Fundamentals of ICANL Accreditation*

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The Intersocietal Commission for the Accreditation of Nuclear Medicine Laboratories (ICANL) has become a nationally recognized accreditation program with the primary goal of providing a multidisciplinary peer review program. The purpose of this paper is to review the structure and mission of the ICANL to help increase awareness of the importance of voluntary accreditation. Included is a broad review of the ICANL standards and their relationship to other nationally published standards and guidelines. A mandatory site visit is an integral part of the program, and specifics of the site visit are discussed along with a summary of the strengths and weaknesses of applicant laboratories. The benefits of voluntary accreditation will become clear as more facilities participate in the program.

Key Words: ICANL; accreditation; standards; site visit

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The program of the Intersocietal Commission for the Accreditation of Nuclear Medicine Laboratories (ICANL) was developed by leaders in the field of nuclear cardiology, nuclear medicine, and PET and was incorporated in December 1997. The ICANL is 1 of 3 intersocietal accreditation organizations that are managed by the Intersocietal Accreditation Commission. The Intersocietal Commission for the Accreditation of Vascular Laboratories was founded in 1990, and the Intersocietal Commission for the Accreditation of Echocardiography Laboratories was founded in 1996. All 3 organizations are unique because of their intersocietal, multidisciplinary approach to writing and maintaining the standards on which their programs are based.

The ICANL is dedicated to promoting high-quality nuclear medicine diagnostic testing in the delivery of health care by providing a peer review process of laboratory accreditation and thereby ensuring high-quality patient care in comprehensive nuclear medicine, nuclear cardiology, or PET. The ICANL board of directors is made up of physician and technologist representatives from 6 specialty membership organizations that include the American Society of Nuclear Cardiology, the American College of Cardiology, the Society of Nuclear Medicine, the Society of Nuclear Medicine Technologist Section, the American College of Nuclear Physicians, and the Academy of Molecular Imaging. The first accreditation program to be developed was for nuclear cardiology, followed closely by a program for general nuclear medicine and PET. Laboratories or facilities that provide diagnostic testing or therapy in any of these areas are eligible to apply for voluntary accreditation.

ROLE OF ACCREDITATION

In general, the role of voluntary accreditation is 2-fold: first, to set and provide realistic and well-defined objective standards of quality, and second, to educate and interact with laboratories to assist in meeting those standards.

The overall purpose of accreditation is to improve the quality of testing and thus assure other members of the health care field (i.e., patients, referring physicians, insurance providers) that the services provided by that facility meet minimum guidelines developed by that particular subspecialty. As the level of competition increases among providers of diagnostic testing, accreditation may be a determining factor in a physician's choice of the facility to which to send patients.

THE ICANL PROGRAM

The ICANL standards form the basis of the accreditation program and were composed by the members of the board of directors, all of whom are practicing physicians and technologists in the fields of nuclear medicine, nuclear cardiology, or PET.

The ICANL standards provide a detailed description of the key elements and requirements of a high-quality nuclear medicine laboratory and serve as the foundation for the accreditation process. The ICANL standards are divided into 3 parts: structure and organization, process of nuclear medicine procedures, and outcome and quality assessment (*1*).

Part 1, structure and organization, includes the following sections: section 1, personnel and supervision (medical di-

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rector, technical director, medical staff, nuclear medicine technologists, direct patient care personnel, and physician and nuclear medicine technologist trainees); section 2, ancillary personnel; section 3, physical facilities; section 4, equipment and instrumentation; and section 5, volume of clinical procedures.

The required experience, training, and credentials of the medical, technical, and other laboratory staff are listed in section 1. Multiple training options are available for the medical director and members of the medical staff, ranging from board certification with formal fellowship training in nuclear medicine or nuclear cardiology to board certification in other specialty areas with a minimum number of years of practice and volume of studies interpreted. The technical director of each facility is required to hold the RT (N) or CNMT credential and have at least 3 y of nuclear medicine experience. All technologists working in the facility must be credentialed by July 2005. The decision to delay mandatory credentialing for all nuclear medicine technologists was made primarily because of the severe shortage of credentialed technologists and the inability of many good facilities to recruit and hire credentialed staff.

All staff members, both medical and technical, are required to have 15 h of continuing medical education (CME) relevant to nuclear medicine, nuclear cardiology, or PET every 3 y. Currently, those laboratories submitting their first application are given leniency on this requirement, and if the remainder of the application is in compliance with the ICANL standards, a 1-y provisional accreditation is granted to allow time to acquire the 15 h of CME. All staff must have the CME within that 1-y period. At reaccreditation, all staff are required to have the CME, or the application decision will be delayed until evidence of compliance is provided. The remainder of part 1 lists the requirements for the physical facilities, equipment and instrumentation, and procedure volumes.

Part 2, process of nuclear medicine procedures, includes the following sections: section 1, general protocol guidelines; section 2, clinical procedure protocols; section 3, equipment quality control protocols; section 4, radiation safety and radioactive materials handling protocols; section 5, administrative and other protocols; section 6, image interpretation and reporting protocols; and section 7, therapy performance and reporting protocols. Each section describes the necessary components of each specific protocol required for consistent operation including but not limited to patient identification, pregnancy and breast-feeding protocols, diagnostic imaging, and stress and therapy protocols. Each section also outlines the required components of quality control procedures for imaging and nonimaging equipment and details radiation safety and handling procedures. Standards for image interpretation and reporting are also described.

Part 3, outcome and quality assessment, contains the following sections: section 1, quality assessment (administrative, technical, and interpretative and therapeutic); section 2, patient satisfaction; section 3, referring physician satisfaction; and section 4, quality assessment meetings. Each section describes the requirements for assessing the quality of nuclear medicine procedures. This includes quality assurance of equipment, imaging procedures, and imaging results. It also describes requirements for assessment of the accuracy and reproducibility of interpretation and measures used for assessing patient and physician satisfaction.

APPLICATION PROCESS

Laboratories may apply for accreditation in nuclear cardiology, general nuclear medicine, PET, or comprehensive nuclear medicine testing. The application consists of detailed questionnaires and includes a CD-ROM for completing the accreditation documents. The applicant laboratory must document and provide evidence that the laboratory complies with the ICANL standards.

A typical application for accreditation is accompanied by much documentation, including the professional credentials of medical and technical staff, a list of imaging and nonimaging equipment, and written imaging and stress procedure protocols. Additionally, the laboratories must submit selected patient studies in digital format for SPECT studies, hard copies of reconstructed and processed images for nuclear medicine and PET studies, and copies of the final reports that were sent to referring physicians. For nuclear cardiology accreditation, the laboratory may apply for radionuclide myocardial perfusion imaging (RMPI) and equilibrium radionuclide angiography, if performed. A minimum of 5 RMPI cases must be submitted using the random selection criteria outlined in the application. Applications for equilibrium radionuclide angiography must include 5 randomly selected cases. All the cases except one must have pathologic imaging findings. For PET accreditation, the laboratory must indicate which areas of PET testing it provides—oncologic, neurologic, or cardiac—and submit a total of 10 case studies representing a mix of all areas that are performed in the laboratory. For general nuclear medicine accreditation, the cases must represent all aspects of nuclear medicine testing provided in the laboratory and must be grouped by body system, with 2 cases per system submitted for review but not to exceed 24. The areas that a facility may choose to apply include gastrointestinal system imaging; central nervous system imaging; endocrine system imaging; endocrine system nonimaging (e.g., radioiodine uptake); skeletal system imaging; genitourinary system imaging; pulmonary system imaging; infection imaging; tumor imaging; hematopoietic, reticuloendothelial, and lymphatic imaging; other types of cardiovascular imaging; and nuclear medicine therapy.

For comprehensive accreditation that includes nuclear cardiology as well as general nuclear medicine or PET, at least 3 of the 24 studies must be myocardial perfusion studies and 3 must be PET studies, if applicable.

REVIEW PROCESS

Each application is reviewed independently by an ICANL-trained physician and technologist. They objectively evaluate whether the submitted written material substantially complies with the ICANL standards. Most important, however, is that they judge the quality of images and final reports. Some evaluated aspects of the case studies include motion, artifact, count density, filtering, and interpretation. Each reviewer makes an independent decision on the basis of the submitted material and reports to the board of directors of the ICANL. The final accreditation decision is then determined by the ICANL board of directors after consideration of the application review findings and the site visit findings.

SITE VISIT PROCESS

To ensure the most accurate assessment of the operations of each facility, the ICANL incorporated a site visit into the existing accreditation process in July 2002. The site visit provides the ICANL board of directors with an additional, day-to-day perspective of the testing practices of each applicant facility. This additional information is considered, along with the findings of the 2 application reviewers, when the operations of each applicant facility are evaluated. In addition, the site visits provide the opportunity for further peer-review benefits to the staff members of the applicant facilities. Site visits are conducted by one individual and are generally completed within a single business day. Although most onsite visits are conducted by technologists, physicians and scientists participate as site visitors as well.

During the site visit, the following documentation is evaluated by the site visitor: facility policy and procedures manuals (i.e., procedures for clinical protocols, equipment quality control, radiation safety, and administration); radiation safety documents; dosage records; results of prior Nuclear Regulatory Commission and state inspections (if any), with any corrective actions undertaken, if required; training and in-service records for all personnel in the facility who handle or are potentially exposed to radioactive materials, including all authorized users; technical procedure manual; quality control records (and phantom studies, if available) for γ-cameras and other equipment; and quality assessment policies and documentation.

In addition, the site visit includes a review of a few randomly selected nuclear medicine imaging studies (5–10) and their accompanying reports. The facility is asked to make certain a technologist or physician is available to assist the site visitor by displaying studies on the imaging computer.

ACCREDITATION DECISIONS

Laboratories that are determined to be in substantial compliance with the ICANL standards after their application review and site visit are granted accreditation for a 3-y period, or in some instances (e.g., lack of CME for all staff members), a provisional 1-y accreditation will be granted. After correction of the listed deficiencies, new certificates are sent to the laboratory for the remainder of the 3-y cycle. Laboratories not in substantial compliance receive one of the following decisions: either accreditation is delayed pending correction of identified deficiencies or submission of additional documents, or accreditation is denied. Accreditation is rarely denied, as the intent of the program is to be educational and not punitive. Any laboratory denied accreditation may appeal the decision of the ICANL and, if deemed appropriate by the Board of Directors, may be reevaluated by a new review panel.

COMMON REASONS FOR DELAY

Typically, 50%–60% of the laboratories that apply for accreditation are delayed for correction of specific deficiencies (Fig. 1). The length of the delay depends on the significance of the delay issues and generally takes between 2 wk and 6 mo to correct. The percentage of laboratories that are delayed has steadily increased since the ICANL program was initiated. Several reasons for this increase have been suggested, but the most likely reason is that a larger percentage of laboratories are applying because of reimbursement issues and generally are not prepared to meet the ICANL standards. Achieving accreditation is usually easier when sufficient time has been devoted to completing the application and ensuring that all written procedures and protocols comply with the ICANL standards. Some of the most common deficiencies include the following.

Missing, Incomplete, or Incorrect Protocols

All areas listed in part 2 of the ICANL standards must have detailed written protocols containing all required elements. Some of the most frequently omitted protocols include a policy on theft or loss of radioactive materials, a patient identification protocol, the as-low-as-reasonably-achievable protocol, and a list of who may handle or ad-

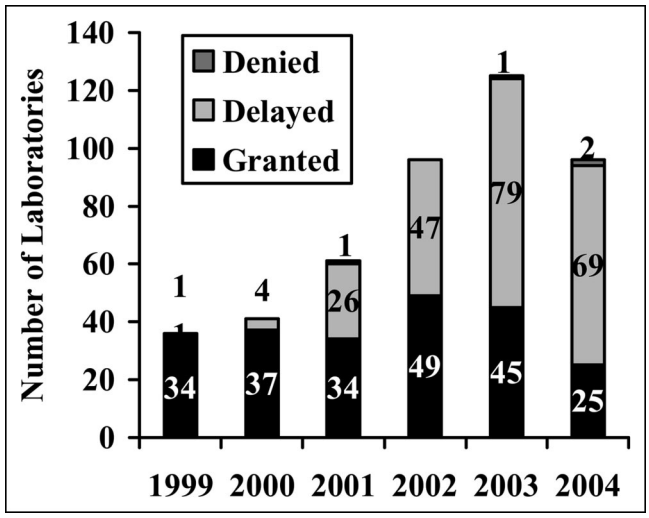

FIGURE 1. Initial laboratory decisions.

minister radionuclides (authorized user physicians, nuclear medicine technologists, trained nurses, or others who are properly trained and approved, as appropriate) (*2,3*).

Some protocols, although included, frequently lack the required details. For instance, the application requires submission of complete, detailed acquisition, processing, and display protocols that include camera setup (collimator, window setting, etc.); patient and camera positioning; camera- or computer-specific acquisition protocols including timing of views, time or counts per view, and number of views; SPECT/PET-specific parameters; computer-specific processing protocols including filtering; and computer-specific display protocols. These protocols must be site specific and sufficiently detailed to allow anyone not familiar with the camera or computer to operate it correctly (*4,5*). Frequently, laboratories submit copies of only their automated protocols without any software-specific details. Some other often-omitted protocols include the frequency of symptom assessment during and after exercise; treatment of adverse effects; and patient instructions, including instructions for patients with dietary or medication restrictions.

Occasionally, all the protocols are included and contain all the required details, but some details are not consistent with the ICANL standards, the American Society of Nuclear Cardiology guidelines (*4,5*), the American College of Cardiology/American Heart Association Exercise guidelines (*6*), or the Society of Nuclear Medicine guidelines (*2,7*). An example of an incorrect protocol would be one that describes use of a single-head camera for RMPI SPECT using 32 projections at 20 s per stop (this would be the equivalent of a 16-min acquisition on a single-head camera). The American Society of Nuclear Cardiology guidelines recommend typically 32–64 projections over a 180° orbit. Ideally, 64 projections (32 per head) over a 180° rotation (right anterior oblique to left posterior oblique) at approximately 20–25 s per view is preferred when using a dual-head γ-camera (total acquisition time, about 16 min). For single-detector systems, the total time for an emission acquisition ultimately is based on how long a patient can tolerate the procedure without moving, balanced by the need to acquire sufficient counts. Optionally, when using a single-head γ-camera, 32 views may be used at 40–50 s per view for enhanced statistics. Other frequently incorrect protocol issues include timing of injection during exercise and patient instruction on pregnancy, breast-feeding, or dietary restrictions.

Final Report Issues

Many applications are delayed for issues related solely to the final reports. The 2 most frequent issues are confusing and inconsistent reports that lack a conclusion and lack timeliness. Many reports contain details of the study performed but fail to conclude whether the findings are normal or abnormal (*8*). Concern exists that the referring physician may not adequately treat the patient because of inconclusive results. In addition, some reports lack specific required components such as the actual administered dose of the radiopharmaceutical, patient age and sex, and physician signature.

The ICANL standards require that the final report be signed by the interpreting physician within 2 working days after completion of the examination. Many of the final reports clearly have taken much longer, and concern exists that the patient is not receiving optimal and timely care because of the lateness of reports. Generally, the reviewers expect to see at least 80% of the reports finalized in 2 working days.

Site Visit Issues

Because the site visit is designed to observe patient testing, adherence to safe radiation practices, and proper documentation of all procedures, there are many deficiencies that, when found during the site visit, may delay a decision on a laboratory. Some of the more significant deficiencies include improper injection technique such as injections administered by staff who are not wearing gloves or ring badges, lack of security for the radiopharmaceuticals or the hot lab, missing or inadequate written protocols or documentation for radiation safety or handling, expired or missing emergency drugs, and inadequate testing or discharge of the defibrillator on a regular basis.

THE VALUE OF ACCREDITATION

Voluntary accreditation of nuclear medicine, nuclear cardiology, and PET laboratories is important for setting objective standards of quality and thus enhancing the quality of services in a health care environment that demands greater accountability. The standards developed by the ICANL reflect the consensus of a broad-based group of experts drawn from clinical practice and academia. Once standards of quality are defined, the accreditation program also has an important educational role. Once granted accreditation, a laboratory receives a summary of reviewer and site visitor findings to be used as part of the improvement process. Through consistent and objective evaluation, constructive criticism, feedback, and reevaluation, the ICANL expects that the quality of nuclear medicine, nuclear cardiology, and PET services will be enhanced substantially

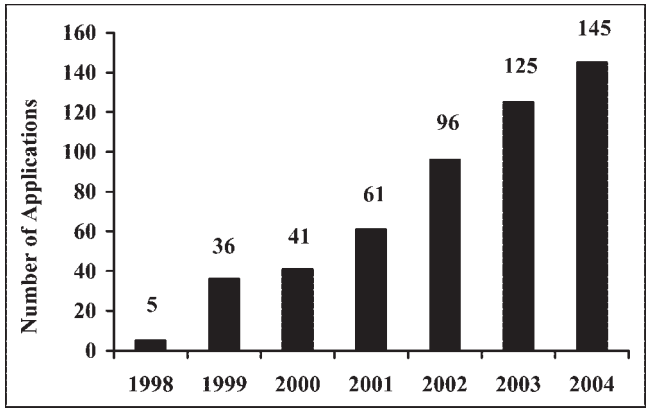

FIGURE 2. Application decisions by year.

and become uniform. The laboratory is also provided a camera-ready ICANL logo to use on reports and letterhead, a press release, and publication of the accreditation in the ICANL newsletter and on the Web site.

STATISTICS

Since 1997, more than 500 laboratories have applied for accreditation. Of those, 93% are accredited in nuclear cardiology, 9% in general nuclear medicine, and 3% in PET (Fig. 2). Most facilities (80%) that apply are in private offices or clinics, and the rest are hospital based. The high percentage of office-based practices applying for accreditation is due largely to several local payment policies that require accreditation for payment of services. The trend of laboratories applying for ICANL accreditation over time is depicted in Figure 3.

Of the laboratories that have applied for accreditation, most are accredited in RMPI (Fig. 3). This, too, may be due in part to recent payment policies enacted by several private insurers requiring nuclear cardiology accreditation for reimbursement. Whatever the reason, accreditation is clearly easier to complete when voluntary rather than rushed because of payment policies.

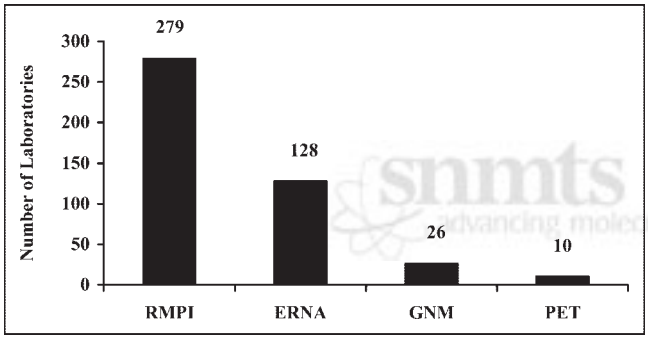

FIGURE 3. Areas of accreditation. ERNA = equilibrium radionuclide angiography; GNM = general nuclear medicine.

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The ICANL is an independent nonprofit professional organization. For more information, contact the ICANL at 8840 Stanford Blvd., Suite 4900, Columbia, MD 21045; telephone, 800-838-2110; fax, 410-872-0030; Web site, http//:www.icanl.org.

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