CMR 11.00 applies to all Risk-bearing Provider Organizations and Accountable Care Organizations subject to the requirements of M.G.L. c. 176O, § 24, M.G.L. c. 6D, §§ 15 and 16. 958 CMR 11.00 establishes requirements for administering internal appeals processes and establishes the requirements for external review of appeals submitted by or on behalf of Patients of Risk-bearing Provider Organizations and Accountable Care Organizations.

11.02: Definitions

As used in 958 CMR 11.00, the following words shall have the following meaning:

Accountable Care Organization or ACO. An organization certified by the Commission as an Accountable Care Organization pursuant to M.G.L. c. 6D, § 15.

ACO or RBPO Participant. A Health Care Provider or entity that participates, through billing, in the Accountable Care Organization's or Risk-bearing Provider Organization's Alternative Payment Contract(s).

Actively Practicing. A Health Care Professional who regularly treats patients in a clinical setting.

Alternative Payment Contract. Any contract between a Provider or Provider Organization and a Health Care Payer, employer or individual, which utilizes alternative payment methodologies, as defined under M.G.L. c. 6D, § 1.

11.02: continued

Authorized Representative. A patients's guardian, conservator, holder of a power of attorney, health care agent designated pursuant to M.G.L. c. 210, family member, or other person authorized by the patient in writing or by law with respect to a specific internal appeal or external review, provided that if the patient is unable to designate a representative, where such designation would otherwise be required, a guardian, conservator, holder of a power of attorney, or family member in that order of priority may be the patient's representative or may appoint another responsible party to serve as the patient's Authorized Representative. If the Authorized Representative is a Health Care Provider, the patient must specify a named individual who will act on behalf of the Authorized Representative and a telephone number for that individual.

Carrier. An insurer licensed or otherwise authorized to transact accident and health insurance under M.G.L. c. 175; a nonprofit hospital service corporation organized under M.G.L. c. 176A; a nonprofit Medical Service Corporation organized under M.G.L. c. 176B; or a Health Maintenance Organization organized under M.G.L. c. 176G; and an organization entering into a preferred provider arrangement under M.G.L. c. 176I, but not including an Employer purchasing coverage or acting on behalf of its employees or the employees of one or more subsidiaries or affiliated corporations of the Employer; provided that, unless otherwise noted, Carrier shall not include any entity to the extent it offers a policy, certificate or contract that provides coverage solely for dental care services or vision care services.

Commission. The Health Policy Commission established in M.G.L. c. 6D.

External Review Agency. An independent review organization, which is an entity or company under contract with the Commission to conduct independent reviews pursuant to 958 CMR 11.00. Each External Review Agency shall be accredited by a national accrediting organization.

Financial Affiliation or Financial Relationship. Any financial interest in a Carrier or RBPO or ACO provided that the term Financial Affiliation shall not include revenue received from a Carrier by a clinical reviewer for health services rendered to insureds.

Health Care Professional. A physician or other health care practitioner licensed, accredited or certified to perform specified health services consistent with law.

Health Care Provider or Provider. A Health Care Professional or facility.

Internal Reviewer. An individual directed by the RBPO or ACO to review internal appeals, who has a clinical background with an active license to practice and who was not involved in the decision about which the Patient appealed and is not under direct supervision of the individual who made the decision about which the Patient appealed.

Material Familial Affiliation. Any relationship as a spouse, child, parent, sibling, spouse's parent, spouse's child, child's parent, child's spouse, sibling's spouse, domestic partner, aunt, uncle, foster parent or foster child.

Material Professional Affiliation. Any Health Care Professional-patient relationship, any partnership or employment relationship, a shareholder or similar ownership interest in a professional corporation, or any independent contractor arrangement that constitutes a Financial Affiliation.

Office of Patient Protection. The office within the Commission established by M.G.L. c. 6D, § 16.

Patient. An individual who chooses or is attributed to the Risk-bearing Provider Organization or Accountable Care Organization for medical or behavioral health care, and for whom such services are paid under an Alternative Payment Contract with a Carrier, excluding Medicare, Medicare Advantage, and Medicaid patients.

11.02: continued

Primary Care Provider. A Health Care Professional qualified to provide general medical care for common health care problems, who supervises, coordinates, prescribes, or otherwise provides or proposes health care services, initiates referrals for specialist care, and maintains continuity of care within the scope of his or her practice.

Provider Organization. Any corporation, partnership, business trust, association or organized group of persons, which is in the business of health care delivery or management, whether incorporated or not, that represents one or more Health Care Providers in contracting with health care payers for the payments of health care services; provided, however, that the definition shall include, but not be limited to, physician organizations, physician hospital organizations, independent practice associations, Provider networks, Accountable Care Organizations and any other organization that contracts with health care payers for payment for health care services.

Risk-bearing Provider Organization or RBPO. A Provider Organization that has obtained a Risk Certificate from the Division of Insurance pursuant to 211 CMR 155.00: *Risk-bearing Provider Organizations*.

Same or Similar Specialty. The Health Care Professional has similar credentials and licensure as those who typically provide the treatment in question and has experience treating the same condition that is the subject of the appeal. Such experience shall extend to the treatment of children in a grievance involving a child where the age of the Patient is relevant to the determination under 958 CMR 11.21.

Terminal Illness. An illness that is likely, within a reasonable degree of medical certainty, to cause one's death within six months, or as otherwise defined in § 1861(dd)(3)(A) of the Social Security Act (42 U.S.C. 1395x(dd)(3)(A)).

Urgent Medical Need. The risk of serious harm to the Patient is so immediate that the provision of appealed services should not await the standard 14-day response time for an internal appeal or the standard 21-day response time for an external review. Urgent Medical Need may occur when a Patient is receiving emergency services, ongoing services, or the Patient has a Terminal Illness. Urgent Medical Need occurs where a delay may seriously jeopardize the health of the Patient or otherwise jeopardize the Patient's ability to regain maximum function.

11.03: Right to an Internal Appeal

(1) Risk-bearing Provider Organizations or Accountable Care Organizations shall maintain an internal appeal process that provides for adequate consideration and timely resolution of Patient concerns about denials, restrictions, or limitations of care.

(2) The internal appeals processes shall apply to decisions of the RBPO, ACO or the ACO or RBPO Participants relating to denials, restrictions or limitations of care regarding:

(a) Referrals to Providers not affiliated with the RBPO or ACO;
(b) The type or intensity of treatment or services;
(c) Timely access to treatment or services; and
(d) Other concerns related to the Patient's care provided by an RBPO or ACO or RBPO or ACO Participant that are related to Provider participation in an Alternative Payment Contract.

(3) The RBPO or ACO shall not:

(a) Require a Patient to submit such an appeal in writing.
(b) Prevent a Patient from seeking medical opinions outside of the RBPO or ACO.
(c) Terminate any medical or behavioral health services being provided to the Patient during the internal appeal or external review, including medical or behavioral health services which began prior to the Patient appeal and are the subject of the appeals process in 958 CMR 11.00; or
(d) Limit or restrict access to appeals process in 958 CMR 11.00.

11.04: Information on Internal Appeals

(1) The RBPO or ACO shall make information about its internal appeals process available to Patients and the public through the following means:

(a) Notice available in writing at all locations where Patients regularly seek care; and

(b) Hard copy or electronic copy of the notice to Patients upon request.

(2) The RBPO or ACO, upon Primary Care Provider selection or Patient attribution, may provide notice by mail, email, website, patient portal or distribute the notice directly to Patients during an office visit.

(3) Notices shall include how to make an appeal. Such notices shall inform Patients of the right to authorize a representative to act on the Patient's behalf during the appeals process. The RBPO or ACO may require the Patient to authorize a representative in writing.

(4) Notices shall include the toll-free number, website, and email address maintained by the Office of Patient Protection.

11.05: Form and Manner of Request for Internals Appeals

(1) The RBPO or ACO shall adopt a process to accept appeals by telephone, in person, by mail, or by electronic means, provided that an oral appeal made by the Patient or the Patient's Authorized Representative shall be reduced to writing by the RBPO or ACO and a copy forwarded to the Patient or the Patient's Authorized Representative.

(2) Where an appeal requires review of a Patient's medical records such appeal shall include, if necessary, a form signed by the Patient or the Patient's Authorized Representative authorizing the release of medical and treatment information relevant to the appeal.

11.06: Risk-bearing Provider Organization and Accountable Care Organization Records of Appeals

Each RBPO or ACO shall establish a system for maintaining records of each appeal made by a Patient or on his or her behalf, and response thereto, for a period of seven years, which records shall be subject to inspection by the Commissioner of Insurance and the Office of Patient Protection.

11.07: Time Limits for Resolution of Internal Appeals

(1) The RBPO or ACO shall provide the Patient, or the Patient's Authorized Representative, with a written resolution of the appeal within 14 calendar days of receipt of the original appeal.

(2) The RBPO or ACO shall provide the Patient, or the Patient's Authorized Representative, with a written resolution of the expedited internal appeal concerning an Urgent Medical Need within three business days.

11.08: Internal Reviewers

(1) The RBPO or ACO shall ensure that an Internal Reviewer determines the resolution of the internal appeal.

(2) An Internal Reviewer shall determine whether the Patient has an Urgent Medical Need that warrants an expedited internal appeal. The Internal Reviewer determining Urgent Medical Need and the Internal Reviewer determining the resolution of the internal appeal may be the same individual.

11.09: Form of Written Resolution of the Internal Appeal

(1) Each written resolution of an internal appeal shall include a clear summary explanation of the basis for the decision, including a substantive clinical justification for the decision, and identification of the specific information considered.

(2) The written resolution on the Patient's appeal shall prominently provide information on the Patient's right to appeal the decision to the Office of Patient Protection and information on how to file a request for external review including, but not limited to:

(a) A paper copy of the form prescribed by the Office of Patient Protection for the request for external review, as well as instructions for locating the form on the Office of Patient Protection's website;

(b) The toll-free number, website, and email address maintained by the Office of Patient Protection; and

(c) A list of documents and information available to the Patient from the RBPO or ACO, including a list of the Patient's medical records and other documents and information relied upon by the RBPO or ACO in the internal appeal. The RBPO or ACO shall include instructions for obtaining these documents.

11.10: External Review

A Patient or a Patient's Authorized Representative who seeks further review of a denial or restriction by an RBPO or ACO and whose concerns were not resolved through the internal appeals process may request an external review of the internal appeal decision by filing a request in writing with the Office of Patient Protection within 30 calendar days of the Patient's receipt of the written resolution of the internal appeal decision.

11.11: Expedited External Review

(1) The Patient or Patient's Authorized Representative may request an expedited external review, which shall be determined by the External Review Agency.

(2) A request for expedited external review by a Patient or the Patient's Authorized Representative shall be included in the external review request, on the external review request form issued by the Office of Patient Protection. Each request for an expedited review shall contain a description, in writing, from the Patient or Patient's Authorized Representative demonstrating the Patient's Urgent Medical Need and may include other information, including medical records, from the Patient or the Patient's Authorized Representative.

(3) The External Review Agency shall order the external review to be expedited where it determines that there is an Urgent Medical Need.

(4) The External Review Agency shall order that the external review be expedited within 24 hours of receiving the request for expedited external review from the Office of Patient Protection.

11.12: Fees

(1) The cost for an external review shall be borne by the involved RBPO or ACO. Upon completion of the external review, the Office of Patient Protection or the External Review Agency shall bill the involved RBPO or ACO the amount established pursuant to contract between the Commission and the assigned External Review Agency.

(2) There shall be no cost borne by the Patient requesting an external review.

11.13: Consent to Release of Medical Information

(1) Any request for external review pursuant to 958 CMR 11.10 shall include the signature of the Patient or the Patient's Authorized Representative authorizing the release and forwarding of medical information and records relevant to the subject matter of the external review to the External Review Agency, in a matter consistent with state and federal law.

11.13: continued

(2) In connection with any request for an external review, the RBPO or ACO shall ensure that the Patient, and where applicable the Patient's Authorized Representative, has timely access to any relevant medical information and records relating to the Patient in the possession of the RBPO or ACO, in accordance with applicable state and federal law.

11.14: Form and Manner of Request for External Review

(1) Requests for external review submitted by the Patient or the Patient's Authorized Representative shall:

(a) Be on a form prescribed by the Office of Patient Protection;

(b) Include the signature of the Patient or the Patient's Authorized Representative consenting to the release of medical information; and

(c) Include a copy of the written resolution of the internal appeal issued by the RBPO or ACO.

11.15: Screening of Requests for External Review

(1) The Office of Patient Protection shall screen all Patient requests for external reviews to determine if they:

(a) Comply with the requirements of 958 CMR 11.00;

(b) Do not involve an issue within the purview of the Patient's Carrier; and

(c) Result from an RBPO's or ACO's written resolution of the internal appeal upholding the decision that is the subject of the appeal; provided, however, that no written resolution is necessary where the RBPO or ACO has failed to comply with timelines for the internal appeals process.

11.16: Requests Ineligible for External Review – Notification

Notification of the rejection of a request for external review for failure to meet requirements in 958 CMR 11.15 shall be issued by the Office of Patient Protection to the Patient or the Patient's Authorized Representative within 72 hours of a receipt of a request for an expedited review and within six business days of a receipt of a request for all other reviews. The notification shall set forth the specific reason why the request has been determined ineligible for an external review.

11.17: Assignment of External Reviews

Upon the determination by the Office of Patient Protection that a Patient's request for review is eligible for external review, the external review request shall be assigned promptly to an External Review Agency by the Office of Patient Protection on a random basis. The Office of Patient Protection shall forward a copy of the Patient's request for an external review together with any related documentation filed with the Office by the Patient to the External Review Agency.

11.18: Notification of Assignment and Request for Information

(1) Upon the assignment of a request to an External Review Agency, the Office of Patient Protection shall notify the Patient, the Patient's Authorized Representative if applicable, and the involved RBPO or ACO that the request has been assigned and shall identify the selected External Review Agency, and where applicable, identify that the review is being considered on an expedited basis. A copy of the Patient's written authorization for the release of medical records and information shall be included with the notification.

(2) Upon receipt of an external review assignment, the External Review Agency shall assign the review to an external reviewer who did not participate in any of the RBPO's or ACO's prior decisions on the denial or restriction. The external reviewers shall be Actively Practicing Health Care Professionals in the Same or Similar Specialty who typically treat the medical or behavioral health condition, perform the procedure or provide the treatment that is the subject of the external review.

11.19: Medical Records and Other Information

(1) The RBPO or ACO, as authorized pursuant to 958 CMR 11.13, shall forward the Patient's medical and treatment records relevant to the review and created by or in the possession or control of the RBPO or ACO, to the identified External Review Agency.

(a) In a non-expedited review, any such information shall be forwarded within three business days of receipt of the notification provided pursuant to 958 CMR 11.18.

(b) In an expedited review, any such information shall be forwarded within one business day of receipt of the notification provided pursuant to 958 CMR 11.18.

(2) The Patient or the Patient's Authorized Representative may submit additional medical evidence or other relevant information to the External Review Agency and also provide a copy to the RBPO or ACO.

(a) The Office of Patient Protection will notify the Patient or the Patient's Authorized Representative of the right to submit additional medical evidence or other relevant information in its communications with the Patient or Patient's Authorized Representative.

(b) In a non-expedited review, any such additional medical evidence or other relevant information shall be reviewed by the External Review Agency if received within five calendar days from the date of notice from the Office of Patient Protection. Any such additional medical evidence or other relevant information may be reviewed by the External Review Agency if received more than five calendar days from the date of the notice from the Office of Patient Protection, but before the decision is rendered.

(c) In an expedited review, any such additional medical evidence or other relevant information shall be reviewed by the External Review Agency if received within 24 hours of the Patient's or Patient's Authorized Representative's filing of the request for expedited external review. Any such additional medical evidence or other relevant information may be reviewed by the External Review Agency if received more than 24 hours after the Patient's or Patient's Authorized Representative's filing of the request for expedited external review but before the decision is rendered.

11.20: Conflict of Interest

(1) External review agencies shall ensure that the External Review Agency and the external reviewers assigned to any external review:

(a) Shall have no Material Professional, Material Familial, or Financial Affiliation with any party that is the subject of the review; and

(b) Shall have no Material Professional, Material Familial or Financial Affiliation with any party that participated in the denial or restriction that is the subject of review.

(2) The Office of Patient Protection shall not contract with any External Review Agency which owns or controls, or is owned or controlled by a Carrier or utilization review organization or an RBPO or ACO, the sponsor of a group health plan, a trade association plans or issuers, or a trade association of Health Care Providers.

(3) Decisions by the External Review Agency regarding the hiring, compensation, termination, promotion, or other similar matters with respect to the external reviewer must not be based upon the likelihood that that the external reviewer will support the denial or restriction of care.

11.21: Decisions and Notice

(1) The External Review Agency shall determine whether the requested referral, treatment or service that is the subject of the review is likely to produce a more clinically beneficial outcome for the Patient than the referral, treatment or service recommended by the RBPO or ACO.

(2) The External Review Agency shall base its determination whether the requested referral, treatment or service is likely to produce a more clinically beneficial outcome for the Patient on a review of the following factors:

(a) The Patient's clinical history, including prior clinical relationships;

(b) The availability, within the RBPO or ACO, of a Health Care Professional with the appropriate training and experience to meet the particular health care needs of the Patient, including timely access;

(c) Generally accepted principles of professional medical practice;

11.21: continued

(d) The efficacy of the requested treatment or service, based on scientific evidence, professional standards and expert opinion, in improving health outcomes; and
(e) Other factors the External Review Agency considers relevant to the Patient's ability to access the requested referral, treatment, or service.

(3) The final decision of the External Review Agency shall be in writing and shall contain the following information:
(a) An analysis of the medical evidence and how the evidence supports the findings of the external reviewer;
(b) An explanation of why the requested referral, treatment or service was found or was not found to likely produce a more clinically beneficial outcome for the Patient than the referral, treatment or service recommended by the RBPO or ACO;
(c) A list of any medical literature or references relied upon in making the decision; and
(d) A statement that the decision is final and binding.

(4) The External Review Agency shall provide a final copy of the decision to the Patient, and the Patient's Authorized Representative and the RBPO or ACO. Where the Patient is a minor or person with a legal guardian, the External Review Agency shall provide the Patient's copy of the final decision to the Patient's parent or legal guardian.

(5) For non-expedited reviews, the External Review Agency shall issue its final disposition within 21 calendar days from its receipt of assignment from the Office of Patient Protection.

(6) For expedited reviews, the External Review Agency shall issue its final disposition within 72 hours of receipt of the assignment from the Office of Patient Protection.

(7) Each External Review Agency shall retain records of all external review requests, decisions, and notices for three years from the date of the final disposition, and shall make these records available upon request to the Office of Patient Protection.

(8) The decision of the External Review Agency shall be binding on the RBPO and the Patient, or the ACO and the Patient as to the matter that is the subject of the appeal. The decision does not prohibit the patient from requesting an internal appeal or requesting external review of a future decision of the RBPO or ACO pursuant to 958 CMR 11.00 based on materially different or changed relevant factors in 958 CMR 11.21(2).

(9) Upon a written request by the Patient, the Patient's Authorized Representative or the RBPO or ACO, and at the sole discretion of the Director of the Office of Patient Protection, the External Review Agency may be directed to retract and revise a decision only upon a finding of material procedural error or clear factual error which is evident on the face of the decision. Any such written request must be received by the Office of Patient Protection within seven calendar days of the date of receipt of the External Review Agency's final decision in order to be considered.

(10) If the External Review Agency overturns an RBPO or ACO decision in whole or in part, the RBPO or ACO shall notify the Patient within two business days of receipt of the written decision from the External Review Agency. Such notice shall:
(a) Acknowledge the decision of the External Review Agency;
(b) Advise the Patient of any additional procedures for obtaining the requested services; and
(c) Advise the Patient of the name and phone number of the person at the RBPO or ACO who will assist the Patient with obtaining the referral, treatment or service.

(11) The RBPO or ACO shall comply with the External Review Agency's decision.

11.22: Confidentiality

No RBPO or ACO or External Review Agency or external reviewer shall, except as specifically authorized by an appropriate release signed by a Patient or a Patient's Authorized Representative authorized by law, release medical and treatment information or other information obtained as part of an internal appeal or external review, except to the Office of Patient Protection and as otherwise authorized or required by law.

11.23: Reporting Requirements

(1) Each RBPO or ACO shall provide the following information to the Office of Patient Protection no later than April 1st of each year. Such information shall be submitted in a manner specified by the Office of Patient Protection or using a template or form developed by the Office of Patient Protection.

(a) A copy of the Patient notice used by the RBPO or ACO.

(b) A summary report of the Patient appeals received by the RBPO or ACO. Summary reports shall not include any information identifying Patients, but shall include the number of appeals and the resolutions of such appeals. Appeals shall be classified into the following categories of denials, restrictions or limitations:

1. Referrals to Providers not affiliated with the RBPO or ACO.
2. Type or intensity of treatment or services.
3. Denials or restrictions on timely access to treatment or services.
4. Other. For appeals categorized as "other", the RBPO or ACO shall include a brief description of the Patient's concern.

(c) A description of the RBPO's or ACO's appeals process to resolve Patient appeals, including the title and clinical background of the Internal Reviewer(s);

(d) A description or example of a written resolution of an appeal upholding the RBPO or ACO decision and a description or example of a written resolution of an appeal overturning the RBPO or ACO decision.

(e) The name, telephone number and email address of the person or persons within the RBPO or ACO who will serve as the general contact for the Office of Patient Protection for internal appeals and external reviews. If this contact information changes, the RBPO or ACO shall provide the new information in writing to the Office of Patient Protection within ten business days following the change.

(2) If a Patient concern is resolved at the point of care or service, either with clinical or administrative staff, then the RBPO or ACO is not required to report that concern as an internal appeal.

11.24: Severability

If any section or portion of a section of 958 CMR 11.00 or the applicability thereof is held invalid or unconstitutional by any court of competent jurisdiction, the remainder of 958 CMR 11.00 or the applicability thereof to other persons, entities, or circumstances shall not thereby be affected.

REGULATORY AUTHORITY

958 CMR 11.00: M.G.L. c. 176O, § 24; M.G.L. c. 6D, §§ 15 and 16.

NON-TEXT PAGE