



Intersocietal Commission for the Accreditation of Nuclear Medicine Laboratories

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News Release

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For Immediate Release
June 1, 2009

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ICANL Offers a New Accreditation Pathway for Laboratories Utilizing Emerging Technologies: *New Software Algorithms and New Camera Technologies*

Ellicott City, MD—The Intersocietal Commission for the Accreditation of Nuclear Medicine Laboratories (ICANL) announced today that it will accept accreditation applications from laboratories utilizing new technologies and other novel imaging approaches that, to date, are not included within the guidelines published by the professional societies. Such laboratories will apply for accreditation via the ICANL Online Accreditation application and undergo further evaluation by way of the new **Emerging Technologies Pathway**.

With emphasis on ensuring quality patient care, the following provisions have been established. When there is a new technology that utilizes parameters that are outside of the currently accepted *ICANL Standards*, utilization of the new technology must demonstrate the following:

- **Clinical validation** - The technology must perform, as intended, to produce clinical results that are equal to or better than currently accepted technologies, based on published, peer-reviewed data. This would include a clear delineation of the clinical scenario to which it applies (indications/diagnoses) and the method of utilization (procedure).
- **Reproducibility** - For instrumentation, there must be clearly defined quality control procedures and data to show stability of the device, when used as indicated.

New Software Algorithms or New Equipment Hardware Technology

Laboratories using standard imaging equipment but utilizing imaging reconstruction algorithms not currently incorporated in the published imaging guidelines (i.e. half-time) or laboratories using new hardware technology with FDA 510K clearance that is not incorporated into professional organization guidelines, *are* required to perform a physiologic phantom study to determine defect/image reproducibility using the laboratory's actual imaging parameters. These laboratories are also required to demonstrate compliance with manufacturers' recommended quality control by submitting results of quality control testing. In addition, documentation of adequate training and competency of the technical staff, relevant to the new technology is required.

Pharmaceuticals and Radiopharmaceuticals

Laboratories using FDA approved pharmaceuticals and radiopharmaceuticals, according to FDA labeled uses, are not required to submit additional documentation for accreditation.

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Standard Conventional Technology

For laboratories using standard conventional technology and imaging approaches currently incorporated in the guidelines published by the professional societies, no further documentation is required as part of the accreditation process. For instance, laboratories utilizing SPECT imaging based on Anger camera equipment using filtered back projection reconstruction are required to adhere to published guidelines and thus no additional documentation is necessary.



A JOINT PROGRAM BY ICANL AND SNM

Offered jointly by the ICANL and the Society of Nuclear Medicine (SNM), the newly launched **Quality Assessment Patient Simulator Program** provides laboratories with the physiologic phantom required to identify and quantify areas of abnormality and determine the diagnostic significance of these findings. Laboratories applying through the **Emerging Technologies Pathway** are required to submit the results of the patient simulator program to the ICANL for evaluation and grading, based upon objectives judging defect reproducibility and image quality. Laboratory reporting of images will also be evaluated.

The first module to be released, the Cardiac SPECT Phantom, is available to test the applicant laboratory's ability to acquire and process SPECT rest/stress myocardial perfusion studies, identify and quantify areas of perfusion abnormality and determine the diagnostic significance of these findings. Participating laboratories will purchase the **Quality Assessment Patient Simulator Program** from the ICANL for \$500 and will have thirty (30) days from receipt of the patient simulator to submit the results. Laboratories will be required to submit the phantom results/questionnaire and all images used to make the clinical diagnosis, in addition to their laboratory's imaging protocol. The laboratory's submitted results will be graded by the ICANL using objective criteria.

As part of the **Quality Assessment Patient Simulator Program**, phantoms for general nuclear medicine and PET technology are under development.

"The ICANL seeks a balance between maintaining standards for quality patient care while not impeding the evolution of technology. By offering the new **Emerging Technologies Pathway** and making available the corresponding ICANL/SNM **Quality Assessment Patient Simulator Program**, we are providing laboratories with the means and tools by which to evaluate these new technological developments and ensure that they are providing quality patient care", remarked Sue Abreu, MD, FACNP, President of the ICANL Board of Directors.

To learn more about the ICANL's new **Emerging Technologies Pathway** and the **Quality Assessment Patient Simulator Program** during the SNM's 2009 Annual Meeting in Toronto, plan to attend the SNM Arena exhibit hall presentation with Mary Beth Farrell, MS, CNMT, NCT, RT(N), ICANL Technical Manager, and Sue Abreu, MD, FACNP, ICANL President, (Sunday, June 14th at 12pm) or visit the ICANL in booth 115 in the exhibit hall.

About the ICANL

To date, more than 2,000 nuclear medicine, nuclear cardiology and PET laboratories are accredited by the ICANL. The ICANL was created in 1998 by uniting physicians and technologists from the sponsoring organizations (listed on the first page). Collaborating together, those physicians and technologists composed the body of work known as *The Standards*, an extensive document defining the minimal requirements for facilities to provide quality care. Facilities use *The Standards* as both a guideline and the foundation to create and achieve realistic quality care goals. Participation in the accreditation process is voluntary. Accreditation signifies that a laboratory has been reviewed by an independent agency and that the applicant facility was found to be in substantial compliance with objective standards of quality. While participation in the accreditation process is considered voluntary, a multitude of private insurers, as well as Medicare carriers, have instituted policies linking reimbursement to the accreditation status of the laboratory. For more information visit www.icanl.org.