■ Implementation of the 1988 Clinical Laboratory Improvement Amendments (CLIA)

On February 28, 1992, the Department of Health and Human Services (HHS) published the final rule on the Clinical Laboratory Improvement Amendments of 1988 (CLIA) in the federal register. The regulations state that they apply to "laboratories that examine human specimens for the diagnosis, prevention, or treatment of any disease or impairment of or the assessment of health of human beings."

An earlier CLIA final rule was published on March 14, 1990. According to the rule itself, "we chose not to make proposed personnel requirements final so that we could propose and establish personnel standards that are in accordance with testing performed, as mandated by CLIA. The March 14, 1990 final rule, then, has been the basis for regulating the quality of laboratory services while we are going through the rulemaking procedure to implement fully the provisions of CLIA." The 1992 final rule, which did prescribe personnel requirements, caused some confusion and raised questions among nuclear medicine technologists, physicians, and others who are affected by the new CLIA regulations. HHS has attempted to address some of these concerns in its January 19, 1993 CLIA final rule, also published in the federal register.

The CLIA regulations delineate different sets of rules for each of the three types of laboratory tests: low complexity (for which a laboratory can apply for a certificate of waiver), moderate complexity, and high complexity. All nuclear medicine procedures fall under the high complexity standard. Among the concerns raised by the 1992 CLIA final rule is the requirement that each clinical laboratory staff member who performs high complexity testing have a bachelor's or an associate's degree by September 1, 1997 (federal register, vol. 57, no. 40, February 28, 1992, p. 7183, § 493.1489). The 1992 CLIA final rule offers a justification for this change in the education requirements for laboratory personnel. "Since we placed only the most difficult test systems, assays, and examinations in the high complexity category, we strengthened somewhat the high complexity testing requirements by requiring individuals conducting such testing to have, at a minimum, an associate degree in science. Until September 1, 1997, we will allow a high school graduate to perform high complexity testing under the on-site supervision of a general supervisor. The director requirements remain at the MD, DO, or doctoral levels, or previously qualified under the March 14, 1990 regulation. For certain qualifications where employees have to upgrade their education in order to meet the regulatory requirements, we have provided a phase-in period to allow time for completion of the necessary course work."

However, despite the intent of the regulations to create a more highly educated laboratory workforce, there are a number of "escape clauses" in the 1992 final rule, which allow certain laboratory personnel to be grandfathered out of the need to attain a bachelor's or associate's degree. § 493.1489(b) states that the individual has to meet one of six requirements, which are then outlined. Requirement (3) states that an individual performing high complexity testing must "have previously qualified or could have qualified as a technologist under [the March 14, 1990 CLIA final rule, § 493.1433], on or before February 28, 1992."

To qualify under the 1990 CLIA final rule just referenced, an individual has to meet one of six requirements outlined in § 493.1433(b) (pp. 9606-9607 of the March 14, 1990 federal register). Some of these six choices, (2)-(4), require the individual to complete a certain amount of college study with varying amounts of credit hours in certain subjects, such as chemistry and biology. One choice, (5), accepts as CLIA-qualified any individual who was "performing the duties of a laboratory technologist at any time between July 1, 1961 and January 1, 1968 and has had at least ten years of pertinent laboratory experience prior to January 1, 1968. (This required experience may be met by the substitution of education for experience.)"

The last choice, (6), accepts as CLIA-qualified any individual who "achieves a satisfactory grade in a proficiency examination approved by HHS." The last such test given by HHS was in 1987, and those who took the test quite some time ago, may have had the test administered by the Department of Health, Education, and Welfare (HEW), HHS's predecessor agency.

According to Judy Yost, of the Health Care Financing Administration's (HCFA) Office of Survey and Certification, Health Standards, and Quality Bureau, the grandfather clauses in the March 1990 CLIA final rule are permanent. So anyone who can qualify under any of § 493.1433(b) subsections referenced above will not have to attain a bachelor's or associates's degree by September 1, 1997 in order to remain in compliance with CLIA's personnel standards.

For small laboratories with a very limited number of personnel, meeting the educational requirements for the top-level staff may be cumbersome. However, as noted by Helen Drew, CNMT, chief technologist of in-patient services for nuclear medicine, at Johns Hopkins Hospital, Baltimore, Maryland, one individual can assume a number of titles within the laboratory: for instance, the director can also be the technical supervisor. Thus, if there is one person who fulfills the CLIA-required education credentials for two positions in the laboratory, that person can be appointed to both titles.

Yost points out that the January 1993 CLIA final rule also contains

what she refers to as an "ongoing grandfather clause." This clause states that "for individuals qualified under § 493.1489(b)(4) [i.e., those having earned a high school diploma or equivalent], who were performing high complexity testing on or before January 19, 1993, the requirements of paragraph (b)(7) of this section are not effective [(b)(7) requires that those with only a high school degree perform high complexity testing under the onsite direct supervision of a general supervisor], provided that all high complexity testing performed by the individual in the absence of a general supervisor is reviewed within 24 hours by a general supervisor" who meets CLIA qualifications. There is no cutoff date to this exception so it will remain in force indefinitely, unless or until HHS changes the CLIA rules again.

Actually, the likelihood that there will be further amendments to the CLIA regulations is quite strong. In the January 1993 CLIA final rule, HHS says, "We received approximately 16,000 comments in response to the publication of the February 28, 1992 regulations.... Our intention is to respond fully to these comments in a later publication." Yost adds that HCFA and the Centers for Disease Control and Prevention (CDC) are about halfway through the comments they have received from the public, including comments received from medical specialty groups. Then they will meet with the Clinical Laboratory Improvement Advisory Committee (CLIAC), which has a meeting scheduled for May 1993. Yost indicates that all of the involved federal agencies may come up with a permanent grandfather clause for technologists who are currently performing clinical laboratory testing with no more than a high school degree, but she says that the timetable is quite vague. If such a change should occur, it could easily take two or three years.

The CLIAC was established by HHS in the 1992 CLIA final rule to "advise and make recommendations on technical and scientific aspects" of the CLIA regulations. The committee or a subcommittee must meet at least once per year and is authorized to "review and make recommendations concerning: criteria for categorizing tests and examinations of moderate and high complexity; determination of waived tests; personnel standards; patient test mangement, quality control, quality assurance standards; proficiency testing standards; applicability to the standards of new technology; and other issues relevant to part 493, if requested by HHS."

Further revisions to the Clinical Laboratory Improvement Amendments (CLIA) regulations are likely after the Department of Health and Human Services (HHS) wades through the 16,000 public comments received.

The American Medical Association (AMA) submitted a statement to the CLIAC on February 17, 1993, responding to the January 19, 1993 CLIA final rule and suggesting revisions to specific parts of the CLIA regulations. Among its other concerns, the AMA stated that "the regulations provide no consideration of problems of patient access to laboratory services in 'health professions shortage,' 'underserved,' or 'rural' areas. Laboratories in these areas would have to close if they find it financially impossible to comply with the regulations or if there is an inadequate supply of trained personnel. Patients would then be required to travel long distances for laboratory services." The AMA recommends that "an exception to the CLIA regulations also should be given to laboratories which are the 'sole community source' of laboratory services.... Furthermore, free public health clinics should not be required to pay the CLIA certificate fees."

The AMA also urged that physicians using a common clinic all be allowed to use the same CLIA number; the present system requires each physician submitting a Medicare claim to have an individual CLIA certificate. "The AMA recommends that a single CLIA ID number be utilized by all physicians using the same laboratory for their testing. CLIA was designed to regulate laboratory services not the individuals ordering tests from the laboratory. Whether the physicians are organized in a formal group practice or are merely 'sharing' laboratory equipment should make no difference for CLIA purposes."

The AMA also noted in its statement that it has formed a Partnership, an organization consisting of sixteen medical societies, which will "provide a forum for sharing information on CLIA to assist physicians in understanding the regulations and to provide the government with information concerning issues related to the implementation of the regulations."

Drew cites the American Association of Clinical Chemistry as one organization that is currently holding sessions in different cities around the U.S. to educate people who work in clinical laboratories on the CLIA regulations. She notes that the aim is to help these people cut through the paperwork and continually evolving rules to aid them in complying with CLIA.

For those who have questions concerning their CLIA applications, or related questions, HHS has set up a CLIA hotline, which is staffed Monday-Friday, 8 A.M.-5 P.M. EST: (410) 290-5850. Yost suggests that those who have more technical questions about the CLIA regulations contact one of HCFA's ten regional offices. She notes that each HCFA regional office has a laboratory consultant who is conversant with the CLIA regulations.

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