

How to Apply – Getting Started

Understanding the ICANL Accreditation Process

The ICANL is committed to helping your lab understand the accreditation process. For your lab's convenience, the ICANL provides the following concise summary of the key components of the accreditation program. The ICANL is fully staffed with customer service-oriented clinical and administrative personnel trained to guide you through the application process. For further assistance, please call 800-838-2110 or e-mail Mary Beth Farrell at farrell@intersocietal.org.

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Part I:

The *ICANL Standards*

The 2010 ICANL Standards for Nuclear Cardiology, Nuclear Medicine and PET Accreditation are now available for download as a PDF on the ICANL website. The *Standards* are divided into three parts: Part A – Structure, Organization and Definitions; Part B – Procedures and Protocols; and Part C – Quality Improvement.

Serving the laboratory as the accompanying guide through the ICANL accreditation process, the *Standards* must be referenced when completing the ICANL Online Accreditation application. Whether applying for first-time accreditation or reaccreditation, the first step toward success is a review of the *Standards* by every member of the laboratory staff involved in the application process.

DOWNLOAD THE 2010 ICANL STANDARDS

To download the PDF of the *Standards* online, please visit www.icanl.org/icanl/apply/standards.htm

Part II: Case Studies

CASE STUDY SELECTION REQUIREMENTS AND INSTRUCTIONS

Case study submissions are required in order to assess the interpretative and technical quality of the laboratory. Case study requirements have been grouped into the following categories:

- **NUCLEAR CARDIOLOGY (See Pages 5-6 in this document)**
 - **GENERAL NUCLEAR MEDICINE, COMPREHENSIVE, PET AND MULTIPLE SITES (See Page 7 in this document)**
 - **MOBILE SERVICES ONLY (NO FIXED LABORATORY SITE) (See Page 8 in this document)**
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HOW TO SEND A SUBMISSION

- Please submit all images utilized in the interpretation of a study by a physician.
 - Laboratories should submit sample cases from as many medical and technical staff members that interpret or perform any nuclear medicine examinations in the laboratory as possible.
 - **Two reviewers evaluate every application; therefore it is imperative that all case study materials submitted to the ICANL be sent in duplicate.**
 - For laboratories unable to submit digital images, high quality black-and-white and color copies of processed images may be submitted on paper.
 - Case selection is **not** camera dependent. You may select cases from any camera in your laboratory. Not more than one (1) case per procedure type should be normal.
 - All (or both) cases from multiple sites must be abnormal.
 - Cases are to be **contemporary** (performed with current personnel on current equipment). If more than one physician interpreting procedures in the laboratory, the selected cases should represent as many staff members as possible.
 - Abnormal studies have positive findings or demonstrate pathology. For example, an MPI study with breast or subdiaphragmatic attenuation would not qualify as abnormal.
-

LABELING YOUR SUBMISSION

Label all cases (an adhesive label affixed to each page is recommended), including any disks or hard copies, with:

1. Laboratory name/site location
2. Patient name
3. Date of study
4. Type of study

CASE STUDY SELECTION REQUIREMENTS AND INSTRUCTIONS:

Nuclear Cardiology

MYOCARDIAL PERFUSION IMAGING (RMPI) CASES:

Laboratories are required to submit five (5) complete RMPI studies. In addition to the five cases, laboratories are required to submit two abnormal reports (without any images or clinical data) from each interpreting physician listed in the application. All studies and reports should reflect the highest quality of studies performed in the laboratory.

All cases must be selected from studies performed two months prior to the expected submission of the application. For example, if a laboratory intends to submit the application on January 1, the cases can be chosen from the beginning of November through December 31.

Cases are selected as follows: Only one study may be normal. There must be one study demonstrating myocardial infarction, one study demonstrating ischemia, and one study demonstrating significant regional or global wall motion and one additional abnormal study. At least one of the studies must be an exercise stress study and there must be at least one pharmacologic stress study.

In addition, the cases must have been interpreted by as many different physicians as possible, performed by different technologists and if more than one camera is present in the laboratory, cases must be selected from each camera in use. For instance, if there are five interpreting physicians in the laboratory, then there must be one case from each physician. If there are two physicians interpreting studies for the laboratory, then three case studies must be from one physician and two case studies from the other physician.

MPI CASE STUDIES:

5 studies:

- 1 study must be normal
- 1 study must demonstrate ischemia
- 1 study must demonstrate infarction
- 1 study must demonstrate significant wall motion abnormality
- 1 study must be abnormal as listed above

Of the 5 studies:

- At least one study must be a pharmacologic stress
- At least one study must be an exercise stress

And 2 additional abnormal reports from each interpreting physician listed in the application.

WHAT TO SUBMIT:

As stated previously, laboratories are instructed to submit all images utilized in the interpretation of a study. Therefore, for cardiac case studies, laboratories should submit:

- Movies of planar projection images, cine data (if available)
- Reconstructed stress-rest slices (gray scale and color)
- Quantitative data, polar maps, etc.
- Movie-gated SPECT slices (if available)

- Gated SPECT slices in end diastole and end systole
- LV volume curve and calculated LVEF
- EKG tracing (rest, each stage of exercise, peak stress, recovery, final recovery)

EQUILIBRIUM RADIONUCLIDE ANGIOGRAPHY (ERNA OR GATED BLOOD POOL):

A total of five (5) case studies are selected up to a year prior to the date of your application submission. Include at least three abnormal studies for a total of five (5) case studies. You must submit images/documentation of the LA045, Anterior, Left Lateral views at a minimum.

CARDIAC PET:

A total of five (5) PET case studies are required. Only one (1) case may be normal.

Electronic Digital Data Change:

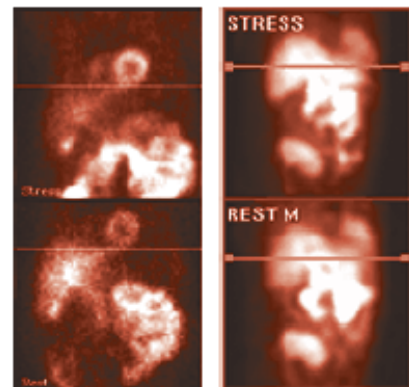
Digital raw data is no longer required or accepted for cardiac case study submission. The preferred method for submitting case study documentation is processed image data in digital image format, supplied on CD or DVD. No optical disks will be accepted.

Laboratories may provide screen captures of static images as JPEG (Joint Photographic Experts Group), TIFF (Tagged Image File Format) or BMP (Bitmap Digital Images) files. Or they may submit equipment-specific images with an embedded, image-specific reader (i.e., DICOM viewer) included. Movies may be submitted as MPEG (Moving Picture Expert Group), AVI (Audio Video Interleave), QuickTime or Windows Media Player.

Please remember that images supplied on CD or DVD *must* be able to be viewed or opened on any computer. It is suggested that laboratories open and test the CDs or DVDs on different computers prior to submission to ensure that the ICANL staff and reviewers will be capable of viewing the cases using various systems.

The ICANL understands that some laboratories may not have the equipment necessary to submit images or screen captures on a CD or DVD. If a laboratory is unable to submit digital images due to lack of equipment, they may submit high quality black-and-white and color copies of all processed images on paper.

The *ICANL Standards* (B6.1.6.5) require that a laboratory must have the ability to transmit current or archived patient studies to an outside, non-affiliated entity in a format that is of interpretable quality. This transmission may take place in either electronic or hard-copy format.



CASE STUDY SELECTION REQUIREMENTS AND INSTRUCTIONS: **General Nuclear Medicine, Comprehensive, PET and Multiple Sites**

All cases must be contemporary and may be from up to one year prior. No more than one case per area or category is to be normal. Abnormal cases are preferred.

GENERAL NUCLEAR MEDICINE (Excluding Nuclear Cardiology and PET):

For each area in which accreditation is requested, submit two (2) cases not to exceed 24 cases total:

- Gastrointestinal System: 2 cases
 - Central Nervous System: 2 cases
 - Endocrine System: 2 cases
 - Endocrine System Non-Imaging (RAI Uptake): 2 cases (*Note: Only submit if not applying for endocrine system*)
 - Skeletal System: 2 cases
 - Genitourinary System: 2 cases
 - Pulmonary System: 2 cases
 - Infectious Disease Processes: 2 cases
 - Tumors: 2 cases
 - Hematopoietic, Reticuloendothelial, Lymphatic: 2 cases
 - Therapy: 2 cases
-

COMPREHENSIVE NUCLEAR MEDICINE (Including GNM and NUCLEAR CARDIOLOGY and/or PET):

- For each area of General Nuclear Medicine in which accreditation is requested, submit two (2) cases (as described above).
 - If also applying for Comprehensive with Nuclear Cardiology, submit three (3) cases (1 normal, 2 abnormal) for each area in which accreditation is requested (MPI and/or ERNA).
 - If applying for Comprehensive with PET, submit three (3) PET cases for each area in which accreditation is requested.
-

PET (Oncologic, Neurologic and Cardiac) Only Applicants:

- If applying for PET accreditation and *not* GNM, submit five (5) cases from each category (oncology, neurology and/or cardiology).
 - No more than one case per exam type should be normal.
-

MULTIPLE SITES:

- Select two (2) abnormal, contemporary cases of any imaging area in which the multiple site lab is applying. The two cases are in addition to the above requirements for the primary site.

NOTE: Screen captures of **static images** (for General Nuclear Medicine and/or PET applicants) may be submitted as JPEG, TIFF or BMP files or as equipment specific images with an embedded, image-specific reader (i.e. DICOM data with corresponding DICOM viewer).

CASE STUDY SELECTION REQUIREMENTS AND INSTRUCTIONS: Mobile Services Only (No Fixed Laboratory Site)

To better assess the work being performed by an entire mobile service, a minimum number of cases are to be submitted for review from each unit.

1-2 MOBILE UNITS

MPI — 5 cases; if two units, at least three cases will be submitted from one unit and two from the other. At least four cases must be abnormal.

ERNA — 5 cases; if two units, at least three cases will be submitted from one unit and two from the other. At least four cases must be abnormal.

GNM — 2 cases per body system, not to exceed 24 cases total. If there are two units, one abnormal case from each unit per body system.

PET — 5 cases from each category (oncology, neurology and/or cardiology). If two units, submit 3 cases from one unit and two from the other unit.

3 OR MORE MOBILE UNITS

MPI — 2 abnormal cases from each unit.

ERNA — 2 abnormal cases from each unit.

GNM — 2 cases per body system not to exceed 24 cases total, representing as many units as possible.

PET — A minimum of 6 cases representing at least two cases from each unit. If there are more than five units, two cases per unit not to exceed 30 cases.

FIXED LABORATORIES WHERE TESTING IS PERFORMED AND MOBILE UNITS

Cases from fixed laboratory site:

MPI — 5 cases; at least four cases must be abnormal.

ERNA — 5 cases; at least three cases must be abnormal.

GNM — 2 cases per body system, not to exceed 24 cases total. At least one case

PET — 5 cases from each category (oncology, neurology and/or cardiology).

Cases from mobile units:

In addition to the above cases from each primary site, include 2 abnormal cases for each type of mobile testing (MPI, ERNA, GNM, PET) **from each unit.**

HIPAA Concerns?

All materials submitted to the ICANL will be handled with strict confidentiality in accordance with HIPAA regulations.

Part III: Additional Required Items

The following additional items are required as part of the ICANL Application, and must be submitted along with the application:

- Overview of the laboratory
- Staff qualifications – e.g. board certificates, medical licenses, CME, BLS/ACLS certification
- Nuclear Regulatory Commission/State Radioactive Materials License
- Patient Identification Protocol
- Pregnancy/Breast Feeding Protocol
- Clinical Imaging Protocol for all procedures performed
- Exercise/Pharmacologic Stress Protocols

To view samples of the protocols above, visit the Sample Documents section of the ICANL website at www.icanl.org/icanl/apply/sampledocs.htm.

Part IV: Accreditation Fees

FEE FOR ACCESS TO ONLINE ACCREDITATION

The one-time fee to purchase access to ICANL Online Accreditation is \$200. This fee provides your laboratory with personalized access to ICANL Online Accreditation, notification of periodic updates to the online *Standards*, and everything you need to apply for accreditation. Once the order is placed, the laboratory is not obligated to apply for accreditation within any given period of time. Access to ICANL Online Accreditation and your account is good for the life of your facility.

APPLICATION FEE

The fees to apply for accreditation are:

\$3800 . . . Comprehensive Nuclear Medicine Accreditation
(Nuclear Medicine Testing and Nuclear Cardiology Testing and/or PET Testing)

Or:

\$3300 . . . Nuclear Cardiology Testing only

\$3300 . . . Nuclear Medicine Testing only

\$3300 . . . PET Testing only

Any laboratory with more than one site may be eligible to apply for **multiple site accreditation**, and will be charged **\$750** for each site. (The base site is excluded from this fee.)

NOTE: There is no fee for repeat submission of case studies if the lab is delayed.

Note: Application fees should not be paid until the laboratory submits the online application for accreditation.

MULTIPLE SITES AND MOBILE SERVICES

For more on the Multiple Site Policy, visit www.icanl.org/icanl/accreditation/multiplesite.htm

For more on the Mobile Site Policy, visit www.icanl.org/icanl/accreditation/mobile.htm

FEE CALCULATOR

Need an estimate on your laboratory's fees? Try our online Application Fee Calculator at www.icanl.org/icanl/accreditation/fees.htm

Part V: IAC Agreement

The Agreement

All ICANL applications submitted after January 1, 2010 will not have their decision rendered without submitting a completed IAC Accreditation Agreement.

DOWNLOAD THE IAC ACCREDITATION AGREEMENT

To download the Accreditation Agreement online, please visit www.icanl.org/iac/accreditation/agreement.htm

Completing the Accreditation Agreement

The following items should be given particular attention when completing the document:

- The current Agreement document must be submitted.
- Photocopies or scanned computer-altered Agreements will not be accepted.
- The Agreement must be appropriately signed by a person authorized to enter into the Agreement on behalf of the laboratory.
- If applying for accreditation with more than one of the IAC divisions (i.e., ICAVL and ICAEL), an Agreement for each type of accreditation must be completed.
- Any changes to the Agreement must be pre-approved by the IAC and will incur a \$200.00 fee.

To avoid any unnecessary delay in notification of, or a lapse in, your accreditation status, please take care to review each page of the Agreement before returning it and the appropriate application fees.

HIPAA Compliance and the Accreditation Agreement

To ensure compliance with the regulations set forth by the Health Insurance Portability and Accountability Act (HIPAA), the Accreditation Agreement includes a Business Associate Agreement (BA) defining the IAC as a “business associate” and defining its duties and obligations as such.

LABS USING ANY AGREEMENT OTHER THAN IAC BUSINESS ASSOCIATE AGREEMENT

For laboratories using any Business Associate Agreement other than the IAC Business Associate Agreement, the Addendum to Business Associate Agreement must be completed. To download the addendum, visit www.icanl.org/iac/accreditation/agreement.htm

ALL LABORATORIES WITH AGREEMENT, OWNERSHIP OR OPERATIONS CHANGES

For more information on Laboratories with Agreement, Ownership or Operations Changes please visit, www.icanl.org/iac/accreditation/agree_namechange.htm

Part VI:

The Application: Online Accreditation

Applications are accepted at any time throughout the year. **Most labs will receive their accreditation decision within 2-3 months of submission of a complete application.**

USING ONLINE ACCREDITATION

Online accreditation is available for use by laboratories when applying for accreditation for the first time or for reaccreditation. The IAC is pleased to make this innovative online format available to the diagnostic imaging community.

LABS APPLYING FOR ACCREDITATION FOR THE FIRST TIME

Laboratories that have never applied for accreditation in one of the IAC divisions and have never paid for the \$200 online access fee must create an account. To create a new account for your lab, please visit www.icanl.org/icanl/apply/application.htm and click on **Create a New Account Now**.

LABS BEGINNING REACCREDITATION THAT HAVE PREVIOUSLY PURCHASED ACCREDITATION MATERIALS OR RECEIVED ACCOUNT ACCESS INFORMATION

All laboratories are provided with user ID and password information in order to access the account. To create a new account for your lab, please visit www.icanl.org/icanl/apply/application.htm and click on **Access Your Account Now**. For assistance with your login information, contact the ICANL staff at 800-838-2110 or e-mail icanl@intersocietal.org.

MULTI-MODALITY LABORATORIES THAT ARE ACCREDITED BY ANY IAC DIVISION OR THAT HAVE AN ESTABLISHED ONLINE ACCREDITATION ACCOUNT

A multi-modality account is for a laboratory or group of labs that are applying for initial accreditation or reaccreditation for more than one IAC division. Call 800-838-2110 or e-mail online-app-help@intersocietal.org to request more information about adding another modality to an existing account or to combine separate online accounts.

ABOUT ONLINE ACCREDITATION

USER FRIENDLY

The IAC application data is easily accessible from almost any computer with internet access. Users may enter data from the laboratory work place and many other off site locations such as a home office or a public library.

SECURE USABILITY

Multiple users may access the account 24/7 with a unique user ID and password. All account and application data retained via adherence to SSL certification and compliance.

PAPERLESS SUBMISSION

Applicant laboratories are required to upload and submit all attachments electronically. (Note: Case study materials, i.e. reports, hard copy and CDs, must still be shipped to the ICANL office, in duplicate.) The online accreditation application makes the uploading of electronic or scanned documents an easy process. Upon being prompted within the application questionnaire for a specific document, the user clicks "browse," selects the appropriate document from their computer or memory/storage device and then clicks "open." The document is uploaded to the correct location within the application and then saved once the user navigates away from that presentation by clicking the "previous," "next" or "end" button at the bottom of the screen. Only certain file types (.txt., .doc, .docx, .rtf, .tiff, .gif, .jpg, .jpeg, .png, .pdf, .xls and .xlsx) may be used when uploading attachments to the application questions. The file size for each document must be less than 4 MB. This includes .zip/compressed files.

Part VII: Accreditation Decisions

Once the Board of Directors makes the final determination on a laboratory's accreditation application, the ICANL will advise each lab of the decision via a personalized notification letter. This letter, sent to the Medical and Technical Directors, is tailored specifically to explain the accreditation decision and when required, to request any additional documentation to further support adherence to the *ICANL Standards*.

Below are the various accreditation decisions that are rendered by the board, as well as guidelines for interpreting the notification letter.

1. GRANT

A laboratory to whom accreditation is granted has demonstrated substantial compliance to the *ICANL Standards*. This laboratory's notification letter will be accompanied by a portfolio containing the official certificate bearing the laboratory's name and area(s) of testing in which the accreditation is granted, a press release, and a CD containing the ICANL Accredited Laboratory logo. The notification letter describes the contents of the portfolio, explains proper usage of the logo, lists staff contact information and advises laboratories of their responsibility to notify the ICANL of changes in laboratory operation.

**Note: Effective 1/2010, to be in compliance with the requirements of the Centers of Medicare and Medicaid Services (CMS) as an accrediting organization for the Medicare Improvements for Patients and Providers Act (MIPPA), the IAC divisions no longer grant one-year, provisional accreditation.*

2. DELAY

A laboratory whose accreditation is delayed will receive a notification letter outlining the deficiencies identified during the application review and/or site visit/audit and the additional information requested by the ICANL Board needed to grant accreditation.

- a. Upon receiving a delayed accreditation decision, the laboratory will:
 1. have one year to provide the additionally requested documentation demonstrating adherence to the Standards as outlined in the accreditation notification letter;
 2. be permitted to submit one set of delay material to the ICANL free of charge;
 3. be assessed a \$200 review fee if, after providing the first submission of additional material, the laboratory still has not demonstrated compliance and further information is required;
 4. have a maximum of three delay material submissions to demonstrate compliance;
 5. if continued non-compliance is documented after review of the three submissions, the application will be denied and the laboratory will be required to resubmit a complete accreditation application and application fees.
- b. The additional delay material is typically reviewed within four weeks after receipt by the IAC. Laboratories are then notified of the findings of the delay material review.
- c. If granted accreditation, the final portfolio is sent.
- d. Laboratories can be granted accreditation in some areas while delayed in others. This notification will include certificate(s) for those areas granted accreditation and details regarding the delay of any other section(s).

3. SITE VISIT

The Board of Directors may determine that a site visit is required in order to better assess the laboratory and determine the final accreditation decision. In this case, the site visit notification letter simply informs the laboratory that a visit is requested and provides instructions for arranging the visit.

4. DENY

No application for accreditation will ever be initially denied; laboratories would first receive a notification of a delay or a site visit. A notification of denial may be sent if a laboratory fails three times to demonstrate substantial compliance to the *ICANL Standards*.

ACCREDITATION TIMELINE

- Evaluation and modification of lab process
- Completion/submission of online application
- Internal review of the application for completion by an ICANL application processor
- Review by physician and technologist reviewer
- Either site visit or audit
- Board review of findings
- Accreditation for three years

NOTE: After receipt of the application materials to the ICANL, most labs will receive an accreditation decision within 2-3 months.

Part VIII: Helpful Resources

- View and download Sample Documents at www.icanl.org/icanl/apply/sampledocs.htm
- ICANL On Demand Webcasts available at www.icanl.org/icanl/community/ondemand.htm
- Free webinars offered
- E-mail blasts
- FAQs available at www.icanl.org/icanl/accreditation/faq.htm
- Reimbursement Updates
- Workshops/Live Lectures

Remember, the ICANL is here to help. The ICANL is fully staffed with clinical and administrative personnel trained to guide you through the application process. Call 800-838-2110 or e-mail us today for assistance.