CLIN. CHEM. 33/2, 328–336 (1987)

Quality Assurance in Changing Times: Proposals for Reform and Research in the Clinical Laboratory Field[1]

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The U.S. Department of Health and Human Services recently commissioned a comprehensive analysis of the effectiveness and appropriateness of federal clinical regulations. The analysis found that many federal regulations are technically obsolescent and many may be operationally unnecessary as a result of changing laboratory technology and changed federal reimbursement policies. Among changes recommended by the HHS-funded analysis are: (*a*) the regulatory classification system based upon physical location of laboratories is no longer appropriate and should be replaced with a classification system reflecting laboratory functions; (*b*) a single, uniform set of federal regulations should be developed that covers all civilian laboratories receiving federal reimbursement or operating in interstate commerce; (*c*) a revised federal regulatory system should emphasize measures of performance such as personnel and inspection requirements; and (*d*) clinical laboratory regulations should be based upon objective data to the maximum extent possible.

This special report summarizes a study commissioned by the Office of the Assistant Secretary for Health for Planning and Evaluation (ASPE) of the U.S. Department of Health and Human Services to assess the effectiveness of federal quality assurance (*1*) regulations for clinical laboratories in meeting their objectives of protecting the public health (*2*). The ASPE study, completed in April 1986, was identified by the Office of Management and Budget as a priority analysis in the administration's 1985 regulatory reform program (*3*).

Study Objectives

The two primary objectives of the ASPE study were:

(1) to assess the appropriateness and effectiveness of clinical laboratory regulations under Medicare and the Clinical Laboratory Improvement Act of 1976, as amended (CLIA); and

(2) to identify and analyze alternatives to current federal requirements.

Structure of the Analysis

The work program produced by ASPE defined three primary tasks and a series of subtasks to achieve these objectives:

Task I: Compare and contrast Medicare and CLIA laboratory regulations in conjunction with selected state regulatory requirements for clinical laboratories and voluntary standards employed by the College of American Pathologists, the Joint Commission on Accreditation of Hospitals, and the American Osteopathic Association to identify: (*a*) common requirements; (*b*) inconsistencies or conflicts among programs; and (*c*) gaps in requirements, including failure to encompass certain laboratory settings or aspects of laboratory performance.

Task II: Review and analyze existing empirical research regarding the efficacy of regulatory requirements in assuring laboratory quality, thereby meeting statutory objectives of protecting public health. Where empirical evidence was not available to assess the federal regulations, the contractor was charged with identifying the best-informed professional judgment on the topic. Task II contained a set of five subtasks:

(*a*) Determine what evidence or qualified professional judgment supports a conclusion that specific regulatory requirements are "beneficial"—that is, improve laboratory performance and (or) reduce cost.

(*b*) Determine what evidence or qualified professional judgment supports a conclusion that specific regulatory requirements have negligible or detrimental effects on quality and (or) costs of services.

(*c*) Determine how reimbursement policies such as the move to prospective payment and diagnostic related group payments have affected sites, frequency, quality, and costs of clinical laboratory services, and forecast future effects of these policies.

(*d*) Determine if reimbursement policies such as prospective payment systems have led to shifts in providers of services between for-profit and non-profit providers of services.

(*e*) Determine to what extent changes in laboratory technology have affected costs, quality, and sites of clinical laboratory testing.

Task III: On the basis of findings of Tasks I and II, identify and evaluate alternatives to current regulatory requirements that hold promise for assuring high laboratory performance while reducing costs or holding them at acceptable levels.

Before describing the methods used in carrying out these tasks, it is important to note that the implicit logic in identifying inconsistencies in requirements between Medicare and CLIA (Clinical Laboratory Improvement Act) regulations and assessing the efficacy of existing requirements is to determine if the federal government should move to a *uniform* set of clinical laboratory regulations. The implicit logic in identifying gaps in coverage and assessing the appropriateness of federal exemptions is to determine if the gaps in regulatory coverage create the risk of potentially lower levels of public health protection than elimination of the gaps would entail.

It is also important to note that the primary focus of the

[1] This Special Report is based upon an oral presentation of the same title given by the author at the Fourth Annual Institute on Critical Issues in Health Laboratory Practice, September 17, 1986, at Spring Hill Center, Wayzata, Minnesota. Kenney (Dr. P. H.; M. C. P.) was principal investigator in the study, which was done by Macro Systems, Inc., Silver Spring, MD. The report is available in paper and on film from the National Technical Information Service: NTIS no. PB862104401AS (793) 487 4650.

This report does not necessarily reflect the views of the American Association for Clinical Chemistry. An article on this study appeared in the July 1986 issue of *Clinical Chemistry News*.

entire study was to determine the effectiveness of federal regulations in protecting the public health at reasonable cost—in other words, the central focus of the analysis was to be cost-effectiveness (*4*).

Context of the Regulatory Review

Cost Containment

There has been a substantial increase in laboratory testing and associated costs to patients and (or) third-party payors during the past two decades since federal regulations were put in place. The costs of clinical laboratory services are seen as an important component of the general inflation in medical and health-care costs of the past 10 to 15 years. At present, there is a heightened concern with controlling unnecessary costs associated with laboratory testing and with regulating clinical laboratories.

The Health Care Financing Association (HCFA) estimated that total Medicare expenditures for outpatient laboratory testing in FY 1984 were $1.6 billion. About half of this amount went to hospitals, with 80% of the remaining $800 million going to physicians' office laboratories and 20% going to independent laboratories (*5*). HCFA did not have a data system that could track laboratory expenditures for inpatients, which are certainly also substantial.

Market Estimates

During the past two decades there has been a rapid growth in markets for clinical laboratory services with growth rates varying in different sectors of the market. The American Hospital Association (AHA) in 1985 estimated that there was a 20% annual growth rate for laboratory testing in the 1960s and 1970s. The AHA estimates that the 1985 market for all testing services was at $20 billion, with $10 billion in hospital laboratories and $5 billion each in the independent and physician's office settings (*6*). E. I. Du Pont de Nemours and Company estimated (*7*) utilization volumes and market percentages in 1985 by setting 51% of testing volume in hospital laboratories (over three billion tests), 30% in independent laboratories (1.8 billion tests), 11% in physicians' office laboratories (66 million tests); and 8% in the home (48 million tests). Du Pont estimates that the overall market will nearly double by 1990, with the physician's office setting growing at 15% per year.

Physician's Office Testing—the New Growth Area

Hospitals magazine identified the physician's office setting as the "new growth area" in the market (*6*). A sense of the growth in the volume of testing in this setting may be seen in the Boston Biomedical Consultants forecast of 2.7 billion tests with revenues of $16 billion in clinics and physicians' offices by 1990, a 14% growth rate per year and a fourfold increase in revenues over 1985 (*8*).

Changing Laboratory Technology

Existing federal quality-assurance regulations are consensus-based rather than data-driven. They reflect a consensus of professional thought and relative political-power positions that existed in the mid-1960s, and as such are based upon technological, economic, and political conditions current two decades ago. A central feature of earlier laboratory technology was that it was highly labor intensive, requiring the efforts of extensively trained, dextrous workers, who proceeded through a series of complicated manual-testing steps. Each step in the process was subject to human error. As a result, there was a need for extensive technical training and socialization of laboratory personnel into professional norms. Beginning in the 1950s, semi-automated systems entered the market that mechanically performed some of the previously manual test steps. By the mid-1960s laboratory testing was still largely dependent upon manual operations performed by technologists and technicians.

A set of "good laboratory practices" designed to bring about uniform standards of practice and performance in laboratories was developed by the profession in response to the sensitivity to human error that was associated with manual and semi-automated systems. These standards were incorporated into voluntary quality-assurance programs and were later adopted in large part by federal and state regulatory programs for clinical laboratories. In general, these standards of good laboratory practice and their related regulations were not empirically tested to determine their efficacy in assuring accurate, precise laboratory testing.

Since the federal regulations were adopted there have been revolutionary changes in laboratory technology involving three components: a continuous growth of new tests from research centers, refinements in previously developed tests, and the miniaturization and computerization (automation) of laboratory testing methods. Along with automation has come the introduction of prepackaged reagents. The primary features of automation of laboratory testing and use of prepackaged reagents are the reduction or almost complete elimination of analytical testing steps subject to human error, and the development of feedback loops to internally monitor and control the quality of testing.

Miniaturization of laboratory technology has opened the possibility for a major decentralization of testing to sites distant from centralized hospital or reference (independent) laboratories. It is now possible to conduct increasingly accurate and precise testing, especially in chemistry and hematology, in physicians' offices, isolated clinics, and on the wards or at the bedside.

Changed Laboratory Payment Policies

By the mid-1970s, rising federal health and medical expenditures had become a major political issue. Beginning with the Omnibus Budget Reconciliation Act of 1980, a series of changes in Medicare and Medicaid reimbursement policies for clinical laboratory services was initiated in an attempt to substantially reduce federal expenditures for these services. Section 916 of the Budget Reconciliation Act of 1980 put a cap on open-ended "reasonable-charge" laboratory fees, thereby creating incentives for physicians to do laboratory tests in their own office, in order to recover diminished revenues from markups previously applied to tests referred to independent or hospital laboratories, and from reductions in income they later experienced under the 1984 freezes in physicians' payments for medical services under the Deficit Reduction Act.

Prospective payment for inpatient laboratory testing (DRGs) converted hospital laboratories from revenue centers to cost centers. There is evidence that pre-admission and post-discharge testing shifted to other settings where separate reimbursement is still allowed, especially the unregulated laboratories in physicians' offices.

Reclassification of clinical pathologist services under the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA) substantially limited Part B Medicare Reimbursement payments to pathologists, further reducing hospital laboratory income. This added additional incentives for hospitals to

reduce costs, both by reducing numbers of tests per admission and by reducing unit costs—in other words, to seek increased efficiency through automation.

The Interaction of Changing Technology and Changed Reimbursement Policies

Rapidly changing laboratory technology and changes in federal reimbursement policies have interacted to initiate a restructuring of the clinical laboratory industry that is resulting in the shift of millions of tests among various laboratory settings. New settings in which tests are performed are emerging: free-standing urgent-care centers, free-standing diagnostic centers, and mobile laboratories. New laboratory-ownership patterns are also developing, such as a movement in response to changes in reimbursement. For example, physicians who are not in group practices are forming limited partnerships to provide themselves with laboratory services outside of the umbrella of federal or state regulation.

This restructuring of laboratory testing has not been reflected in changed regulatory requirements, which address neither the new technology nor the decentralization of laboratory testing that currently is underway. A major feature of the ASPE study was to assess the current regulations in the light of these two major changes, and to recommend appropriate reform of existing quality-assurance regulations.

Study Methodology

Fundamentally, the study was a collaborative effort on a nationwide basis. Our primary role as researchers was to collect, collate, and synthesize data and ideas from a wide variety of participants in the clinical laboratory arena. As a first step, we conducted an extensive literature review, which, to my knowledge, produced the most complete bibliography on the topic of laboratory regulations available to date.

We also used an extensive interview process, which involved face-to-face or telephone interviews with workers at many levels in the clinical laboratory field representing public and private agencies, manufacturers and their representatives, leading academic authorities, and laboratory workers. Some of the institutions included in this interview process were: the American Association for Clinical Chemistry, the Health Care Financing Administration (HCFA); The Centers for Disease Control (CDC); The Food and Drug Administration (FDA); agencies regulating clinical laboratories in California, Pennsylvania, New York, and a number of other states; The Joint Commission on Accreditation of Hospitals (JCAH); the College of American Pathologists (CAP); the American Osteopathic Association (AOA); the American Society for Medical Technology (ASMT); the American Society of Clinical Pathologists (ASCP); the American Association of Bioanalysts (AAB); the National Committee on Clinical Laboratory Standards (NCCLS); the Health Industry Manufacturers' Association (HIMA); and some individual manufacturers. The names of the 134 individuals interviewed are listed in an appendix to the report (*9*).

In addition to providing much of the content of the final report, these interviews constituted one feature of a three-part quality-assurance program for the study itself. Many of those interviewed were contacted on a number of occasions during the eight-month study and invited to comment on our ideas as they evolved during the investigation. In this way the research team received continual feedback on the project as it unfolded. A second quality-assurance mechanism was provided by a federal interagency review committee, composed of representatives from ASPE, CDC, and HCFA, which met periodically to guide our efforts. As a third quality-assurance mechanism for the study an independent group of 10 reviewers who are recognized as leaders in various aspects of clinical laboratory activities was invited to review the final report as it was being drafted. All of them offered valuable suggestions for refining chapter drafts and contributed greatly to the overall quality of the final product. (See Appendix A for a list of these independent reviewers.)

Study Findings—General

Public Health in the Clinical Laboratory Context

Although the stated purpose of quality-assurance regulations for clinical laboratories is to protect the public health, *the concept of public health in the clinical laboratory context is undefined,* either in the professional literature or in legislation. Under these conditions it is not possible to assess the efficacy of federal regulations in meeting their stated purpose of protecting public health. The focus of the ASPE study was forced to shift to the efficacy of federal regulations in assuring acceptable levels of accuracy and precision of laboratory testing—the tacitly accepted operational definition of public-health protection in the clinical laboratory arena.

Cost-Effectiveness

We found no cost-effectiveness studies of the current sets of federal regulations governing clinical laboratories in the literature, nor of any state standards or voluntary accreditation requirements. Perhaps more importantly, we found that at the present time *it is not possible to develop cost-effectiveness analysis of federal quality-assurance requirements for clinical laboratories,* because there are no specified effectiveness criteria (e.g., public health, accuracy, or precision) that can serve as program objectives, nor are there cost data available to assess achievement of program effectiveness in meeting objectives.

Obsolete Regulatory Classification System

At present, laboratories are categorized for regulatory purposes on the basis of their physical location—i.e., whether they are situated in hospitals, physicians' (or group practice) offices, or in other settings. Laboratories in the residual category are labeled "independent." There are three levels of ambiguity to this typology.

Independent laboratories. "Independent" laboratories may be individual units in large regional or national chains. Their ownership is not "independent" in the classical economic sense of the term. The defining characteristic of "independent" laboratories is that they are in physical locations where physicians and patients do not directly interact. Independent laboratories must operate under more stringent and burdensome federal regulations than are applied to hospital laboratories—and, of course, more stringent regulations than physicians' and group-practice laboratories, which are not regulated at all under either Medicare or CLIA (some states regulate some physicians' and group-practice laboratories). They are placed at a competitive disadvantage as a result of these more-stringent regulations, although there is no empirical justification for this discriminatory policy, which assumes that physician–pa-

tient interaction on the premises offers greater assurance of quality than in the "independent" setting.

Physicians' office laboratories. The term "physicians' office laboratory" implies a small laboratory in the office of a solo practitioner or a very small group practice (perhaps two to three physicians). However, the term is routinely used to include laboratories in much more substantial group practices. Indeed, there may be hundreds of partners in group practices with exempt laboratories. Laboratories in large group practices may be very extensive and functionally equivalent to hospital or independent community laboratories, and in many cases may do a larger volume of work than many hospital or independent laboratories while remaining exempt from regulation. This is an important point, because one of the primary justifications for exempting physicians' office laboratories from regulation is an assumption of low volume and therefore low public-health risk. And, as has been pointed out above, changing laboratory technology and federal reimbursement policies are interacting to dramatically increase volume of testing in this unregulated setting. There is some empirical evidence to indicate that low laboratory volume is associated with poorer performance, ironically indicating increased risk to the public health at low test volumes (*10–14*). In addition, there is evidence that a dimension related to volume—namely, the scope of laboratory services offered—is also inversely related to laboratory performance (*15, 16*).

The second key justification for exempting physicians' and group practice laboratories is the assumption that laboratory testing in a physician's office is an integral part of the practice of medicine. The M.D. degree in the primary care setting is treated as a necessary and sufficient condition to assure clinical laboratory quality. However, a series of court cases and attorneys-general opinions in the hospital setting have found that the production of laboratory reports is not the practice of medicine. The assumption that laboratory work is an integral part of the practice of medicine may no longer be a persuasive argument for exempting laboratories in primary-care settings. In addition, there is a small but increasing body of empirical evidence that indicates that levels of accuracy and precision of testing in the unregulated settings are consistently lower than work done in regulated laboratories (*15, 17*).

New laboratory test settings. The third level of ambiguity in the regulatory typology is centered on the newly emerging settings for laboratory testing: free-standing primary and emergency-care centers, free-standing diagnostic centers, mobile laboratories, independent laboratories operating in hospitals under contract with hospitals, networks of satellite laboratories operated by hospitals outside of central hospital facilities, and the changing ownership patterns already described. These new developments have not been addressed in quality-assurance regulations under Medicare.

These three levels of ambiguity serve to illuminate the inappropriate nature of the present regulatory typology. Although it is increasingly clear that this typology is obsolete, given current technological and financial conditions, there is little evidence that it was justified even when it was originally adopted into the federal regulations two decades ago.

The Three-Part Quality-Assurance Regulatory System

In federal, state, and voluntary quality-assurance requirements three sets of regulations are used, corresponding to Donabedian's classic three-part quality-assurance typology in medicine (*18*): structure, process, and outcome.

Structural requirements refer both to physical characteristics of laboratories and to their tables of organization for their personnel. *Process* requirements specify procedures such as periodic quality-control steps that must be followed by laboratories to make certain that their testing methods are in control. They include provisions for inspections of laboratories to make certain that process requirements are being followed. *Outcome* requirements refer to measurements of laboratory performance—the accuracy and precision of test reports. In general, federal, state, and voluntary programs require that laboratories successfully participate in mailed proficiency-testing programs to assess outcome. An essential feature of this three-part system is that both structural and process standards are *surrogates* for performance. It is assumed that compliance with structural and process is equivalent to good laboratory performance.

There are very few well-crafted empirical studies designed to analyze the effectiveness of individual regulations in each of these categories in assuring acceptable performance, or to analyze the efficacy of the clusters of regulations in the structural, process, and outcome categories. Finally, there are few well-designed studies assessing the effectiveness of regulatory systems as systems in assuring acceptable levels of laboratory performance.

Specific Study Findings—Empirical Data

Overall Laboratory Performance

There has been a sustained and substantial improvement in laboratory performance during the past two decades since federal regulations for clinical laboratories were put in place (*29*). Laboratory performance in general is now consistently at acceptable or very high levels (*20, 21*). There is documented evidence of substantial and sustained improvement in regulated laboratories (*22–30*). Several factors appear to be behind this sustained improvement and continued high level of laboratory performance, including improved technology, increased and improved voluntary quality-assurance programs (which were themselves partially triggered by the federal regulatory programs), improved education of laboratory personnel, and the existence and enforcement of mandatory federal (and some state) regulatory programs.

Although it is not possible to definitively ascribe to each of these factors precise credit for the observed improvement in laboratory performance, there is evidence to suggest that mandatory regulatory programs have been effective in improving and maintaining accuracy and precision in regulated clinical laboratories (*15, 17, 31, 32*). There are no specific studies comparing the effectiveness of Medicare and CLIA regulatory programs.

There is also clear evidence that laboratory performance is strongly affected by the analytical methods used by laboratories (*33*).

Effectiveness of Regulatory Requirements

Personnel (Structural) Requirements

There is little empirical evidence supporting requirements for individual personnel requirements. Nor is there evidence to support the more-stringent, discriminatory personnel standards applied to independent laboratories that are not applied to hospital laboratories. The requirement that laboratories be directed by persons with earned doctorates has been challenged by some studies (*15, 17, 34–36*).

There is limited evidence (*37*) that specialization of supervisors and technical personnel is important to good laboratory performance.

Process (Quality-Control) Requirements

Few studies have been designed to assess the efficacy of individual process requirements in assuring acceptable precision and accuracy. One investigation (*37*) found that there is no statistical relationship between deficiencies measured on inspection and proficiency-testing results, indicating that the surrogate process requirements do not measure the same dimension of laboratory performance that is measured by proficiency testing. This finding calls into question the validity of the inspection process. The need for quality-control requirements is not challenged by the profession, but the frequency presently mandated for quality-control runs with automated equipment *has* been challenged. We found no studies that conclusively assess the effectiveness of quality-control requirements.

Outcome Requirements

There is evidence that mandatory proficiency testing in and of itself is an effective technique for improving laboratory performance (*32, 38*).

Relationship between Surrogate Performance Measures and Actual Performance

The theoretical relationship between structure and process regulations and actual laboratory performance has not been verified, although attempts have been made to do so (*33, 37, 39, 40*).

In summary: There is strong evidence that systems of mandatory regulations are highly effective in improving clinical laboratory accuracy and precision and in maintaining accuracy and precision at very high levels. However, there is also evidence that a substantial number of individual regulations may be unnecessary and ineffective in maintaining accuracy and precision. Research has not yet been able to distinguish between the core of essential regulations and superfluous regulations that currently are in effect.

Summary of Professional Judgment and Opinion

The literature review and interview process indicated that there is a strong professional consensus for continued laboratory regulation by the federal government. It is generally agreed that personnel standards are required, but agreement over specific requirements is lacking. In general, attitudes toward individual requirements appear to be a function of economic self-interest. There is strong support for a uniform system of federal regulations for laboratories for which participation is mandatory.

There is general agreement that quality-control requirements are essential, although there is also widespread recognition that quality-control standards should be revised to meet changed technological requirements. This recognition is part of a larger interest in reform of federal regulations to meet changed conditions in general, with elimination of unnecessary or obsolete standards, simplification of the entire set of regulations, and increased flexibility of the regulatory system to respond to changing technology as key points. The need to reduce dependence on surrogate measures of laboratory quality and to increase reliance on performance measures, both accuracy and precision, is broadly supported. There is strong, though not unanimous support for linking performance standards to medical-usefulness criteria rather than continuing to use the current arbitrary standards to judge whether performance is satisfactory or unsatisfactory.

The value of mandatory proficiency testing is generally recognized, although certain weaknesses in the system now in use are repeatedly cited. The key weakness is that proficiency testing is widely believed to measure the best a laboratory can do rather than its routine performance, because special consideration may be given to proficiency test samples.

There is strong support for the maintenance of a federal partnership with voluntary quality-assurance programs and state agencies. This translates into support for decentralization of regulatory functions, insofar as possible.

There is increasing acceptance of the need to provide appropriate levels of regulation for currently unregulated laboratories, although consensus on this issue has not been achieved. There is a strong factor of economic self-interest attaching to the positions of the various respondents.

The theme of major reform of the present regulatory system for clinical laboratories contains several key components in addition to those already identified, including (*a*) that a professional consensus will be necessary to achieve a major reform of the system; and (*b*) that such a consensus will require as a necessary (but not sufficient) condition a strong base of empirical evidence supporting proposed changes.

Regulatory Policy for the Future

Alternative Approaches to Federal Regulation of Clinical Laboratories

There are three basic approaches the federal government could take towards regulation of clinical laboratories in the future. The first would be to withdraw from clinical laboratory regulation entirely, leaving quality assurance to the states or the marketplace. The second would be to maintain present regulatory approaches with little or no change. The third would be to implement a series of strategies designed to substantially reform the present system to reflect current technological and economic conditions affecting clinical laboratories.

Total federal deregulation. The option of complete withdrawal by the federal government from regulation of clinical laboratories is not supported by empirical evidence; rather, it is contraindicated by evidence showing sustained improvement in laboratory performance that in large measure is a result of federal regulations. There is a strong national consensus in the laboratory community that favors maintaining federal regulatory oversight of clinical laboratories. In addition to the apparent success of mandatory federal regulations in improving laboratory performance, the magnitude of federal reimbursement for clinical laboratory services indicates a substantial federal interest in continued assurance of high-quality laboratory performance. Complete deregulation of clinical laboratories is neither feasible nor appropriate. Such an action would result in a substantial decline in public health protection and a patchwork of differing private voluntary and mandatory state requirements, which would not cover a substantial proportion of laboratories.

Maintain the existing federal regulatory approach. Changing laboratory technology and changing federal reimbursement policies for clinical laboratories are interacting to

create conditions requiring a substantial restructuring of federal laboratory regulations. The federal regulatory process has been too inflexible to allow adequate changes in regulations to reflect changed and changing technology. In addition the shift by the federal government away from open-ended "cost-plus" reimbursement to prospective payment or capped reimbursement is directly or indirectly restructuring the provision of clinical laboratory services in the United States in ways that make necessary a thorough overhaul of federal quality-assurance regulations for clinical laboratories.

Goals for regulatory reform. The literature review and interview process led to a series of proposed goals to guide a major restructuring of federal quality-assurance regulations for clinical laboratories. A revised regulatory system should:

- provide minimum national public health protection levels as measured by laboratory performance for all civilian laboratories receiving federal reimbursement for clinical laboratory service or operating in interstate commerce
- involve reasonable compliance and administrative costs
- be grounded in empirical evidence to the maximum extent feasible; unnecessary surrogate measures of laboratory performance should be eliminated
- use regulatory categories that are based on laboratory function and (or) technology rather than spatial location
- provide uniform and equitable standards for laboratories within revised regulatory categories that reflect present technology and operating conditions
- be flexible enough to take into account different needs in different settings and to change readily as technology and other exogenous variables change
- provide for maximum involvement of state and private quality-assurance programs
- address the linkages between laboratory-reimbursement policies and quality-assurance regulations; revised quality-assurance regulations should not create incentives for improper utilization of laboratory services

Recommended Strategies for Regulatory Reform

Six recommended strategies for reform of clinical-laboratory quality-assurance regulations were presented in the report. They are not mutually exclusive and are designed to be phased in as empirical evidence is developed to support detailed regulatory requirements and as professional consensus is developed in support of the proposed revisions.

1. Consolidation of federal regulatory programs into a single uniform federal quality-assurance program. The Medicare and CLIA programs should be consolidated under Medicare into a single uniform regulatory system for federally regulated clinical laboratories. The consolidated regulatory system would contain features of the present Medicare and CLIA programs plus additions or modifications that logically follow from the other five recommended reform strategies.

2. Universal regulatory coverage. All civilian clinical laboratories receiving federal funding, including the laboratories now exempt, should come under the uniform consolidated federal clinical-laboratory quality-assurance standards recommended in the first strategy. Those uniform standards should be tailored to a new classification system for clinical laboratories, which is described below.

3. Simplification of federal clinical-laboratory quality-assurance regulations. The consolidated set of federal clinical-laboratory regulations should be simplified to reflect empirically determined need. The entire set of federal personnel regulations for clinical laboratories should be systematically evaluated to determine which requirements are essential and which are marginally effective or ineffective. Quality-control requirements should reflect current and changing technology, and objective analyses should be undertaken to determine the efficacy of current inspection requirements. All following strategies are subsets of this simplification strategy.

4. New regulatory typology. A strong recommendation was made to replace the current obsolete and inappropriate system for classifying laboratories for regulatory purposes. Two options were presented in the report. The first is a three-tiered system based on the medical-services model. The second is a two-tiered system based upon technologies used by participating laboratories.

(*a*) Three-Tiered System: Under the three-tiered option, laboratories would be classified according to whether they provide services to primary-, secondary-, or tertiary-care patients, and would be identified as Class I, Class II, and Class III laboratories. Class I laboratories would operate in the primary-care setting: solo-practitioners' offices and small- to medium-size private group-practice offices, free-standing urgent-care facilities, and publically supported primary-care clinics (e.g., rural health clinics, Indian health clinics, and the like). They would be restricted to a specified (but expandable) list of procedures approved for use in Class I laboratories, which would be largely defined by operational complexity or degree of automation. As tests become less complex and more automated, they would be added to the approved list for Class I laboratories.

Because the major quality-assurance protection for this class of laboratories would come from FDA approval of the test processes and equipment, these laboratories would have a minimal set of regulatory requirements, which would include:

- licensure of the laboratory director, whether a physician or outside non-physician director employed by the facility;
- certification that the persons conducting the tests are trained to operate the equipment used in the laboratory;
- conformity to appropriate quality-control requirements, which might include following manufacturers' recommended quality-control practices, if these are certified as effective by the FDA, or participation in an approved regional quality-control program; and
- successful participation in an approved proficiency-testing service.

Primarily, Class II laboratories would serve inpatients in community hospitals who are receiving or are about to receive secondary medical care. These laboratories would be in hospitals, in laboratories presently defined as "independent," in medium to large group practices, in free-standing emergency or diagnostic centers, and in other relevant settings. They would perform a wide range of tests, possibly defined by HCFA reimbursement experience.

Class III laboratories would be those in tertiary-care hospitals and regional or national referral laboratories independent of hospitals and would provide all tests provided in both Class I and II laboratories, but would be defined by their function of providing relatively low-volume, esoteric tests that require very highly trained supervisors and bench personnel and that require extraordinary quality-control efforts.

Class II laboratories would have more extensive personnel standards than Class I, and Class III laboratories would have more restrictive standards than Class II laboratories,

at least insofar as they perform more-complex tests. No clear list of those standards was presented by respondents consulted for this project; those standards would have to be developed in conjunction with research efforts designed to determine appropriate requirements. Detailed quality-control requirements for both Class II and Class III laboratories would also be developed through a research process designed as part of the reassessment of current standards, which is part of the overall strategy of regulatory reform. Class I, II, and III laboratories would all be required to meet identical outcome standards through proficiency-testing requirements.

(*b*) Two-Tiered Option: The three-tiered option was developed as a result of many interviews with leading members of the laboratory profession. A draft of this proposal was shared with many other respondents and discussed in personal interviews. A number of respondents criticized the design as unworkable, because in their opinion there is no valid operational distinction between Class II and Class III laboratories, although they agreed that there is an operational distinction between Class I (primary care) laboratories and other laboratories with more-complex testing services. These respondents suggested a two-tiered classification system. The first tier would be identical to the Class I laboratories in the first option. However, all other laboratories would be combined into a second tier. Under this option the two tiers would be distinguished by the degree of automation used. Class I laboratories would be restricted to fully automated procedures (*41*).

The second option presents the same four sets of regulatory requirements for Class I laboratories, and would involve a more extensive set of structure and process standards for the remaining laboratories grouped into Class II laboratories under this proposal. The structure and process standards for these laboratories would be developed as a result of the reassessment process proposed above. Outcome requirements would be the same for both Class I and Class II laboratories.

Before leaving this topic, it is important to point out that there is a dissenting view on the topic of identical outcome measures for Class I laboratories and for other classes of laboratories. This view holds that the advantages for patient care of quick turnaround time for laboratory tests in the physicians' (and group practice) setting warrant a lessening of outcome standards for Class I laboratories.

5. Assess appropriateness of increased reliance on outcome measures. There is sufficient empirical evidence presently available to question many existing structural and process (surrogate) requirements and to warrant a full-scale feasibility study to determine if it is possible to eliminate or simplify many surrogate requirments while developing improved systems for assessing laboratory performance that produce increased confidence in measurements of outcome. The Centers for Disease Control should be given responsibility to

- assess empirically the extent to which mailed proficiency-testing reflects routine laboratory performance;
- assist the laboratory profession in redesigning mailed proficiency testing to more accurately reflect routine laboratory performance, if proficiency testing as now practiced is shown not to adequately reflect routine performance;
- assist the laboratory profession in coordinating mailed proficiency testing with other forms of proficiency testing to more accurately reflect routine laboratory performance, if warranted by assessments of mailed proficiency testing as currently practiced;
- empirically assess the extent to which measures of intralaboratory precision can be used for regulatory enforcement purposes; and
- assess the appropriateness of decision criteria used to determine satisfactory and unsatisfactory performance of outcome measurements; this assessment should compare the present system of using variable cut-points with arbitrary statistical limits (95% acceptable performance based upon results falling in the central four standard deviations of the distribution of scores being evaluated) with fixed cutoff values, perhaps based upon clinical decision-making parameters.

In addition, the processes used by the Food and Drug Administration (FDA) to evaluate and approve laboratory testing systems should be linked directly to quality-assurance regulations in a way that will allow increased reliance on FDA approval of automated laboratory equipment.

6. Assess feasibility of decentralization of enforcement responsibility. It will remain necessary for the federal government to operate a national federal quality-assurance program regulating clinical laboratories, but it may be possible for the federal government to further decentralize enforcement responsibilities to states and voluntary agencies. The federal government might be thought of as "the regulator of last resort" under this approach. State and voluntary quality-assurance programs could be accepted by the federal government as providing public health protection comparable to that provided by the federal requirements. State or voluntary programs would have to demonstrate that actual *performance* levels of laboratories under their systems meet minimum federal performance requirements. The core of such a decentralization would be the development of ways to determine if programs operated by state and voluntary agencies actually provide such levels of public health protection. The current practice of validating decentralized programs (e.g., granting deemed status) if they are "equal or more stringent" in their requirements for surrogate standards would have to be abandoned in favor of reliance on demonstrated comparability of outcome measurements between the federal and decentralized programs.

These recommended reform strategies reflect four underlying themes in both the literature search and personal interviews: cost-effectiveness, equity, flexibility, and decentralization. There are three other features of the report which were not placed in the above list of themes but which deserve specific attention. Two are closely linked. First, the report notes that, "In order to bring about substantial restructuring of clinical laboratory regulations, a deliberately planned research and development program will be required to secure necessary empirical evidence to support proposed restructuring." This observation underlies a series of recommendations for empirical research to fortify regulatory provisions and leads directly to the second theme: in order to minimize ineffective or inequitable regulations, the burden of proof that proposed regulatory provisions are empirically warranted should rest upon those proposing the regulations. The third feature tying together all themes of the report is the recommendation that the Department consider a centralized federal administrative structure for clinical laboratories similar to the projected Office of Clinical Laboratories proposed by Congress in the 1975 and succeeding proposed amendments to CLIA. Such an Office of Clinical Laboratories would be expected to formulate a

coherent set of quality assurance, utilization, reimbursement, and research policies for clinical laboratories and to administer those policies effectively.

The ASPE study indicates that a nationwide review of quality-assurance standards for clinical laboratories and the development of a major restructuring of the federal approach to clinical laboratories are warranted.

Appendix A. *List of External Reviewers of Drafts of the ASPE Report*

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Notes

1. The terms "quality assurance" and "quality control" are often used interchangeably in discussions of mandatory clinical laboratory regulations or voluntary accreditation requirements. However, it is helpful to distinguish conceptually between the two terms to avoid confusion between two distinct but related features of laboratory performance. Quality *assurance* may be thought of as referring to systems of *external* requirements placed upon clinical laboratories by either governmental regulatory agencies or private accreditation organizations. Quality *control* may be thought of as referring to those *internal* activities undertaken by laboratories to assure that their results are accurate and reliable. Quality-control requirements may or may not be required by quality-assurance systems. This usage follows T. P. Whitehead and F. P. Woodford in "External Quality Assessment of Clinical Laboratories in the United Kingdom" (J Clin Pathol 1981; 34:947–57). A third related term, used by Bailey, which is also helpful in focusing analysis and discussion—"quality ensurance." Quality *ensurance* refers to the appropriate ordering of laboratory tests by physicians and correct utilization of laboratory test reports by physicians. This is the realm of medical decision-making. "Quality" in this case does not refer to the analytical accuracy or precision of the testing process, but the impact of the testing process on the patient's health status as a function of medical decision-making. See Richard M. Bailey, *Clinical Laboratories and the Practice of Medicine: An Economic Perspective,* Berkeley, CA: McCutchan Publishing Corp., 1979.

2. Kenney ML, Greenberg DP. *Final report on assessment of clinical laboratory regulations.* Submitted to the Office of the Assistant Secretary for Planning and Evaluation, DHHS, by Macro Systems, Inc., Silver Spring, MD, April 8, 1986.

3. Office of Management & Budget. The regulatory program of the United States. OMB Release 85-20, August 8, 1985.

4. "Cost-effectiveness" is here used in the technical sense used in the field of economics: an assessment of the relationship between the monetary costs and non-monetary benefits of a public policy.

5. Health Care Financing Administration, Bureau of Program Operations. "Report of laboratory task force," February 15, 1984.

6. *Hospitals,* Vol. 59, No. 20, October 16, 1985.

7. Presentation by Mr. H. B. Trepagnier, E. I. du Pont de Nemours & Co., at the American Public Health Association Annual Meeting in Washington, DC, November 20, 1985.

8. Cited in Pieter Halter: "Technology advances fuel in-office testing." Primary Care Technology, September–October, 1985.

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41. The concept of a laboratory classification system based upon technology used by the participating laboratories was suggested by Judith Barr, who is a member of the board of directors of the American Society for Medical Technology (ASMT) and associate dean and associate professor of medical laboratory science, College of Pharmacy and Allied Health Professions, Northeastern University. An ASMT position paper drafted by Dean Barr which presents this concept in detail is contained in the *Reference Manual* of the 4th Annual Institute on Clinical Laboratory Reimbursement & Policy, September 11–13, 1986, sponsored by the Washington G-2 Reports.