

20th INTERNATIONAL MEETING ON RADIATION PROCESSING | BANGKOK, THAILAND | NOVEMBER 7-11, 2022



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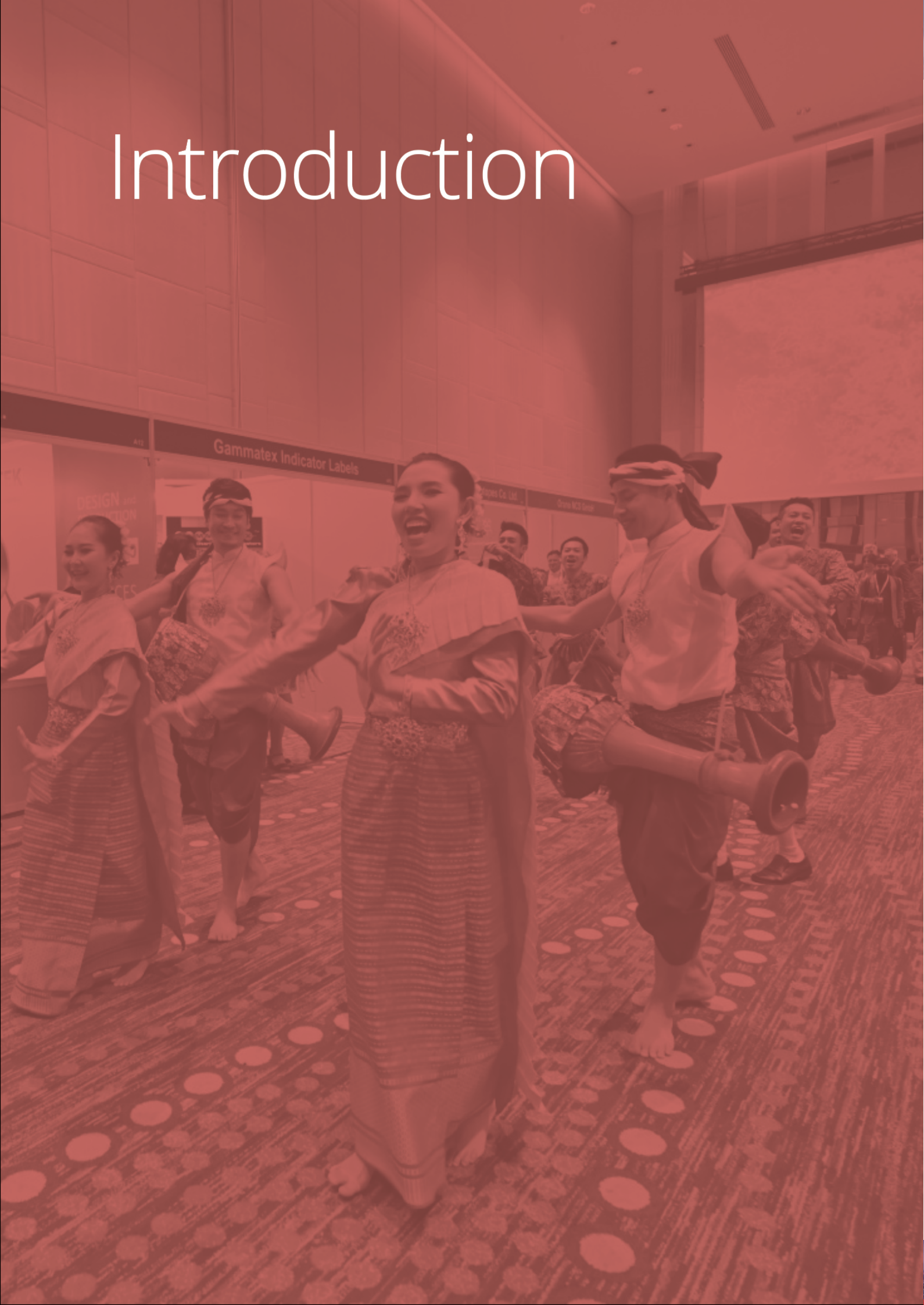
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Introduction



IMRP20 FOR THE GLOBAL IRRADIATION COMMUNITY

The 20th International Meeting on Radiation Processing (IMRP20) organised by the International Irradiation Association (iia) was held in Bangkok, Thailand on November 7-11, 2022.

Due to the Covid-19 pandemic, IMRP20 came three and a half years after IMRP19. Participants were enthusiastic about meeting again after such a long time. The five days of the conference were rich in contents and activities and this document can only capture some of them. However, we hope that the readers will find it to be a valuable summary and reflection of the state of radiation processing in 2022.

The iia thanks all contributors to this document including the session Chairs and Moderators that provided a summary of their sessions and panel discussions. Some of the summaries supplied may have been modified slightly for clarity and impartiality.

The members of the Program Committee were:

- Yves Hénon, Chair
- Xavier Coqueret, Université Reims Champagne Ardennes
- Bart Croonenborghs, Sterigenics
- Philippe Dethier, Mevex
- Michel Hervé, STERIS AST
- Anil Kohli
- Thawatchai Onjun, TINT
- Ben Reilly, Steritech
- Richard Wiens, Nordion
- Yin Yuji, CIRC

The program of oral presentations was divided into two days of plenary sessions (on the first and fourth days) and three dedicated forums of six sessions each (on the second and third days).



Monday, Nov 7	Tuesday, Nov 8			Wednesday, Nov 9			Thursday, Nov 10	Friday, Nov 11	
Opening & Welcome	Radiation Technology Forum	Radiation Sterilization Forum	Phyto-sanitary Irradiation Forum	Radiation Technology Forum	Radiation Sterilization Forum	Phyto-sanitary Irradiation Forum	Plenary: Environmental Applications	iia/WINS Workshop on the Security of Gamma Irradiation Facilities	Technical Visits: STERIS & TINT
Plenary: Dosimetry & Modelling				Plenary: Diversity in Applications					
Plenary: Radiation Chemistry				Posters - Exhibition - Networking			Plenary: Radiation Processing		
Plenary: Advanced Polymers							Awards & Closing iia General Assembly		

Forum Session	1	2	3	4	5	6
	Gamma			EB-X		
Radiation Technology	Cobalt-60 Supply Chain	Gamma Irradiators Technology	Gamma Safety and Security Panel Discussion	Progress in EB-X Technology	Implementing EB-X Technology	Panel: EB-X Use, Trends & Challenges
Radiation Sterilization	Sterilization Standards (AAMI)	Competency in Sterilization (SfSAP)	Product Qualification	Process Control	Biopharma & Materials	Panel Discussions
Phytosanitary Irradiation	Commercial Trade	Post-Harvest	Treatment Efficacy	Infrastructure & Technology	Regulatory Developments	Panel: Growing Use of PI

For the second time, a training course for students and young professionals took place during the week before the conference. In addition, IMRP20 also included a professional exhibition, posters presentations and several side events giving participants the opportunity to network. On the fifth day, a workshop was arranged along with tours of two irradiation facilities.

KEY MESSAGES FROM THE PROGRAM

The success and growth of radiation processing continues. In most regions, demand is exceeding processing capacity and this is especially true for the largest volumes contracted, i.e. the sterilisation of single use healthcare products. High energy and high power accelerators, many of which will be capable of producing X-Rays, are being installed to partly fill the gap, but demand for such equipment also appears to exceed supply, at least in the short to mid-term.



It is in the field of polymers, especially natural polymers, that research is the most active, particularly in the Asia-Pacific region. While there is no major new high volume application in sight, commercial applications are ever more diverse as the example of irradiation of cannabis inflorescences shows.

Irradiation offers interesting technical solutions to improve the quality of waters and air and to remedy environmental problems such as harmful algae blooms. Two municipalities in India are using gamma irradiation for dry sludge treatment. Economic feasibility remains the main obstacle to a wider application.

Many sessions of the program included a presentation on modelling. Modelling offers an affordable way to process a large amount of data, to test a system or a configuration before building it, and to answer the “what if...” questions. Modelling is now used in the optimisation of biological shielding and dose distribution studies for qualification exercises.

The current difficulties regarding the supply of cobalt-60 were a main topic of the gamma irradiation sessions. Nordion, the main supplier, is taking various initiatives to increase cobalt-60 production. Russia, China and Argentina are keeping their production at reasonably consistent levels and India, who produces mainly for the domestic market, will soon double its production volume. With demand for sterilisation expected to double over time, the availability of all sterilisation technologies, including ethylene oxide, remains critical. Accelerators will partly contribute to meeting the capacity challenge. Conversion to accelerated electrons and X-Rays from currently used sterilisation modalities is costly and there are bottlenecks in the number of machines that can be installed.

The Radiation Sterilisation Forum benefited from the involvement of the Association for the Advancement of Medical Instrumentation (AAMI) and the Society for Sterility Assurance Professionals (SfSAP). These and other organisations now cooperate more closely to help medical device manufacturers meet increasingly complex regulatory requirements. New industry standards being developed to address these challenges demonstrate the benefit of collaboration. The sessions reflected a growing interest in the effects of X-Rays on materials and in the use of modelling for process qualification.

The Phytosanitary Irradiation Forum was the first international event on the topic since 2019. The use of irradiation as a phytosanitary treatment has steadily grown, to an estimated 70,000 tons in 2022. However, it is still an underused irradiation application and not used at all in some areas. Establishing more generic doses and reinforcing international collaboration on regulations and product pathways will foster further trade growth. The fact that some countries remain closed to the import of fresh irradiated produce remains an important obstacle for expansion.



SPONSORS AND EXHIBITORS

The IMRP20 experience was enhanced considerably by the organisations that sponsored and exhibited at the meeting.

The success and long term viability of IMRP is made possible by the support of sponsors. The iia particularly thanks STERIS and MEVEX that were Regional Sponsors of IMRP20 and made the largest financial contribution to the meeting. Thanks also go to CGN, IBA, Nordion and Sterigenics that were top tier IMRP20 Ruby Partners and to all other sponsoring organisations.

IMRP is a unique opportunity for suppliers to the radiation processing industry to meet their customers and prospects from around the world in a single place over several days. 19 organisations chose to exhibit at IMRP20 and promote a wide range of products and services to the international audience.

For further details of the IMRP20 sponsors and exhibitors please see Appendix 6 (Directory of Sponsors and Exhibitors).

REGIONAL SPONSORS



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IAEA at IMRP

The IAEA has NGO status with the IAEA and for many years the Agency has been associated with IMRP. At IMRP20, the IAEA graciously supported seven students and researchers from IAEA member states to attend the Pre-IMRP Training Course as well as the conference. These seven students and researchers were:

- Mr. Anh Quoc Le (Vietnam)
- Ms. Ganga Madurakanthi (Sri Lanka)
- Mr. Phonesavanh Lathdavong (Laos)
- Ms. Zürah Cinar Esin (Turkey)
- Mr. Alvin Gallardo (Philippines)
- Dr. Jordan F. Madrid (Philippines)
- Dr. Subhendu Ray Chowdhury (India)

This support enables the science and technology of radiation processing to be shared widely within IAEA Member States and the broader academic community.

The Agency also had three delegates from the Department of Nuclear Sciences and Applications present at the conference:

- Mr. Bumsoo Han and Ms. Valeria Starovoitova from the Division of Physical and Chemical Sciences.
- Ms. Vanessa Simoes Dias de Castro, of the Insect Pest Control Laboratory of the Joint FAO/IAEA Centre of Nuclear Techniques in Food and Agriculture;



The program





IMRP20 PRE-CONFERENCE TRAINING COURSE
**RADIATION PROCESSING FOR ADVANCED
AND RENEWABLE MATERIALS – FROM
BASICS TO INDUSTRIALIZATION**

Kasetsart University, Bangkok, Thailand
November 2-4, 2022



Presented together with the 20th International Meeting on Radiation Processing

PRE-IMRP TRAINING COURSE IN RADIATION PROCESSING AT KASETSART UNIVERSITY

The 3-day long training course was organised by Prof. Wanvimol Phasanpan (Kasetsart University, Thailand) and Prof. Xavier Coqueret (University Reims Champagne Ardennes, France) in association with iia. The President of Kasetsart University and the Dean of the Faculty of Science graciously opened the course.



The course consisted of 14 lectures and 2 demonstrations covering the following topics:

1. Basics of radiation processing

- Radiation-matter interaction, penetration of radiation
- Dose control and dosimetry
- Radiation processing technologies (low and high energies)
- Overview of commercial industrial applications

2. Fundamental radiation chemistry

- Ionisation of matter, primary species, timeframe, mechanism
- Quantification of radiation effects: G-values
- Kinetic studies based on pulse radiolysis
- Monitoring of radiation-induced reactions

3. Radiation cross-linking of thermoplastics and elastomers

- Principles and applications
- Determination of $G(X)$ and $G(S)$, theoretical models, analytics
- Ageing of materials after irradiation

4. Radiation-induced polymerization

- Basics of polymerization chemistry / analytics
- Curing by cross-linking polymerization (inks, coatings, compos.)
- Radiation-induced graft polymerization (basics, applications)

5. Advanced applications

- Radiation-induced formation of hydrogels and nanogels
- Radiolytic synthesis of metal nanoparticles,
- Other nanostructured materials
- Natural polymers (polysaccharides, proteins, lignocellulosic products)
- Environmental protection and remediation

6. Biological effects of radiation processing

- Basics on effects of ionising radiation on living organisms
- Sterilisation of healthcare products
- Food and agricultural applications



Lectures were given by:

- Xavier Coqueret (University Reims Champagne Ardennes, France)
- Piotr Ulanski (Lodz University, Poland)
- Wanvimol Phasanpan (Kasetsart University, Thailand)
- Kasinee Hemvichian (TINT, Thailand)
- Bumsoo Han (IAEA)
- Yves Henon (iia)
- Nishad Durandhar (Microtrol, India)

The oral presentations were complemented by demonstrations in the laboratories of the university and a visit to the irradiation facilities of the Thailand Institute of Nuclear Technology.



The course was attended by 20 graduate students (MSc, PhD) and young professionals from 13 countries: Argentina, Germany, India, Indonesia, Italy, Laos, Philippines, South Africa, Sri Lanka, Thailand, Turkey, UK, and Vietnam.





The attendees were thus given a comprehensive insight into, and understanding of, the radiation processing of advanced and renewable materials. As at IMRP19 in Strasbourg, France, nearly all participants also attended the main conference during the following week and it was obvious that the course had created new friendships that should last beyond the event. Through the complementarity of their scientific and technological contents, synergies are created between the course and the main conference. It is hoped that future leaders for the radiation processing research and industry will emerge from the group.

CONFERENCE OPENING SESSION

The opening of IMRP20 was preceded by a short film that highlighted the journey of IMRP from Puerto Rico in 1976 to Thailand in 2022. The film also remembered some of the organisations that played an important part in the early years of irradiation and departed friends from science and industry.

The Chair of the IMRP20 Organising Committee, Martin Comben, formally opened IMRP20 by highlighting how the meeting brings together all the right people to take on the challenges and opportunities that face radiation processing and move the technologies,



business and science forward. The Regional Sponsors, STERIS and MEVEX, were thanked for their significant contribution to IMRP20 along with the other sponsors that supported the meeting. The Thailand Institute of Nuclear Technology (TINT) were thanked for their support with local arrangements and the IAEA were thanked for their financial contribution that enabled iia to support 7 students and researchers to attend IMRP and the pre-conference training course.

Mike Eaton, on behalf of Regional Sponsor STERIS, welcomed participants to IMRP20 and Thailand. He followed by summarising a changing world and changing demands from users of irradiation brought about by vaccine supply pressure, shifts in global supply chains and other industry challenges leading to an increasing gap between irradiation capacity and demand. STERIS has responded by deploying greater X-Rays and expanding electron beam processing where possible, thereby reducing their reliance on a single source of sterilisation. Finally, he reinforced the role of IMRP in helping people and organisations stay relevant to the developments in industry through sharing information, creating alignment and facilitating networking and collaboration.

Dr. Thawatchai Onjun, Executive Director of TINT, and Dr. BumSoo Han of IAEA welcomed participants to IMRP20 and Thailand and spoke of the importance of irradiation and the value of radiation processing applications.

Paul Wynne, Chairman and Director of iia, started his review of the industry by paying tribute to John Masefield and his great contribution to radiation processing. He stated that the irradiation industry continues to have a positive impact on the lives of a significant proportion of the global population, yet few politicians and even fewer members of the public are aware of the importance of irradiation technologies. The future of radiation processing remains bright but not without challenges. It is regrettable that some markets or applications face challenges due to poorly informed or non-scientifically based laws or regulations and occasionally to the absence of an economic incentive or regulation to stimulate demand. Paul's key points were as follows:

- All irradiation technologies – gamma, EB and X-Rays are important and will remain so for the foreseeable future.
- In the short to medium term, users of gamma face capacity challenges but the non-irradiation technology EO faces different and potentially even greater challenges.
- The lead times to install additional irradiation capacity can be quite long and our industry needs to acquire new skills to help in the selection and running of EB/X-Rays equipment.
- In the coming few years available sterilisation capacity may struggle to cope with increasing demand from the healthcare market.
- It is unlikely that significant sterilisation capacity, using high energy accelerators, will transfer inhouse, at least in the short term.
- The impact of global energy insecurity is a new concern that needs to be considered.
- The increasing age of those in our community is also of concern.



Paul concluded his speech by requesting all industry participants to avoid negativity that creates tension and division and to do all in our power to maintain the precious spirit of friendship and collaboration that has served us well.

The full text of Paul Wynne's opening statement is given in Appendix 1.

The Chair of the IMRP20 Programme Committee, Yves Hénon, presented a review of the history of IMRP and how meetings have evolved since 1976. He underlined the challenges of creating the IMRP20 program in times of a global pandemic and the pleasure of finally having the irradiation community together again. Yves thanked the members of the Programme Committee for their time and efforts and for creating a rich program with plenary sessions, three parallel focussed forums, panel discussions, Q&A, online polling, posters, awards, a training course, workshop and technical tours.

PLENARY SESSIONS

Dosimetry and modelling (Plenary 2)

Moderator: Florent Kuntz, Aerial, Strasbourg, France

In introduction to the session, the moderator went back on the history of high dose dosimetry dedicated to radiation processing. Recent innovations in the magnetic resonance detectors coupled to alanine pellets (NIST) and on low energy electron beam calorimetry (LEEB) (Risö DTU) were presented. Both new methods have interesting advantages, such as reduced measurement time for alanine and reduced uncertainty for LEEB calorimetry.

Monte Carlo simulation/modelling occupied a large part of this session in light of the significant developments currently taking place.

Compared to similar existing software, PUFFIn (PNNL) will be easier to use and require much less work in training and obtaining dose results; it is hoped that this will attract many more users who would otherwise not use such software.

Triple Ring Technologies presented the development of a simulation tool that provides an easy interface for using CAD models and significantly speeds up simulation times. First results show a significant acceleration of simulation times using modern GPU (Graphics Processing Unit) cards.

Finally, Aerial presented the benefits of Monte Carlo simulations of low and high energy electron beam sterilisation of dose mappings using CT images, based on experience gained in radiation therapy and radiation imaging. High-resolution 3D images of dose distributions within the products were presented. This new approach, which results in a large amount of dose information available in this simulation model, provides a fresh look at the interpretation of data in terms of minimum/maximum dose zones and dose uniformity using statistical analysis.



Radiation chemistry (Plenary 3)

Moderator: Prof. Xavier Coqueret, Université de Reims Champagne Ardenne, France

Prof. O. Güven, IMRP laureate, reviewed the evolution of radiation chemistry over the past 80 years and emphasised the progress in the tools that are used. Early developments of radiation processing were rapidly followed by industrial applications because of the unique properties of some irradiated polymers. Researchers joined efforts to establish radiation chemistry as a new discipline connected to other scientific and application areas. Covering selected milestones, Prof. Güven highlighted the contributions of the pioneers and subsequent generations. He concluded his talk with a selection of current and future applications of polymers radiation processing.

Nicolas Ludwik reported on a comparison of EB and X-Rays irradiation applied to a series of representative thermoplastics treated under various conditions of dose level, dose rate, and temperature. A variety of physico-chemical and mechanical features were characterised on the irradiated specimens. Besides the constitution of a broad database which will be enriched by further experiments conducted within Team Nablo, the conclusions drawn from this study confirmed the prime effects of radiation dose and of temperature during irradiation, whereas the dose rate did not seem to influence the effects on properties. Next steps will address the influence of oxidative environments during irradiation. This presentation was part of the work carried out by Team Nablo.

Radiation-induced cross-linking of suitable hydrosoluble polymers is a very effective method for producing hydrogels. Slavomir Kadlubowski clearly described the main experimental factors controlling the characteristic dimensions of the formed hydrogels, from nanometric single polymer chains to swollen microparticles and macrogels. Based on an analysis of a complex set of reactions mediated by free radical species, simulation methods such as the Dynamic Liquid Lattice were presented as a reliable means to evaluate the rate constants of reactions occurring between the polymeric components and the reactive intermediates produced upon irradiation. Comparison between simulations and experimental data obtained through various parametric studies confirmed the relevance and overall accuracy of the theoretical model. Reactions conducted in presence of specific scavengers however suggest the need for additional side-reactions to be taken into account to fit more precisely the plots describing the observed changes. The results acquired so far already point to the strong potential of this type of approach for designing optimised polymer-based materials.

The use of radiation in synthetic organic chemistry is a little-explored and certainly an under-exploited opportunity to produce value-added chemicals by clean activation processes. The paper presented by J. W. Lee reported on the radiation-mediated formation of a monosaccharide - terpene conjugate starting from solutions of geraniol and glucose. Both electron beam and gamma irradiation yield the desired geranyl beta-D-glucopyranoside in high yield with a similar efficiency. This synthetic process is an attractive alternative to the



extraction from *R. sachalinensis* roots of a conjugate product of interest for cosmetic applications.

In his overview of the recent activities conducted at the Philippines Nuclear Research Institute, Jordan Madrid provided a unique series of examples illustrating the recent and upcoming developments mentioned by Prof. O. Güven. A variety of well-controlled processes were applied to decrease the molecular weight of carrageenan, the obtained product exhibiting excellent activity as a plant growth promoter now commercialised to domestic farmers. Other applications in development include the use of polysaccharide-based hydrogel wound dressing and hemostatic agents, heavy metal adsorbents immobilised on natural fibres for the de-pollution of liquid industrial effluents, and light-weight composites materials reinforced with radiation-modified natural fibres to enhance their mechanical performances.

The session demonstrated the vitality of radiation chemistry and outlined future challenges as well as new potentialities in synthetic organic chemistry, basic diffusion-controlled kinetics of free radicals and new openings for advanced materials addressing current societal and environmental needs.

Advanced polymers (Plenary 4)

Moderator: Prof. Olgun Guven, Hacettepe University, Ankara, Turkey

In his overview of trends in radiation chemistry and technology of polymers Dr. P. Ulanski emphasised the needs and expectations of the society under the terms *going green, small, smart and flexible* in developing new materials. He presented a survey of recent developments in radiation crosslinking of natural polymers, radiation-assisted recycling of plastic waste, radiation modification of polymers for environmental protection. He further went on to discuss recent developments in biomedical applications of radiation synthesised functional nanogels for local internal radiotherapy for drug transport into the cells. Radiation grafting for the preparation of advanced membranes was shown by the modification of surfaces for cell sheet engineering.

Dr. W. Pasanphan described the synthesis of a super water absorbent by radiation-induced graft polymerization of acrylic acid onto cellulose. Detailed analysis of swelling behaviour of absorbents was reported as a function of particle size and pH of the medium. Lab-scale preparation was successfully upscaled for the production of large volumes of super water absorbents which were later applied for the growth promotion of baby corn in the field.

Dr. S. Chowdhury's presentation was quite opposite to the scope of the previous paper, namely converting a fully hydrophilic substance into a hydrophobic one. The idea was to prepare superhydrophobic cotton as a new material with multiple potential applications. The main aim of removing organic toxic materials and oils from aqueous media was successfully demonstrated. Cotton cellulose has been used as the substrate for radiation



grafting of decyl methacrylate to impart superhydrophobicity. Commercial viability of the process was shown by considering the availability and the cost of materials and the method used.

Reactive processing polymers are generally performed by using chemical additives. Dr. M. Müller introduced the concept of using low energy electron beams during melt compounding of polymers. A continuous electron-induced reactive processing system was described with an application on a biopolymer mixture of PLA/PCL. The compatibility of these two polymers was shown to be improved with enhanced toughness. Usable dose range determined as less than 40 kGy makes this process also economically attractive.

Dr. N. Girard-Perier in her presentation tried to find an answer to the question of whether gamma, e-beam and X-Rays interact equivalently with a polymeric material. They investigated the effect of radiation from the point of view of micro (ESR, determination of extractables), macro (Thermal analysis, DSC, viscoelasticity, DMA), and product levels (Biocompatibility, ISO 1093-5, and functional tests) on a PE/EVOH/PE packaging film. They concluded that the impact of ionising radiation is equivalent to an absorbed dose of 50kGy for the film investigated.

The presentations made in this session clearly demonstrated the power and versatile applications of ionising radiation, more explicitly e-beams in the modification of polymers. The examples covered such a wide range from natural polymers to synthetic packaging films, nanogels to cell sheets, super hydrophilicity to super hydrophobicity, agriculture to biopolymers, and incorporation of electron accelerators into conventional polymer processing systems.

Environmental applications (Plenary 5)

Moderator: Rob Edgecock, University of Huddersfield, Huddersfield, United Kingdom

The environment is an area of particular concern and importance for the future and also one in which radiation technology might have a significant impact. It is also an area with challenges that need to be overcome before the potential of radiation can be fully exploited. These include the conservative nature of many companies working in this area and the negative impression that many organisations with an interest in environmental matters have of ionising radiation.

This session consisted of three presentations, two on new studies of the use of electron beams and one on production systems using gamma radiation for the treatment of sewage sludge. The first of the new studies was an initiative from the IAEA on the use of radiation technology for the recycling of plastic waste presented by Dr Bum Soo Han (IAEA). Dr Han demonstrated the very negative impact that both bulk and microplastics are already having on the environment. He explained that the new IAEA initiative on the use of radiation with plastics will help to deal with this problem in two ways. The first will be in the monitoring of plastic pollution in coastal and marine ecosystems. The second will be as a complement to



traditional mechanical and chemical recycling methods. This will include sorting mechanically treated plastic waste according to polymer type, breaking down plastic polymers into smaller components to be used as raw materials for new plastic products, treating plastic so that it can be amalgamated with other material to make more durable products and converting plastic into fuel and feedstocks through radiolysis.

Prof Suresh D. Pillai showed the results of recent studies of the use of electron beams to treat the cyanotoxins released by cyanobacterial blooms. These pose a risk to animal and human health if ingested and concerns over the public health implications of these toxins in water supplies have increased due to rising occurrence of these blooms. *Microcystis aeruginosa* is a common cyanobacterium associated with these blooms and is responsible for producing the potent cyclic hepatotoxin microcystin-LR (MC-LR). The studies done indicate that doses as low as 2 kGy are lethal to *M. aeruginosa* cells and induce cell lysis. Even lower doses are required for degradation of the parent MC-LR toxin. However, it was observed that there is a delay in cell lysis after irradiation where *M. aeruginosa* cells may still be metabolically active and able to synthesise microcystin. Further studies are required to understand the cellular responses after treatment.

Prof Lalit Varshney described two production systems using gamma rays to treat dry city sludge before its use on agricultural land. He explained that there is currently an imbalance in fertiliser use, with a reduction in organic fertiliser leading to a reduction in soil quality. He showed that dry sewage sludge hygienised with gamma rays is a valuable source of organic fertiliser meeting all the requirements in India and elsewhere. He described how this has been implemented for two cities, Ahmedabad and Indore, which are the appropriate size for gamma sources. He further explained that it is possible to treat the sludge from larger cities but said that this would require the use of electron beams. This work is a very important demonstration that radiation can be used for this application.

Diversity in applications (Plenary 6)

Moderator: Yves Henon, *iia*, United Kingdom

The session covered tools and applications that had not been addressed during the rest of the conference and demonstrated the incredible diversity in beneficial uses of irradiation. Controlling microbial contamination of dried food ingredients is a classic application of irradiation but the Swiss food engineering group Bühler is offering a new approach with a compact machine using low energy electrons. 'Laatu' is the commercial name of a self-shielded machine with a small footprint that has now been commercialised for spice processing and validated for 5-log reduction of *Salmonella*.

Irradiation is a tool used for the attenuation of vaccines. A scientist from the Mahidol University in Bangkok presented the work still under development to create a vaccine with inactivated zika virus which is especially dangerous for pregnant women.



Dr Simone Schopf gave some details on several potential applications of low energy electron irradiation (LEEI) being investigated by the Fraunhofer FEP Institute in Germany. These include bioleaching through LEEI-stimulated bacteria, interaction with immune cells, selective surface modification, and sterilisation of glutaraldehyde-free preparation of biological tissues.

Irradiation of cannabis is a growing commercial application as more countries are liberalising the use of medical cannabis. Dr Suwimol of TINT presented the work carried out in Thailand confirming the absence of effects of gamma rays, electron beams and X-rays on the main characteristics of inflorescences. The session was concluded by a review of an application that has brought immense benefits to agricultural production and trade. Dr Vanessa Dias (IAEA) gave an excellent overview of the Sterile Insect Technique, its principles, its applications, and its economic benefits.

RADIATION TECHNOLOGY FORUM

Cobalt-60 supply chain (Session Tech 1)

Moderator: Richard Wiens, Nordion, Ottawa, Canada

The session focused on recent developments in the global supply of Cobalt-60. It was acknowledged that the supply of cobalt-60 continues to grow in support of growing demand that is particularly due to an increase in medical device sterilisation requirements. Global efforts to increase supply are paying off, particularly with the recent resurgence of interest in nuclear power – which also provides the vast majority of cobalt-60 – as part of the solution towards fighting climate change. The three speakers focused on different aspects of the supply chain.

Corby Nicholson, Director of Operations at Nordion, shared steps that are being taken to improve the overall efficiency of the supply chain. These include an increase in recycling, made possible, in part, by Nordion's investment in new production infrastructure such as a dedicated, specialised hot cell for spent source recovery, as well as expansion of transportation capability through the use of Shipper-Owned Containers (SOC) and customised flat racks. Corby also detailed a new source design, the R1860, which seeks to further increase the use of lower activity sources while optimising rack space through a consolidation approach. There was also a reference to development of machine-learning-based scheduling software as a way to make more effective use of installed curies.

Dr. Kris Passerba, Marketing Manager at Westinghouse, provided an update on the joint project with Nordion to develop technology for producing cobalt-60 in Pressurized Water Reactors (PWRs). This would provide considerable scalability for cobalt production, as over 75% of operating reactors worldwide are PWRs, including 65 alone in the U.S., which will be the focus for initial deployment. Although the overall approach to producing cobalt-60 is similar to that used for CANDUs and RBMKs (cobalt-59 targets inserted into the reactor to



absorb neutrons), PWRs present some unique operating conditions. The development of the technology is well under way, and several utilities have been engaged for implementation.

German Arambarri, Production Manager at Dioxitek SA, gave an overview of his company's capabilities, using cobalt from the recently refurbished Embalse reactor in Argentina, which has been producing cobalt since 1990, and will now continue to produce for the next 25 years. The reactor re-started production in 2021 and is able to produce approximately 4.5 MCi for each 18 month operating cycle. Dioxitek operates a facility in Ezeiza, which includes one hot cell and two pools for manufacturing several different cobalt-60 source configurations. Dioxitek, with their partner Nuclearis, has made a concerted effort to modernise the supply chain for cobalt-59 slugs, which are a strategic input to the process. Dioxitek is also working with their partner IMPSA to develop new transport containers for shipment of cobalt-60 sources.

Gamma irradiators technology (Session Tech 2)

Moderator: Daniel Perticaro, Ionics, Buenos Aires, Argentina

The moderator opened the session by highlighting the interest in solutions that improve the design, efficiency and range of applications for gamma irradiators.

Arjun Vas of Symec Engineers presented ideas for making irradiation of food products such as grains, onions, spices, fruits and vegetables more viable in India. The objective is to mitigate against issues such as the seasonal nature of these products, spoilage and waste, and the lack of logistics and regulatory framework. Challenges include the sheer volume of many products that require processing and the integration of irradiation into the other supply steps such as cold chain, sorting, grading, packaging and storage. Symec presented various irradiator conveyor and tote systems and integration solutions, case studies and business cases to address these challenges.

The French company TRAD Tests & Radiations presented their RayXpert 3D modelling and dose calculation software. This Monte Carlo software can be used for optimising the loading of cobalt-60 pencils in a source rack for optimum irradiator performance. The software is first used to precisely model the irradiator and the product which can then be marked with virtual dose points to be used for dose mapping or routine dosimetry. The source rack is then modelled with the individual cobalt-60 source positions and activities. Irradiation cycle scenarios are performed and the merged dose to product is calculated and easily visualised. The software can be used to predict dose to product and DUR, including prior to a cobalt-60 reload, and first studies show very good agreement between the software predicted dose and actual measured dose.

Chris Howard of Nordion presented on how scheduling can be used to improve gamma irradiator efficiency. Nordion has a large amount of historical data and has been studying how the scheduling process can be improved and standardised. An example of a simple



improvement is to adjust cycle times daily rather than monthly to allow for cobalt-60 decay – this alone can improve throughput by 0.5%, say 500 totes per year for a typical irradiator with a large mix of products.

Nordion has been developing software that enables easy analysis of data for schedulers and uses machine learning that can use historical data to accurately predict cycle times and provide suggestions to schedulers. A demo of this software showed the various user interfaces including the dashboard, orders to be scheduled, turnaround times, scheduling calendar and tools to provide feedback on, for example, excess dose. Next steps to use mathematical modelling to define the irradiator and the flow of product together with scheduling or simulated trial processing is under development.

Gamma safety and security (Session Tech 3)

Moderator: Martin Comben, iia, United Kingdom

The moderator started the session by explaining that the terms safety and security are often confused. The term ‘safety’ should be used to describe protection from accidents and ‘security’ used to describe protection from crime or deliberate harm. The way that organisations manage safety is very different to how it prepares for a malicious act. The irradiation industry has an exemplary safety and security record.

The regulation around security is some years behind those covering safety. However industry is highly engaged in security matters and there are high levels of collaboration, such as through the iia Gamma Working Group that has developed industry specific security best practice. Seven key areas of security were summarised and it was demonstrated how industry has adopted continuous improvement and has adapted to evolving risks and threats and adopted new methodologies and technologies as they become available.

Greg Fulford and David Jackson, representing the Gamma Irradiation Processing Alliance (GIPA), presented on Radiation Safety in Gamma Irradiation. The case for safety was presented along with the root cause of accidents, current regulation and the role of key individuals. Safety by design and safety systems and their preventative maintenance and routine testing were described.

Meghan Van Den Avyle, representing Sandia National Laboratories, presented a summary of their project to develop a new physical protection system for gamma irradiators. The objective is to develop a low cost non-proprietary system that will prevent the theft of cobalt-60 sources by introducing an obscurant into the irradiator pool water should there be a security incident at the irradiator. The obscurant would hide the cobalt-60 sources and prevent their removal. The project development and system testing was described along with the benefits and drawbacks of using air bubbles and Titania Aqueous Dispersant (TAD, white paint) as an obscurant. Issues relating to obscurant deployment and removal and the



impact of the obscurant on the cobalt-60 sources, as well as future project work were described.

The panellists for the discussion on 'The current status and future of gamma irradiation' were:

- Christoph Herkens (IONISOS),
- Vikram Kalia (Microtrol and IIAI),
- Daniel Perticaro (IONICS and ALATI),
- Mark Thomas (STERIS),
- Richard Wiens (Nordion).

It was acknowledged that gamma irradiation does have its challenges with a tightness in cobalt-60 supply and those relating to the use of radioactive material. It was noted that the other major sterilisation technology, ethylene oxide, is also under pressure in the US. Christoph Herkens advised that there is not the same level of pressure on ethylene oxide in Europe but he is keeping an eye on any developments. The volumes of manufactured medical devices and subsequently the demand for sterilisation is expected to approximately double over the next 10 years. The growing gap between capacity and demand will be challenging. Whilst transfer of product to e-beam and X-Rays goes part way to addressing this challenge, it is not possible to increase machine numbers at the rate required. Richard Wiens summarised the various Nordion initiatives to increase cobalt-60 production and was also able to confirm that Russian cobalt-60 production was continuing as previously reported. Vikram Kalia reported that availability of cobalt-60 is not an issue for Indian users due to local production that was forecast to double in the short term. Daniel Perticaro reported a similar situation in Latin America due to cobalt-60 production in Argentina. The conclusion was that all sterilisation technologies have their challenges and all will remain critical in meeting the global sterilisation needs.

Progress in EB-X technology (Session Tech 4)

Moderator: Philippe Dethier, STERIS, Mont Saint Guibert, Belgium

This session reviewed progress made with electron beam and X-Rays technologies. Arnaud Pierard from IBA presented their portfolio of e-beam and X-Rays irradiation solutions called Beyond. Beyond systems are powered by the Rhodotron and include conveying and control systems. IBA are working to improve the sustainability of Beyond by, for example, increasing the Rhodotron power efficiency by using solid state power sources and employing variable scanning. Thomas Kroc from FNAL in the US presented a number of designs for high-power linear accelerators using superconducting RF systems principally done at the US National Labs FNAL, SLAC and JLAB. The aim of these is to achieve high power, but with higher RF efficiency and a smaller size than other options. Studies are also underway on the use of



industrial modulators as power sources, rather than klystrons, due to the higher efficiency and much lower cost.

Greg Haycox from MEVEX presented KonnTRACK, a system for the overall control and monitoring of the sterilisation process using X-Rays, gamma and e-beam. The aim is to design and utilise the radiation system to optimise the delivery of the beam to increase efficiency and reduce costs. Ludovic Eychenne from TRAD introduced the use of the Monte Carlo technique for radiation processing and showed the advances made in modelling tools over the years. He demonstrated the advantages that modelling can bring to the industry, in particular better DUR and improved validation of the process. The final presentation in this session was given by Alexander Murokh of RadiaBeam. He showed the evolution of the company into the radiation processing industry, the development of their high power systems and reviewed some use cases on custom Linear Accelerator development for specific projects with unique needs.

Implementing EB-X technology (Session Tech 5)

Moderator: Jeremy Brison, IBA Industrial, Belgium

The Tech-5 session focused on the practical implementation of e-beam and X-Rays technologies in the real world. As an introduction, the moderator showed the progress in the number of e-beam and X-Rays projects over time, which shows an accelerating increase of the installed beam power in the coming years. The figure also shows that X-Rays penetration is gradually increasing from a few percent to almost fifty percent of the installed base power in 2030. Does that mean that all barriers to adoption have suddenly disappeared, or is it due to other modalities facing a temporary stress that could be resolved in the near future? As an example, the gap in data comparing modalities was identified as an improvement needed at the last IMRP; did we make progress as a community?

The first answer is provided by Team Nablo lead by Mark Murphy, and represented by Professor Suresh Pillai on the stage. The presentation demonstrated that several scientific studies are now available to compare gamma, EB and X-Rays on relevant medical devices and raw materials. Measurable differences were observed between modalities, but these changes are minimal. Remarkable effects are mostly due to dose and dose rate effects on polycarbonate and polyvinyl chloride (PVC) polymers, for which e-beam was the most yellowing. The presentation also showed examples of DURs obtained for 10 commercial products in boxes, illustrating the viability of e-beam for many products. Only one product required repackaging. Finally, a new simple Monte Carlo based tool, PUFFIn, was presented. The tool is very accessible and can be used to verify the dose profiles in 3D in any geometry.

In the second presentation, Vanessa Vargas from Sandia Lab presented two surveys about the acceptance and the usage of e-beam and X-Rays as an alternative to cobalt-60. The presentation helped to understand the evolution of drivers and impediments to the adoption of e-beam and X-Rays for both medical device sterilisation and food applications.



The presentation showed that regulation is still a concern in terms of complexity and cost for sterilisation. The complexity of the technology is still a burden as well. For food application, the results were too varied to reach a clear conclusion, even if equipment and start-up costs seemed to be a major concern.

To follow, Samuel Dorey from Sartorius presented an extensive perspective on the implementation of X-Rays for single use bioprocess system sterilisation. The presentation nicely represented all the challenges addressed by the industry, covering all aspects of regulatory, material science, process equivalence, customer acceptance, and finally education and training. A great team spirit was demonstrated by the BPSA members to address the business continuity of their industry.

Finally, a joint presentation was given by Eric Beers from MEVEX and Murray Lynch from Steritech to illustrate a successful implementation a versatile e-beam and X-Rays duo facility in Australia. The presentation nicely showed how the complementary approach of an equipment manufacturer and a local business and political leader resulted in a very successful facility, and a technical and business reference for our industry. Eric explained the design of the accelerators and the pallet conveyor, which allows pallets as well as boxes on special trays.

The session was concluded by an open panel discussion, in which presenters exchanged positively on the future of accelerator-based irradiation solutions and businesses.

Panel discussion: EB-X use/ trends and challenges (Session Tech 6)

Moderator: Philippe Dethier, STERIS, Mont Saint Guibert, Belgium

Panellists:

- Brian McEvoy - STERIS
- John Schlecht - Sterigenics
- Larry Nichols - Steri-Tek
- Thomas Kroc - Fermilab
- Eric Beers - MEVEX
- Yunli Liu - CGN Dasheng
- Thomas Servais - IBA

The panellists were asked about several topics on the trends and challenges of accelerator-based systems. It was widely accepted that the X-Rays market is growing quickly mainly driven by the need for more processing capacity to cope with the growing medical device industry. E-beam sterilisation is growing steadily, and food irradiation is still at its infancy but gaining more and more importance. China was identified as a strong market with hundreds of accelerators sold every year. In Europe and North America, the main accelerator technologies for high energy application are linear and recirculating RF accelerators. Developments are still ongoing when it comes to superconducting radio



frequency (SRF) accelerators. Manufacturers recognized that the situation today is much more challenging than 5 or 10 years ago in terms of manufacturing planning. Manufacturers had to invest into manufacturing capabilities to cope with the demand linked to the growth with X-Rays systems. Service providers highlighted that a big effort is being put on revalidating gamma products to X-Rays. Some complex products such as implants are particularly challenging to revalidate. Reducing downtime was one of the most important needs for the users of accelerator-based systems.

In-line accelerators were identified as a potential application, but manufacturers highlighted the challenge in designing a standard in-line accelerator system. Every in-line system would require customization in the product handling design, making standardisation almost impossible and leading to high-cost systems.



RADIATION STERILISATION FORUM

Sterilisation standards today and tomorrow (Session Rad-Ster 1)

Moderator: Byron Lambert, Abbot Laboratories, USA

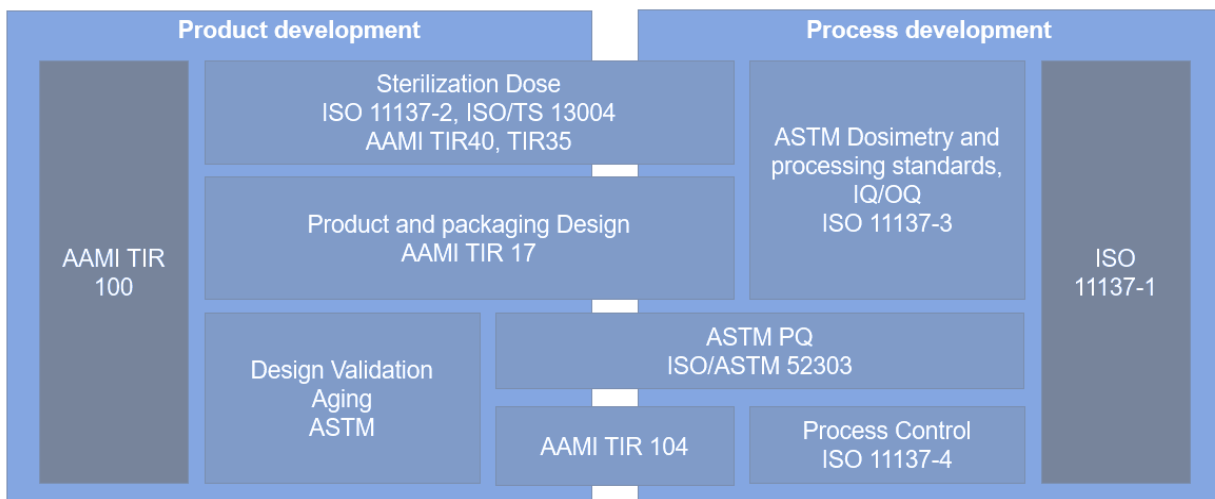
Byron Lambert highlighted the contribution AAMI. Developing standards is a major part of AAMI with a primary focus on cooperation across the industry and cross-functional collaboration to achieve their goals.

Amanda Benedict, AAMI, VP Standards, presented *The Global Standardization and Harmonization Imperative*. AAMI is leading ISO move toward calculation tools for ISO 11137-2 radiation sterilisation standard dose establishment methods through implementation of one for AAMI TIR 76, Method VD_{max}^{SD-S} calculation tool. AAMI is also implementing new pathways for providing information to the industry, Consensus Reports. This was used during Covid some ten times.

An overview of ISO Technical Committee 198, *Sterilization of health care products*, was provided for context for the Working Group that develops radiation sterilisation standards. The standards are harmonised with CEN/TC 204 and have a liaison with ISO/TC 85 and ASTM. Ms. Benedict closed by calling participants to participate in the standards development process.

Emily Craven, Boston Scientific, Global Sterility Assurance Director, elaborated on the synergistic role of ISO, AAMI and ASTM standards. In general, ASTM standards provide the specific 'how to' methods to comply with ISO requirements. Several examples for the roadmap from requirements to guidance (ISO) to methods (ASTM) were provided.

Interrelationship of standards for product development and process development:



The strategy for ISO 11137 radiation sterilisation standards was reviewed and progress reported. This includes: 1) the promotion of all Method VD_{max} doses between 15 and 35 kGy at 2.5 kGy intervals to ISO standards; 2) collaborate with ASTM to normatively reference

ASTM standards within ISO documents (foundational for future revision of 11137-3 and -4); and the current expansive project to revise 11137-1. Forthcoming Part 1 changes were envisioned to be:

- The allowable limits for the assessment of potential induced radioactivity increased to 11 MeV for electrons and 7.5 MeV for X-rays
- Language has been added that will further enable parametric release
- The section on transfer of maximum and minimum dose has been simplified to align with AAMI TIR 104
- More flexibility has been added to the interval of time between quarterly dose audits, e.g. no more than a 4 month interval with 4 dose audits per year
- Section added on evaluation and methods for product adoption
- New Guidance added on maximum acceptable dose establishment

Competency in sterilization (Session Rad-Ster 2)

Moderator: Arthur Dumba, The Society for Sterility Assurance Professionals (SfSAP), Selzach, Switzerland

The session focused on how SfSAP is creating Learning Frameworks and Learning Outcomes that can be used by education delivery organisations (EDOs) to provide industry harmonised and agreed training, and by regulators to evaluate compliance with the following regulations, directives and standards:

- MDR Annex VII: Requirements to be met by Notified Bodies
- ISO 13485:2016 Clause 6.2: Requirements to be met by Medical Device Manufacturers
- Guide to FDA International Inspections Field Management Directive No. 13 A
- MDSAP G0002.1004 Companion Document Annex 2: Audit of Requirements for Sterile Medical Devices

The Learning Framework contains the modules that are key to becoming competent in the specific modality. Each module has defined learning outcomes that are contained in the Learning Outcomes document. The Learning Outcomes contains the key learning objectives that should be achieved to demonstrate competency in that module.

Auditors and regulators can use the frameworks to:

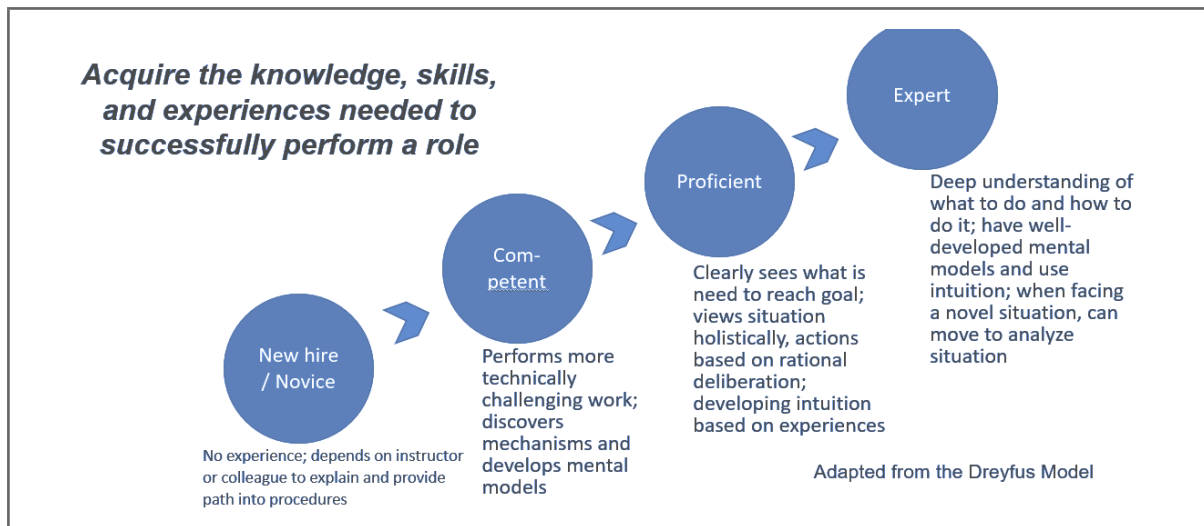
- Determine the competencies required to achieve the audit & regulatory compliance obligations faced by manufacturers
- Support the development of auditors and regulators to demonstrate 'competency'

It takes a collaborative approach to develop competent professionals. Training within healthcare organisations needs to develop and move from the current state of Read and Learn to the future state which delivers the ability for learners to be able to Execute and



Demonstrate that they can Consistently apply what they have learned. Training involves three elements: Tutor, Learner and Education Delivering Organization.

The framework supports the journey in becoming an expert or maintaining expertise. The adapted Dreyfus model can help identify one's position on the spectrum.



To support individuals and organisations in gaining the appropriate education, training, skills and experience the SfSAP has learning frameworks that can be used for the following.

- Develop training plans
- Determine training courses that should be attended
- Understand the competency elements (Know, Apply, Execute and Demonstrate) that are required.
- Understand the learning outcomes required for courses attended or training taken.
- Monitor progress towards demonstrating competency.

Product qualification session (Rad-Ster 3)

Moderator: Bart Croonenborghs, Sterigenics, Leuven, Belgium

The session focused on aspects of qualifying products in compliance with the standards and regulations that are applicable to providing healthcare products that have been sterilised using ionising radiation.

Martell Winters discussed a way other than the SIP approach commonly used for large, complex products or bulk materials that would potentially enable for the determination of a more representative product bioburden and a lower sterilisation dose. Tony Sollis presented on a decision tree for the source of radiation to use for audits of the sterilisation dose (photon or electron) when sterilisation processing occurs in electron beam and provided the conclusions of a review performed within STERIS about the potential for lowering the sterilisation dose for product currently qualified using Method VDmax25. It was stated that for approximately 80% of these, the sterilisation dose could be 20 kGy or less.

Pierre Reppert presented measurements of induced radioactivity in medical devices irradiated with 7 MeV X-Rays performed by STERIS since 2011. Only 40% of all samples tested were slightly activated and all of them could be declared compatible with X-Rays treatment following an assessment of the induced activity.

Nick Brydon summarised existing literature regarding the effect of sterilisation on bacterial endotoxins with attention drawn to industry regulations to show how such regulations are aligned (or not) with published data. In summary, he concluded that numerous experiments have shown a significant dose-dependent reduction in pyrogenicity and/or LAL reactivity of endotoxins following sterilisation using gamma as well as electron beam, but that he was not aware of any studies using X-Rays.

Aaron Neighbour presented on the attempts to find a solution to the shortage of N95 filtering facepiece respirators during the Covid-19 pandemic by processing used masks for potential reuse. He stated that his company went through numerous iterations over the course of months, where the resulting electron beam irradiation process was concluded to be not significantly degrading the filtration efficiency of any of the tested respirators (maintaining 90-93%).

Process control (Session Rad-Ster 4)

Moderator: Hervé Michel, STERIS, Daniken, Switzerland

Control of the routine process is an essential part of sterilisation. Currently, during the routine process, release is based on the measurement of dosimeters placed at frequencies and locations defined during performance qualification. The use of dosimeters has been well accepted for decades but today, thanks to the improved computational capacity of computers, dose simulation tools are being considered. These tools do not replace dosimetry but can be used to give additional information to qualify or monitor the sterilisation process on dose distribution without irradiating actual products. During the session, three presenters gave an overview of two such simulation tools.

Dr Daniel Badali, from Triple Ring Technologies in Canada, presented a web-based innovative software that can be used at different steps of the qualification process and for the three types of ionising radiation. Monte Carlo simulation needs a lot of computational capacity and access to this resource usually requires a significant investment and a knowledge of the physics of particles and coding. The software will have a user interface that allows users to enter CAD models. The web application will then use a cloud server. An irradiator design database is integrated in the application, to perform the simulation and determine the dose distribution within the CAD model. The application is still under development.

Dr. Samuel Dorey from Sartorius France discussed Monte Carlo simulation but from an end user's perspective. Sartorius has very complex products to be sterilised and a large portfolio



of product types. Performance qualification or grouping products into processing categories for routine processing requires a lot of dose mappings, so a lot of time and dosimeters. A comparison of dose distribution in a complex product found with Monte Carlo simulation using the RayXpert software and with alanine dosimetry was presented. The match between the simulation and standard method results is very good, confirming that Monte Carlo tools available on the market are suitable for modelling complex products.

What happens to dose distribution in the interval between two dosimeters? Damien Prieels of IBA Belgium presented a very innovative detector which will allow real time dosimetry in X-Rays sterilisation. The detector derives from a technology currently used in radiotherapy and enhanced for use with the higher dose rate used in sterilisation applications. The detector allows real-time measurement of X-Rays beam flux during routine processing as the photon flux is continuously measured. It can also measure the signature of a product being processed with a high reproducibility and this functionality could be used to ensure that the product processed is equivalent to the product which has been qualified. Some additional studies are needed before commercialization but IBA is confident that the technical challenges will be overcome.

Session Rad-Ster 5 – biopharma and materials

Moderator: Nishad B Dhurandhar, MICROTROL Sterilisation Services Pvt. Ltd., Mumbai, India,

The main focus of the session was on irradiation of SUS (single use systems) that are increasingly important in the biopharmaceutical industry. These systems usually consist of plastic components such as bags, tubings, filters etc. and have been traditionally sterilised by gamma radiation. Considering the uncertainties on the future supply situation of cobalt-60, the use of X-Rays as a substitute to gamma irradiation is being studied. A wealth of encouraging results regarding the key issue of material compatibility including characteristics such as thermal properties, durability, conductivity has already been accumulated. From this point of view, the risk of switching over to X-Rays could be rather low as material equivalence from both forms of irradiation could be demonstrated. Functional performance of the system components was also deemed equivalent. However the change will likely require long approval time from regulators for this change to take place, which calls for continuous engagement with them.

The validation of single use systems irradiation was also presented, using a master product family approach or a simulated product family approach to establish a sterilisation dose. The fluid paths of SUS should be the focus of any validation-related testing. Testing exterior surfaces instead could lead to false positives.



A consensus report by AAMI on an emergency use ventilator (SUS equipment) was discussed. This might be converted into a Technical Information Report (TIR).

The concluding presentation of the session discussed the possibilities of real time release of product versus the traditional validation based product release.

Session Rad-Ster 6 - panel discussions

Panel Discussion 1

Is parametric / real time / irradiator-based release on the horizon?

Moderator: Adam Whaites, Cytiva

Panellists:

- Mark Bailey - DTU
- Emily Craven - Boston Scientific
- Florent Kuntz - Aerial
- Josef Mittendorfer - consultant to Mediscan
- Damien Priels - IBA Industrial
- John Williams - Medtronic

The panel discussion started with a presentation by Josef Mittendorfer discussing the aggregation of process values obtained with a TT300 Rhodotron that characterises the process. Under certain conditions, such as proper validation, calibration and good maintenance of the machine, it appears that, in routine, the data generated by good machines can be trusted as much as - if not more than - dosimetry data with their occasional outliers. Other panellists emphasised the value of traditional dosimetry. For OQ and PQ at least, it seems unlikely that dosimeters will be dispensed with in the foreseeable future. The regulatory evolution that will allow an irradiator-based release will take time and will require very strong arguments. ISO 11137 will open the possibility but there is still a long way to go. Even if it is not necessarily the case, removing something is usually seen as a decrease in quality assurance. However, machine based release certainly has advantages: quick detection that something is wrong with the process, continuous monitoring vs. “probing” with dosimeters, and maybe cost. To a majority of the audience, it seems to be the direction towards which radiation sterilisation should be going. What is true with the most modern accelerators is probably not true with older types of accelerators. Precisely knowing the energy, not only the beam current, is crucial. A shift in energy will affect the dose so it must not go unnoticed. Many machines need to be improved to measure the energy in real time.

Risk management will be a key exercise in the decision. A participant in the audience pointed to the fact that the risk-based approach is being increasingly adopted in other industries. It might not be about dosimetry versus parametric but more about measuring



the influence quantities and deciding when dosimetry is preferable or when parametric release is preferable. Radiation processing should also look more at what is happening in the field of cancer therapy dosimetry where interesting new developments are taking place, moving away from film dosimeters, and of course without any possible compromise on quality assurance.

Panel discussion 2

Transferring healthcare products between radiation sources

Moderator: Emily Craven, Boston Scientific

Panellists:

- James Hathcock – Pall Biosciences
- Samuel Dorey – Sartorius
- Byron Lambert – Abbott
- Christophe Deneux – BD
- Hervé Michel – STERIS

The purpose of this session was to have a discussion around the work currently being done in industry in transferring healthcare products which are sterilised using one radiation source type to another, for example, from gamma to X-Rays. The session started with some polling questions to the audience on their interest and involvement in transferring healthcare products between radiation sources.

The discussion started with questions to two members of the bioprocessing industry, Samuel Dorey from Sartorius and James Hathcock from Pall Biosciences. The bioprocessing industry was an early advocate of switching to X-Rays and the panellists shared some lessons learned from the Bioprocessing Systems Alliance collaboration, which brought together resources from several otherwise competing companies with a common goal towards publishing data and sharing information that could help their industry collectively adapt to the changing capacity landscape. They also spoke about the importance of education and the role that organisations like the International Irradiation Association can play to further this type of information sharing.

Byron Lambert from Abbott and Christophe Deneux from BD spoke as medical device manufacturers about technical aspects of transferring between radiation sources, and the ability to make risk-based approaches to transfers vs full requalification. There was a discussion around dose rate and irradiation temperature as the most impactful parameters on product, per guidance in both ISO 11137-1 and AAMI TIR 104. There was also a great discussion on the similarities between the interactions of different radiation sources at the molecular level, it all comes down to secondary electrons interacting with materials and microorganisms.



Finally, the panel heard from Hervé Michel, representing STERIS, who was able to speak to the future plans in the contract sterilisation business to continue to support all radiation source types, but with active projects building out infrastructure specific to machine source. The growth of the medical device industry will necessitate all three of electron beam, X-Rays and gamma sterilisation in order to meet capacity demands.

PHYTOSANITARY IRRADIATION FORUM

Commercial trade (Session Phyto 1)

Moderator: Peter Roberts, Radiation Advisory Services, Lower Hutt, New Zealand

The moderator provided a summary of the global status of phytosanitary irradiation. He noted the rapid growth in global trade, from a few thousand tons in 2007 to almost 50,000 tons in 2019. The potential for further growth is huge but there are challenges due to the uneven adoption of standards, regulations and biosecurity protocols.

Arved Deecke of Benebion presented information on commercial trade in irradiated fruits from Mexico. Guava was the main fruit irradiated initially in 2012 but guava and mangoes now contribute almost equally. Small amounts of manzano pepper, star fruit, orange, grapefruit, fig, dragon fruit and pitaya are treated. The irradiated fruits are destined for the US market. Total volumes treated rose from approximately 7,000 tonnes in 2012 to an expected 40,000 tonnes in 2022. Benebion expects to diversify its gamma plant into other applications of irradiation and eventually spin off the phytosanitary work to a new facility.

Ben Reilly updated participants on recent growth on export and domestic trade in Australia. Steritech operates a gamma plant near Brisbane and a newer X-Rays facility that opened in Melbourne in 2021. Small volumes of irradiated fruit were exported from 2004 and volumes grew rapidly especially from 2018 to 2021. In 2022, regulatory change and the new facility further increased volumes treated to 9,000 pallets. Domestic (inter-state) trade has grown especially rapidly to 14% of total trade. Continued growth is foreseen as exporters recognize the competitive advantages of irradiation treatments. Australia exports irradiated produce to 6 countries and imports from 4 countries. Mr Reilly noted that progressive ideas for labelling were being tried and that there was no consumer resistance.

The situation in Vietnam was outlined by Ms Tuyat Dinh of the Plant Protection Department. Two gamma facilities and one accelerator plant treat fruits for export. One is government owned, the others are privately operated. Seven fruits are now treated with markets in the US, Australia, New Zealand and Chile. Export volumes peaked at 7,500 tonnes in 2019 but Covid-19 has caused a significant decrease

South Africa has exported small amounts of irradiated table grapes and more is irradiated on arrival in the US. Cherin Balt described the technical limitations for low dose treatment of fresh fruit at the HEPRO multipurpose gamma facility in Cape Town. She also described the infrastructure and social issues that were preventing full utilisation of the technology.



Mr Harshan Doshi (India) said two of the three Agrosurg facilities were approved for phytosanitary irradiation. India had 4 treatment facilities in total. He outlined the role of agencies involved in approving phytosanitary treatments. Irradiated produce was sent to the US from 2007 and Australia from 2017, mainly mangoes but also pomegranates. Prior to Covid-19, 1,400 tonnes were exported in total. Exports have now resumed. India faced logistic challenges due to the distances between facilities and growing areas while air freight was very expensive. Different requirements for importing countries and the current under-utilisation added to difficulties.

Post-harvest (Session Phyto 2)

Moderator: John Golding, NSW Department of Primary Industries, Australia

Phytosanitary irradiation is a market access treatment which is facilitating increased world trade of fresh fruit and vegetables. While growing world trade of irradiated produce attests to the relatively minor effects of irradiation on fruit quality and consumer acceptability, there are some occasional and intermittent fruit quality issues which can affect final fruit quality and therefore market acceptability. To give industry and traders confidence in the routine use of irradiation, practical solutions to these potential issues need to be identified, quantified and developed. This is the challenge for postharvest researchers and industry and was highlighted in this session.

The majority of postharvest research on the effects of irradiation on fruit and vegetable quality has been empirical in nature with little attention to the underlying physiology of the treatment. These observational studies are a good first start to appreciate the nature of the treatment on fruit quality, but there is a need to move beyond these observations. It is now important to start to develop a broader understanding of the fundamental physiological mechanisms that are affected by phytosanitary irradiation. For example enhanced fruit softening is a common quality attribute that is commonly observed in some postharvest research studies, but it is important to understand how this softening can be commercially managed. The availability of new molecular techniques such as transcriptomics are now allowing for a greater fundamental understanding of fruit physiology. The application of these new techniques will elucidate the effects of irradiation on fruit ripening and will allow the potential to develop strategies to manage potential issues such as fruit softening.

In addition to understanding the fundamental basis of the effects of irradiation on fruit quality, it will be critical to identify and manage the effects of different pre- and postharvest factors that affect final product quality. There are numerous agronomic, harvest and postharvest factors which interact to affect postharvest storage life and consumer acceptability. It will be important that future practical R&D is conducted to overcome commercial barriers to provide improved fruit availability and quality to consumers. Strategic research programs like the Australian Hort Innovation project - 'Building capacity in irradiation – pathways to export' (Project AM19002) will be critical to the success of developing phytosanitary irradiation into the future.



This session outlined the breadth of research being conducted to facilitate trade and improve fruit quality outcomes following phytosanitary irradiation treatment. Practical examples from New Zealand, United States and Thailand were presented to show the commercial applicability of phytosanitary irradiation and management of pre-harvest management factors (maturity using NIR) and postharvest factors (controlled and modified atmosphere storage) to optimise fruit quality. The breadth of research from Thailand on the quality responses of irradiation treatment on an important Thai mango, 'Nam Dok Mai Si Thong' illustrates the importance of irradiation as a potential market access treatment in Thailand and regional significance of local R&D to solve specific local issues. The session concluded with a summary of the benefits of strategic and fundamental fruit quality R&D to support trade.

Treatment efficacy (Session Phyto 3)

Moderator: Peter Roberts, Radiation Advisory Services, Lower Hutt, New Zealand

Yves Hénon presented on behalf of Peter Follett (USDA-ARS) who was unable to travel. After reviewing the advantages of irradiation treatments and the basis for confidence in it, Mr Hénon reviewed the tolerance of insect species to irradiation. Specific doses had been validated for many important quarantine pests. The concept of a generic dose, a specified dose to treat a taxonomically defined group of pests, was introduced as a means of simplifying biosecurity protocols by covering everything else that might be of regulatory concern. He reviewed the history of generic doses and noted that developing generic doses should be set at the highest possible taxonomic level. It was proposed that generic doses could be set at the Order level rather than the Family level based on the best available data.

Vanessa Dias reported on the research conducted by the Joint Division of the FAO/IAEA based in Seibersdorf, Austria. She traced its involvement in the development of phytosanitary irradiation from the 1970s to the present. Work at its insect pest control laboratory included work on 4 fruit fly species and efficacy at low oxygen concentrations. Work confirmed that 80Gy was a phytosanitary dose for *D.szukii*. An important part of the Joint Division's work was its management of the Co-ordinated Research Project (CRPs). The past contribution of CRPs to ISPM 18 and USDA-APHIS rules on treatments and the concept of generic doses was mentioned. Twelve countries are participating in a present CRP on Novel Irradiation Technology for Phytosanitary Treatments. Research is being conducted on a range of pests using low energy sources and exploring dose rate and energy effects on efficacy.

Research projects within the USDA-APHIS were outlined by Corey Penca. Research was conducted by its own scientists and by external contractors. The first part of the presentation highlighted the external research by topic. USDA scientists were also participating in a Cooperative Research Project run by the IAEA that concentrated on the irradiation of mealybugs and thrips. The second half of the talk discussed the work



developing an understanding of how generic doses could be reliably developed. At any level (species, genera, family etc.), radio tolerance would have a probability distribution. The parameters of the distribution can be obtained from a subset of the taxa and an estimate made of the proportion that would fall either side of the proposed generic dose. Such species sensitivity distributions were well established in ecotoxicology. Data and statistics were then presented for Tephritidae and Curculionidae based on generic doses of 150Gy and 175Gy respectively.

Infrastructure and technology (Session Phyto 4)

Moderator: Mr. Murray Lynch, Steritech, Dandenong South, Australia

Based on his own experience, the moderator underlined that phytosanitary irradiation is much more than just irradiation. Handling perishable products makes logistics critical, hence the need for a proper infrastructure with the required supporting services, as well as engagement with all stakeholders.

Florent Kuntz gave a summary of the most important aspects of dosimetry, delivering the specified minimum doses being one of the main pillars of process efficiency. Many products irradiated for phytosanitary purpose have high densities and the specified dose range can be tight. The doses are below 1 kGy, which requires dosimeters that are sensitive enough. However there is nothing specific about dosimetry for phytosanitary irradiation so the experience with other applications of irradiation can be used.

IBA showed results of several dose mappings for fresh produce (apples, mangoes, citrus, blueberries) using electron beams or X-Rays produced by their machines with various operating parameters and modalities. Using 7 MeV X-Rays considerably improves uniformity and throughput. Actual dosimetry and modelling yielded data that matched well. The challenges of processing a large number of boxes per time unit with electrons were elaborated. Tests on sensory and chemical characteristics of various fruits confirmed previous results.

Steritech presented their EB-X irradiator now operating in Melbourne. Though volumes treated for phytosanitary purpose are relatively limited compared to medical sterilisation, the requirements for validation are similar. Performance qualification for each type of product is tedious and costly but creating processing families with worst case configurations reduces the burden.

Indonesia has favourable food regulations, adequate irradiation capacity and good fruit export opportunities. However, in spite of the foreign assistance received so far, the country has been stumbling on the implementation of a quality management system that would meet the requirements of potential importing countries.



Regulatory development (Session Phyto 5)

Moderator: James Allan, Australian Embassy, Hanoi, Vietnam

Phytosanitary treatments and irradiation are heavily regulated. This session intended to address regulation development, how regulations are delivered and the impact it has on industry and consumers. How do we start to develop and refine regulation to ensure it is fit for purpose and keeping pace with change?

Cory Penca from USDA PPQ gave an update on the US phytosanitary irradiation program. Over the recent years, imports of fresh irradiated produce from Mexico, Peru and Australia have substantially increased though Covid-19 has an impact on global volumes.

Ben Reilly from Steritech gave a commercial perspective on how industry views regulations. He reminded that the ban of chemical phytosanitary treatments like dimethoate triggered the development of irradiation. Regulations are needed to warrant biosecurity, especially in the case of a treatment that is not always lethal, and protect the integrity and reputation of the treatment. However, regulations must also be appropriate, allow smooth flow of product, and allow for innovation. In Australia, having a blanket authorization to irradiate all fruit and vegetables rather than authorising one product at a time was a major step forward but it took 21 years to change the FSANZ standard. Australia has also implemented a domestic pathway (ICA 55) written generically to allow any fresh produce to be irradiated for domestic distribution of products that do not have a treatment requirement in the event of a pest incursion. Excessive and varying labelling requirements remain a problem. Besides being often misinterpreted by industry, they mean that product cannot be redirected to another destination, in case a flight is missed for example. Australia has been successful in implementing bilateral agreements with New Zealand, Thailand, Vietnam, and USA but the fact that major markets such as Japan and the European Union remain closed to irradiated produce is a major frustration. Wider harmonisation of food irradiation regulations is really needed. Peter Roberts showed that increasing the permitted maximum energy of X-Rays to 7.5 MeV would provide a safe means of treating food at lower cost. Efficiency of X-Rays production is increased in the range 40 to 50% at the higher voltage. This translates into more rapid treatment time, quicker turnaround of the product in the facility and decreased costs. USA, Canada, India, Indonesia and South Korea have already changed their domestic regulations but the Codex General Standard still states 5 MeV as the maximum energy for X-Rays.

Heidi Kotilainen of Bühler presented the results of an online study with a sample of 600 persons in Germany, Spain, and Finland regarding the acceptance of irradiated blueberries. No irradiated fresh food product is offered in these countries. The study showed differences between countries regarding potential acceptance, with Germany being the most reluctant and Spain the least suspicious. Informing on the technology tends to lower acceptance while mentioning the benefits improves acceptance.



Sally Ormiston explained why the Australian Department of Agriculture views phytosanitary irradiation as a tool to facilitate trade. Australia exports 70% of its agricultural production and keeps looking for new export opportunities, diversifying partners and responding to the growing demand, especially for premium tropical fruit. From a strategic trade policy approach, irradiation has many desirable attributes. Irradiation is a highly efficacious alternative to chemicals and meets growing sustainability requirements. It is simple, fast, and allows an uninterrupted cold chain. It is not without challenges: the uptake of the technology is slow, there are regulatory barriers in some countries, there is limited access to suitable facilities, and there is a lack of awareness among traders and retailers. But sales disprove a rejection of the technology by consumers. Considering that the technology is underused, the Department will actively encourage industry to consider phytosanitary irradiation. It is, among other initiatives, developing education tools such as the irradiation insight education package, a series of short videos.

Panel discussion (Session Phyto 6)

Panellists:

- Cherin Balt, Hepro, South Africa
- Arved Deecke, Benebion, Mexico
- Vanessa Dias, IAEA
- Mirianne Jovanoski, Department of Agriculture, Horticultural Trade Policy, Australia
- Cory Penca, USDA-APHIS-PPQ, USA
- Ben Reilly, Steritech, Australia

Commercial phytosanitary irradiation has steadily grown since international trade started around 2005. Though the volume traded in 2021 has probably reached about 80,000 tons, this remains a rather small figure in absolute terms. Irradiated fresh produce do not have access to premium markets such as Japan, South Korea and the European Union. The purpose of the panel was to discuss the actions that the current actors could give the impetus to support further growth of phytosanitary irradiation.

It was agreed that establishing more generic doses and having them approved at ISPM level is necessary. The Coordinated Research Projects (CRP) of the IAEA provide an excellent framework for international collaboration. With its clear roadmap and its harmonised approach, it is expected that CRP D61026 *Phytosanitary Treatment of Food Commodities and Promotion of Trade* launched in late 2021 will be even more productive than the previous CRP. Research carried out elsewhere is being used to give directions to establish doses for groups as high as possible taxonomically, with dose values as low as possible to provide flexibility in commercial processing since it will be difficult to remove the upper limit dose of 1,000 Gy. Research must continue on the effects of irradiation on fruit quality and it is often initiated by industry and growers.



The lack of regulatory harmonisation is an obstacle to trade. As an example, only a few countries allow X-Rays irradiation of foods at 7.5 MeV. Australia requires irradiation prior to entry while irradiation at the port of entry is common practice in the US. Differences in regulatory requirements can be on labels or other details of the pathways but in all cases they create difficulties for the industry. International cooperation might remove some of the obstacles. Exchange of experience on retailers' and consumers' acceptance and labelling would be beneficial for those in countries showing reticence towards irradiation. Experience on implementation of bilateral agreements could also be shared. The arbitrary upper limit of 1 kGy for fruit and vegetables irradiation creates technical difficulties but living with it might be easier than removing it. It was suggested that an 'how to' manual that would contain best practice, examples of biosecurity protocols and marketing considerations would be most useful to promote phytosanitary irradiation.

In conclusion, there is a clear need for more international collaboration to support further growth of phytosanitary irradiation. Events such as this Phytosanitary Irradiation Forum are great opportunities for researchers, NPPOs and industry to listen to each other and to foster international cooperation. This event should be periodically repeated in different locations. In the intervals, the Phytosanitary Irradiation Platform (PsIP) could also be used by the different stakeholders to keep the conversation going.



CLOSING PLENARY SESSION

The session included a review of IMRP20, views expressed by the audience via on-line polling and a debate by panel members in response to two important questions relating to the future irradiation industry.

Paul Wynne opened the session by reviewing the main lessons learnt from IMRP20 and noted that the meeting remains relevant and important. It continues to act as a bridge between science and business, is an excellent forum which brings together people with disparate interests, varied expertise and from diverse geographic locations. IMRP20 has highlighted that the irradiation industry continues to evolve. The meeting continues to provide an excellent way of enabling new participants to understand the global industry and to develop a valuable network of contacts. The average age of IMRP20 participants appears to be coming down and continues to provide new and long-time attendees with value. This year 360 attendees from more than 40 countries are present whilst 24 students from 13 countries attended the pre-conference workshop at Kasetsart University. The perennial debate over plenary vs. break-out format continues but the aim of IMRP20 was to bring together the widest possible audience so that IMRP20 includes a number of components many of which could have been a stand-alone meeting.

To continue to benefit from IMRP20, attendees were encouraged to continue to use the conference App and to upload a photo to their personal profile to facilitate enhanced networking opportunities. The iia will also evaluate the possibility of creating an IMRP LinkedIn account.

Poll Question 1

Do you think that all three irradiation technologies – gamma, e-beam and X-Rays - will still be used in 20 years?

The audience response was a resounding “Yes”.

A panel discussion moderated by Paul Wynne took place with a panel of five industry leaders representing a broad range of irradiation community interests:

- **Alain Strasser**, Managing Director of Aerial, a highly respected innovation partner that has irradiation science and research in its DNA.
- **Andreas Ostrowicki**, Managing Director of BGS, a highly respected contract irradiation service provider using both gamma and accelerator technology in Germany.
- **Mike Eaton**, Managing Director EMEA and APAC at STERIS, a leading international contract irradiation service provider.



- **Riaz Bandali**, President of Nordion which is part of the Sotera Health group.
- **Thomas Servais**, President IBA Industrial, a leading international supplier of accelerator technology.

Two topics were debated: (a) the sustainability of irradiation technologies and (b) which application/s should receive more support?

Panel Question 1

The sustainability of irradiation technologies

Alain Strasser: *“Demand remains strong across most application sectors. Sustainability requires that there is reliable and sustainable access to sources of both gamma and accelerator technology, that there is a pipeline of new talent joining our industry and that our industry continues to innovate and strengthen opportunities for technology transfer between academia and industry. IMRP is an important component as well as the iia’s leadership initiative and our links with the IAEA.”*

Andreas Ostrowicki: *“There is a growing tension between the need for energy (electricity), the shift from fossil energy sources and nuclear to renewables in Europe and the increasing use of electrically powered cars and heating systems that require access to electrical power. One of the consequences of this trend is that accelerators must become more energy efficient. For the foreseeable future all irradiation technologies will continue to be required. Gamma and hence access to cobalt 60 will remain important. Our industry requires greater public support hence greater understanding. We must attract new talent to join our industry.”*

Mike Eaton: *“The present imbalance between demand and available capacity will continue and is driving investment in electron beam and X-Rays technology. Gamma will probably flat-line in terms of overall capacity but will fall as a proportion of overall capacity as markets grow and growth is satisfied by investment in EB and X-Rays. Operational reliability and hence up-time for accelerator technology remains important along with the availability of spares and technical support. Progress is being made as markets adopt EB and X-Rays but acceptance is hampered by regulatory compliance requirements when processing medical products.”*

Riaz Bandali: *“Acknowledged that demand for cobalt-60 exceeds supply at the present time but indicated that significant investments and pathways are in place to increase supply in the mid term. Meanwhile ongoing demand growth combined with recent geopolitical events mean that satisfying overall market demand will remain challenging in the near term. It was noted that capacity and ramp up challenges exist in competing technologies, EO, X-rays and E-beam which mean that ensuring access to all irradiation/sterilisation technologies will*



remain important to global healthcare. The political response to geopolitical challenges has been positive and it is increasingly recognised that nuclear power must be part of any transition to a carbon neutral world and to satisfy global energy demands.”

Thomas Servais: *“Highlighted that sustainability requires that a technology/product should satisfy a number of key criteria – ‘User’ where irradiation provides demonstrable benefits to a range of materials and products, ‘Corporates’ where use of the technology is commercially profitable and hence benefits shareholders, ‘The Planet’ where irradiation provides low carbon and environmental solutions, ‘Society’ which benefits by having access to products and services that enhance the quality of life and ‘ Individuals’ who learn new skills. On this basis irradiation is a sustainable pathway and all technologies will continue to be required.”*

Poll Question 2

What does sustainability mean for the audience?

Audience members had very diverse opinions with many words being used to describe their opinions. Words such as public, energy, countries, technologies, environment appeared multiple times.

Panel Question 2

Which irradiation application should receive more support?

Mike Eaton: *“Medical products could benefit from support in transitioning from one technology to another given the complexity that manufacturers currently face when changing sterilisation modality. Phytosanitary, whilst still a niche application, shows promise and could benefit from more support.”*

Riaz Bandali: *“Greater awareness of the importance of radioisotopes in healthcare (medicine, pharma and sterilisation) would be beneficial but educating the public is a big topic and challenge.”*

Thomas Servais: *“Environmental applications showing enormous promise have not been widely adopted because of the associated cost and/or lack of commercial incentive. Acceptance will require regulatory support.”*

Andreas Ostrowicki: *“Greater awareness of the importance of irradiation in the supply of sterile medical devices by both the public and authorities is important. Irradiation is especially important in the transition to a low carbon world where electrical power, battery and associated systems, rely heavily on advances in polymer irradiation (crosslinking) science.”*



Alain Strasser: *“The need for more technology resource centres. Irradiation remains the most elegant way to deposit energy into products in applications as diverse as polymer recycling and pharmaceuticals.”*

In conclusion, some applications could clearly benefit from support to stimulate demand or to avoid unnecessary regulatory or legislative restrictions.

Poll Question 3

Which applications should receive more support?

Education featured highly in responses from the audience. It is important to define the applications requiring support. In the case of environmental applications, the challenge is that, in most areas, there is neither a financial incentive nor a regulatory obligation to use irradiation. Environmental applications could therefore benefit from the imposition of a regulatory obligation on companies who create pollution to take action to mitigate their impact on the environment.

Closing comments from the panel

Alain Strasser: *“We need IMRP - the conference is important. We need industrial sponsors and greater user engagement. Aerial is an IAEA collaborating centre and iia should remain closely linked to ICARST held at the IAEA.”*

Andreas Ostrowicki: *“IMRP remains very important as a venue to network and learn about topical issues and developments. There is a need for greater public awareness and greater engagement with irradiation users to encourage engagement between stakeholders. It would be valuable to have more application users (of products improved by irradiation) at IMRP.”*

Mike Eaton: *“Number of applications and range of attendees at IMRP20 is encouraging. All technologies including EO face challenges. As the world changes and demand for irradiation continues to evolve, we will need to be more efficient in the use of energy. This will continue to be a key challenge for accelerator manufacturers.”*

Riaz Bandali: *“The opportunities to use irradiation for beneficial purposes continues to grow. We should use this conference and other forums to raise awareness and collaborate for the benefit of the whole community.”*

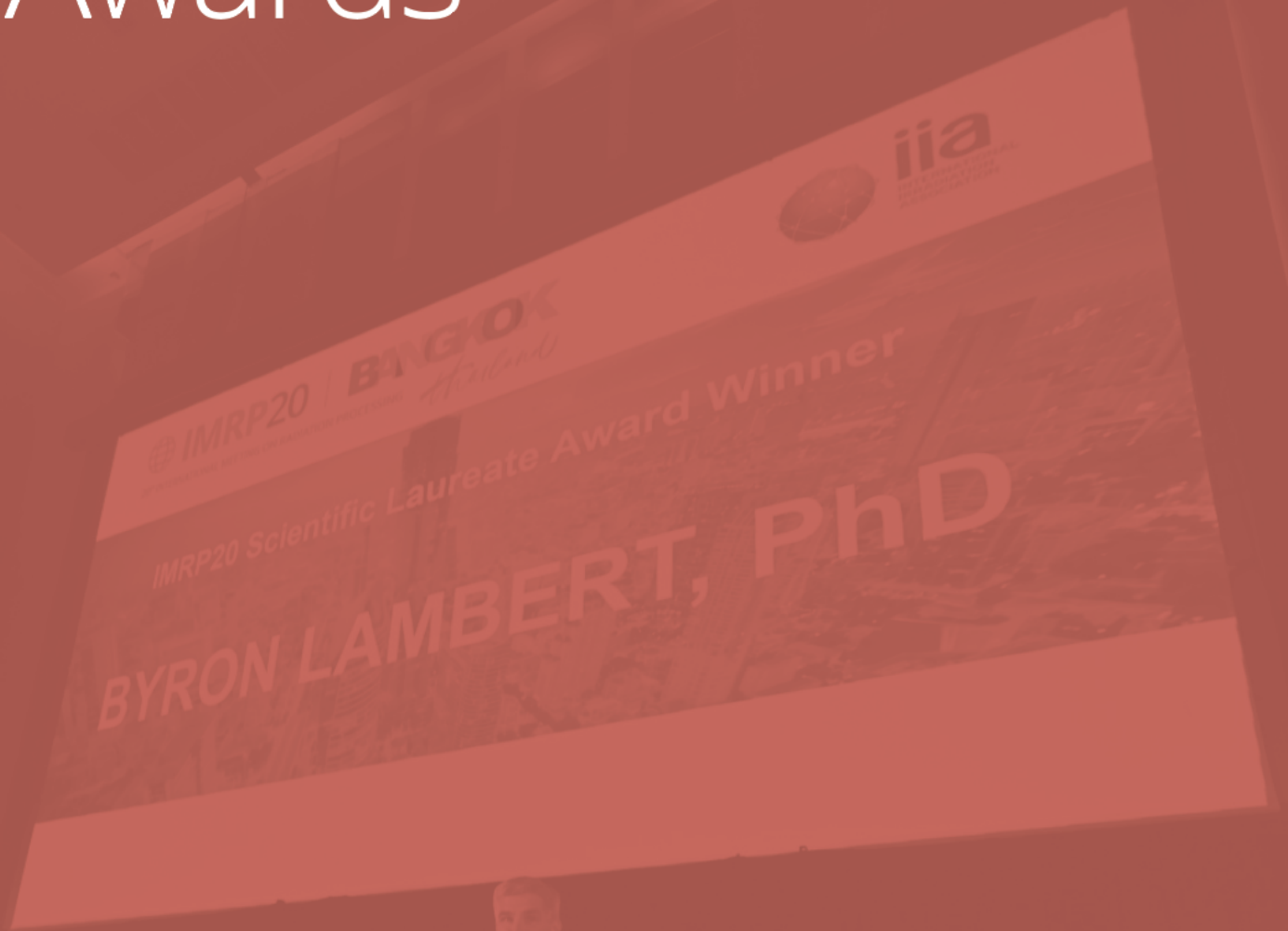
Thomas Servais: *“Networking can’t be underestimated. Maintaining IMRP as a face-to-face meeting remains important, clustering meetings around key issues.”*



Closing Comments

Demand for sterilisation capacity remains strong and we can conclude that the consensus is that all irradiation and sterilisation technologies will continue to be required. Today gamma faces capacity issues but alternatives technologies such as EO face even greater challenges. The timeline to install new equipment is lengthy, whichever technology is being planned, and we need new skills to install and use this equipment. We don't see much capacity going in-house. Education, training and attracting new young and technically proficient entrants to our industry remain important.

Awards



IMRP LAUREATES

The award is given to individuals who have had a significant impact on the commercial or scientific application of irradiation and to those who have contributed to the development of the irradiation industry. Laureate awards were introduced at the second International Meeting on Radiation Processing held in Miami in 1978. Usually there are two Award winners, a Business Laureate and Scientific Laureate. Over the past 44 years, 39 Laureates have been awarded.

LAUREATES	IMRP #	YEAR
Charles Artandi, Paul Cooke	2	1978
William Baird, Arthur Charlesby	3	1980
Toshikazu Higashino	4	1982
John Masefield, Vivian Stannett	5	1984
Ken Morganstern, Joe Silverman	6	1987
Frank Fraser, Frank Ley, Sam Nablo	7	1989
Marshall Cleland, Joseph Farkas	8	1992
Jan Leemhorst, William McLaughlin, Pierre Vidal	9	1994
Sueo Machi, Arne Miller	10	1997
Masaaki Takehisa, Alan Tallentire	11	1999
Joyce Hansen, Robert Morrissey	12	2001
Yves Jongen, George West	13	2003
John Corley, Theo Sadat, James Whitby	14	2006
Dieter Ehlermann, Rocco Basson	15	2008
Olgun Güven, John Kowalski, Wang Chuangzhen	16	2011
Andrzej Chmielewski, Paul Minbiole	17	2013
Mohamad Al-Sheikhly, Zhang Xianghua	18	2016
Yves Henon, Maria Helena Sampa	19	2019

The Laureate Awards were introduced by Martin Comben (ia) and presented by Olgun Güven, past IMRP Laureate.





The recipient of the IMRP 20 Scientific Laureate Award was **Byron Lambert**.

Introduction by Martin Comben, iia:

The winner of the Scientific Award received 3 nominations from prominent members of our community and also received 3 very passionate letters of support referring to our winner as a mentor, a teacher, a leader, someone who understands their audience and brings out the best in people.

Our winner is a senior sterilisation scientist working in industry having started his career in 1982 as a graduate research assistant working under Professor Joe Silverman, who himself was also a Laureate award winner back in 1987.

The recipient's list of academic achievements, publications, patents and awards are too long to detail. I would just like to highlight two areas of leadership.

Our winner is currently on the AAMI Committee on Standards Strategy and has previously been Co-chair of 3 AAMI WGs responsible for the development of radiation sterilisation standards, for providing material compatibility guidance and for assurance of sterility. Also working on standards through ISO as Convenor of the International WG responsible for developing radiation sterilisation standards. So we are lucky to have this person on our side.

I have been lucky enough to work with our winner through iia so, on a personal note, I would like to add 2 things. Firstly, this person is a real contributor to anything in which he is involved, and secondly, he is just the kindest person you'll ever meet.





The recipient of the IMRP 20 Business Laureate Award was Paul Wynne.

Introduction by Martin Comben, iia:

The winner has been at the sharp end of the irradiation industry since 1987, working in various leadership roles with Isotron that became Synergy Health before it was ultimately acquired by STERIS. He is a chartered accountant by training and has held operational and project management roles involving the installation and operation of gamma, electron beam and ethylene oxide technologies in China, South-East Asia, Europe and South Africa.

Perhaps more importantly, the recipient is a passionate advocate of irradiation technologies and applications. He has an unwavering belief in the contribution that irradiation makes to the health, wellbeing, economy, and environment the world over. He was one of the founding directors of iia in 2004 and became Director & General Manager of the International Irradiation Association in 2011 where he has continued to support the global development of gamma, e-beam and more recently X-Rays technology. Recently he has supported the creation of the Society for Sterility Assurance Professionals. He is now Chairman and Director General of iia and, quite simply, both the association and IMRP are only as successful, as effective and as well respected because of his leadership.



POSTER AWARDS

A total of 52 posters were presented during the conference. The Programme Committee established a short list of 20 posters in different categories. A Poster Committee chaired by Prof. Xavier Coqueret (Université Reims Champagne Ardennes, France), composed of Prof. Piot Ulanski (University of Lodz, Poland), Prof. Wanwimol Pasanpham (Kasetsart University, Bangkok, Thailand), Prof. Olgun Güven (Turkey), Dr. Suwimol Jettawatana (TINT, Thailand), Jeremy Brison (IBA, Belgium), Chris Howard (Sotera Health, Canada) and Yves Henon (iia) selected the three best posters. The Best Poster Awards were presented by Thomas Servais of IBA Industrial.



#1. Best poster (and Research Poster Award)

Enhanced bioleaching using electron stimulated bacteria (Poster #33)

Simone Schopf, Bornkessel Sophie, Scherer Matthias, Dietze Marleen, Ulla König.

Medical and Biotechnological Applications, Fraunhofer Institute for Organic Electronics, Electron Beam and Plasma Technology, Dresden, Germany

Improved Bioleaching through Electron-Stimulated Bacteria



S. Schopf, M. Scherer, S. Bornkessel, M. Wypior, M. Dietze, U. König

Fraunhofer-Institute for Organic Electronics, Electron Beam and Plasma Technology Dresden, Germany

20th INTERNATIONAL MEETING ON RADIATION PROCESSING

Poster #33

Background and Goals

The mobilization of metal cations from often almost insoluble ores by microbiological processes is referred to as **bioleaching**, being now a worldwide established **geobio-technological process**, mainly employed for copper, cobalt, nickel, zinc, gold, and uranium. The bioleaching **bacteria**, such as *Acidithiobacillus ferrooxidans*, can accelerate sulfide ore dissolution and convert metals into a soluble form [1]. **Chalcopyrite** represents approximately 70 % of the world's copper reserves. However, chalcopyrite is very recalcitrant and bioleaching is inhibited at ambient temperature by the formation of a passivation layer. To date, bioleaching of chalcopyrite has not been successfully commercialized. One hypothesis suggests that very low doses of ionizing radiation can induce a **biopositive effect (radiation hormesis)** [2]. Therefore, we investigated whether **Low Energy Electron Irradiation (LEEI)** can trigger a stimulating effect on bacterial activity and copper bioleaching rates.



LEEI Equipment and Procedure

For the irradiation of the bacterial suspension we developed a novel set-up, based on a vessel on a magnetic stirrer to move the fluid during irradiation [3]. We determined the depth dose distribution by modelling and experimentally (Fig. 1 A, B).

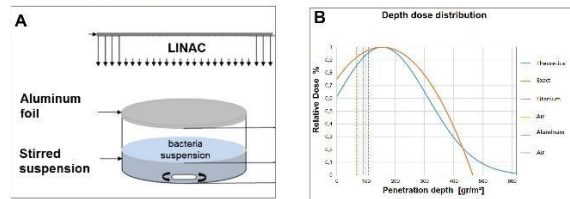


Fig. 1: A: Irradiation set-up; B: Theoretical model of the depth dose distribution

Suspensions were irradiated for different time points (Fig. 2 A, B) in the LEEI-research facility REAMODE using a static module (Fig. 2 D, E).

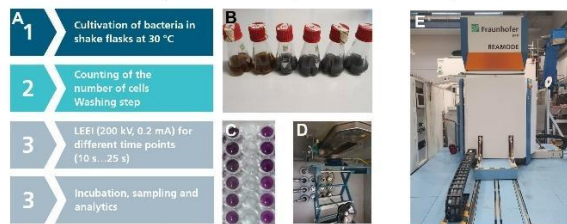


Fig. 2: A: Work-flow for LEEI of bioleaching bacteria [4]; B, C: Cultivation flasks and iron assay; D, E: LEEI facility REAMODE (Reactive Modification with Electrons) and static module.

Bioleaching Results after LEEI of Bacteria

Prior to LEEI, the bacteria were grown, collected, and the number of cells determined. After LEEI, the progress of copper bioleaching was monitored by the concentration of dissolved ferrous, ferric and copper ions. The development of the pH was also recorded (Fig. 3 A-D). Our results demonstrated, that the **concentration of dissolved copper leached by LEEI-treated bacteria was reproducibly higher** compared to non-irradiated control cultures.

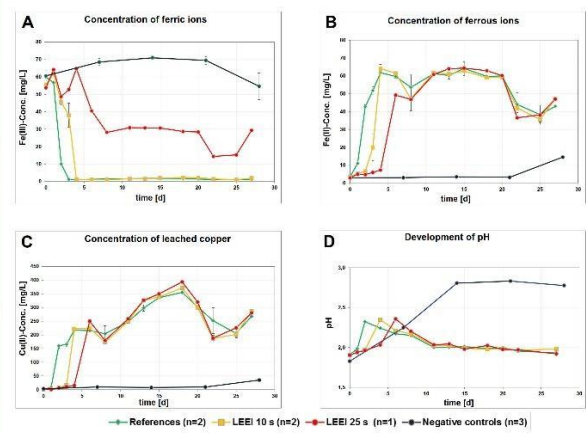


Fig. 3: Process monitoring of copper bioleaching. A, B: Development of ferric and ferrous ions; C: Concentration of dissolved copper; D: Development of the pH.

Conclusion

With regard to LEEI of bioleaching bacteria for the winning of copper the major findings were:

- 10 s LEEI-treated bacteria showed a 1.4 - fold higher copper leaching rate compared to non-irradiated cultures (Fig. 4)
- 25 s LEEI treatment had no positive effect on copper bioleaching
- LEEI-treated bacteria showed growth delay

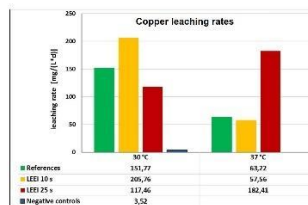


Fig. 4: Comparison of absolute copper leaching rates

Outlook

To optimize the system we are developing:

- an automated irradiation process for suspensions in the low dose range
- A technology for the upscaling of the process in a bioreactor
- Improved methods for the determination of the metabolic activity

Kontakt
Dr. Simone Schopf
simone.schopf@fep.fraunhofer.de
Winterbergstraße 28
01277 Dresden

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We kindly acknowledge A. Poremba for excellent support on routine dosimetry and S. Gerschwé for lab support.

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#2. Industry Poster Award

What is considered conforming product for underdosed radiation-sterilised products? (Poster #30)

Martell Winters¹, Aaron DeMent², John Schlecht⁴, Kevin O'Hara³.

¹ Nelson Laboratories a division of Sotera Health, Salt Lake, UT, United States; ² Sterigenics a division of Sotera Health, Oak Brook, IL, United States; ³ Sterigenics a division of Sotera Health, Ottawa, ON, Canada; ⁴ Sterigenics a division of Sotera Health, Bridgeport, NJ, United States



WHAT IS CONSIDERED CONFORMING PRODUCT FOR UNDERDOSED RADIATION-STERILIZED PRODUCT? RISK-BASED FACTORS TO CONSIDER

Question:

$D_{ster} = 25$ kGy, dose delivered = 24.8 kGy
Is the product conforming to 10^{-6} ?
Is there any potential impact to patients?

How do we define sterile product?

Typically: 10^{-6} SAL What is meant by 10^{-6} ?
Does $10^{-5.95} = 10^{-6}$? Does $10^{-5.5} = 10^{-6}$?
ISO 11137-2 does not specify significant figures (e.g., 10^{-6} , $10^{-6.0}$ or $10^{-6.00}$).
Considering all variables, SAL 10^{-6} might be possible even when D_{ster} is not achieved during processing.

Understanding VD_{max}^{25}

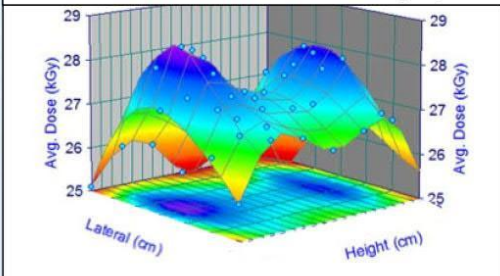
Verification dose allows $\pm 10\%$
Example: 300 CFU = target dose of 8.6 kGy, range of 7.7-9.5 kGy
Delivered dose from initial or recent verification dose: 8.1-9.1 kGy
Max dose of 9.1 \rightarrow Could be target dose of 8.3 kGy = 24.7 kGy
(AAMI TIR76 VD_{max} Calculation Tool)
Therefore: data might support D_{ster} of 24.7 kGy for 10^{-6} .
Also consider current bioburden with TIR76 tool

What SAL must be met with the product?

Is SAL of $10^{-5.95}$ acceptable from risk assessment?
Total Log Reduction = TLR Product Bioburden = BB
Delivered Dose = DD Average D value = D_{10}
 $SAL = TLR - \log_{10}BB$ and $TLR = DD / D_{10}$
Combined: $SAL = (DD / D_{10}) - \log_{10}BB$
Then: $D_{10} = DD / (SAL + \log_{10}BB)$
 \rightarrow Solve for D_{10}
 \rightarrow Use D_{10} with DD to calculate SAL obtained (SAL_o)

What percentage of product receives the min dose?

Typically quite small: if 10% of a product box was underdosed, is it possible that the products still achieved an SAL of $10^{-6.0}$ overall? Can individual boxes in irradiation container be segregated?



BIOBURDEN COUNT					
	1	10	100	300	1,000
DD	SAL_o	SAL_o	SAL_o	SAL_o	SAL_o
24.9	6.0	6.0	6.0	6.0	6.0
24.8	6.0	5.9	5.9	5.9	5.9
24.7	5.9	5.9	5.9	5.9	5.9

Takeaway:

24.9 kGy might give an acceptable SAL

If 10^{-6} is required (i.e., not $10^{-6.0}$)

	1	10	100	300	1,000
DD	SAL_o	SAL_o	SAL_o	SAL_o	SAL_o
24.9	6	6	6	6	6
24.8	6	6	6	6	6
24.7	6	6	6	6	6
24.6	6	6	6	6	6
24.5	6	6	6	6	6
24.4	6	6	6	6	6
24.3	6	6	6	6	6

Other questions to consider:

Why did the product receive $< D_{ster}$?
Investigation may still be warranted.
Do you usually obtain 0 positives?

Authors:

Martell Winters, mwinters@nelsonlabs.com
John Schlecht, jschlecht@sterigenics.com
Aaron DeMent, adement@sterigenics.com
Kevin O'Hara, kohara@sterigenics.com





#3. Student Poster Award

Electron beam processing of poly(acrylic acid) in the synthesis of targeted cancer nano radiopharmaceuticals (Poster #37)

Beata Rurarz^{1,2}, Joanna Raczkowska¹, Kinga Urbanek², Dominika Habrowska-Gorczyńska², Marta Koziel², Karolina Kowalska², Sławomir Kadlubowski¹, Michał Maurin³, Agnieszka Sawicka³, Urszula Karczmarczyk³, Agnieszka Piastowska-Ciesielska², Piotr Ulanski¹.

¹Institute of Applied Radiation Chemistry, Lodz University of Technology, Lodz, Poland; ²Department of Cell Cultures and Genomic Analysis, Medical University of Lodz, Lodz, Poland; ³Radioisotope Centre POLATOM, National Centre for Nuclear Research, Otwock, Poland





Electron beam processing of poly(acrylic acid) in the synthesis of targeted cancer nanoradiopharmaceuticals

B.P. Rurarz^{1,2*}, J. Raczkowska¹, S. Kadłubowski¹, K.A. Urbanek², D.E. Habrowska-Górczyńska², M.J. Koziet², K. Kowalska², M. Maurin³, U. Karczmarczyk³, A. Piastowska-Ciesielska², P. Ułański¹

¹Institute of Applied Radiation Chemistry, Faculty of Chemistry, Lodz University of Technology, Lodz, Poland

²Medical University of Lodz, Department of Cell Cultures and Genomic Analysis, Lodz, Poland

³National Centre for Nuclear Research, Radioisotope Centre POLATOM, Otwock, Poland

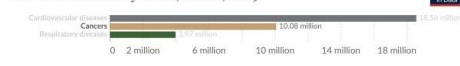
*beata.rurarz@dokt.p.lodz.pl



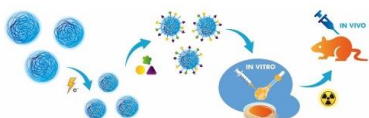
1. BACKGROUND AND SCOPE OF PRESENTED RESEARCH

Despite many efforts, cancer remains a major challenge for medicine professionals and scientists around the world. According to data published by University of Oxford in cooperation with Global Change Data Lab, cancer is the second leading cause of death worldwide. Therefore, there is a constant need for new therapeutic and diagnostic modalities which can improve the situation.

Number of deaths by cause, World, 2019



Source: IHME, Global Burden of Disease. OurWorldInData.org/causes-of-death + CC BY



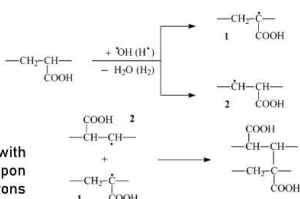
Nanotechnology is believed to bring about change in the field of oncology and revolutionize current cancer management strategies. Therefore, in our research we synthesize state-of-the-art biocompatible polymer nanostructures in the process of preparative pulse radiolysis. We start with dilute aqueous solution of poly(acrylic acid) (PAA), which forms nanogels (NG) upon irradiation. Next, we functionalize these nanogels with ligands containing targeting moieties and radionuclide chelators. So prepared nanocarriers are finally radiolabelled with therapeutic and theranostic isotopes and tested on *in-vitro* prostate cancer model (human prostate adenocarcinoma cell line PC-3), as well as *in-vivo* (Balb/c mice - biodistribution).

2. POLY(ACRYLIC ACID) NANOGELS

Nanogel synthesis is driven by the reactive species generated during water radiolysis. They lead to changes in molecular structure of poly(acrylic acid) and formation of internal crosslinks within the polymer coils.



We use 2 batches of linear PAA with nominal Mw 250kDa and 450kDa. Upon pulse irradiation with 6 MeV electrons from a linear accelerator, we obtain colloidal stable nanogels of ca. 50 nm and 90 nm size, respectively.



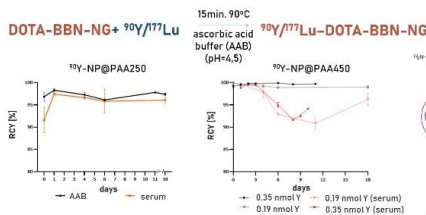
S. Kadłubowski, *Macromolecules*, vol. 36, no. 7, pp. 2484–2492, 2003.

3. FUNCTIONALIZATION OF NANOGELS

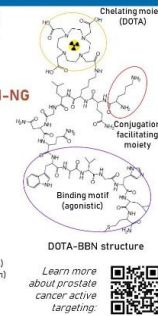
Functionalization of nanogels towards functional nanocarriers is achieved in one-pot synthesis. Among various conjugation chemistries tested, triazine-based procedure allows best coupling yield - virtually 100% of peptide is successfully bound to carboxylic groups present in PAA nanostructures, as assessed with BCA protein assay.

4. ACTIVE TARGETING & RADIOLABELING

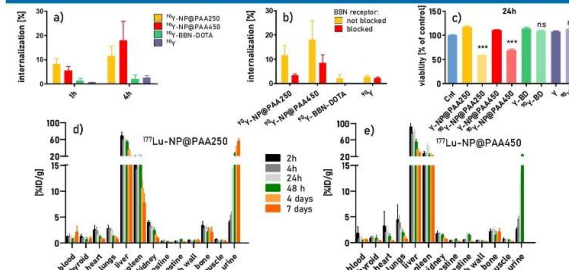
Active targeting towards prostate cancer cells and radiolabeling is enabled by using engineered ligand - bombesin derivative (DOTA-BBN).



Radiolabeling stability (in ascorbic acid buffer at RT and in serum solution at 37°C); RCY - radiochemical purity.



5. PERFORMANCE OF NANOCARRIERS



Nanocarriers improve radioisotope internalization in PC-3 cells (a), and this effect is greatly driven by the conjugated targeting ligand (b). Significant decrease of PC-3 cells viability shows therapeutic potential of radiolabelled carriers in comparison to their carrier-free and non-radioactive counterparts (c). *In-vivo* studies (d, e) in general show i.a. elimination with urine, and low retention in bones (which proves stability of the radiolabeling). Size of nanoparticles clearly influences the biodistribution, however high retention of both carriers in liver and spleen suggests the need for further optimization of the construct.

6. ACKNOWLEDGEMENTS

This work is supported by the National Science Centre, Poland (2019/33/B/ST5/02125) and the National Center of Research and Development, Poland, in the framework of the project InterChemMed - Interdisciplinary doctoral studies at Lodz public universities (POWR.03.02.00-00-1029/16), co-funded by the European Social Fund. This work is supported by IAEA (CRP F22064, contract 18354, and CRP F22070, contract 23162).



Tours/Workshop



TECHNICAL TOURS

IMRP technical tours are always popular as an opportunity to visit an irradiation facility and learn more about their technologies and operation. For the final day of IMRP20, STERIS AST and the Thailand Institute of Nuclear Technology (TINT) made their facilities available. Both tours were quickly fully booked by 67 participants.

The STERIS AST sites in Thailand are located in Chonburi, approximately 80 km east of Bangkok. The technical tour was of the Chonburi 1 site that offers two gamma irradiators and was recently expanded to include X-Rays irradiation technology. The Chonburi sites along with other sites in the region support STERIS customers in South East Asia through a technology neutral service offering that includes radiation and gas processing options. More information at <https://www.steris-ast.com/site/chonburi-thailand/>

The TINT Irradiation Center is located in the national Technopolis Complex, approximately one hour drive from Bangkok. The Center is equipped with gamma, e-beam and X-rays irradiation technologies and is used to treat a wide range of agricultural, food, industrial and medical products. The centre was the first in the country to be certified by the European Commission for spice irradiation and by USDA for irradiation of a wide range of fresh fruit to be exported to the U.S. The Center also offers a range of services including microbiological, bioburden, sterilisation and cytotoxicity testing.

THE WINS/iia WORKSHOP

This workshop on security of gamma irradiation facilities was jointly hosted by iia and the World Institute for Nuclear Security (WINS). The objectives of the workshop were to share experience from strengthening gamma irradiator security by encouraging participants to discuss their lessons learned, good practices and remaining challenges in designing and implementing security arrangements for these facilities.

The event discussed the importance of a robust organisational structure for security, key physical security features and the role of security awareness and culture amongst staff and managers. It also explored evolving aspects of radiological security and included presentations and discussions on topics such as an ongoing pool water obscurant project and cyber security measures.

This event was interactive and built around presentations from expert speakers. The following presentations formed the basis of plenary and small group discussions that enabled participants to further explore the topics and share their experience and lessons learned:



- International Best Practice on Security of Radioactive Sources Used in Industrial Radiation Processing (Martin Comben, iia)
- Radioactive Material Physical Security Best Practice (David Jackson, STERIS)
- Cybersecurity for Gamma Irradiation Facilities (Michael Rowland, Sandia National Laboratories)
- Developing an Obscurant System to Protect Radiological Sources in Industrial Irradiation Facilities (Michal Kuca, Sandia National Laboratories)
- Introduction to the Methodology for Assessing the Effectiveness of Security at Gamma Irradiation Facilities (Pierre Legoux, WINS)

An online voting system allowed participants to anonymously provide feedback and give their opinions on several topics. Feedback identified security areas that are usually well covered by operators and those that may require further attention. Topics of discussion included the importance of security culture, interaction with law enforcement, confidence in existing cybersecurity measures and security considerations during source installations. Participants reported very diverse levels of maturity in terms of regulatory frameworks with some countries having robust security regulation and others lagging far behind.

Detailed Q&A was held with two participants that have collaborated with iia, WINS and Sandia National Laboratories (SNL) on different security projects. A pilot of the joint iia/WINS security effectiveness assessment methodology was reported as being a very positive experience for the organisation and a few findings and follow-up actions were described. An ongoing iia/SNL cybersecurity project in which a vulnerability assessment will be performed at a gamma irradiator was reported as being of great value to the operator and is expected to result in an industry specific guidance document.

The workshop was attended by 51 delegates from 16 countries. 54% of the participants came from gamma irradiation facilities and 15% were members of regulatory agencies. Remaining participants represented other stakeholders involved in the security of gamma irradiation facilities such as suppliers (irradiators and radioactive sources), law enforcement and academic institutions.



Appendices



APPENDIX 1

Global Review and Tribute to John Masefield

Paul Wynne, iia Chairman and Director General

The irradiation industry is unusual in being underpinned by a spirit of friendship and collaboration. This can perhaps be traced back to early days of the industry when scientists and engineers around the world collaborated and formed lifelong friendships. The spirit of collaboration and friendship is however precious and can easily be lost. In this regard conferences such as IMRP are, I believe, important.

The opening video for IMRP20 paid tribute to the pioneers of the radiation processing industry. Considerably more detail is provided in the book 'Radiation Processing Industry – The Early Years' which we published today.

I would like to pay a special tribute to John Masefield. John had a colourful and interesting life in the irradiation industry which began in the 1950's. He was born in the UK where he studied engineering and physics before emigrating to Canada where he joined AECL. He was involved in the design and construction of one of the first irradiators for Ethicon and later a mobile demonstration potato irradiator. His first company, Irradiated Foods of Canada, failed mainly because of a poor potato harvest but in 1972 he established Isomedix which became one of the leading contract irradiation businesses and one of very few that went through an IPO to be listed on a stock exchange. Many of you will have amusing tales about John who was a great storyteller and good friend. We were very saddened to learn of his passing earlier this year.

Before leaving this introduction, I would like to reflect on the pre-conference workshop that was held at Kasetsart university last week. 24 students from 13 countries participated. The students were motivated and conscious but by the end of day three there was evidence that strong friendships were being forged. This is the group after the closing session.

The evolution of irradiation can perhaps be divided into a number of periods.

- The Age of the Pioneers 1950-1980 during which scientists and engineers developed the early applications of irradiation, built industrial irradiation facilities and established business ventures. In the true spirit of entrepreneurial endeavour some businesses such as John Masefield's potato irradiation business failed but undeterred the pioneers started again. During this period the regulations that many of us take for granted such as the move away from the concept of absolute sterility to sterility assurance levels were developed. These were often complex and time-consuming issues.



- The age of the pioneers was followed by the Age of the Corporations covering a period from 1980 until perhaps 2010. During this period organisations that started as technologies looking for applications began to recognise the importance of the customer which meant that they became technology neutral, often expanding to multi-site and international operations. As organisations grew a number were listed on Stock Exchanges providing access to additional funds and requiring a greater focus on finance, marketing and sales. We began to see a growing number of mergers and acquisitions, which perhaps reached a peak in the early 2000's.
- After 2010 we moved into the Age of the Environment where environmental concerns began to dominate the conversation. These include concerns over the use of ethylene oxide and radioisotopes but also a new focus and interest in using accelerators to address a wide range of environmental concerns. Some of these applications have been known for years but none have been widely adopted as there has been no financial incentive or legal obligation to use them.

The Irradiation industry continues to have a positive impact on the lives of a significant proportion of the global population, yet few politicians and even fewer members of the public are aware of the importance of irradiation technologies. As a consequence, we find ourselves, on occasions, having to work hard and under time pressure to avoid restrictions from proposed legislation. Politicians and regulators are generally uncomfortable engaging with industry preferring to seek input from the scientific community. In this environment the role of the IAEA, industry associations and the scientific community is vital. There is a case for our industry to invest more time highlighting the benefits of irradiation technologies to 21st Century life.

In 2021 the US Academies of Science, Engineering and Medicine published their report *Radioactive Sources: Applications and Alternative Technologies*. The Report listed 15 findings and made 9 recommendations. It noted that radioactive sources continue to be widely used in the US and internationally and that only one application for Category 1 sources had been phased out. The Report acknowledged that the international community had taken action to strengthen the security and accountability of radioactive source management and highlighted that the US Government's goal of replacing radioactive sources with non-radioisotopic technologies would not be realised until all disused sources had been removed and disposed of. The shift to 'alternative technologies' generally interpreted as a switch from gamma to accelerators is complex and time consuming.

One area where alternative technologies have been successfully introduced is blood irradiation, but progress would probably have been much slower were it not for a range of incentive schemes offered to support the transition. The most effective program has been the Cesium Irradiator Replacement Program (CIRP) run by the US DOE through the Office for Radiological Security (ORS).

At the recent 7th Annual Meeting of the Ad Hoc Working Group on Alternatives to High Activity Radioactive Sources there was little reference to industrial irradiation and much



more time spent highlighting the use of medical applications, well logging and new or under used environmental applications such as flue gas, wastewater and microplastic treatments. The alternative to caesium-137 blood irradiation has been a success story but progress in other areas, including well-logging, has been limited and change appears to be a long way off.

Today the growth in the use of industrial accelerators for sterilisation is driven more by the need for capacity than a wish to switch out of using radioactive sources. Where possible, new gamma facilities continue to be constructed however people are beginning to appreciate the benefits of X-Rays in certain circumstances.

Today gamma irradiation and ethylene oxide gas are still the dominant technologies for the sterilisation of medical devices despite significant investment in accelerators offering both EB and X-Rays. It appears extremely unlikely that the sterilisation needs of the healthcare community will be met without continued access to both gamma and EO for the foreseeable future.

In recent decades accelerator technology has made huge progress in terms of efficiency and reliability. The increasing use of high energy RF accelerators and the Rhodotron paved the way via increasing availability and the introduction of X-Rays technology. This vastly expands the range of products that accelerators can process. Today the challenge for accelerator manufacturers is meeting demand whilst operators need to acquire new skills in order to plan the investment and to operate accelerator technology. Recently a new concern – the availability, reliability and cost of electricity is causing investors to ask if stand-by generators, solar and other back-up devices can keep systems operational during power outages.

There is much frustration in the gamma community because of constraints on the current availability of cobalt, however, supply contracts extending out as far as 2064 have been signed, and the ongoing investment in reactor refurbishment provides evidence that gamma will remain available for the foreseeable future. Concerns over the security of isotropic material have been addressed by the gamma community which has been a willing and active participant in the process. Industry collaboration with organisations such as NNSA, Sandia and WINS have been both productive and positive. Denial of shipment is an issue. There are commercial and regulatory reasons for this problem so solutions can be difficult and slow to achieve.

From a technology perspective there is little doubt that the future, for all irradiation technologies, gamma, electron beam and X-Rays, remains bright but that does not mean that there are no challenges.

The applications of irradiation technology continue to grow and demand in most sectors remains strong. Each market or application is subject to its own dynamics and some face challenges mainly related to poorly informed, non-scientifically based, laws or regulations and occasionally to the absence of an economic incentive or regulation to stimulate demand.



In the case of sterilisation gamma irradiation remains critical and EB and X-Rays will continue to be welcomed. Gamma and EO will remain the most important sterilisation technologies for some time. If events prevent this, and they could, the world will encounter a critical shortage in the availability of sterile medical devices. Capacity constraints in gamma and EO are already encouraging the healthcare community to aggressively embrace EB and X-Rays technology but this may not be enough to avoid a short-term crisis.

All the indications are that polymer processing continues to grow and remains an important application for irradiation, but precise estimates are difficult to generate as throughput is mainly undertaken in house or by a limited number of well-respected contract partners using EB technology. The need to maintain intellectual property rights encourages secrecy so the importance of the application can easily be underestimated.

The outlook for food and agricultural applications is mixed. There have been notable success stories such as sterile insect technology (SIT) and mutation plant breeding programs. The growth in use of phytosanitary treatments is encouraging with countries such as Thailand, Australia, New Zealand, the USA and Mexico leading the way.

John Masefield's early investment in Irradiated Foods of Canada failed. The joint FAO/IAEA/WHO committee gave its comprehensive expert report on Food Irradiation in 1980 but this did not result in positive legislation. Today the world appears less receptive to food irradiation than it was 42 years ago despite the fact that it could reduce illness that costs the global economy in excess of \$50 Billion pa.

Environmental Applications are not new but new applications are being identified. Flue-gas, wastewater and sludge treatments are well known. New applications continue to be developed such as one to address micro-plastic pollution in our oceans. These applications are best suited to accelerator technology. Widespread use requires financial or legal incentives which are starting to appear.

In summing up I believe that:

1. All irradiation technologies – gamma, EB and X-Rays are important and will remain so for the foreseeable future
2. In the short to medium term, gamma faces capacity challenges but the non-irradiation technology EO faces potentially even greater challenges.
3. The lead times to install additional irradiation capacity can be quite long and our industry needs to acquire new skills to help in the selection and running of EB/XRays equipment.
4. In the coming few years available sterilisation capacity may struggle to cope with demand from the healthcare market.
5. It is unlikely that significant sterilisation capacity, using high energy accelerators, will transfer inhouse, at least in the short term.
6. Concerns over the impact of energy insecurity are a new concern and these need to be addressed.



7. Of concern is the increasing age of those in our community.

We should do all in our power to maintain the precious spirit of friendship and collaboration that has served us well and should avoid negativity as this creates tension and division.

The IMRP Laureate program is our link with the pioneers of our industry. New Laureates will be recognised on Thursday of this week.

I haven't spoken about the iia Leadership Program. This aims to strengthen the link between science and industry and to bring new talent into our industry. You will hear more about this in the coming days and months.

I would urge you to learn more about the work of the Society for Sterility Assurance Professionals (SfSAP) which is of particular relevance for those providing sterilisation services and don't forget to look at the work of the Phytosanitary Irradiation Platform (PsIP) and the iia gamma working group.

On that note I wish you well and hope that you have an enjoyable and successful IMRP20.



APPENDIX 2

Oral Presentations - Plenary Sessions

This appendix and the following ones list the presentation titles and the authors. A hyperlink to the presentations has been included where presenters have agreed to share them.

Plenary 2 - DOSIMETRY AND MODELLING

Moderator: Florent Kuntz, Aerial, Strasbourg, France

P2.1

[Introduction to dosimetry and modelling](#)

Dr. Florent Kuntz, France, Aerial, Illkirch

P2.2

[Innovative ESR dosimetry system for high dose radiation processing](#)

Dr. Ileana M Pazos, United States, National Institute of Standards and Technology, Gaithersburg

P2.3

[Calorimetry for low-energy electron beam dosimetry with significantly reduced measurement uncertainty](#)

Dr. Mark Bailey, Denmark, Risø High Dose Reference Laboratory, Denmark's Technical University, Roskilde

P2.4

[Industry collaboration to develop a comprehensive software package for use by non-experts to calculate the dose distribution in irradiated polymer-based products](#)

Mr. Randolph A Schwarz, United States, Pacific Northwest National Laboratory, Richland

P2.5

[A virtual dose mapping tool for radiation sterilisation](#)

Dr. Tobias Funk, United States, Triple Ring Technologies, Newark

P2.6

[E-Beam dose mapping: What about modelling the "REAL" product](#)

Dr. Abbas Nasreddine, France, Aerial, Illkirch

Plenary 3 - RADIATION CHEMISTRY

Moderator : Prof. Xavier Coqueret, Université de Reims Champagne Ardenne, France

P3.2

IMRP Odyssey: Reflecting on the past and anticipating the future of radiation processing of polymers

Prof. Olgun Guven, Turkey, Hacettepe University, Ankara

P3.3

Influence of sterilization dose, dose rate and temperature on the effects of radiation on polymers

Dr. Nicolas Ludwig, France, Aerial, Illkirch

P3.4

The role of diffusion in synthesis and physicochemical properties of polymer hydrogels: Simulations and experiments

Dr. Slawomir Kadlubowski, Poland, Lodz University of Technology, Institute of Applied Radiation Chemistry, Łódź

P3.5

Synthesis of geranyl β D-glucopyranoside by electron beam irradiation in aqueous condition with geraniol and glucose

Dr. Ju-Woon Lee, South Korea, PSA Co. Ltd, Pusan

P3.6

Tailoring macromolecular structure and properties for value-added polymers

Dr. Jordan F. Madrid, Philippines, Philippine Nuclear Research Institute, Quezon City



Plenary 4 - ADVANCED POLYMERS

Moderator: Prof. Olgun Guven, Hacettepe University, Ankara, Turkey

P4.2

Latest developments in radiation applications for advanced polymers

Prof. Piotr Ulanski, Poland, Lodz University of Technology, Lodz

P4.3

Super water absorbents by radiation induced graft polymerization: From synthesis to lab evaluation and in-field testing

Prof. Wanvimol Pasanphan, Thailand, Kasetsart University, Bangkok

P4.4

Effects of X-ray, electron beam and gamma irradiation on PE multilayer film properties

Dr. Nina Girard-Perier, France, Sartorius, Aubagne

P4.5

Continuous electron-induced reactive processing: A sustainable reactive processing method

Dr. Michael T. Müller, Germany, Leibniz Institute of Polymer Research Dresden, Dresden

P4.6

Superhydrophobic cotton: a new material with multiple potential applications

Dr. Subhendu Chowdhury, India, Bhabha Atomic Research Centre Mumbai (BARC), Mumbai

Plenary 5 - ENVIRONMENTAL APPLICATIONS

Moderator: Rob Edgecock, University of Huddersfield, Huddersfield, United Kingdom

P5.1

Introduction to the session

Rob Edgecock, United Kingdom

P5.2

IAEA Initiatives for Recycling of Plastic Wastes by Radiation Technology

Dr. Bum Soo Han, Austria, International Atomic Energy Agency (IAEA), Vienna

P5.3

The cyanotoxin Microcystin-LR and the cyanotoxin-producing cyanobacteria, Microcystis aeruginosa are susceptible to low electron beam doses

Prof. Suresh D Pillai, United States, Texas A&M University, College Station

P5.4

Hygienisation of dry city sewage sludge

Dr. Lalit Varshney, India, Bhabha Atomic Research Centre, Raigarh

Plenary 6 - DIVERSITY IN APPLICATIONS

Moderator: Yves Henon, iia

P6.1

Introduction to the session

Yves Henon, France, iia

P6.2

A new low energy electron beam machine to reduce microbial loads in dry plant-based foods

Miss Heidi Kotilainen, United Kingdom, Buhler Group, London

P6.3

Development of inactivated zika virus vaccine by irradiation

Dr. Boonrat Tassaneetrithep, Thailand, Siriraj Faculty of Medicine, Mahidol University, Bangkok

P6.4

From bioleaching to anti-adhesive coatings: New potential applications of low energy electron beams

Dr. Simone Schopf, Germany, Fraunhofer Institute for Organic Electronics, Electron Beam and Plasma Technology, Dresden

P6.5

Irradiation of medicinal hemp

Dr. Suwimol Jetawattana, Thailand, Thailand Institute of Nuclear Technology, Nakhon Nayok

P6.6

Sterile Insect Technique: 60 years benefiting agriculture and the environment

Dr. Vanessa Dias, Austria, IAEA, Vienna

APPENDIX 3

Oral Presentations - Radiation Technology Forum

Session Tech 1 – Cobalt-60 supply chain

Moderator: Richard Wiens, Nordion, Ottawa, Canada

Tech-1.2

A new reactor platform for Cobalt-60 production

Dr. Kris R Paserba, United States, Westinghouse Electric Company LLC, Butler

Tech-1.3

Improving Co-60 supply chain efficiency

Mr. Corby Nicholson, Canada, Nordion, Ottawa

Tech-1.4

Cobalt-60 production in Argentina

Germán Arambarri, Argentina, Dioxitek, Buenos Aires

Session Tech 2 - Gamma irradiators technology

Moderator: Daniel Perticaro, Ionics, Buenos Aires, Argentina

Tech 2.2

Ideas for making food irradiation more viable

Mr. Arjun Vas, India, Symec Engineers (India) Pvt Ltd, Mumbai

Tech-2.3

Co-60 source optimization using Monte Carlo simulation in a complex industrial context

Mr. Ludovic Eychenne, France, TRAD Tests & Radiations, Labège

Tech-2.4

Improving gamma irradiator efficiency through scheduling

Dr. Chris Howard, Canada, Nordion, Ottawa



Session Tech 3

Moderator: Martin Comben, iia, United Kingdom

Tech-3.1

60 years of safe and secure operation

Martin Comben, iia, United Kingdom

Tech-3.2.1

Radiation safety in gamma irradiation

Dave Jackson, STERIS, United States

Tech-3.2.1

Radiation safety in gamma irradiation

Greg Fulford, Nordion, Canada

Tech-3.3

The storage pool obscuration option

Meghan Van Den Avyle, Sandia National Laboratories, United States

Tech-3.4

Panel: The current status and future of gamma irradiation

Martin Comben, iia, United Kingdom

Session Tech 4

Moderator: Philippe Dethier, STERIS, Mont Saint Guibert, Belgium

Tech-4.2

BEYOND: A new generation of optimized E-beam & X-Ray irradiation solutions

Mr. Arnaud Pierard, Belgium, IBA Industrial, Louvain-la-Neuve

Tech-4.3

Progress in high-power linacs

Thomas Kroc, United States, Fermilab, Batavia

Tech-4.4

State-of-the-art sterilization process control system for gamma, X-ray and E-beam systems

Mr. Greg Haycox, Canada, STERIS, Kanata

Tech-4.5

Progress in modeling tools for better accelerator integration and product validation

Mr. Ludovic Eychenne, France, TRAD Tests & Radiations, Labège

Tech-4.6

Custom linacs for industrial applications

Dr. Alexander Murokh, United States, RadiaBeam Technologies, LLC., Santa Monica

Session Tech 5 – Implementing EB-X Technology

Moderator: Jeremy Brison

Tech 5.1

Introduction to the session

Jeremy Brison, Belgium, IBA Industrial

Tech-5.2

Implementing X-ray for single-use bioprocess systems sterilization

Dr. Samuel Dorey, France, Sartorius, Aubagne

Tech-5.3

Viable alternatives to cobalt-60 for industrial sterilization; future modality trends

Mrs. Vanessa Vargas, United States, Sandia National Laboratories, Albuquerque

Tech-5.4.1

Development of an X-Ray and E-beam system in Australia

Mr. Murray Lynch, Australia, Steritech, Dandenong South

Tech-5.4.2

Development of an X-Ray and E-beam system in Australia

Mr. Eric Beers, Canada, Mevex, Stittsville

Tech-5.5

The needed expansion of X-ray and E-beam for sterilization – progress of Team Nablo, an international collaboration team

Mr. Mark K. Murphy, United States, Pacific Northwest National Laboratory, Richland

APPENDIX 4

Oral Presentations - Radiation Sterilisation Forum

Session Rad-Ster 1 - Sterilization standards today and tomorrow

Moderator: Byron Lambert, Abbot Laboratories, USA

RadSter-1.1

Introduction to the session

Byron Lambert, USA, Abbot Laboratories

RadSter-1.2

The global standardization and harmonization imperative

Ms. Amanda E Benedict, United States, AAMI, Arlington

RadSter-1.2

Radiation sterilization standards ecosystem and accelerated innovation

Emily Craven, Canada, Boston Scientific, Ottawa

Session Rad-Ster 2 - Competency in sterilization

**Moderator: Arthur Dumba, The Society for Sterility Assurance Professionals (SfSAP),
Selzach, Switzerland**

RadSter-2.1

Introduction to the session

Arthur Dumba, Switzerland, SfSAP

RadSter-2.2

Global auditor competency in an evolving radiation sterilization landscape

Kimberly W Patton, United States, PRI, Sumter

RadSter-2.3

Beyond read & learn for SMEs

Mr. Vu Le, United States, Abbott Labs, Temecula

RadSter-2.4

Delivering training to develop competent professionals - Pathways to overcome challenges

Ms. Ivy Louis, India, Vienni® Training & Consulting LLP, Bangalore



RadSter-2.5

The journey from novice to expert and the spectrum of possibilities

Dr. James Vesper, United States, ValSource, Rochester

RadSter-2.6

Conclusion

Arthur Dumba, Switzerland, SfsAP

Session Rad-Ster 3 -Product qualification

Moderator: Bart Croonenborghs, Sterigenics, Leuven, Belgium

RadSter-3.2

Bioburden and sterility testing of product: Select an SIP or a representative product portion?

Mr. Martell Winters, United States, Nelson Laboratories, a division of Sotera Health, Salt Lake

RadSter-3.3

Using E-Beam to sterilize respirators

Mr. Aaron Neighbour, United States, Nutek Bravo, Hayward

RadSter-3.4

Sterilization and endotoxins: A review and regulatory alignment

Mr. Nick Brydon, United States, NextBeam, North Sioux City

RadSter-3.5

Assessing potential induced radioactivity in materials processed with X-ray energy above 5 MeV

Mr. Pierre Reppert, Switzerland, STERIS, Däniken

RadSter-3.6

Sterilization dose qualification

Mr. Anthony J Sollis, United Kingdom, STERIS, Swindon

Session Rad-Ster 4 – Process control

Moderator: Hervé Michel, STERIS, Daniken, Switzerland

RadSter-4.2

Designing product radiation shielding using Monte Carlo simulations

Dr. Daniel Badali, Canada, Triple Ring Technologies, Toronto

RadSter-4.3

Towards real-time dosimetry in X-ray sterilization

Mr. Damien Prieels, Belgium, IBA Industrial, Louvain-la-Neuve

RadSter-4.4

Monte Carlo Simulation benefits to healthcare product manufacturers in radiation processing

Dr. Samuel Dorey, France, Sartorius, Aubagne

Session Rad-Ster 5 – Biopharma and materials

Moderator: Nishad B Dhurandhar, MICROTROL Sterilisation Services Pvt. Ltd., India, Mumbai

RadSter-5.2

Compared impact of gamma and X-rays on single-use system materials to supplement insufficient gamma sterilization capacity with X-ray

Ms. Lucie Delaunay, France, Sartorius, Aubagne

RadSter-5.3

Qualifying X-ray irradiation of single use bioprocessing equipment as an alternative to gamma

Dr. James J Hathcock, United States, Pall Corporation, Needham

RadSter-5.4

Radiation validation of single-use systems (SUS) – an AAMI consensus report

Mr. Martell Winters, United States, Nelson Laboratories, a division of Sotera Health, Salt Lake

RadSter-5.5

Real time release

Mr. Adam Whaites, United Kingdom, Cytiva and The Irradiation Panel

APPENDIX 5

Oral Presentations - Phytosanitary Irradiation Forum

Session Phyto 1 – Commercial trade

Moderator: Peter Roberts, Radiation Advisory Services, Lower Hutt, New Zealand

Phyto-1.1

Welcome and global view

Peter Roberts, New Zealand

Phyto-1.2

Phytosanitary irradiation in Mexico: The first 11 years and an outlook for those to come

Mr. Arved Deecke, Mexico, Benebion

Phyto-1.3

Australian Commercial Update

Mr. Benjamin J Reilly, Australia, Steritech, Nundah

Phyto-1.4

Phytosanitary irradiation in Vietnam

Dinh Thi Anh Tuyet, Vietnam Plant Protection Department

Phyto-1.5

The South African experience

Ms. Cherin D Balt, South Africa, HEPRO Cape (Pty) Ltd, Cape Town

Phyto-1.6

Phytosanitary irradiation scenario in India

Mr. Harshad Doshi, India, Agrosurg Irradiators (I) Pvt.Ltd, Mumbai

Session Phyto 2 – Post-Harvest

Moderator: John Golding, Australia

Phyto-2.1

Introduction: Optimizing quality of irradiated produce

John Golding, NSW Department of Primary Industries, Australia

Phyto-2.2

Apple fruit responses to phytosanitary X-ray treatments

Allan Woolf, The New Zealand Institute for Plant and Food Research Limited, New Zealand

Phyto-2.3

Phytosanitary irradiation and controlled atmosphere storage of Nam Dok Mai Si Thong mango: Economic potential and challenges for international trade

Dr. Suwimol Jetawattana, Thailand, Thailand Institute of Nuclear Technology, Nakhon Nayok

Phyto-2.4

Shelf-life of Nam Dok Mai Si Thong mango irradiated for phytosanitary purpose; influence of modified atmosphere

Dr. Peerasak Chaiprasart, Thailand, Naresuan University, Phitsanulok

Phyto-2.5

NIR spectroscopy for the optimization of postharvest-irradiated Thai mangoes - Management for exportation

Mr. Phongrapi Wichitkunanon, Thailand, Naresuan University, Phitsanulok

Phyto-2.6

Combination of cold and irradiation for citrus

Suresh Pillai, Texas A&M University, United States

Session Phyto 3 – Treatment efficacy

Moderator: Peter Roberts, New Zealand

Phyto-3.2

Treatment efficacy

Peter Follett, USDA-ARS, United States (Presented by Yves Henon)

Phyto-3.3

Research on phytosanitary irradiation efficacy conducted by the Joint FAO/IAEA Centre of Nuclear Techniques in Food and Agriculture

Vanessa Dias, IAEA, Austria

Phyto-3.4

USDA-APHIS-PPQ phytosanitary irradiation treatment development and scientific support

Cory Penca, USDA, APHIS, PPQ, S&T, United States

Session Phyto 4 – Infrastructure and technology

Moderator: Mr. Murray Lynch, Steritech, Dandenong South, Australia

Phyto-4.2

Dosimetry; The key element of confidence in phytosanitary irradiation

Florent Kuntz, Aerial, France

Phyto-4.3

X-ray solutions for phytosanitary applications with economic and process performance details

Cody Wilson, IBA Industrial, United States & Ariadne Vargas, iia

Phyto-4.4

Treating pallets with multiple densities with X-rays

Macdarragh O'Neill, Steritech, Australia

Phyto-4.5

Challenges to adopt PI

Bimo Saputro, National Agency for Research and Innovation (BRIN), Indonesia

Session Phyto 5 – Regulatory development

Moderator: James Allan, Australian Embassy Vietnam, Hanoi, Vietnam

Phyto-5.2

USDA-APHIS-PPQ irradiation program update

Cory Penca, USDA, APHIS, PPQ, S&T, United States

Phyto-5.3

A commercial perspective on national regulations

Benjamin Reilly, Steritech, Australia

Phyto-5.4

Effect of labelling fresh blueberry with information on irradiation on Finnish, German and Spanish consumers

Heidi Kotilainen, Buhler Group, United Kingdom

Phyto-5.5

Phytosanitary irradiation: A tool to facilitate trade

Sally Ormiston, Department of Agriculture, Fisheries and Forestry, Australia

Phyto-5.6

Maximum energy limit for X-rays: Codex or economics ?

Peter Roberts, Radiation Advisory Services, New Zealand

APPENDIX 6

Sponsors and Exhibitors

IMRP is the world's largest gathering of organisations that supply radiation processing equipment and services and other irradiation related products. The following list of companies that sponsored and exhibited at IMRP20 serves as a directory of leading suppliers to the irradiation industries.



Aerial

<https://www.aerial-crt.com/>

Aerial's research and development studies are conducted with industrial companies, research centres and universities. In order to meet the wide variety of demands, Aerial runs an experimental irradiation facility with a high energy Rhodotron electron accelerator, a medium energy Van de Graaff, a low energy X-ray cabinet and very efficient laboratories (dosimetry, microbiology, physical chemistry, sensory analysis and freeze drying).

Thanks to the various and complementary competences of its 30 employees, Aerial presents a unique and original offer for technology transfer to a large variety of industries. As a major dosimetry partner, Aerial provides training, IQ/OQ/PQ support, calibration of dosimetry systems and offers custom optical and EPR dosimetry equipment, DosASAP, AerODE and AerEDE.



BGS Beta-Gamma-Service GmbH & Co.

<https://en.bgs.eu/>

BGS is a leading service and solution provider in the industrial application of beta and gamma rays for radiation sterilisation and radiation crosslinking. Using beta and gamma rays, pathogenic germs are destroyed fast, reliably and in an environmentally friendly manner, and plastics are refined in such a way that they are more resistant to heat, wear and chemical influences. As an innovative forerunner and pioneer in the industry, we have co-developed methods that are today state-of-the-art technology.



CGN Dasheng Electron Accelerator Technology Co., Ltd.
<https://www.cgndea.com/>

CGN Dasheng Electron Accelerator Technology Co., Ltd is a comprehensive nuclear technology application of high-tech companies. It's professionally engaged in researching, producing and selling the electron accelerator. Moreover, radiation processing, high-tech materials, the application of the electron beam and detecting service is also available.

CGN Dasheng Company is the most complete model supplier in the area of middle and low energy electron accelerators and the biggest radiation service provider. The industry-leading irradiation cross-linking polymer material is also CGN Dasheng Company's production. By now it has been the most complete industry base in the area of electron accelerators and the applications of nuclear technology.



Dioxitek S.A.
<https://dioxitek.com.ar/en/#/>

Dioxitek S.A. is a state corporation which is part of the Argentine Nuclear industry. It has been a key part of the nuclear energy companies since 1997.

Our company main activities are (1) the production of uranium dioxide later used in in the manufacturing of fuel assemblies, clads and zircaloy rods, and (2) the design, production and fabrication of cobalt-60 sealed sources which are provided for the health care system and the industry which are used to treat cancer related diseases, preserve foods, and sterilise medicine surgical supplies, manage pathogenic hospital waste, among others.

Aside from the sources, Molybdenum-99 is commercialised. It is destined for the production of radiopharmaceuticals for the nuclear medicine used in imaging diagnostics.



Etigam B.V.

<https://www.etigam.nl/>

Etigam, founded in the Netherlands in 1980, is dedicated mainly to the development, manufacture and sales of sterilisation indicators. * sterilisation indicators (chemical), mainly used in the sterilisation of medical and pharmaceutical products, packaging materials and for cross-linking of polymers and decontamination of herbs and spices: self-adhesive colour changing dots and labels for Gamma, e-Beam, x-Ray, EO gas and Steam. The radiation sensitive indicators respond to a minimum dose with a colour change of yellow to red. * sterilisation indicators (biological), used to validate and monitor most common sterilisation processes : spore strips, suspensions and self-contained for EO gas (Bac. Atrophaeus), steam (G. Stearothermophilus) and gamma (B. Pumilus).



Gamma-Services Recycling GmbH

<https://www.gamma-recycling.info/en/home>

Gamma-Service Recycling specialises in handling, recycling and supplying radioactive sources incl. shipment for research, medicine, and industry. Our services include decontamination of radionuclide facilities and design, installation and commissioning of irradiation plants. In each business line, we offer turn-key packages with safety and security concepts, customs, package provision and transportation.



Gammatex Indicator Labels

<https://www.gammatex.co.uk/>

Gammatex are the UK's leading supplier of Chemical Process Indicator labels.

We manufacture all our CPI's at our ISO 9001:2015 certified site in the UK in compliance with ISO 11140-1:2014.

Gammatex Radiation Chemical Process Indicator labels are self adhesive labels that undergo a simple colour change when exposed to Gamma or E-Beam radiation. The labels

undergo a clear and distinct colour change from yellow to red when activated.

Products include:

- 12mm Gammatex dots
- Customised Gamma stripe labels
- 26 x 12mm Meto Gun gamma labels
- Multi layer options for special packaging requirements.



dosimetry solutions

GEX Corporation

<https://www.gexcorp.com/>

GEX provides dosimetry products and services used in gamma, e-beam, and X-ray radiation applications, such as medical device sterilisation, surface decontamination, material modification and food irradiation.

Highlight of products and services:

- B3 film dosimeter products for process monitoring, dose mapping, equipment qualification, and research applications.
- DoseControl[®] dosimetry system - controls the measurement process. Users create and maintain dosimetry records with optically measured dosimeters (e.g. B3, FWT, CTA, and PMMA). Can be integrated with ERP/SPC/QMS and other pre and post-process systems. 21 CFR Part 11, Annex 11 compliant software.
- laboratory accredited (NVLAP) to ISO/IEC 17025:2017 offering certified measurement results for transfer-standard alanine dosimeter doses (0.25 kGy to 100.0 kGy).
- Routine dosimetry system calibration planning, data analysis, curve fitting, and uncertainty estimation.

Founded in 1991, GEX maintains a Quality Management System accredited to ISO 9001:2015.



Hopewell Designs

<https://www.hopewelldesigns.com/>

Hopewell Designs is a leading supplier of irradiators systems for calibration, dosimetry, research, and quality control. Our mission is to help our customers excel by delivering industry-leading, life-changing solutions across the entire spectrum of radiation applications.

Hopewell Designs has been delivering quality irradiation systems, shielding, automation systems and custom designs throughout the world since 1994.

We are committed to providing the best possible solutions to our customers.

Products and Services:

- Irradiator Systems: Gamma, Neutron, Beta and X-Ray,
- High dose and self-contained irradiators,
- Radiation Shielding and storage casks,
- DOT 7A Shipping Containers,
- Radiation automation solutions,
- Consulting, training, and service.



IBA

<https://www.iba-industrial.com/>

IBA INDUSTRIAL is the world leader in electron and proton accelerators for industrial applications. Its unique E-beam, X-ray and Proton treatment solutions are used across the world. Today, IBA Industrial brings to the market a new value proposition, an experience it lives with its Customers through the whole journey. This experience is called BEYOND™, a commitment to go above any expectations.

Its end-to-end solutions are available for all meaningful applications such as medical devices sterilisation, food pasteurisation, property enhancement for various materials, etc

IBA Industrial cares about its Customers from start to infinity. It accompanies them in each step of the project from site planning and optimization, engineering, and integration of all



operational sub-systems to assistance in operation and BEYOND.

Over 280 IBA Industrial accelerators are used in the world today, some for more than 50 years.



Institute of Isotopes Co. Ltd.

<https://www.izotop.hu/radiation-technique/>

Founded in 1959, the Institute of Isotopes became a major Hungarian centre for the research, development and production of radioisotopes.

Fields of expertise:

- Radiation technique solutions for medical, research and industrial applications
- Radiosynthesis
- Radiopharmaceuticals
- Radioimmunoassay

Main products, services:

- Industrial sources: Co-60, Ir-192, Cs-137
- Manufacturing and servicing of irradiators:
 - Multipurpose irradiators for commercial field
 - Research irradiators
 - Calibration irradiators
 - Radiation Protection Systems /hot cells, storage boxes and whole body counters, radiation protection walls, doors, A and B(U) type transport containers for safe and secure transportation of radioactive material/
- Transport and storage containers, hot cells

Our engineering background and experience in radiation technique is a strong base for manufacturing radioactive industrial sources, irradiators and radiation protection systems. Our experts support the medical-, food- and agricultural industry with customised applications.

The cooperation with IAEA and different international associations, companies serves as reference for future projects in designing, installing, dismantling, decommissioning.





KAERI - Korea Atomic Energy Research Institute

www.kaeri.re.kr

www.koara.or.kr

www.rcaro.org

KAERI (Korea Atomic Energy Research Institute), KARA (Korea Association for Radiation Application) and RCA (Regional Cooperative Agreement for Research, Development and Training Related to Nuclear Science and Technology for Asia and the Pacific) Regional Office introduce their role and activities mainly focused on radiation and cultural heritage, and radiation drug platform in Korea.



MEVEX

<https://www.mevex.com/>

Mevex is a manufacturer and supplier of integrated sterilisation equipment, with a range of equipment and services from e-beam, X-ray, ethylene oxide (EtO), conveyors and robotics to meet customised needs.

Projects can vary from the supply of a Linear Accelerator (Linac) up to the integration of a validated irradiation system including a conveyor system, process management, automation, and radiation shield design.

Our systems are used most commonly to sterilise life-saving single-use medical devices. A growing application for our systems is food irradiation for phytosanitary purposes, to improve food safety and extend shelf life.



National Center for Electron Beam Research (NCEBR)

<https://ebeam-tamu.org/ebeam-facility>

National Center for Electron Beam Research (NCEBR) at Texas A&M University in College Station, Texas is the leading academic and research organization in the world that is focused on the research, development, and commercialization of Electron Beam (E-Beam) and X-ray technologies for improving the quality of life of peoples and the regional economies around the world.

The goal of the NCEBR is to partner with academia, government, and private industry worldwide to enable application of E-Beam and X-ray technologies. The mission statement of NCEBR is “Harnessing E-Beam and X-ray technologies to Clean, Heal, and Feed the World and Beyond”. The NCEBR serves as an advocate for the promotion of E-Beam and X-ray technologies around the world. The Center is committed to building strong partnerships with the government and private industry in our efforts to move the technology from the research laboratory to the market-place.



Nordion (Canada) Inc.

<https://www.nordion.com/>

Nordion, a Sotera Health company, has been a leading provider of Cobalt-60 to global customers for more than 70 years. The gamma rays emitted by Cobalt-60 are used in the sterilisation and irradiation processes for the medical device, pharmaceutical, food safety and high-performance materials industries.

Nordion not only supplies Cobalt-60 to customers around the world, we build the gamma processing systems. We combine world-class capabilities in electro-mechanical design, controls, radiation physics, dosimetry and regulatory affairs with a global reach in sales, installation and service to lead the industry in delivering end-to-end gamma processing solutions for our customers.

We are committed to operating in a safe, responsible manner that respects the environment and the health of our employees, our customers, and the communities where we operate.



Office of Radiological Security

<https://www.energy.gov/nnsa/office-radiological-security-ors>

The Office of Radiological Security (ORS) works with government, law enforcement, and businesses across the globe to protect radioactive sources used for medical, research, and commercial purposes; remove and dispose of disused radioactive sources; and reduce the global reliance on

high activity radioactive sources through the promotion of viable non-radioisotopic alternative technologies.



Orano NCS GmbH

<https://orano-ncs.com/en/>

Orano NCS GmbH is a global provider of transportation and logistics services in the nuclear logistic business and performs world wide class 7 radioactive transports by all means of conveyance.

During the last thirty years and through the wealth of experience Orano NCS GmbH has gained numerous projects within the nuclear industry with a team of experienced employees. Orano NCS GmbH is capable of solving even complex and difficult tasks. Our company issues transport concepts, permits of transport - import and export - as well as lashing concepts and can develop a specific solution for each requirement.



Sterigenics, a Sotera Health company

<https://sterigenics.com/>

Sterigenics is a leading global provider of outsourced terminal sterilisation services for the medical device, pharmaceutical, food safety and advanced applications markets. With our industry recognized scientific, engineering and regulatory expertise, we help to ensure the safety of millions of patients around the world every year.

Across our 48 global facilities, we offer our customers a complete range of sterilisation services, primarily using the three major technologies: gamma irradiation, ethylene oxide processing and electron beam irradiation, as well as X-Ray and nitrogen dioxide. We are committed to addressing the growing need for sterilisation across the world and partnering with our customers to eliminate threats to human health.

Safeguarding Global Health® – with every product we sterilise.



STERIS

<https://www.steris-ast.com/>

STERIS Applied Sterilization Technologies (AST) is delighted to be Regional Sponsor of the 20th International Meeting on Radiation Processing (IMRP20).

At STERIS, WE HELP OUR CUSTOMERS CREATE A HEALTHIER AND SAFER WORLD by providing innovative healthcare and life sciences product and services around the globe. Through our Applied Sterilization Technologies segment, we are proud to support this Mission through a comprehensive offering that includes sterilisation and testing services, equipment and technologies, and products to support sterilisation testing.



Steritech

<https://steritech.com.au/>

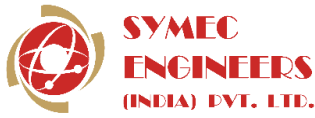
To provide a service of excellence that meets all requirements for all Steritech customers while providing a safe, happy, secure work environment for all Steritech employees. Our goal is to deliver the best in contract sterilisation and decontamination processing.

How we achieve our goal:

- A high standard of service
- Innovative solutions
- Strong relationships with our customers
- Highly trained professionals
- Compliance with safety and environmental regulatory standards
- A strong commitment to research

For almost 40 years, Steritech has been the treatment provider of choice within industries that require sterilisation and decontamination. At Steritech, we are committed to providing our customers not only with the best solution, but also to exceed their expectations.

Our expert team and vast experience ensure our continuing prominence as a leader in the sterilisation and decontamination industry.



Symec Engineers (India) Pvt Ltd

<https://www.symecengineers.com/>

Symec is a company based in India that specialises in automation solutions for nuclear, defence, pharmaceutical and food processing industries.

The company is involved in providing turnkey solutions for Gamma Irradiation facilities, and has been in this space for more than 30 years. In this time, the company has set up a gamma irradiation plants for a wide variety of applications including medical device sterilisation, food irradiation and special applications such as dry sewage hygienization, customised designs for animal blood irradiation, rubber vulcanization and defence applications.

The company has its office and two manufacturing facilities in Mumbai, India, with an in-house team of engineers, technicians and other personnel with decades of experience in building state of the art systems for gamma irradiation, nuclear material handling, process equipment and a wide range of specialised applications.



The Irradiation Panel

<https://www.irradiationpanel.org/>

Formerly known as the Panel on Gamma and Electron Irradiation 'The Irradiation Panel' is a membership organisation dedicated to the advancement, development, promotion, regulation and practice of radiation processing using electron beam, gamma and X-ray technology. Established in 1966 in the United Kingdom it now has members from across Europe and beyond. It meets twice a year to discuss the major issues and challenges facing the industry.



True Indicating, LLC

<https://www.trueindicating.com/>

Established in 2017 with a vision to further sterilisation and disinfection technology. True Indicating LLC is innovative, flexible and focused on meeting client's needs through custom products and services for traditional sterilisation processes as well as new technologies. We've Been in the Industry for Over 20 Years... With over 35 combined years of experience, we can help to develop, evaluate and obtain FDA clearance on custom products for new technologies or offer tried and True traditional configurations for steam, Ethylene Oxide (EO), hydrogen peroxide, dry heat, irradiation, formaldehyde and chlorine dioxide sterilisation and disinfection processes. Let us know how we can help you fulfil your Biological, Enzymatic and Chemical Indicator needs!

APPENDIX 7

Abstracts

Dosimetry – modelling

Poster 4

Presenter: Daniel Badali, Triple Ring Technologies, Toronto, Canada

Differences in gamma and X-ray sterilization: A simulation study

There is currently a push to move away from gamma sterilization for many reasons, such as disruption in the supply chain due to a limited supply of cobalt-60. A promising alternative is X-ray sterilization, which is appealing due to its similarity to gamma sterilization, in that it uses high energy photons.

However, there are fundamental differences between gamma and X-ray sterilization that have significant impact on the resulting dose distributions. In particular, the cobalt-60 used in gamma sterilization produces essentially monoenergetic photons, whereas X-ray sterilization uses a broad energy spectrum produced by a linear accelerator.

In this work we studied the dose delivery mechanisms in gamma/X-ray sterilization. To do so, we used Monte Carlo simulations based on Geant4 which allowed us to turn on/off the interactions that are relevant during sterilization. We simulated the 3D dose distribution delivered to a cube of aluminium by a pencil photon beam of either 1.25 MeV monoenergetic photons (gamma sterilization) or a 7.5 MeV broad spectrum (X-ray sterilization).

The results reveal significant differences in the dominant dose mechanisms. Notably, pair production plays a much bigger role in X-ray sterilization due to the presence of higher energy photons. Similarly, the broad X-ray spectrum also contains lower energy content, which results in elastic Rayleigh scattering contributing significantly to shaping the dose distribution.

In conclusion, although the dose distributions produced by gamma and X-ray sterilization are similar, there are noteworthy differences in the dose delivery mechanisms due to distinction in the energy content in the spectra. Simulations offer unique insight into the underlying photon-matter interactions.



Poster 5

Presenter: Mark Bailey

Energy-range relationships in industrial electron beams between 3 and 12 MeV, using measurements and Monte Carlo calculations using realistic beam models in aluminium and polystyrene

Mark Bailey¹, Emily Craven⁴, Matt Ronan³, Shari Formica², Arne Miller¹.

¹Risø HDRL, DTU Health Technology, Roskilde, Denmark; ²J&J Sterility Assurance, Johnson & Johnson, Raritan, NJ, United States; ³Mevex, Stittsville, ON, Canada; ⁴Sterility Assurance, Boston Scientific, Marlborough, MA, United States

Introduction

Beam energy in industrial electron beams is usually found using depth-dose distributions in aluminium or polymers, utilising equations given in Annex 4 of ISO ASTM 51649 [1]. These relationships were derived using results from earlier Monte Carlo codes, with monoenergetic electron beams.

Here, empirical relationships are derived using more realistic spectra, and the results are then compared with those from the earlier equations.

Body

Monte Carlo calculations (EGSnrc [2]) using a wide range of “realistic” (exponentially-modified Gaussian) spectra were used to generate a large number of depth-dose distributions in aluminium and polystyrene, from which new empirical relationships were derived linking measured range parameters R50 and Rp, and average and most probable energy Ea and Ep.

Measurements performed at three facilities for several energies between 1 and 12 MeV in aluminium wedges and polystyrene stacks, were used as a validation of the calculations.

For aluminium:

$$E_a(\text{MeV}) = 5.55R_{50} + \frac{0.234}{\left(\frac{R_p}{R_{50}} - 0.791\right)^2}$$

$$E_p(\text{MeV}) = 5.38R_p - \frac{0.0895}{\frac{R_p}{R_{50}} - 1.195} + 0.554$$

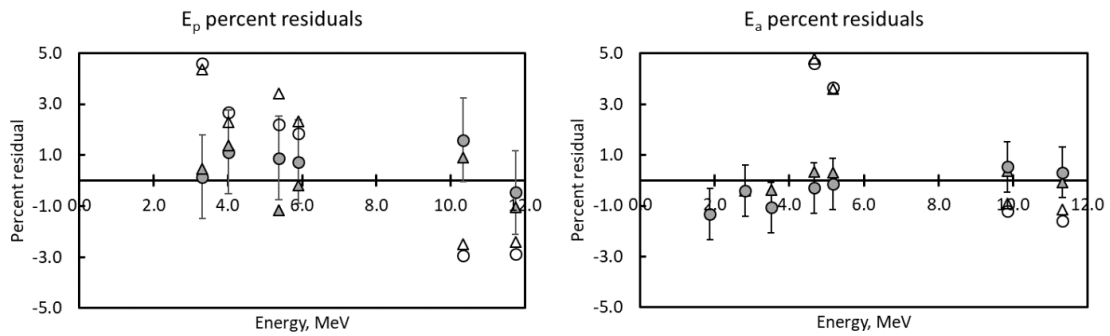


Figure 1: Residuals between the results for E_p (left) and E_a (right) using the equations given above for aluminium (filled symbols) and the explicitly-calculated E_a and E_p from matched Monte Carlo calculation spectra. Results are also shown for the equations A4.4 (E_p) and A4.5 (E_a) from ISO ASTM 51649 (open symbols). Circles: Based on R_{50} and R_p from measured depth-dose distributions. Triangles: From matched Monte Carlo distributions. Error bars represent the total uncertainty at $k = 1$, and are presented on the points derived from measured distributions.

Similar relationships were identified for polystyrene.

Conclusion

These determinations of E_a and E_p demonstrate that the older equations based on monoenergetic spectra show that those equations are still broadly valid. This work is expected to help in continuing development of the standards in use.

References

- 1: ISO ASTM 51649: "Standard Practice for Dosimetry in an Electron Beam Facility for Radiation Processing at Energies Between 300 keV and 25 MeV", www.astm.org, 2014
- 2: Kawrakow I., Rogers D.W.O. "The EGSnrc Code System: Monte Carlo Simulation of Electron and Photon Transport". NRCC Report PIRS 701 (1999), National Research Council of Canada, Ottawa

Poster 12**Presenter: Florent Kuntz**

LEEB food irradiation process control: How can alanine ESR dosimetry help?

Urszula Gryczka¹, Abbas Nasreddine², Sylwester Bułka¹, Florent Kuntz².¹Institute of Nuclear Chemistry and Technology, Warsaw, Poland; ²Aerial, Illkirch, France

Food irradiation is a process of exposing food to ionizing radiation and the recent development is related to the use of low energy electron beams (LEEB) for microbial decontamination. The main parameters influencing the effectiveness of the LEEB food irradiation process are the dose absorbed in treated food, its uniformity on the surface and the thickness of the irradiated food layer. Either delivering a too low dose of radiation or too low energy of electrons may result in an insufficient reduction of microbial load in treated food. Thus, providing both information in reference to treated food is essential for the process characterization.

In the presented study, two dosimetry systems were used to characterise the LEEB food irradiation process and provide information essential for ensuring repeatable irradiation conditions: B3 film with RISOScan software and AerEDE/EPR alanine system.

Irradiation of different weights of peppercorns loaded in a rotating drum was performed at INCT using ILU-6 accelerator and beam of electrons of an energy 300 keV. The uniformity of the dose on the surface was ensured by sample rotation during irradiation and was characterised by B3 films and indirectly with alanine pellets mixed together with the product and submitted to the same process. Alanine was used to estimate electron beam penetration depth indirectly.

It was shown that alanine dosimetry can be implemented to monitor the routine process and demonstrate its conformity according to predefined and product dependent tolerance intervals. Examples of determined parameters are shown for peppercorn irradiation depending on the size of the batch and irradiation conditions i.e. dose rate and energy of electron beam.

Acknowledgement

The IAEA CRP D61025 (Poland RC 24198, France IAEA RA 24344)



Poster 16**Presenter: Abbas Nasreddine**

Validation of Monte Carlo simulation tools: A Benchmarking study of RayXpert®

Abbas Nasreddine⁴, Josef Mittendorfer¹, Damien Prieels², Ludovic Eychenne³, Florent kuntz⁴.

¹High Tech Consulting , Traunkirchen, Austria; ²IBA s.a., Louvain-la-Neuve, Belgium; ³TRAD, Labège, France; ⁴Aerial, Illkirch, France

Monte Carlo simulation is becoming more and more popular thanks to very user-friendly tools. However, the model results must be compared with dosimetric measurements in order for the simulation tools to be validated and finally qualified for the intended purpose.

An ongoing comparative study using the Monte Carlo simulation tool RayXpert (TRAD, France) will be presented. The Aerial feerix® irradiation facility and dosimetry laboratory were used to compare simulation outputs and dosimetry results.

The purpose of the poster is to present comparative results for high energy electron beam irradiations. At this stage, the study, will answer two questions.

- i. what is the impact of the 10 MeV electron energy spectrum on the dose distribution?

For this effect of variations in the electron beam energy spectrum on the depth-dose distribution and penetration depth inside an aluminium wedge will be analyzed and the in-silico results compared to experimental measurements.

- ii. do RayXpert and the dosimetric measurement agree on the dose deposited by scattered electrons in the vicinity of a dense material or at interfaces between materials?

To answer this question, the dose distributions within a specifically designed and fabricated reference product box will be compared. This product is composed of air, polystyrene foam, PVC and stainless steel.

Generally good agreement has been found between model output and dosimetric measurements. Differences between model and experiment are carefully analysed and potential reasons discussed in detail. This benchmarking approach is a contribution to the qualification of the simulation tools and demonstrates the benefits of Monte Carlo simulations to our industry.



Poster 23**Presenter: Arne Miller**

Performance qualification dose mapping – a review

Arne Miller¹.¹DTU Health Technology, Technical University of Denmark, Roskilde, Denmark

Performance Qualification – PQ – Dose mapping is an important step of the validation of a radiation sterilization process. Several requirements must be fulfilled, and choices must be made and justified for the PQ dose map results to be considered valid for establishing the sterilization process parameters. The new PQ dose map report by The Irradiation Panel provides the basis for understanding the requirements and for making sound and justifiable choices where needed.

The Panel report complements the international standards from ISO (1) and ASTM (2) on PQ dose mapping, but it is written in a more narrative style leading the reader through the PQ process.

The report content comprises:

- description of radiation processing facilities, including low and high energy electron beam and X-ray, as well as gamma facilities,
- dosimetry systems, their advantages and limitations as well as their calibration requirements,
- where and how to measure,
- establishing process parameters
- potential, and limitations, of calculation methods (Monte Carlo)

The Irradiation Panel PQ dose mapping report is a useful tool for anyone who wishes to understand and use the international standards on dose mapping as part of the validation of radiation sterilization and other radiation processes.

(1) ISO 2006: ISO 11137-1. Sterilization of health care products – Radiation – Part 1: Requirement for development, validation and routine control of a sterilization process. ISO, Geneva, Switzerland

(2) ISO ASTM, 52303. (2015) Standard Guide for Absorbed-Dose Mapping in Radiation Processing Facilities, ASTM International, 100 Barr Harbor Drive, West Conshohocken PA 19428, USA



Poster 24**Presenter: Abbas Nasreddine**

Study of the absorbed dose rate dependence of the alanine/EPR dosimetry system

Abbas NASREDDINE¹, Hende BOUAICHA¹, Florent KUNTZ¹, Alain STRASSER¹.¹Irradiation and Dosimetry, Aerial, ILLKIRCH GRAFFENSTADEN, France

Alanine/EPR dosimetry system is well known for being robust, precise and having low measurement uncertainty for absorbed dose to water measurements, all, whilst covering a broad dose range (few Gy up to more than 100 kGy). In addition, the alanine/EPR dosimetry system is widely used by NMIs as well as SSDs as a transfer standard dosimetry system for calibration of other systems.

Many influence quantities can change a dosimeter's response. For alanine, literature shows that the dosimeter's response can suffer from a combined dose/dose rate influence, where for dose levels higher than 5 kGy, at dose rates smaller than 2 Gy/s. This could pose a problem during the creation of reference alanine dosimeters by metrology labs, where often ⁶⁰Co sources are used and such sources could have dose rates less than 2 Gy/s. From the user's side, alanine dosimeters could have been calibrated at high dose rates but irradiated at low dose rates in attenuated radiation fields (gamma or low to medium power X-rays), where dose rates could get far below the 2 Gy/s limit.

In this study, an investigation is carried out to characterise the alanine response change with respect to absorbed dose, at different dose rates (0.05 up to 50 Gy/s). Dose rates are calibrated using an ion chamber dosimetry system. 7 MV X-rays are used to irradiate all alanine dosimeters at the different dose levels.

Preliminary results show that, for an absorbed dose of 100 Gy, the response of alanine drops by 12% at a dose rate of 0.05 Gy/s, yet it is stable for dose rates ranging from 0.5 Gy/s up to 50 Gy/s, within 0.8% variation. Further irradiations will be carried out at different dose levels, for multiple dose rates in order to better characterize the influence of absorbed dose/dose rate on the dosimeter's response.



Poster 42**Presenter: Sandra Pawlak**

Validation of the alanine test method

Sandra Pawlak¹.¹High Dose Dosimetry Laboratory, National Commission of Atomic Energy, Ciudad de Buenos Aires, Argentina**Introduction**

Develop activities for the validation of non-standard test methods, developed or designed by de Laboratory. Regulate or systematize the methods for the validation of test and calibration instructions.

Purpose

The goal of validation is to test the suitability of methods as well as the capability of the laboratory. The validation is supported by the statistical parameters of the procedure.

Parameter to measure

Item to test: Alanine pellets.

Validation parameters evaluated:

- Linearity: the verification of the response curve will be carried out analyzing the certified values. Condition to be met:

$$u_{curve} \leq 0,64\% \quad u_{dosimeters} \leq 1,44\%$$

- Precision: the precision of the average of 10 measurements, with 4 pellets each. Condition to be met: Standard deviation less than 1%, $s = \sqrt{\{\sum (x_i - \bar{x})^2\} / (n-1)}$
- Veracity: The samples with certified dose are measured and the difference with respect to the dose reported by the Primary Laboratory is calculated.

$$\text{Condition to be met: } |E_n| \leq 1; (E_n)_i = (x_i - x_{ref}) / \sqrt{[U^2(x_i) + U^2(x_{ref})]}$$

- Range: Calibration curves are constructed and divided in different ranges. Condition to be met: each range overlap and the entire range are covered.
- Robustness: represents the ability of the method to remain unaltered due to small variation in parameters indicating its reliability during normal use.

The difference between the results should be less than 3%.

- Uncertainty: the variable that contributes to the measurement uncertainties are: Primary laboratory, irradiation temperature, mass pellets, calibration curves and dosimeter to dosimeter scatter.

Conclusions

All parameters tested are considered consistent for the intended use.



Poster 38**Presenter: Nguyen Anh Tuan**

The optimal solution for the inhomogeneity of the material irradiated by electron beam and X-ray

Nguyen Anh Tuan¹.¹Faculty of Physics and Engineering Physics, University of Science, Vietnam National University, Ho Chi Minh, Vietnam

Electron linear accelerator with average energy 9.92 ± 0.48 MeV, UELR-10-15S2, was set up and operated at the Research and Development Center for Radiation Technology, Vietnam Atomic Energy Institute, for irradiating foods and medical devices directly without X-ray converter. Inside the homogenous products, the depth-dose curve depends on electron beam energy and product density, and moreover, it also depends on the inhomogeneity of the irradiated material. In this article, the depth-dose distribution is calculated by MCNP simulation code and measured by a film dosimeter inside the inhomogeneous products. The results show that the maximum deviation of the depth-dose curve between inhomogeneous and homogeneous products with the same density is about 20%. So the area density limit for irradiating double sided on the electron beam (9.92 ± 0.48 MeV) is in the range from 6.1 to 9.7 g/cm² instead of 8.5 g/cm² in general. In the case of the decreasing area density limit, we propose an irradiation model using X-ray, so we are building a new irradiation facility using IBA Rhodotron TT300 duo lines.

Radiation Chemistry - Polymers

Poster 2

Presenter: SeungTae Jung

Effect of electron beam irradiation and accelerated thermal aging on properties of LLDPE copper laminates

Seung-Tae Jung^{1,2}, Young-Chang Nho¹, Jin-Kyu Kim¹, Jae-Hak Choi².

¹R&D center, EB Tech Co., Ltd., Daejeon, Korea; ²Department of Polymer Science and Engineering, Chungnam National University, Daejeon, Korea

Polymer materials in contact with copper, such as wires and cables, are oxidized or decomposed during irradiation, manufacturing, or use. In the case of using linear low-density polyethylene as a polymer material and copper and aluminium sheets as the metal in contact with it, we tried to analyze how the metal material in contact with the polymer affects the oxidation of the polymer. When an electric wire or cable is irradiated with an electron beam, it is crosslinked, but oxidation occurs when the polymer radicals formed by electron beam irradiation react with oxygen in the air. In addition, the wire and cable undergo aging due to heat or oxygen in the air during long-term use. In this study, linear low-density polyethylene with or without antioxidants was laminated with copper or aluminium sheets, followed by heat treatment after electron beam irradiation. The degree of oxidation of the linear low-density polyethylene in contact with the metal was evaluated after irradiation, and the deterioration behavior of the laminate was evaluated by analyzing the physical properties of the linear low-density polyethylene after accelerated aging using FTIR, DSC, and tensile strength.



Poster 7**Presenter: Eui-Baek Byun**

Gamma-irradiated isoflavone from *Trifolium pratense* improves antioxidant activity in UVB-exposed HaCaT cells

Eui-Baek Byun¹, Ha-Yeon Song¹, Ho Seong Seo¹, JeongMoo Han¹, Eui-Hong Byun².¹Radiation Research Division, Korea Atomic Energy Research Institute, Jeongeup, Korea; ²Department of Food Science and Technology, Kongju National University, Yesan, Korea

Introduction with objectives: Ionizing radiation is a powerful tool to modify physicochemical and biological properties of natural compounds for pharmaceutical and nutraceutical application. Here, we investigated whether gamma ray improve water solubility and antioxidant activity of BCA, a phytoestrogenic isoflavone of red clover (*Trifolium pratense*).

Body: Gamma ray produced hydroxyethyl derivatives (HBCA1 and HBCA2) from BCA ethanolic solution at 50 kGy. Both HBCA1 and HBCA2 showed the increased 2,2-diphenyl-1-picrylhydrazyl (DPPH) radical scavenging activity over original BCA.

Furthermore, HBCA1 protected human epidermal keratinocytes (HaCaT) more efficiently than original BCA from ultraviolet B (UVB)-induced cell death by reducing reactive oxygen species production and mitochondrial membrane potential loss.

Conclusion: These results suggest that HBCA1, which is produced by gamma irradiation from BCA, could be used as antioxidant agents. Taken together, our findings suggest that structural modification using gamma ray could be a promising strategy for drug discovery.

Reference: Song, Ha-Yeon, et al. "Ionizing radiation technology to improve the physicochemical and biological properties of natural compounds by molecular modification: A review." *Radiation Physics and Chemistry* (2022): 110013.

Blois, Marsden S. "Antioxidant determinations by the use of a stable free radical." *Nature* 181.4617 (1958): 1199-1200.

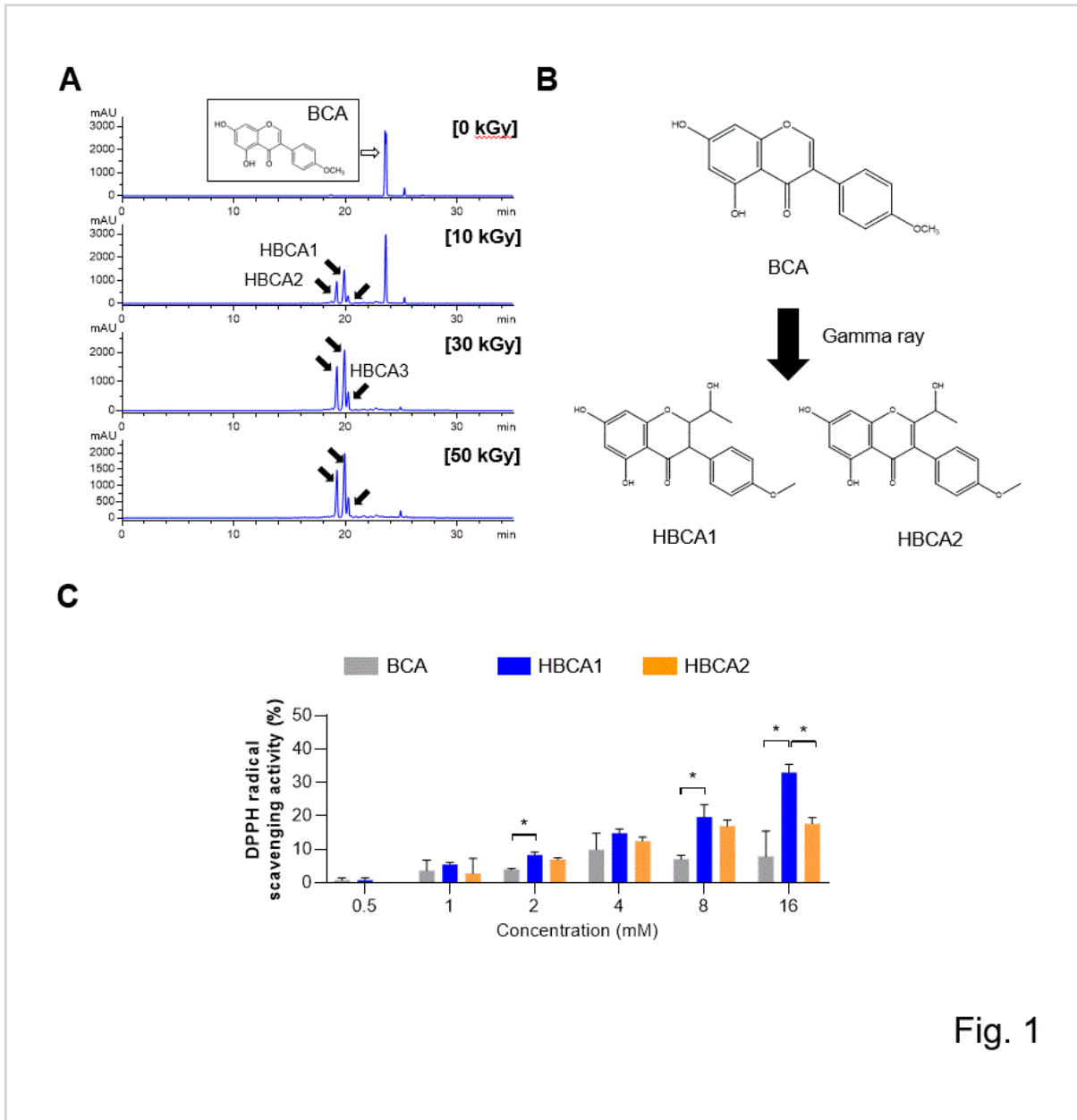


Fig. 1

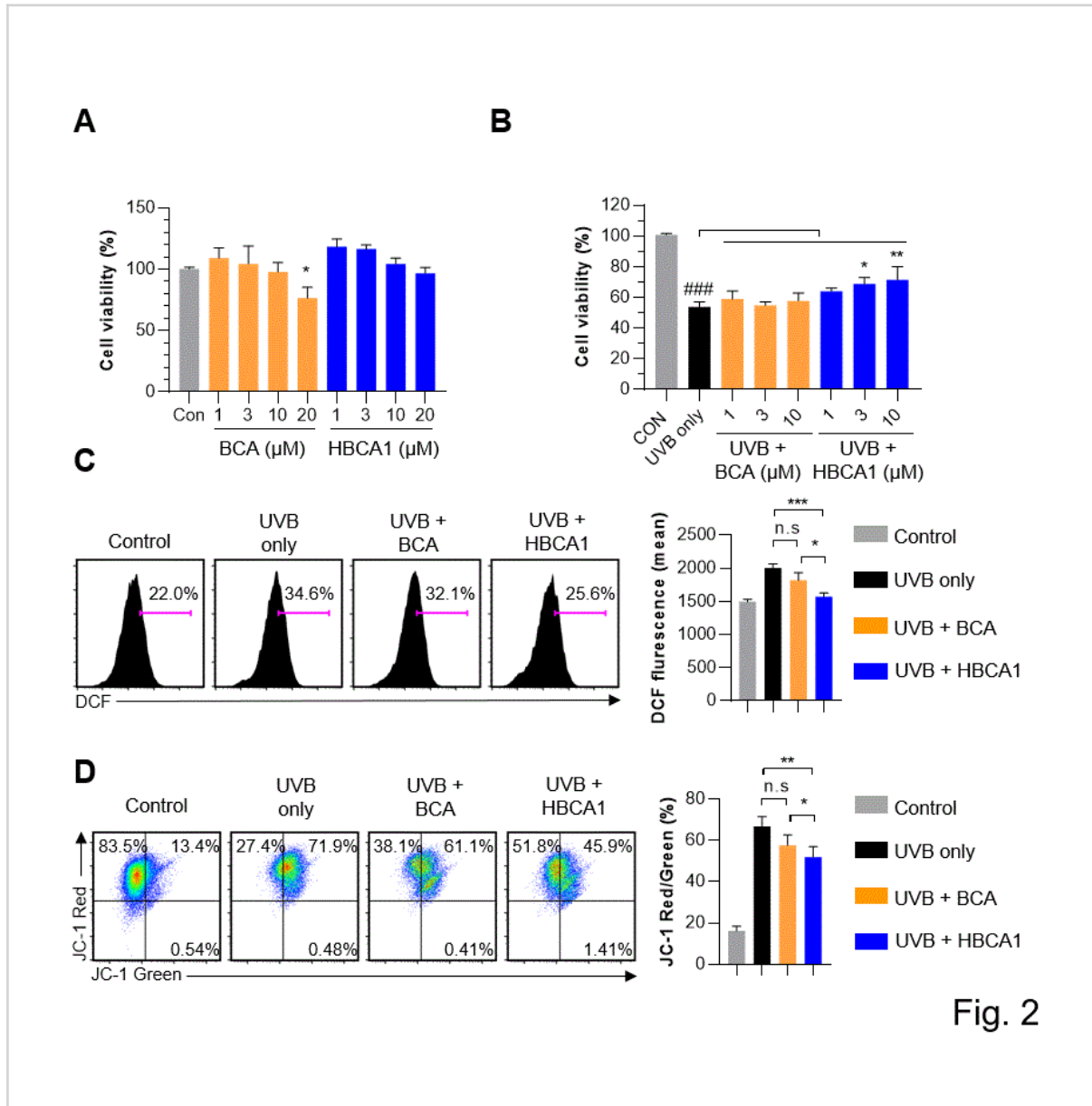


Fig. 2

Poster 14**Presenter: Young-ah Kim**

Human skin penetration effect of low molecular hyaluronic acid using electron beam

Young-ah Kim¹, Ji Hyun Park¹, Tea Sung Ha¹.¹R&D team, Seoul Radiology Services, 37-10, Maengdongsandan-ro, Maengdong-myeon, Eumseong-gun, 27733, Korea, Korea

Hyaluronic acid is a water-soluble polysaccharide with characteristics such as high viscosity, moisturizing ability, biocompatibility. It can be also effective in preventing skin wrinkles. However, its high molecular weight more than 1,000kDa makes it difficult to penetrate epidermis to deliver its functional effects. To overcome this disadvantage, hyaluronic acid was irradiated using 10MeV E-Beam to decrease its molecular weight to less than 100kDa and its effects on transdermal absorption was examined. The molecular weight of hyaluronic acid was measured using gel permeation chromatography. The FTIR spectrum showed no substantial changes of the spectral pattern between before and after electron beam irradiation. To confirm the transdermal absorption ability depending on the molecular weight and content of hyaluronic acid, 3D skin absorption test and anti-aging human efficacy evaluation were performed. In addition, biostability of the materials was proved through the human skin irritation evaluation. In conclusion, low molecular hyaluronic acid is considered to be promising for the functional material of dermo cosmetic patches due to the biostability and high transdermal transmittance.



Poster 17**Presenter: Ju-Woon Lee**

Corchorus olitorius L. (Molokhia leaf) extract irradiated with gamma rays attenuate muscle atrophy via regulating protein turnover and mitochondrial biogenesis in C2C12 cells

Mi-Jin Kwon¹, Ju-Woon Lee^{2,5}, Young Cho³, Kwan-Soo Kim⁴, Sang-Chul Kim⁵, Hao Chen⁶, Chengbi Cui⁷.

¹R&D Center, PSA CO. LTD, Pusan, Korea; ²Headquarter, PSA CO. LTD, Pusan, Korea; ³Department of Pharmacy and Biotechnology, Konyang University, Daejeon, Korea; ⁴Headquarter, Greenpia Technology Inc, Yeosu, Korea; ⁵R&D Center, Greenpia Technology Inc, Yeosu, Korea; ⁶Headquarter, Sichuan Institute of Atomic Energy, Chengdu, P.R. China; ⁷Department of Food Science and Nutrition, Yanbian University, Yanji, P.R. China

OBJECTIVES

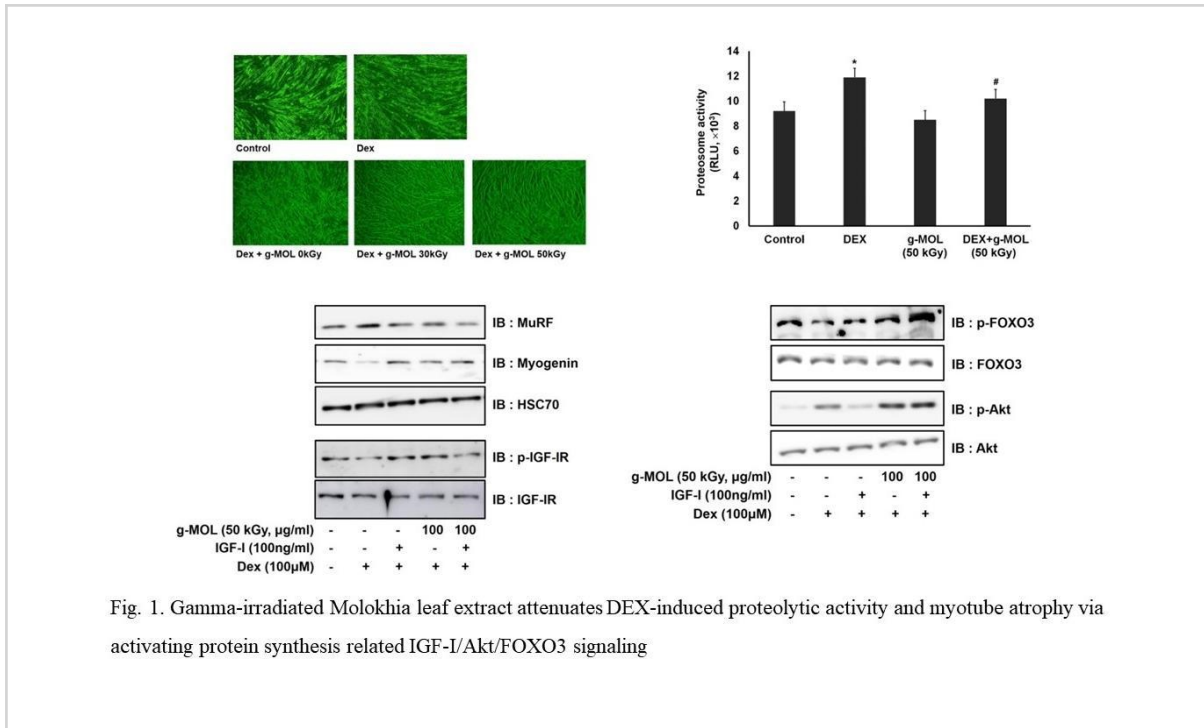
Sarcopenia is a disease of progressive loss of muscle mass due to imbalance of protein synthesis and proteolysis, and tends to emerge with ageing (Bonaldo et al., 2013). It is important to search for effective herbal medicines that can modulate muscle mass. (Yoshioka et al., 2019). *Corchorus Olitorius* L. (Molokhia leaf) is a common Egyptian edible vegetable having high physiological activity. In this study, we investigated the inhibition effects of gamma-irradiated leaf extract (g-MOL) on dexamethasone-induced muscle atrophy in differentiation of C2C12 cells.

EXPERIMENTAL RESULTS

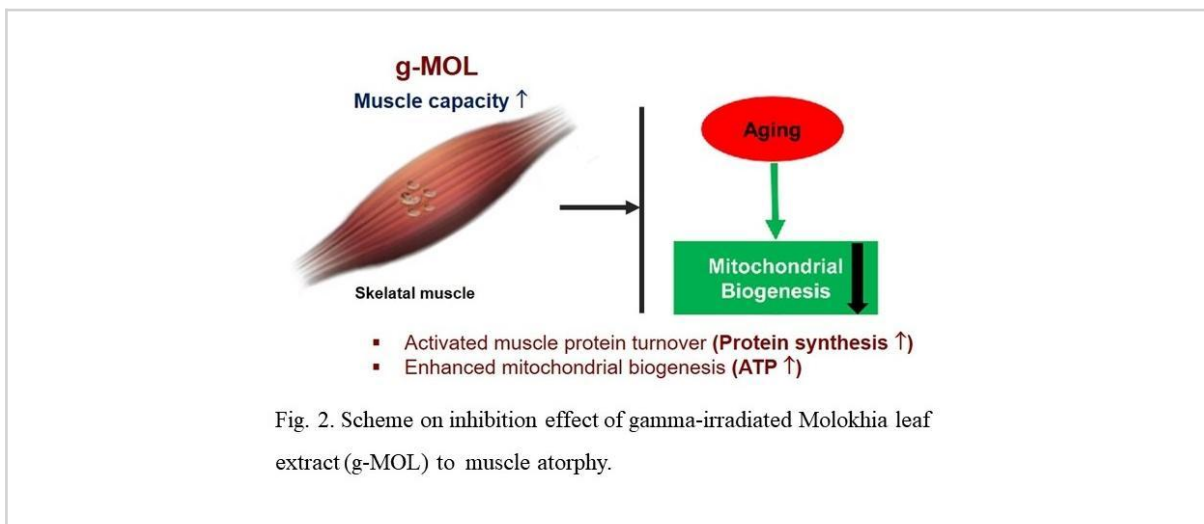
MOL (100 mg/mL) was irradiated in a Co-60 irradiator. g-MOL solution was used in each experiment by treating C2C12 cells with dexamethasone (DEX) to induce muscle atrophy.

We tested if g-MOL exerted an anti-atrophic effect on cultured C2C12 myotubes with DEX. Treatment of cultured myotubes with DEX reduced myotube size and increased proteasome activity, which were attenuated by g-MOL. Also, g-MOL effectively prevented dephosphorylation of fork head box O 3 α and upregulation of muscle-specific ubiquitin ligases in DEX-treated myotubes.





The protective effect of g-MOL on DEX-mediated myotube atrophy was regulated by insulin-like growth factor-1-dependent signaling. As well, g-MOL-stimulated mitochondrial DNA content via SIRT1/PGC-1 α signaling. These findings suggest g-MOL could be used as a valuable natural material that inhibits skeletal muscle atrophy via regulating protein turnover and mitochondrial biogenesis (Martinez et al., 2018).



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Poster 18

Presenter: Ju-Woon Lee

Gamma irradiation on the polysaccharide extracted from *Gloiopeltis furcata* is effective in inhibiting skin inflammation

Mi-Jin Kwon¹, Ju-Woon Lee^{2,5}, Young Cho³, Kwan-Soo Kim⁴, Sang-Chul Kim⁵, Hao Chen⁶, Chengbi Cui⁷.

¹R&D Center, PSA CO. LTD, Pusan, Korea; ²Headquarter, PSA CO. LTD, Pusan, Korea; ³Department of Pharmacy and Biotechnology, Konyang University, Daejeon, Korea; ⁴Headquarter, Greenpia Technology Inc, Yeosu, Korea; ⁵R&D Center, Greenpia Technology Inc, Yeosu, Korea; ⁶Headquarter, Sichuan Institute of Atomic Energy, Chengdu, P.R. China; ⁷Department of Food Science and Nutrition, Yanbian University, Yanji, P.R. China

OBJECTIVES

A sulfated polysaccharides extracted from *Gloiopeltis furcata* (GF-P) had the potential physiological functions that confer antioxidant, antitumor, hyperglycemic, and immune-enhancing properties. The effects of gamma irradiation (GI) on the physiological Activity of polysaccharides have been studied (Choi et al., 2011; Nagasawa et al., 2000), but its effects on GF-P have not yet been established.

EXPERIMENTAL RESULTS

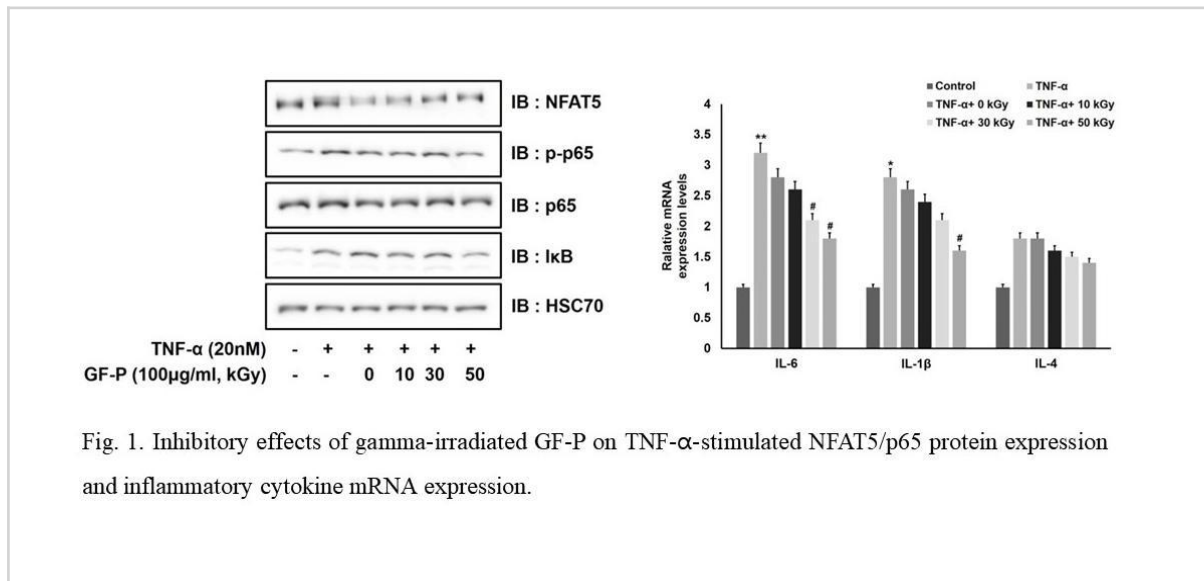
When GF-P was irradiated with gamma ray, the values of chromaticity and UV spectrum changed according to the increase of the irradiation dose. In particular, as a structural change was induced at a dose higher than 30 kGy, the yellowness increased and the values of UV spectrum all increased between 200 and 400 nm.

Table 1. Changes in sugar and viscosity according to gamma irradiation

Irradiation dose	Sugar content ¹⁾ (Glucose, %)	Viscosity ²⁾ (cP)
0 kGy	59.7 ± 2.01	42.5 ± 0.23
10 kGy	64.5 ± 1.67	41.6 ± 0.41
30 kGy	74.8 ± 0.13*	37.5 ± 0.26
50 kGy	79.5 ± 0.87*	33.5 ± 0.41*

^{1, 2)} Values are mean ± SD (n=3). *p<0.05 vs. 0 kGy

Antioxidant effect of gamma-irradiated GF-P (gGF-P) was significantly higher than of non-irradiated GF-P (Souza et al., 2012), whereas the sulfate content in GF-P did not show any differences with the irradiation dose. We further investigated the anti-inflammatory effect of 50 kGy-gGF-P in HaCat keratinocytes exposed to TNF- α , since there has been not reported on the effect of gamma irradiated GF-P on skin inflammation. Gamma irradiated GF-P significantly decreased TNF- α induced NFAT5/NF- κ B expression, which is decreased mRNA levels of proinflammatory cytokines. Taken together, gamma irradiation could be an effective method for an improvement properties with increasing physiological activity of GF-P. It can be considered a potential source of a functional ingredient for manufacturing functional food, pharmaceutical and cosmetic composition.



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Poster 19**Presenter: Ju-Woon Lee**

Generation of high value-added ginsenosides from white ginseng extract solution by ionizing radiation

Ju-Woon Lee^{1,5}, Mi-Jin Kwon², Young Ho Cho³, Kwan-Soo Kim⁴, Sang-Chul Kim⁵, Hao Chen⁶, Chengbi Cui⁷, Youn-Miik Lim⁸, Byungnam Kim⁸.

¹Headquarter, PSA CO. LTD, Pusan, Korea; ²R&D Center, PSA CO. LTD, Pusan, Korea; ³Department of Pharmacy and Biotechnology, Konyang University, Daejeon, Korea; ⁴Headquarter, Greenpia Technology Inc, Yeosu, Korea; ⁵R&D Center, Greenpia Technology Inc, Yeosu, Korea; ⁶Headquarter, Sichuan Institute of Atomic Energy, Chengdu, P.R. China; ⁷Department of Food Science and Nutrition, Yanbian University, Yanji, P.R. China; ⁸Radiation Utilization and Facility Management Division, Korea Atomic Energy Research Institute, Jeongseup, Korea

OBJECTIVES

Processed ginsengs (PG) are traditionally manufactured from white ginseng (WG) by steam for extension of shelf-life and for generation of new ginsenosides (GS). It was reported that Rb1 was converted to Rg3 by gamma irradiation (GI) (Kim et al., 2012). This study was conducted to apply radiation technology (RT) for generation of high value-added GSs.

EXPERIMENT

The extract solution (10% w/v) of WG was prepared and was irradiated at absorbed doses of 5, 10, 15 or 20 kGy. GI was performed in a cobalt-60 irradiator. Electron beam irradiation (EB) was also performed using a 2.5 MeV electron beam accelerator. The contents of GSs, Rb1, Rb4, Rg1, Rg3, Rg5 and Rk1, were analyzed using an HPLC system with a diode array detector (Kang et al., 2018).

RESULTS

Table 1 shows the changes of contents of 6 GSs. It was not observed on the difference of radiation types in all samples. Among GSs, Rb1 and Rg1 were only determined at 0 kGy. New generations of four GSs were apparently observed in all irradiated samples (Song et al., 2022).

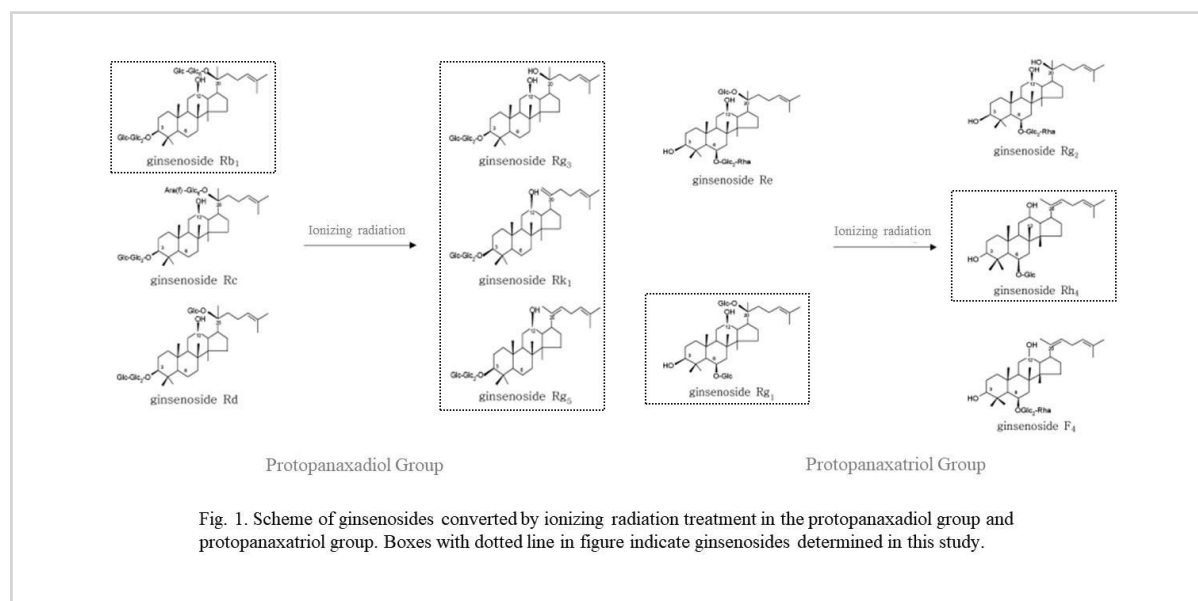


Table 1. Contents of ginsenosides in white ginseng extract solutions treated by gamma irradiation or electron beam irradiation into HPLC analysis.

Radiation type	Dose (kGy)	Content of ginsenoside (mg/g)						SUM
		Rb1	Rg1	Rg3	Rh4	Rk1	Rg5	
Gamma ray	0	1.654	1.742	0	0	0	0	3.396
	5	1.423	1.974	0.162	0.192	0.032	0.112	3.895
	10	1.198	1.463	0.794	0.476	0.346	0.456	4.733
	15	0.826	0.318	1.169	0.874	0.712	0.863	4.762
	20	0.562	0.165	1.806	1.329	1.091	1.293	6.246
Electron beam	5	1.433	1.945	0.202	0.213	0.045	0.108	3.946
	10	1.194	1.508	0.812	0.484	0.374	0.437	4.809
	15	0.897	0.344	1.096	0.908	0.754	0.876	4.875
	20	0.578	0.172	1.881	1.342	1.103	1.295	6.371

ND: not detected into HPLC analysis.

Rb1 and Rg1 might be converted to Rk1 and Rg5 via Rg3 in protopanaxadiol group and to Rh4 via Rh1 in protopanaxatriol, respectively (Fig. 1).



This result appears the similar tendency of the generation of GSs by the steam treatment using at traditional ginseng processing or bioconversion method (Kim et al., 2009). More studies in condition of sample and irradiation environment should be necessary to enhance the effect of RT for practical production with commercial scale.

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 Song, H.Y., et al., 2022. Radiat. Phys. Chem. 194, 110013.

Poster 20

Presenter: Ju-Woon Lee

NF- κ B and Nrf2 signaling pathways contribute to gamma-irradiated fibroin protein-mediated inhibition of TNF- α -induced oxidative stress and inflammation in skin keratinocytes

Mi-Jin Kwon¹, Ju-Woon Lee^{2,5}, Young Cho³, Kwan-Soo Kim⁴, Sang-Chul Kim⁵, Hao Chen⁶, Chengbi Cui⁷.

¹R&D Center, PSA CO. LTD, Pusan, Korea; ²Headquarter, PSA CO. LTD, Pusan, Korea; ³Department of Pharmacy and Biotechnology, Konyang University, Daejeon, Korea; ⁴Headquarter, Greenpia Technology Inc, Yeosu, Korea; ⁵R&D Center, Greenpia Technology Inc, Yeosu, Korea; ⁶Headquarter, Sichuan Institute of Atomic Energy, Chengdu, P.R. China; ⁷Department of Food Science and Nutrition, Yanbian University, Yanji, P.R. China

OBJECTIVES

Silk fibroin protein (FP) has been used for edible and cosmetic products (Asakura et al., 2004). Gamma irradiation improves physiological activity through the modification of the structure of FP (Byun et al., 2010). In this study, we examined whether gamma-irradiated FP (gFP) has a protective effect on TNF- α -induced cellular stress.

EXPERIMENTAL RESULTS

We investigated that FP changed the structure by gamma irradiation through electrophoresis, UV spectrum, and FT-IR. We further investigated the cytoprotective potential of 20 kGy-irradiated FP (gFP20) in HaCaT keratinocytes exposed to extracellular stress.

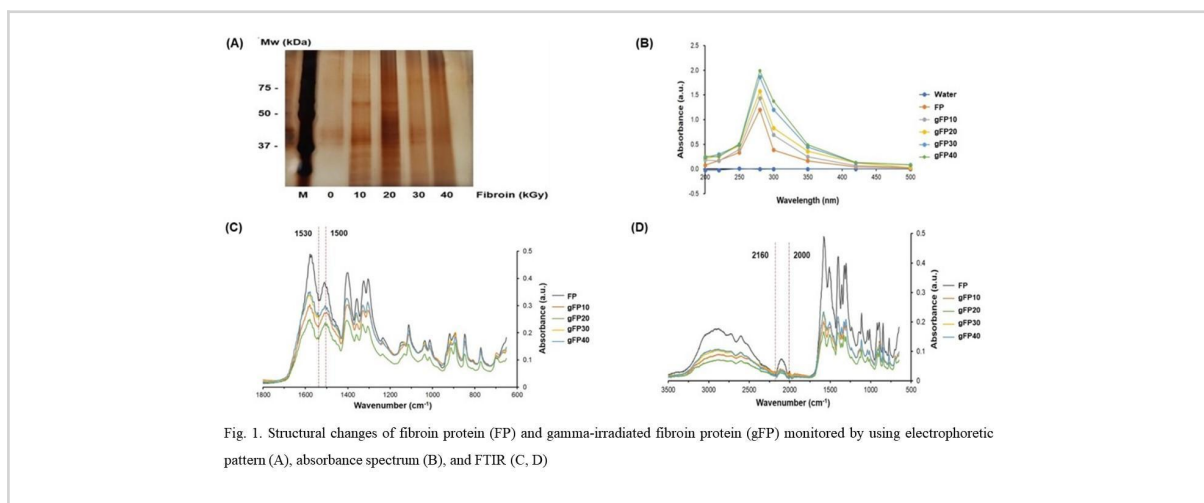


Fig. 1. Structural changes of fibroin protein (FP) and gamma-irradiated fibroin protein (gFP) monitored by using electrophoretic pattern (A), absorbance spectrum (B), and FTIR (C, D)

gFP20 effectively decreased TNF α -induced matrix metalloproteinase (MMP)-1 overexpression. In HaCat cells, gFP20 inhibited the expression of NFAT5/NF- κ B by TNF- α , which decreases the level of inflammatory mediator and pro-inflammatory cytokines (Rallis et al., 2017). Furthermore, gFP20 protected cells from TNF- α -induced oxidative stress by attenuating ROS overexpression and increasing the expression of the HO-1 antioxidant enzyme as the result of the stimulation of translocation into the nucleus of Nrf2 (Kobayashi et al., 2016).

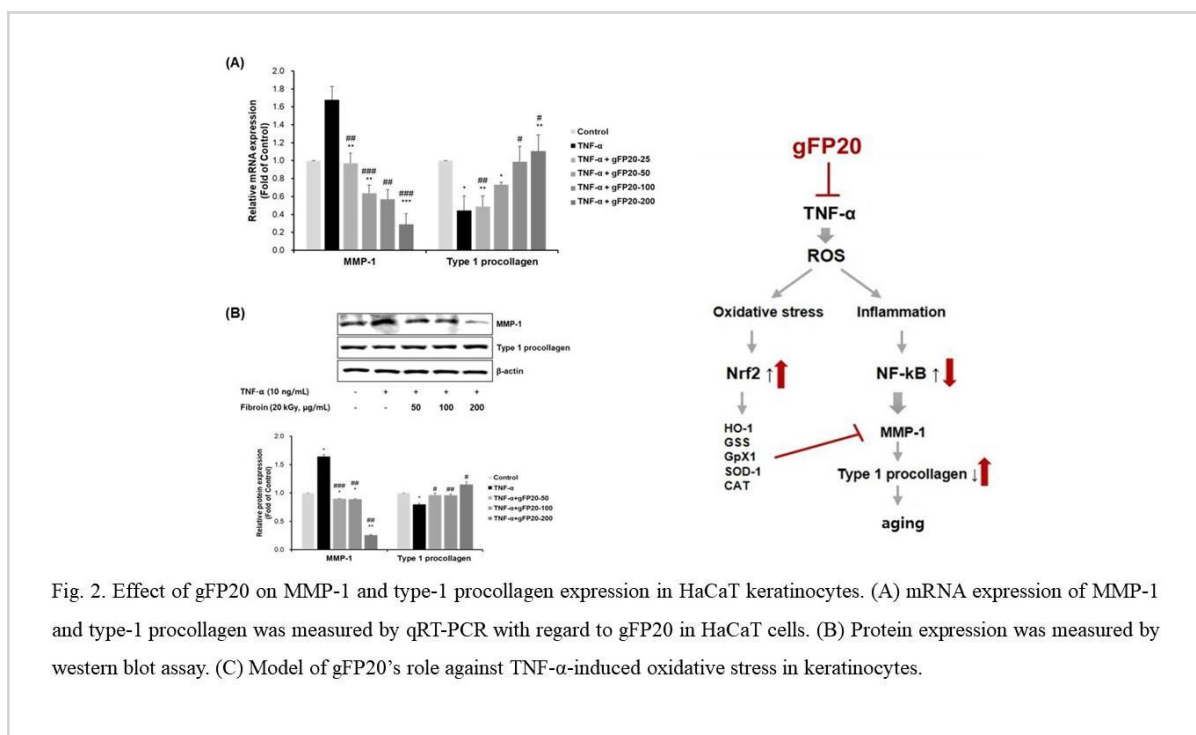


Fig. 2. Effect of gFP20 on MMP-1 and type-1 procollagen expression in HaCaT keratinocytes. (A) mRNA expression of MMP-1 and type-1 procollagen was measured by qRT-PCR with regard to gFP20 in HaCaT cells. (B) Protein expression was measured by western blot assay. (C) Model of gFP20's role against TNF- α -induced oxidative stress in keratinocytes.

FP with low-dose irradiation may be a potential prevention agent with great efficacy for treating oxidative stress and inflammation in skin disease. Taken together, our findings indicate that gFP20 could be considered as a superior functional material of skin-care materials that inhibits MMP-1 and increases collagen.

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Poster 21

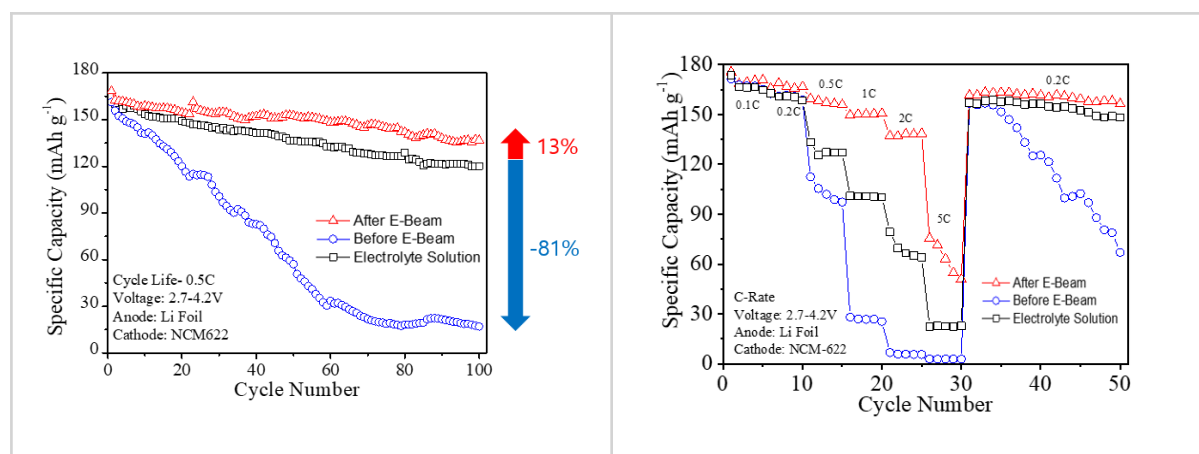
Presenter: Jin Hyeong Kim

In-situ polymerization of gel polymer electrolyte using electron beam technology

Young Hwan Lee¹, Tae Sung Ha¹, Ji Hyun Park¹.¹R&D Lab, Seoul Radiology Services, 37-10, Maengdongsandan-ro, Maengdong-myeon, Eumseong-gun, 27733, Korea

Due to the popularization of portable electronic devices and electric vehicles, the demand for high-performance lithium-ion batteries is increasing, but there are still hurdles to overcome for more public use, such as safety problems which are believed to come from the vulnerabilities of liquid electrolyte to harsh environmental conditions. To solve this problem, a gel electrolyte is a very good alternative. The conventional film-type gel electrolyte manufactured in an ex-situ method makes the process complicated, and not suitable for mass production.

In this work, a series of novel gel polymer electrolytes (GPE) based on poly ethylene glycol (PEG) derivative and acrylate derivative were produced and characterized. To synthesize GPE in an in-situ method, a gel precursor mixed with a PEG derivative, an acrylate derivative, and a liquid electrolyte was injected into the cell and free radical polymerization of monomers performed using 10MeV electron beam irradiation. The characterization of the GPE cell was done by electrochemical impedance spectroscopy (EIS), cyclic voltammetry (CV), discharge and C-rate. EIS showed ionic conductivity of 90% level of liquid electrolyte at room temperature. Capacity retention and reversibility were confirmed from the CV curve. Discharge and C-rate data demonstrate the initial discharge capacity and retention rate.



Poster 22**Presenter: Nicolas Ludwig**

Comparison of X-rays and gamma-rays irradiation of polymer: An EPR study

Nicolas Ludwig¹, Florent Kuntz¹, Samuel Dorey², Nina Girard-Perier², Sylvain Marque³,
Nathalie Dupuy⁴.

¹Aerial CRT, Illkirch, France; ²Sartorius Stedim FMT S.A.S, Aubagne, France; ³ICR, Aix Marseille University, Marseille, France; ⁴IMBE, Aix Marseille University, Marseille, France

In an effort to fill data, knowledge and tool gaps that could reduce the expansion of X-ray for sterilization purpose, a comparative work has been realized on radio-induced free radicals in plastics after X-rays and gamma-rays from 60Co treatment. Radicals generated in polymers are the seeds for short and long-term modifications. Identifying and quantifying them can help evaluating interaction similarities between the two irradiation modalities.

The study presented hereafter has evaluated ~50 grades of polymers from most classical families found in medical and biopharmaceutical applications. The polymer grades have been selected from Sartorius typical components.

Irradiations have been conducted at Aerial feerix® 7 MV X-rays irradiation plant (Illkirch-France) and at Ionisos Dagneux-France facility with 60Co gamma-rays. A unique dose of 50 kGy +/- 10% has been applied for both irradiation modalities.

Measurements have been conducted over one year period of ageing with the following occurrence: Day 1, Week 1 and 2, Month 1, 2, 3 and 6 and Year 1. Between measurements, sample were aged in the dark in a controlled environment (22°C +/- 2°C and 45% +/- 15% RH).

In a qualitative point of view, each material exhibits similar EPR spectra when irradiated with X-rays or gamma-rays. This suggests that same radicals are measured and thus, occurring radiation induced mechanisms are very comparable.

In a quantitative point of view, the large majority of the ~50 materials did not show a significant radical concentration difference produced when irradiated with gamma-rays or X-rays. The general trends which could be established on radical generation between X-rays and gamma-rays will be further discussed.



Poster 29**Presenter: Willaim Leising**

Determining the distortion of 3D printed polypropylene objects as a function of radiation grafting degree and developing a predictive method to counteract the distortion

Willaim Leising^{1,2}.

¹Department of Chemistry, The university of Manchester, Manchester, United Kingdom; ²Dalton Cumbrian Facility, Dalton nuclear institute, Manchester, United Kingdom

Introduction and objectives

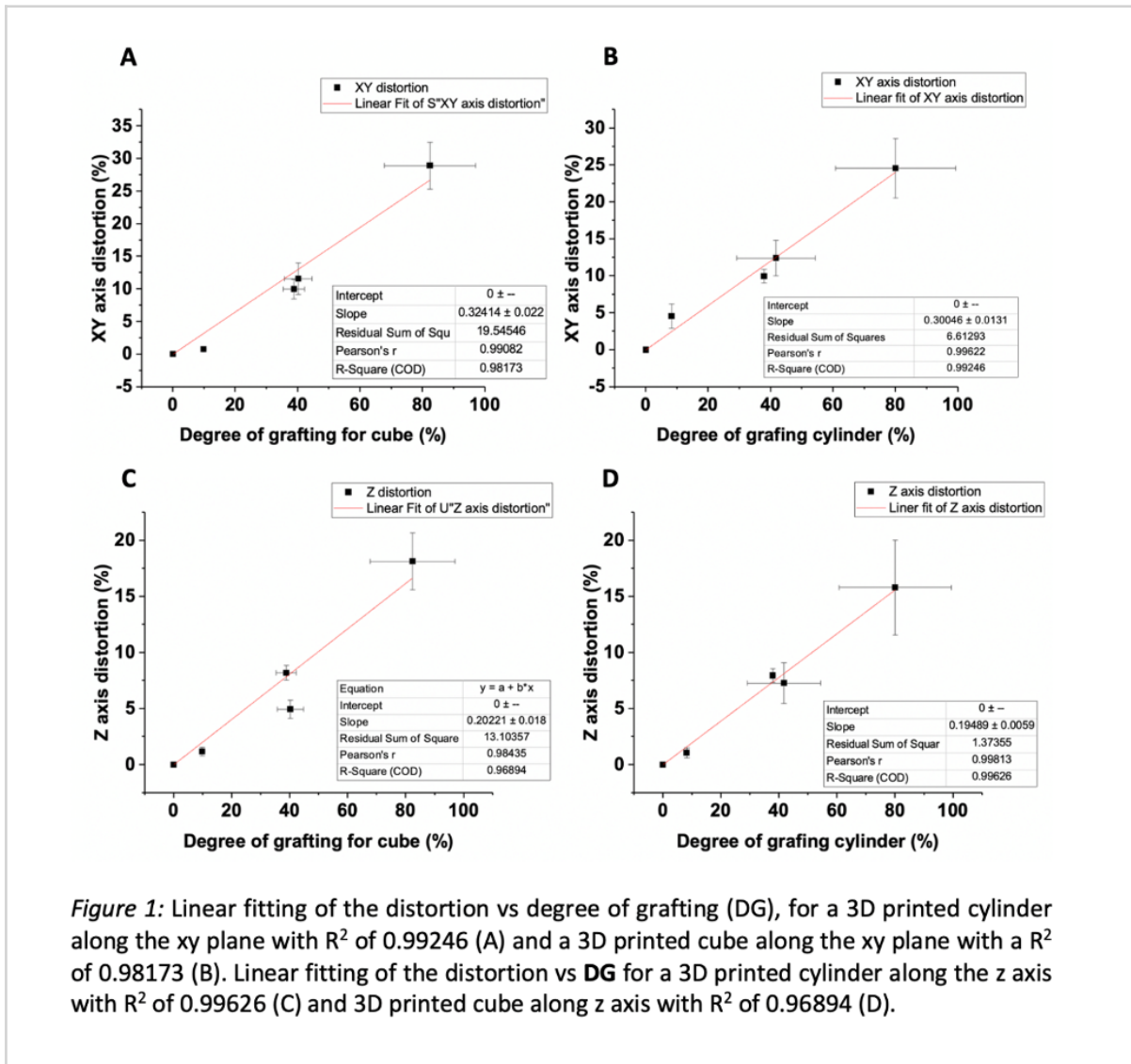
Additive manufacturing (AM) is a well-established technique, however, there are many potential advancements and new application areas remaining to be explored.¹ To the best of our knowledge, no research has been conducted into the radiation grafting of AM parts.

The objective of this study was to successfully graft 3D printed architectures and obtain novel knowledge on the effects of radiation grafting to AM parts.

Findings

This goal was achieved by using radiation grafting of acrylic acid onto polypropylene.² Upon grafting, 3D object distortion and increase in size was observed. These phenomena were determined to be caused by the internal grafting. The increase in size was found to be linear with respect to the Degree of Grafting (DG), with greater distortion in the xy plane compared to the distortion along the z axis (Figure 1).





Obtained data was used to generate scaling factors for varying doses that would allow for the grafted object to be of the desired size. We have shown that the use of scaling is effective, with the error associated with the final size being less than or comparable to a standard 3D printed part (Figure 2).

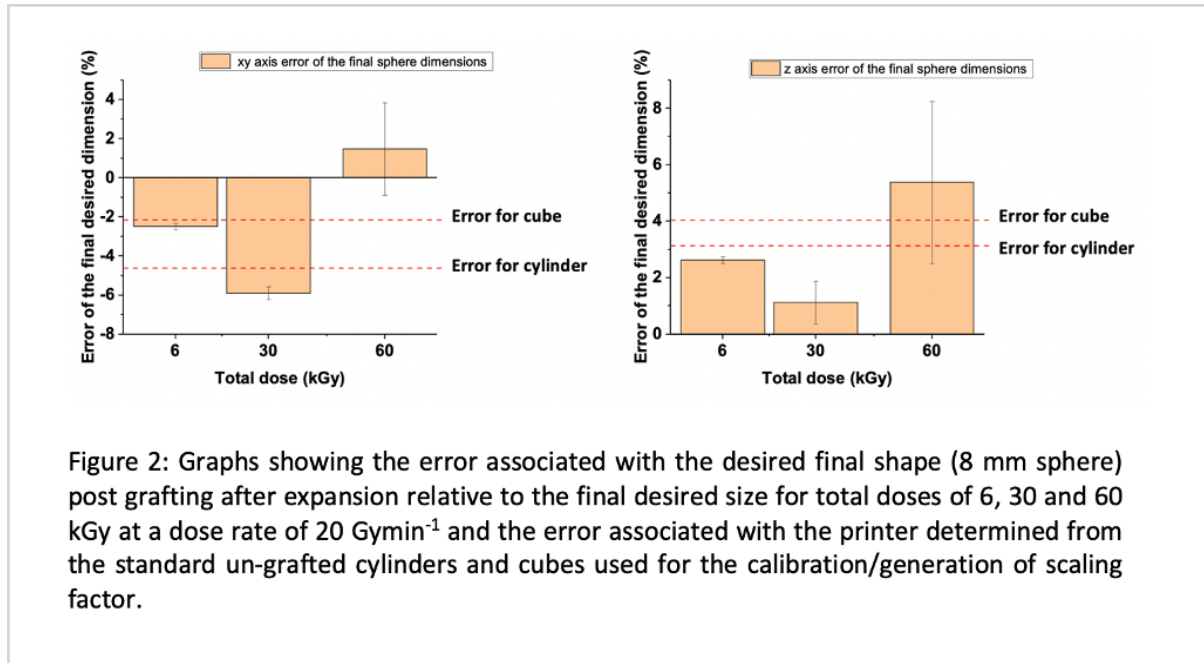


Figure 2: Graphs showing the error associated with the desired final shape (8 mm sphere) post grafting after expansion relative to the final desired size for total doses of 6, 30 and 60 kGy at a dose rate of 20 Gymin^{-1} and the error associated with the printer determined from the standard un-grafted cylinders and cubes used for the calibration/generation of scaling factor.

Conclusion

In this work, we have presented a showcase of successful radiation grafting of AM parts and demonstrated that the distortion caused by grafting can be overcome through the application of scaling factors.

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Poster 43**Presenter: Zühra Çınar Esin**

Effect of radiation on dynamic mechanical properties of platinum-cured silicone elastomers at natural frequency

Zühra Çınar Esin¹, Murat Şen¹, İsmail Saltuk², Nuri Akgerman².¹Chemistry Department Polymer Chemistry Division, Hacettepe University, Ankara, Turkey; ²Tavdi Company, Tavdi Company, Barrington, United States

One of the application areas for silicone elastomers is the production of vibration-damping materials noise and vibration are undesirable in many structures, such as rockets, spacecraft, automobiles, and white goods because they reduce the performance, stability, and lifetime of such structures High-damping silicone elastomers used in space technology and nuclear technology are exposed to radiation. Thus, investigation of the effects of ionizing radiation on the damping capacity of silicone elastomers is important. In our recent study, we investigated the impact of radiation on silicone elastomers' damping and energy dissipation properties in static conditions at low frequencies [1]. This study aims to determine the effect of radiation on the damping capacity of phenyl-vinyl-methyl-polysiloxane (PVMQ) and vinyl-methyl-polysiloxane (VMQ) elastomers at the natural frequency by using a Dynamic Mechanical Yertzley Oscillograph (DMYO-5). VMQ and PVMQ elastomers were cured in the presence of a Pt-catalyst and then irradiated up to 80 kGy. To examine the effect of absorbed dose on the dynamic mechanical properties of silicone elastomers at a natural frequency such as tan delta, Yertzley resilience, Yertzley hysteresis, dynamic compressibility, absorbed energy and energy density were calculated using DMYO. As a result, these studies have proven that the dynamic mechanical properties of silicon elastomer, such as energy dissipation and damping at the natural frequency, can be changed in a controlled manner with ionizing radiation. It has also been observed that if VMQ or PVMQ is used in the preparation of silicon elastomer-based damping material, the effect of ionizing radiation on the dynamic mechanical properties is different.



Technology

Poster 8

Presenter: Frank Cocina

Establishment of a new type B shipping program and first use of the 380B (LA-UR-22-25034)

Frank Cocina¹, Shea Cotton¹, Mark Wald-Hopkins¹, Curtis Weyerman¹, Todd Bauer¹.

¹National Nuclear Security Administration, US Department of Energy, Washington, DC, United States

Without proper end-of-life management, disused sealed radioactive sources (DSRSs) become vulnerable to loss, theft, or sabotage that can result in accidents and incidents. Type B quantities of radioactive material can be particularly hard to manage due to complexity and costs associated with their transportation. Historically, a major part of this issue stems from the lack of certified Type B packaging.

To help address this issue, in 2009 the U.S. Department of Energy (DOE), National Nuclear Security Administration (NNSA) Office of Radiological Security (ORS) directed Los Alamos National Laboratory (LANL) to design, test, certify, and fabricate Type B packaging for domestic and international use. Through these efforts, the NNSA Model 380-B Type B packaging was developed. The U.S. Nuclear Regulatory Commission (NRC) certified the 380-B in 2017, and since then, one unit has been fabricated and brought into operation.

The 380-B is a shielded container designed primarily for domestic (US) transportation of DSRSs in self-shielded irradiators. Maximum activities of Cs-137 and Co-60 payloads are 1505 TBq and 285 TBq, respectively. The 380-B is mounted on a dedicated trailer outfitted with a number of features to ensure safety and effective operation. The container is also leak-tight allowing for the transport of both special and normal form materials.

The 380-B was put into service on May 1, 2021. This was a major achievement for ORS/LANL after putting years of effort into the 380B, its operational infrastructure and processes. The source recovery was of a blood irradiator containing ~62 TBq of Cs-137. This packaging is now a fixture in ORS's fleet of Type B containers aiding in the safe and compliant decommissioning of self-shielded irradiators in the US.



Poster 15

Presenter: Thomas Kroc

Monte Carlo investigation of the equivalency of the electron and photon spectra of e-beam, X-ray, and gamma radiation

Thomas Kroc¹.¹IARC, Fermilab, Batavia, IL, United States**Introduction**

The initial energy spectra of e-beam, X-ray, and gamma sources (Figure 1) for radiation sterilization suggest great dissimilarity in their interaction with materials to be sterilized. However, the energy of ionization events that produce doses is orders of magnitude less than the initial energy of the incident radiation. This work will show that the spectra of energies of the photons and, ultimately, the electrons of the three modalities are indistinguishable in the energy range of importance.

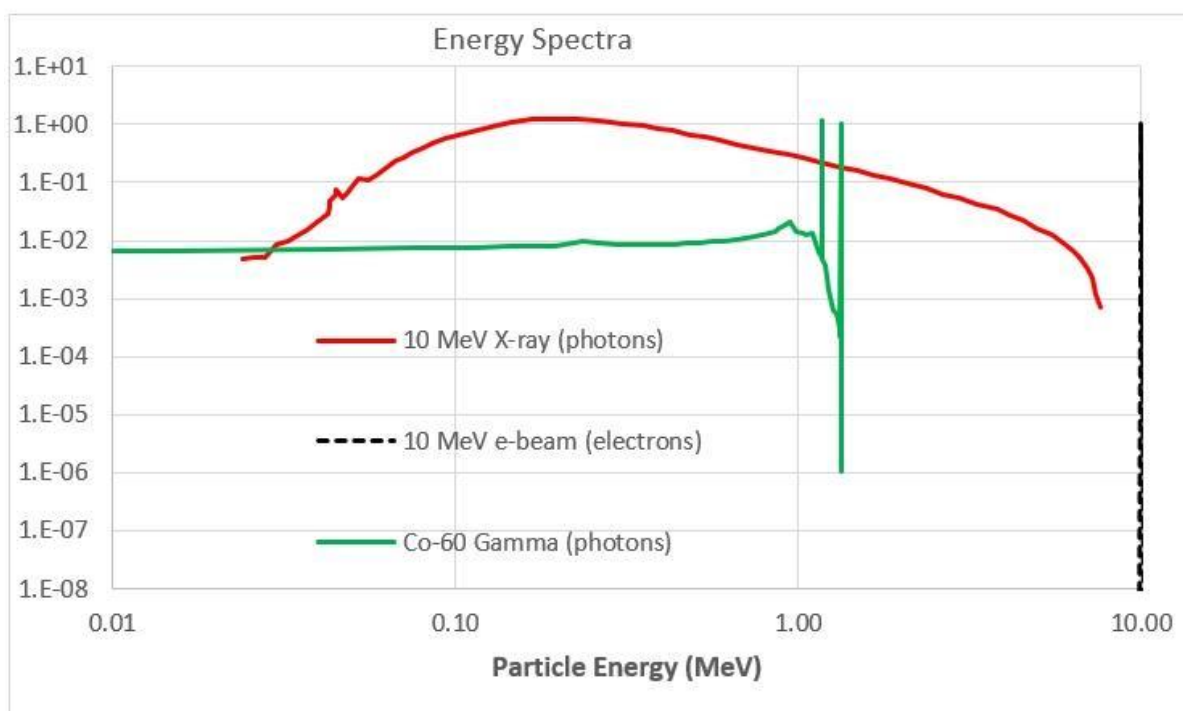


Figure 1 Energy spectra of photons or electrons exiting their ideal sources for three modalities.

Body

Monte Carlo simulations using MCNP[1] were conducted to simulate the interaction of 10 MeV electrons, 7.5 MeV X-rays, and gamma rays from Cobalt-60 onto totes filled with a polyethylene/air mixture. The spectra of the photons and electrons from all interaction processes were plotted and analyzed for each modality.

Conclusion

Dose is a measure of ionization. Therefore, it is primarily the electrons below 500 keV (the average energy of a Compton electron) that determine the dose delivered to a material. The lack of any significant difference in the spectra of the electrons below 500 keV between these modalities indicates that there should be no difference in their dose deposition due to energy.

References

[1] C.J. Werner(editor), "MCNP Users Manual - Code Version 6.2", Los Alamos National Laboratory, report LA-UR-17-29981 (2017).

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Poster 26**Presenter: Amit Samanta**

Advantage of electron beam crosslinking compare to chemical curing for wire and cable application

Research And Development, Apar Industries Limited, Umbergaon, India

Advantage of electron beam crosslinking compare to chemical curing for wire and cable application

Apar Industries limited manufactured different varieties of cables like HT XLPE, LT XLPE, Optical fibre & Elastomeric cables. Elastomeric cables can be crosslinked by chemical curing as well as E-beam curing. Chemical curing is done by adding curing agents like peroxide & Sulphur with compound & crosslinked in presence of heat. Normal medium voltage & high voltage cables are manufactured by chemical curing. E-beam curing cables does not require a curing agent. β ray knocks the polymer chain & bond brakes which generates free radical. This free radical links & crosslinking happens. Chemical cured cables are flexible compared to E-beam cured cable & used in moving applications. E-beam cured cables are less flexible which is used in fixed applications. E-beam curing cable can be used at high operating temperatures up to 250 °C. Chemical curing cables normally archives up to 90°C. operating temperature. E-beam cured cable can be manufactured in low thickness and weight compared to chemical curing cables as no curing agent added. Maximum number of polymer like Nylon, PVC, and ETFE including polyolefin can be crosslinked by beam. Nylon, PVC & ETFE cannot be crosslinked by chemical curing.



Poster 27**Presenter: Son Vo**

Criteria to consider for modularity change between gamma and electron beam for food products: Challenges and opportunities. From a service provider point of view

Son Vo², Thi Thu Van Phan¹.¹R&D, APIRA - An Phu Irradiation JSC, Binh Duong, Vietnam; ²Management, APIRA - An Phu Irradiation JSC, Bac Ninh, Vietnam

Low-wavelength gamma rays carry high energy, and therefore have a higher ionic potential than other types of rays when processed. However, due to the difficulty in access to Cobalt-60 in the current market condition E-beam irradiation technology are becoming more popular. Unlike medical devices, food products are not required to go through a rigorous validation stage. However, there are still some important criteria to consider when making the switch.

Firstly, E-Beam irradiation technology uses a modern automatic conveyor system to transport products from the loading area to the irradiation chamber, usually box by box. Comparing, to Gamma irradiation using mainly tote boxes or pallets. It is important for the box's dimensions are within the limit of the conveyor.

Secondly, Due to the nature difference characteristic of Gamma ray and Electron particle in penetration into the products it is important to ensure the arrangement of bags/products are similar when performing dose mapping. Otherwise, it wouldn't be possible to achieve the desired dose. This would require a strict commitment between service provider and customer to keep the products information secured from other customers.

Thirdly, depending on the type of food products they would have different characteristics to pay attention to. For example, some dry herbs and spices products having concerns about the color of the products to fade, brighten, or darken the products natural color. Some seafood products under certain conditions could produce different aroma when cooked compared to the control sample. There should be a thorough check with the customer's quality department to balance between the change in the aroma, looks, taste of the food products and the sterility of the product.



Poster 31**Presenter: Simone Schopf**

Development of anti-adhesive coatings by using low-energy electron beam technology

Nic Gürtler¹, Simone Schopf¹, Ulla König¹.¹Medical and Biotechnological Applications, Fraunhofer Institute for Organic Electronics, Electron Beam and Plasma Technology, Dresden, Germany

Development of anti-adhesive coatings by using low-energy electron beam technology

Surface functionalization provides both materials with innovative and improved properties as well as custom-designed and selective functions. Technologies for surface treatment are manifold and introduce surficial characteristics according to the functional requirements such as antimicrobial, biocompatible or anti-fouling properties. Surface modification techniques are often used in the field of biomaterial research as a starting point for the performance of new medical devices. Low-energy, non-thermal electron beam technology (e-beam) represents a multifunctional tool with a wide range of applications, which can be used specifically for the functionalization of surfaces. Applying e- beam technology, surfaces can be either sterilized gently, surface properties can be effectively modulated or materials can be gradually crosslinked. The electron beam process is particularly gentle on materials since the low acceleration voltage causes minor material heating. In low energy electron beam processes, material surfaces can be functionalized at accelerating voltages of up to 200kV. Through a targeted selection of process parameters, it is possible to produce surfaces with tailored properties.[1] Substances, such as polymers or natural substances, can be covalently immobilized on a material surface through the e-beam process (e-beam grafting). It is therefore possible to produce substances with antimicrobial, biocompatible or anti-fouling properties. Low-energy electron beam technology can be easily integrated into in-line processes to realize modification of large areas. By extending the range of polymers or even natural substances, e-beam grafting can be applied in many biomedical fields.



Healthcare

Poster 1

Presenter: Yeonhee Kim

Study of antiviral activities against H1N1 influenza virus of copper nanoparticles prepared by high energy E-beam

Yeonhee Kim¹, Tae Sung Ha¹, Ji Hyun Park¹.

¹R&D Team , Seoul Radiology Services, Eumsung-gun, Korea

Recently the world has encountered a number of viruses, and various efforts are being made to overcome them, such as searching for substances with antiviral properties. Among metals known to have antibacterial and antiviral properties, copper is getting a lot of attention because it is cost-effective and readily available. When copper is nano-sized, it has a completely different size and shape, and new properties appear. From these properties, copper nanoparticles showing excellent efficacy in the antiviral test using the MDCK cell line were prepared, and the antiviral test was performed by applying them to the film coating. Copper nanoparticles used for film coating had a size of about 150nm and a relatively constant spherical shape. When manufacturing copper nanoparticles, ethylene glycol and distilled water were used as solvents, $\text{CuSO}_4 \cdot 5\text{H}_2\text{O}$ as a precursor, a dispersant, and a stabilizer were used, and they were manufactured in an environmentally friendly process through electron-beam irradiation. Copper nanoparticles were characterized by using SEM, TEM, EDS, DLS, and XRD for size, shape and composition. Copper nanoparticles which have antiviral properties are expected to be applicable not only to film coatings but also to paints, indoors and outdoors, where people can reach.



Poster 9**Presenter: Eric Crawley**

A practical approach to establishing a 2x process for e-beam sterilization of medical devices

Eric Crawley¹, Byron Lambert¹, Vu Le¹.¹Assurance of Sterility Task Force, Abbott Medical, Temecula, CA, United States

Changing radiation sterilization modalities can be challenging with medical devices that have a narrow dose range. Particularly, a change from Gamma to E-beam can be challenging because the e-beam process may increase dose uniformity ratio (DUR) depending on the loading configuration used. Developing a process that allows for product to be sterilized more than once is not common for radiation due to the material effects on sensitive polymers. To optimize processing, considerations must be made early in the product development and sterilization validation life cycle such as sterilization dose, maximum acceptable dose (MAD), and alternative dose mapping configurations.

In practice, to achieve two times sterilization processing capability, the combined total maximum absorbed dose to product from the 1st and 2nd sterilization process should be below the established MAD of the product. Typically, a 2x process would consider doubling the max dose delivered to the product from the 1x process (e.g a 1x dose range of 25 – 50 would have a max dose of 100 kGy and require an established MAD of 100 kGy). For sensitive polymers, a MAD of 100 kGy may not be possible. The evaluation of alternate product configurations and lower sterilization dose may solve this problem.

A dose ranging study to assess product performance impact of polytetrafluoroethylene (PTFE) across 30 – 90 kGy is reported (see Figure 1) to evaluate if a product can be re-sterilized based on a current validated dose range of 25 – 50 kGy. The outcome showed that the traditional 25 – 50 kGy processing range did not allow for a 2x process, however lowering the sterilization dose to 20 kGy and increasing MAD to 65 kGy allowed for the opportunity for processing a 2nd time with an alternate loading configuration (low DUR).



Poster 13**Presenter: Jakob Hjørringgaard**

Comparison of the microbicidal effectiveness of 150 kV X-rays and cobalt-60 gamma rays

Jakob Hjørringgaard¹, Arne Miller¹, Claus Andersen¹, Dominique Cloetta², Willi Wandfluh², Alan Tallentire³.

¹Department of Health Technology, Technical University of Denmark, Roskilde, Denmark; ²ebeam Technologies, COMET AG, Flamatt, Switzerland; ³Independent, Wilmslow, United Kingdom

Background

In two previous papers it has been shown that the dose response of *Bacillus pumilus* spores, irradiated under specified standardized conditions, is independent of beam quality for a wide range of beam qualities (Tallentire et al., 2010; Tallentire and Miller, 2015). To expand the range of beam qualities covered by the conclusions of the previous papers we investigate the response of *B. pumilus* spores subjected to irradiation in a 150 kV X-ray beam.

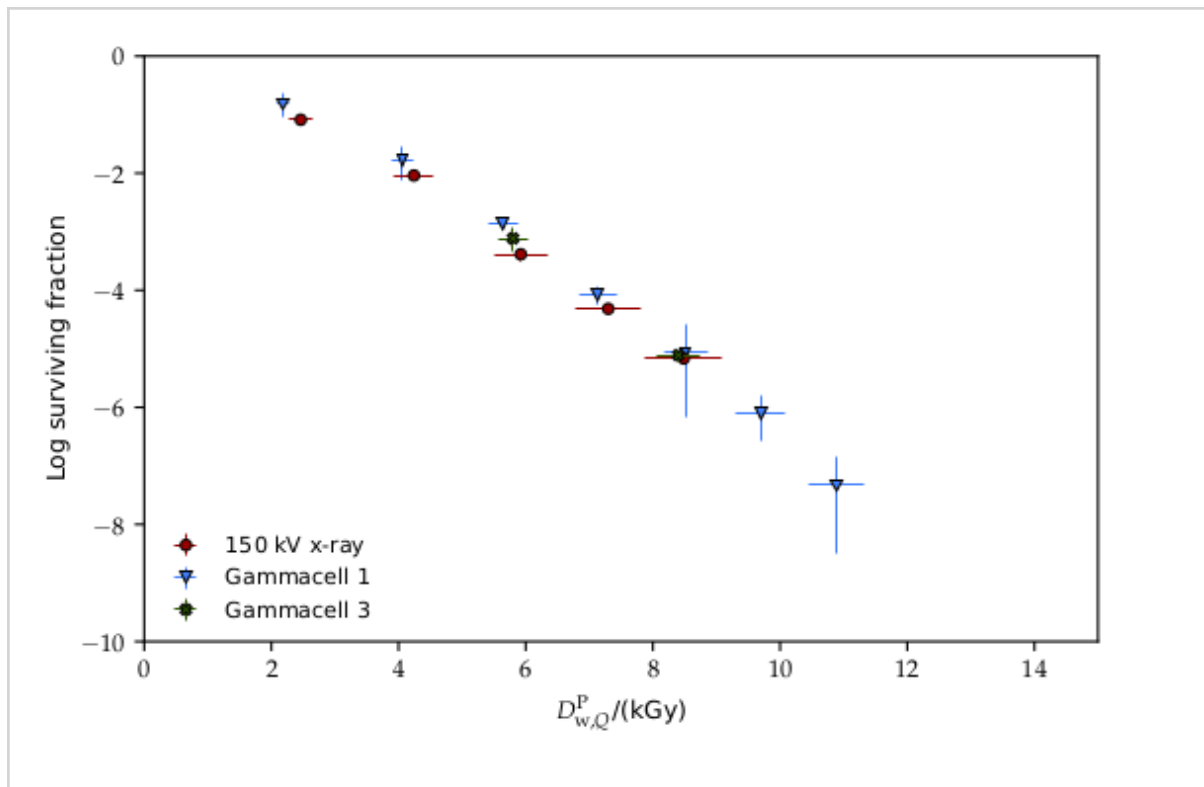
Body

Microbiological test pieces comprised of test filters with a known number of hydrated *B. pumilus* spores located on the surface of a GS grade cellulose acetate membrane filter placed in a Petri dish was used.

X-irradiation of test pieces was done using an XBA-200/270H X-ray tube. Gamma irradiation of test pieces was performed in a Nordion GC-220 Gammacell. The dose to test filters was measured during irradiation using both alanine film and pellet dosimeters. The alanine dosimeters are calibrated in cobalt-60 with traceability to NPL.

The survival curves obtained from irradiation in the two radiation fields are shown in Figure 1. It is evident that a common response function can describe the survivability of *B. pumilus* spores in these beam qualities.





Conclusion

The radiation response of water-hydrated *B. pumilus* spores to a 150 kV X-ray beam was found to be identical to the response to cobalt-60 gamma rays within experimental uncertainties.

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Poster 30**Presenter: Martell Winters**

What is considered conforming product for underdosed radiation-sterilized product?

Martell Winters¹, Aaron DeMent², John Schlecht⁴, Kevin O'Hara³.

¹Nelson Laboratories a division of Sotera Health, Salt Lake, UT, United States; ²Sterigenics a division of Sotera Health, Oak Brook, IL, United States; ³Sterigenics a division of Sotera Health, Ottawa, ON, Canada; ⁴Sterigenics a division of Sotera Health, Bridgeport, NJ, United States

For radiation sterilization, what is considered a conforming product with respect to delivery of the minimum sterilization dose? For example, is 24.9 kGy conforming to a 25 kGy minimum sterilization dose? Logically, it seems that a 24.9 kGy dose does not incorporate any additional potential impact to patient safety. However, where is the cut-off point?

Answers to these questions will be provided through a mathematical assessment including reverse calculating the corresponding sterilization dose that would still result in a rounded SAL value of $10^{-6.0}$ and 10^{-6} , depending on whether the SAL must be rounded to one tenth of the exponent, or to a whole number exponent. The rationales and formulas will be discussed along with showing examples and different options for rounding. If an industry-wide rationale can be established to easily assess a product that is slightly underdosed, it could result in significant cost and time savings when these events occur.



Poster 32**Presenter: Simone Schopf**

Interaction of Accelerated Low-Energy Electrons with Immune Cells

Madleen Rietscher¹, Simone Schopf¹, Lysann Kenner¹, Ulla König¹.¹Medical and Biotechnological Applications, Fraunhofer Institute for Organic Electronics, Electron Beam and Plasma Technology FEP, Dresden, Germany

Interaction of Accelerated Low-Energy Electrons with Immune Cells

Electron beam technology, based on accelerated electrons, is increasingly used in biological applications. Here, the impact of increasing doses of Low-Energy Electron Irradiation (LEEI) on the human leukemic T-cell line Jurkat was tested. By varying the irradiation parameters, different cellular effects were achieved. Using the OPP-System as experimental setup, combined with an acceleration voltage of 200 keV, Jurkat cells were treated with doses ranging from 50 Gy to 250 Gy. The irradiated cells were retrieved, and several distinctive targets of the ionizing radiation were examined.

A reduction of the cellular viability, metabolism, and mitochondrial membrane potential ($\Delta\Psi_M$) was observed in a dose-dependent way. Cell cultures treated with 108 Gy to 142 Gy were able to partially restore their viability and $\Delta\Psi_M$ within the subsequent 192-h cultivation period.

Analysis of the cell cycle did not reveal arrest of the cell cycle phases due to the high doses applied. Nevertheless, parallels to the findings of the assessed cellular viability and $\Delta\Psi_M$ were found. While samples with doses above 180 Gy predominantly went into apoptosis, cell cultures irradiated with up to 150 Gy were able to restore their cell cycle to a certain extent.

Assessment of radiation-induced DNA damage by Comet- Assay and immunofluorescent marking of histone γ -H2AX, revealed an increase of DNA strand breaks immediately after irradiation. Instead of repairing the lesions, they progressively increased in all irradiated samples after 48 h.

In conclusion, we have found that high doses of LEEI impair functional properties of T-cells in a dose - dependent manner.



Poster 37**Presenter: Beata Rurarz**

Electron beam processing of poly(acrylic acid) in the synthesis of targeted cancer nanoradiopharmaceuticals

Beata Rurarz^{1,2}, Joanna Raczowska¹, Kinga Urbanek², Dominika Habrowska- Gorczynska², Marta Koziel², Karolina Kowalska², Sławomir Kadlubowski¹, Michał Maurin³, Agnieszka Sawicka³, Urszula Karczmarczyk³, Agnieszka Piastowska- Ciesielska², Piotr Ulanski¹.

¹Institute of Applied Radiation Chemistry, Lodz University of Technology, Lodz, Poland; ²Department of Cell Cultures and Genomic Analysis, Medical University of Lodz, Lodz, Poland; ³Radioisotope Centre POLATOM, National Centre for Nuclear Research, Otwock, Poland

Nanotechnology is expected to revolutionize the field of cancer management [1]. Among numerous strategies for nanosystems development, radiation synthesis of nanogels is emerging as a relatively simple technique with great potential. In the radiation method, water-soluble polymers can be chemically crosslinked due to reactive species generated during water radiolysis [2]. Hereby, we explore the radiation method to produce nanomaterials of superior quality for applications in oncological theranostics [3].

We synthesize stable [4] nanogels based on poly(acrylic acid) using fast electrons from linear accelerator. We functionalize them with radioisotope-chelating bombesin derivative with affinity to gastrin releasing peptide receptor, abundantly expressed in many cancers. Chelating moiety enables radiolabelling with β - and γ -emitting nuclides, suitable for eradication of fast dividing cancer cells and diagnostic detection, respectively.

We have found that nanocarriers notably improve in-vitro radioisotope internalization in prostate cancer cells and this effect is greatly driven by the targeting ligand. Significant decrease of prostate cells viability shows therapeutic potential of radiolabelled carriers in comparison to their carrier-free and non-radioactive counterparts. In-vivo studies in general show stability of the radiolabelling, however size of nanoparticles clearly influences the biodistribution. We hope that upon further optimization we will be able to achieve an efficient and safe nanosystem able to eradicate prostate tumors also in in-vivo setting.

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Others

Poster 3

Presenter: Nalaka Rathnayake

Evaluation of electron beam technology for Sri Lanka's export and domestic markets

Oscar Acuna¹, Suresh Pillai¹, Jennifer Elster³, Nalaka Priyanga Rathnayake².

¹Food Science and Technology, Texas A&M University, National Center for Electron Beam Research (NCEBR), Texas A&M University, College Station, TX, United States; ²Radiation Technology, Sri Lanka Atomic Energy Board, Colombo, Sri Lanka; ³US Department of Energy, NNSA, ORS, Pacific Northwest National Laboratory (PNNL), Richland, WA, United States

Access to nuclear technologies is critical for countries around the world. Besides the use of nuclear technologies for medicine, irradiation of single use medical devices, food pasteurization and phytosanitary treatments constitute the other major application of nuclear technologies. Cobalt-60 is the legacy industrial irradiation technology world. Sri Lanka has two cobalt-60 based panoramic irradiation facilities. One of them is privately owned, while the other is a Sri Lanka Atomic Energy Board (SLAEB) owned and operated cobalt-60 irradiation facility at the Sri Lanka Gamma Centre (SLGC). The facility, which started operating in 2014 was designed to cater to both the food/agricultural products industry and the medical industry. However, the demand for surgical products (~ 99% gloves) has been so heavy that only a small portion of its capacity is available for other applications. Given the increasing costs of cobalt-60 re-loading and other challenges, SLAEB is evaluating the use of alternative technologies such as eBeam technology for the country's expansion of industrial irradiation capacity for both commercial and to foster R&D. The US National Nuclear Security Administration's Office of Radiological Security (NNSA-ORS) in collaboration Pacific Northwest National Laboratory (PNNL) with SLAEB and the National Center for Electron Beam Research (NCEBR) at Texas A&M University is currently evaluating eBeam technology to meet Sri Lanka's export and domestic markets. The on-going study is aimed at identifying the specific applications of the technology in both the industrial and the agricultural sectors and identifying the equipment specifications that would be most appropriate to meet Sri Lanka's needs.



Poster 25**Presenter: Suresh Pillai**

Innovation X- A generalized approach for identifying suitable locations for establishing electron beam and X-ray facilities in the United States

Rebecca Cunningham¹, Aryan Pai¹, Suresh Pillai¹.¹National Center for Electron Beam Research, Texas A&M University, College Station, TX, United States

Electron beam (eBeam) and X-ray technologies are crucial for high value applications around the world such as sterilization (of single-use medical supplies), decontamination (of animal feed, spices), pasteurization (of foods, food ingredients), phytosanitary applications, and polymer modifications (of wires, cables and automobile polymers). There is significant interest by the entrepreneurial community in investing in this multi-million dollar technology in the United States and around the world. However, other than cursory business reports estimating the size of the different markets, there is no publicly available information assisting the investor community in understanding the technology, nor is there a game plan to help decide where to locate eBeam and/or X-ray facilities. Very often, such information is cloaked as "business-sensitive" confidential information. Texas A&M University's Innovation-X program is a student-led program aimed at demystifying the technology, as well as providing an open source blue-print to identify optimal locations for such facilities. We chose Texas as the example US state for deciding where to locate such facilities. We were agnostic in terms of the specific application. A generalized approach of identifying suitable eBeam/X-ray facility locations has been developed. The approach involves mining industry databases, chambers of commerce databases, and US Government's SIC and NAICS codes for locations of potential end-user businesses. SimplyAnalytics and Tableau were used to graphically display the locations of these businesses along with economic "opportunity zones" maps. Porter's 5 Forces analysis was also included in the approach. Several locations in Texas are suitable for panoramic as well as potential in-house eBeam operations.



Poster 33**Presenter: Simone Schopf**

Enhanced bioleaching using electron stimulated bacteria

Simone Schopf¹, Bornkessel Sophie¹, Scherer Matthias¹, Dietze Marleen¹, Ulla König¹.¹Medical and Biotechnological Applications, Fraunhofer Institute for Organic Electronics, Electron Beam and Plasma Technology, Dresden, Germany

Enhanced Bioleaching of Chalcopyrite Using Electron-Stimulated Bacteria

Bioleaching is a biotechnological process that applies microorganisms to extract valuable metals from usually low-grade sulfidic ores and concentrates. Chalcopyrite (CuFeS₂) is the most abundant and widespread copper-bearing mineral. Unlike many other copper sulfides, chalcopyrite is particularly recalcitrant to hydrometallurgical processes. Bioleaching of sulfide minerals is an electrochemical process, involving the transfer of electrons. In this work, we used low energy electron irradiation (LEEI) to promote the biotechnological process of chalcopyrite dissolution via stimulation the bacteria with low doses of external electrons.

A small scale setup was used to irradiate the bacterial suspensions. Briefly, a crystallizing dish was placed on a magnetic stirrer to stir the bacterial suspensions. For irradiation, the low-energy accelerated electron plant REAMODE with a 200 keV electron beam was used. The bacterial suspensions were irradiated at a beam current of 0.1 mA and 200 KV for different time periods. The deposited dose was routinely measured with radiochromic films. Additionally, a liquid research dosimeter based on a solution of triphenyltetrazolium chloride was used.

The electron-stimulated bacteria were used as inoculum for bioleaching approaches. Bioleaching was performed with a solid load of 1 % (w/v) fine grained chalcopyrite. Samples were taken for determination of the pH, and the concentrations of dissolved ferrous-, ferric- and copper (Cu²⁺). These are crucial parameters for monitoring the success of the biotechnological process. It was deduced that electron-stimulated bacteria contributed to an enhanced copper leaching rate.



Poster 34**Presenter: Yoav Gazit**

Effects of phytosanitary irradiations on the quality and postharvest storage performance of 'Orri' mandarins

Yoav Gazit¹, Ron Porat².

¹The "Israel Cohen" Institute for Biological Control, Plants Production and Marketing Board, Yehud-Monosson, Israel; ²Postharvest Science of Fresh Produce, ARO, the Volcani Institute, Rishon LeZion, Israel

Introduction

The use of phytosanitary irradiation (PI) as a measure is continuously increasing in many countries. In Israel, irradiation has commercially been used for sanitation of dry produce, and PI is currently being considered for fresh produce applications as well. The key objective of the current study was to examine the potential benefit of PI to the Israeli agriculture export, and especially for citrus fruit, where 'Orri' mandarin (Orri) is the premium exported variety.

Objectives

The main objective of this study was to assess the effects of PI on the quality and postharvest storage performance of Orri.

Materials and methods

Orri were irradiated in a Co-60 industrial tote irradiator by manually exposing the fruit to two doses of 98.5 ± 10.2 Gy and 282.4 ± 26.9 Gy. The irradiated and non-irradiated control fruits were then stored at 5°C and 90% RH for 4 or 9 weeks, and afterwards transferred for one or two more weeks to shelf-life conditions at 20°C. Fruit quality was evaluated at time zero and after the various storage periods, and included measurements of: firmness; weight loss; peel color; peel damage and decay; total soluble solids (TSS) and titratable acidity (TA); vitamin C (ascorbic acid) content; ethanol levels; and flavor acceptability.

Results

The key finding of the current study was that the tested PI treatments did not affect any of the quality parameters of Orri. All of the detected changes observed in the irradiated fruit during prolonged postharvest storage were not significantly different from those observed in control non-irradiated fruit.

Conclusions

Our findings demonstrated that PI had no adverse effects on the quality and postharvest storage performance of Orri, and thus could be considered as an effective phytosanitary measure.

Poster 36**Presenter: Henni Widyastuti**

Comparison of 2 MeV and 10 MeV electron beam machine (EBM) in degrading antinutritional phytic acid compound in Indonesian variety mitani soybean flour

Rindy Panca Tanhindarto¹, Suwimol Jetawattana³, Deudeu Lasmawati¹, Indra Mustika Pratama¹, Henni Widyastuti¹, Rafi Eko Hindarto², Ashri Mukti Benita¹, Zubaidah Irawati¹.

¹Research Center for Radiation Process Technology (PRTPR), BATAN, National Research and Innovation Agency (BRIN), South Jakarta, Indonesia; ²Department of Agriculture, Faculty of Animal and Agriculture Sciences, Diponegoro University, Semarang, Indonesia; ³Thailand Institute of Nuclear Technology (TINT), Bangkok, Thailand

Irradiation technology using Co-60 and machine sources (electron beams and X-rays have been widely used in the food sector for sanitary and phytosanitary. In recent years, many studies have been carried out on irradiation technology for food modification, one of which is to degrade antinutrient compounds phytic acid. This study aims to compare the effectiveness of two electron beam machines with 2 MeV and 10 MeV energies in degrading phytic acid compounds found in Indonesian soybean varieties Mitani (Yellow Soybean). Soy powder samples weighing 72 grams were packaged in polyethylene plastic and irradiated at 2 electron beam facilities, 2 MeV GJ 2 in BATAN, Indonesia, and 10 MeV GEMS in TINT, Thailand. Irradiation was carried out using two techniques, single-sided with dose variations of 0, 10, 20, 30, 40, 50 kGy and double-sided (dose fractionation) with a total dose of 0, 10, 20, 30, 40, 50 kGy. The results showed that both facilities with an energy of 2 MeV and n 10 MeV could degrade phytic acid compounds in soybeans. For doses < 30 kGy, the one-sided irradiation technique with 2 MeV and 10 MeV EBM was effective in degrading phytic acid up to 40-50% compared to the two-sided irradiation technique. For energy > 30 kGy, irradiation with the energy of 10 MeV one-sided technique can degrade phytic acid compounds up to 81.15%.



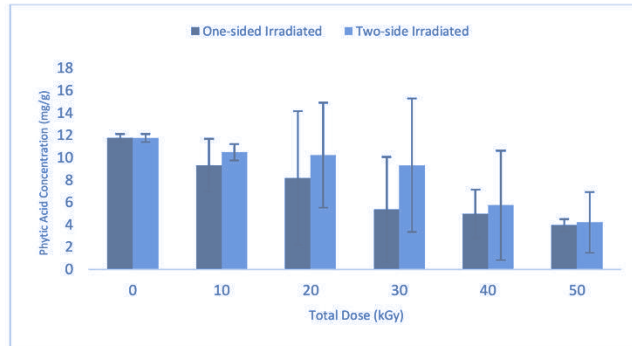


Figure 1. Phytic acid concentration after irradiated with 2 MeV GJ 2 EBM, BATAN

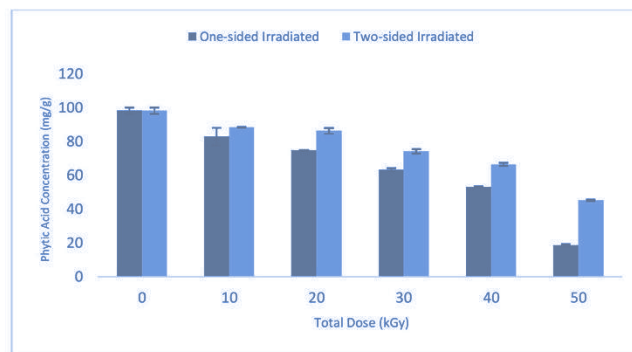


Figure 2. Phytic acid concentration after irradiated with 10 MeV GEMS EBM, TINT

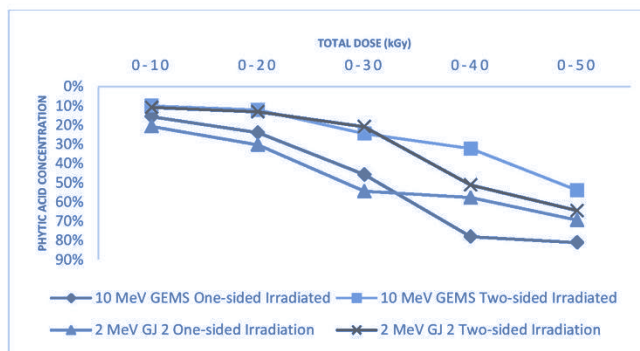
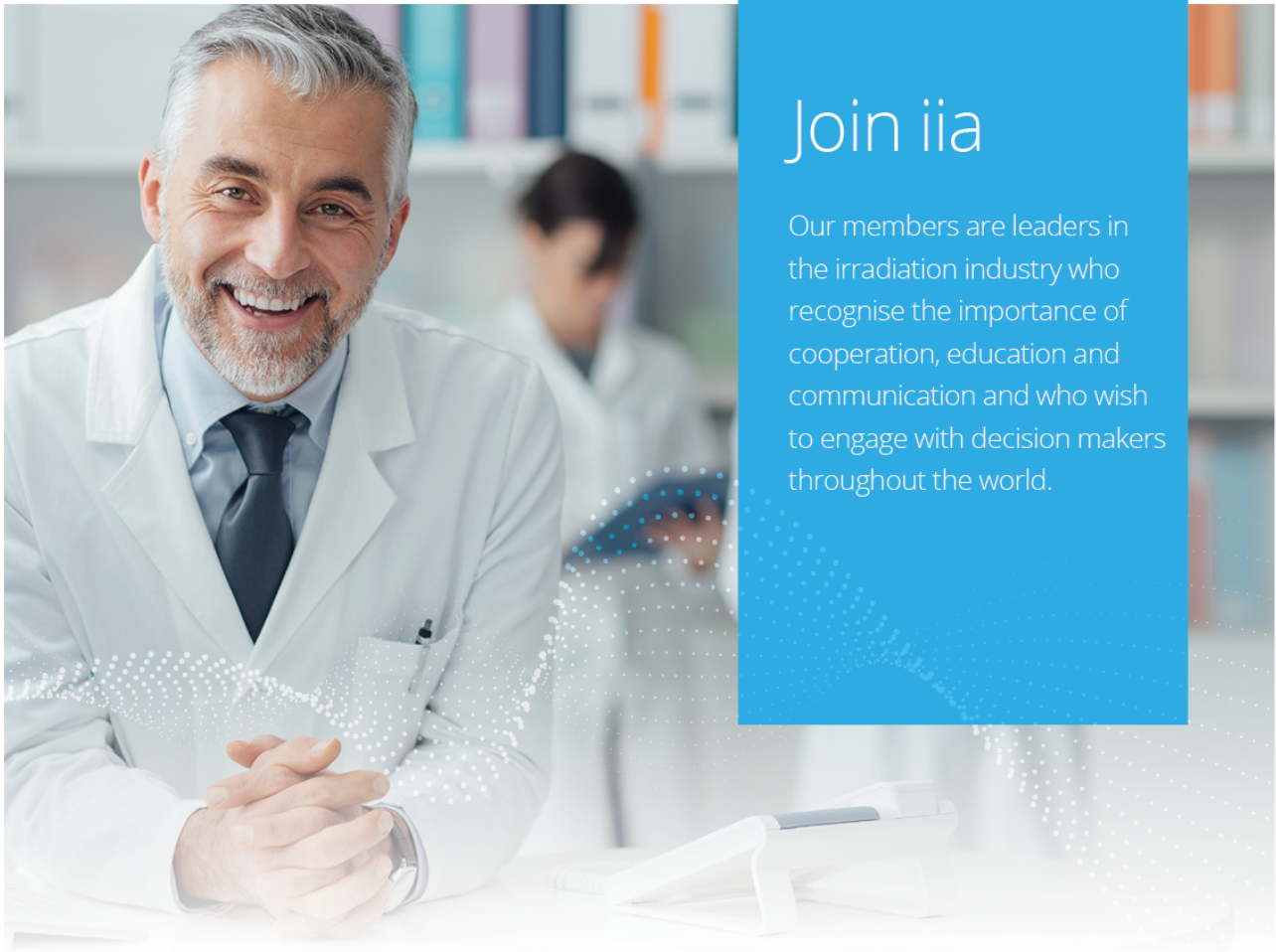


Figure 3. Phytic acid reduction towards total dose



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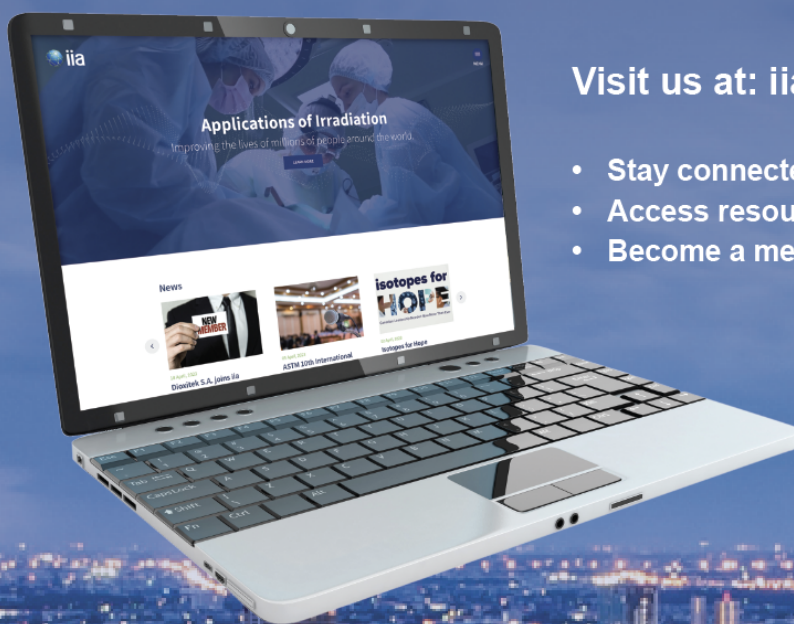
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