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**Intersocietal Accreditation Commission**

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# Accreditation Program Policies & Procedures

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## I. About the Intersocietal Accreditation Commission

### Mission Statement

The IAC is a preeminent leader in contributing to continuous improvement in health care by its exclusive dedication in recognizing and establishing value driven, quality standards through collaboration with professional medical membership organizations and in providing peer review accreditation.

The **Intersocietal Accreditation Commission (IAC)** is a North American, nonprofit organization in operation to evaluate and accredit diagnostic imaging facilities, thus improving the quality of patient care provided in private offices, clinics and hospitals where such medical tests are provided. There are five Divisions within the IAC:

- The Intersocietal Commission for the Accreditation of Vascular Laboratories (ICAVL) Created in 1990
- The Intersocietal Commission for the Accreditation of Echocardiography Laboratories (ICAEL) Created in 1996
- The Intersocietal Commission for the Accreditation of Nuclear Medicine Laboratories (ICANL) Created in 1997
- The Intersocietal Commission for the Accreditation of Magnetic Resonance Laboratories (ICAMRL) Created in 2000
- The Intersocietal Commission for the Accreditation of Computed Tomography Laboratories (ICACTL) Created in 2007

Designed to help laboratories attain the highest possible imaging quality to improve patient care, each of the accreditation programs is composed of two critical steps. The first is an **internal self-assessment** by laboratory staff. During the accreditation process, applicant laboratories must submit documentation of their daily operations, including sample case studies along with their corresponding final reports. While completing the application, laboratories are required to identify and correct potential problems, revising protocols and validating quality assurance programs. The second step in the process is a **confidential peer review** by members of the medical community. Accreditation is granted only to those facilities that are found to be providing quality patient care, in compliance with the published *Standards*. Participation in the accreditation process demonstrates the diagnostic imaging facility's commitment to the provision of quality care. Laboratories are encouraged to use accreditation as the foundation to create and achieve realistic patient care goals. Because accreditation is renewed every three years, a long-term commitment to quality care and self-assessment is developed and maintained.

Each Division is lead by a Division Board. Using common goals and methods, each Division Board establishes the *Standards* and policies for accreditation within its specific diagnostic medical specialty and renders accreditation decisions. The Division Boards are composed of representatives from organizations outside of the IAC who support the Division's activities, as well as members at large with specific expertise. (A list of the sponsoring organizations and their current representatives can be located on the IAC websites.) These representatives come from a variety of specialties delivering and/or utilizing specific imaging modalities. To the extent possible, all are required to work in or be affiliated with an IAC accredited laboratory, and

they cannot be employed by industry or provide accreditation consulting services. Representatives from each of the five Divisions compose the Board of Directors that governs the IAC as a whole.

For additional information regarding each of the IAC Divisions please visit the websites:

- Vascular – [www.icavl.org](http://www.icavl.org)
- Echocardiography – [www.icael.org](http://www.icael.org)
- Nuclear Cardiology / Nuclear Medicine – [www.icanl.org](http://www.icanl.org)
- Magnetic Resonance – [www.icamrl.org](http://www.icamrl.org)
- Computed Tomography – [www.icactl.org](http://www.icactl.org)

The IAC accreditation programs are similarly structured across Divisions and whenever possible utilize common operational policies and procedures. However, due to the inherent differences between the diagnostic modalities and the functioning of each Division, there are some policies that differ and these exceptions are noted here in these Policies and Procedures.

**A grant of accreditation by the IAC is recognition of a laboratory's performance at the time of application. Accreditation does not constitute a warranty of complete or continuous compliance. Each laboratory is solely responsible for ensuring the quality and safety of its services.**

## **II. Changes to the *Standards***

- 1.** The *Standards* are periodically reviewed and updated. Laboratories will be notified of changes to the published *Standards*, and the most current version of the *Standards* can be viewed or printed from the IAC websites.
- 2.** Accredited laboratories must continuously adhere to the *Standards* in order to maintain accreditation. The IAC will typically extend a grace period of six months in order for laboratories to adjust their practices if necessary in order to meet updated *Standards*. However, the IAC reserves the right to require compliance within a shorter period of time if determined necessary for public health and safety.
- 3.** The IAC will conform the *Standards* to any changes in Medicare statutory requirements authorized by section 1834(e) of the Social Security Act. The IAC will maintain or adopt *Standards* that are equal to, or more stringent than, those of Medicare.
- 4.** The IAC will notify the Centers for Medicare and Medicaid Services (“CMS”), in writing, at least thirty (30) calendar days in advance of the effective date of any significant proposed changes in the *Standards*.

### III. Application Requirements

**1. Newly Operational Laboratories.** Laboratories are eligible to apply for accreditation at any time after becoming operational. However, a laboratory must be able to supply the required application information and representative case studies with required pathology.

**2. Testing Areas.** Laboratories may apply for a single testing area or multiple areas within each Division. It is not necessary for laboratories to apply for accreditation in all testing areas they perform. However, accreditation is valid for only those areas of testing for which the laboratory applied and was granted accreditation. Accreditation applies only to the specific testing area(s) for which it was granted, and does not include any other testing services offered by the laboratory.

**3. Testing Volumes.** The volume of studies specified in the *Standards* is a recommendation only and not an application requirement. Laboratories are not prohibited from applying for accreditation if they do not meet the recommended volumes.

#### 4. Multiple Sites

**A.** Multiple sites refer to two or more fixed laboratory sites owned and operated by the same corporation (or other form of legal entity). The sites are all part of one legal entity (corporation, LLC, etc.) generally under one Employer Identification Number (“EIN”). If a site has a different EIN, it must contact the IAC Director of Accreditation.

**B.** Multiple sites may apply with the main laboratory site on a single application if the sites meet all of the requirements published in the Division *Standards*. Additional application information will be required and additional fees will apply.

**C.** For multiple site applications:

**i.** All correspondence will go through the institution listed on the Accreditation Agreement.

**ii.** Each site may be granted accreditation independently.

**iii.** Certificates are provided to each site granted accreditation and each site is published on the IAC Division website.

**iv.** In general, the laboratory site with the highest testing volumes will be named as the main site. However, this may vary based upon the operational structure of the laboratory.

**v.** The accreditation will be “owned” only by the legal entity with the EIN listed on the application.

**D.** Multiple sites are not required to apply for identical testing areas. Each multiple site may apply only for the examinations that are performed at the site.

**E.** An accredited laboratory may add an additional site at any time during the period when accreditation is valid by completing the multiple site application supplement and

submitting the required additional fees. If granted, all of the sites will expire at the time of the original accreditation decision.

## **5. Mobile Services**

A mobile service is comprised of one or more units (technologist and equipment) that provide testing services at one or more locations.

**A.** Mobile units may apply with the main laboratory site on a single application if the units meet all of the requirements published in the Division *Standards*. Additional application information will be required and additional fees may apply.

**B.** A mobile service may apply as a component of a fixed site application or solely as a mobile service.

**i.** If applying as a component of a fixed site application, the mobile site supplement portion of the application must be completed in conjunction with the main site application.

**ii.** If applying solely as a mobile service, both the main application and mobile supplement must be completed for the service.

**C.** All sites serviced by the mobile unit(s) must be listed in the initial application. If any sites are added or deleted the IAC Division must be notified.

**D.** Accreditation for a mobile service is granted collectively. Individual sites serviced by the mobile units are not considered accredited although the names and addresses of all sites will be maintained in the IAC database.

**E.** One certificate is issued for the mobile service entity as listed in the Accreditation Agreement.

**F.** All correspondence will go through the institution or company address(es) and personnel listed in the application.

**G.** For information regarding the required mobile unit case studies, please refer to the appropriate application and or Division website.

## **IV. Accreditation Agreement & Application Fees**

**1.** Each laboratory seeking accreditation must return a signed Accreditation Agreement to the IAC. Laboratories should review this document carefully. It creates a contract between the laboratory and the IAC, and the IAC is committed to enforcing its terms in order to protect the integrity of the accreditation program and the general public as consumers.

2. An application decision will not be rendered without a signed Accreditation Agreement on file. After the Agreement is reviewed and signed by a member of the IAC staff, a copy will be returned to the laboratory.
3. The following items should be given particular attention when completing the Accreditation Agreement:
  - A. The most current Accreditation Agreement document must be submitted and can be downloaded from the IAC websites.
  - B. Any changes requested to the standard Accreditation Agreement will be assessed a fee for changes and all changes must be initiated through the IAC website <http://intersocietal.org/intersocietal.htm> and must be approved by the IAC.
  - C. A new Accreditation Agreement must be submitted with each application for reaccreditation.
  - D. The Accreditation Agreement must be submitted with a handwritten signature. Photocopies, faxes, and .pdf copies will be accepted, but computer-printed signatures will not be accepted.
  - E. The Agreement must be appropriately signed and witnessed. The only acceptable signatures are those of the Medical Director or an officer of the laboratory (or the legal entity which owns the laboratory). The Technical Director or another member of the laboratory staff may sign as the witness. There is no need to have the signatures notarized.
4. The Accreditation Agreement includes a Business Associate Agreement which covers IAC responsibilities under the Health Insurance Portability and Accountability Act (“HIPAA”) regarding individually identifiable health information submitted through the application process.
5. Application and other fees are listed in the Accreditation Agreement. An application decision will not be rendered without full payment of application fees.
6. The laboratory is responsible for maintaining a copy of its application and other materials submitted to the IAC. Copies may be obtained from the IAC, subject to duplication fees.

## **V. Application Submission & Accreditation Cycles**

1. Applications are processed upon receipt in the IAC office.
2. Laboratories applying for reaccreditation must submit their application at least four months prior to the expiration date of their current accreditation (on the accreditation certificates) to avoid a lapse in their accreditation.
3. Accreditation is granted for a three-year period. This three-year period begins without exception on the decision date on which the Division Board initially renders its accreditation decision. Accreditation is not extended beyond the three-year period for any reason.

4. In order for a laboratory to avoid a lapse in its accreditation at the end of a three-year period, it must submit a reaccreditation application at least four months prior to the expiration date. The IAC will make efforts to remind a laboratory of its reaccreditation submission deadline 12 to 14 months prior to the expiration date. However, it is the laboratory's responsibility to apply for reaccreditation by the deadline.
5. Upon notification of a delayed accreditation decision, laboratories applying for reaccreditation are extended a sixty-day grace period in order to provide the requested information and avoid a lapse in their accreditation. If the information is not received within this time period, the laboratory's accreditation will expire. This sixty-day grace period is automatically reflected in the expiration dates of the laboratory listing on the IAC websites.
6. If a laboratory's accreditation expires the laboratory will be required to file a reaccreditation application to restore its accreditation. If accreditation has lapsed for more than three years, the laboratory must reapply as an initial applicant.

## **VI. Application Review Process**

### **1. In-House Review.**

- A. Each submitted application is assigned an identification number and laboratory information is entered in the IAC database.
- B. An in-house review is performed by IAC staff and consists of a review of the application only for completeness: that questions have been answered, attachments are included and the appropriate numbers of case studies have been submitted. The technical aspects of the application (such as the content of protocols, quality assurance statistics or the quality of the case studies) are not reviewed during this phase. The laboratory will not be notified at this time of any lack of adherence to the *Standards*. The goal of the in-house review is only to help ensure that every application is as complete as possible for the peer reviewers.
- C. As part of the In-House review the IAC will verify current physician licensure through the applicable regulatory website. In addition, through the Office of the Inspector General (OIG) website, the IAC will identify any providers included in the List of Excluded Individuals/Entities.
- D. If missing information is identified, the laboratory is notified in writing via fax and/or by telephone. The laboratory will have ten (10) business days to submit the missing information. If the information is not provided within this time, the application may be held until the next month, returned to the laboratory, or (if the lack of information will not preclude a review) submitted for review without the information.

**E.** Any requested information submitted to the IAC office is included with the application whenever possible. If the application has been sent out for review prior to receiving the requested items, attempts are made to have this additional material included in the application and reviewed. However, this might not always be possible and the laboratory might be notified of the missing items after the final application review by the Division Board.

**2. Application Review.**

**A.** A minimum of two peer reviewers review each application simultaneously but independently. All reviewers use uniform application review forms in their evaluation of the laboratory. It is during this process that the application and case studies which include image quality evaluation and final report content are reviewed and substantial compliance with the *Standards* is documented.

**B.** The recommendations and comments of the reviewers are compiled and reviewed by Division Technical Managers and other IAC clinical staff (such as the Associate Technical Managers, Director of Accreditation, and CEO).

**C.** The review findings and recommendations are presented to the Division Board at its next quarterly meeting. The Division Board makes the accreditation decision.

**VII. Application Reviewers**

**1.** To be eligible to serve as an application reviewer, an individual must meet the following requirements:

**A.** Employment in an accredited laboratory (Note: newly formed Divisions may have reviewers that are working in laboratories not currently accredited by the IAC, however they must meet this requirement within one year.);

**B.** Appropriate technical credentials and/or medical experience and training as required by the *Standards*;

**C.** A minimum of five years full-time experience within the specialty field specific to the IAC Division; and

**D.** Familiarity with the accreditation process and *Standards*.

**2.** Those active application reviewers who leave the employment of an accredited laboratory for employment in areas outside of the laboratory, but relevant to their specialty field (i.e. teaching, research) will be given consideration to maintain active review status on a case-by-case basis. Individuals who retire from practice may participate as application reviewers if the appropriate specialty credentials are maintained.

**3.** Application reviewers must complete an IAC training course prior to reviewing any application.

4. Application reviewers must sign an engagement agreement and abide by IAC requirements regarding conflicts of interest, confidentiality, and HIPAA compliance. (Please see the agreement form for further information.)
5. Application reviewers receive an honorarium for their participation. The amount is established by the Division Board of Directors.

## **VIII. Accreditation Decisions**

1. **Decision-makers.** The Division Board makes the accreditation decision. The members of each Division Board are divided into two groups so that in the event of an appeal, the appeal can be considered by individuals who were not involved in the original decision.
2. **Accreditation Decisions.** The four decisions that can be rendered by the Division Board are listed below. A decision is made for each section of the application; all areas will not necessarily be given the same decision.
  - A. **Granted:** The laboratory is granted accreditation.
  - B. **Delayed:** The laboratory is required to submit additional evidence of compliance prior to the final decision. However, accreditation (if granted) will expire three-years from the date of the original “delayed” decision.
  - C. **Site Visit:** The laboratory is required to undergo a site visit prior to the Division Board making a final decision.
  - D. **Denied:** Accreditation is denied.
3. **Denial of Accreditation.** Denial of accreditation will not be rendered as an initial accreditation decision; however, a laboratory may be denied accreditation for any of the following, but not limited to the following:
  - A. The maximum number of delay material submissions has been submitted (total of three) and substantial compliance to the *Standards* has not been documented.
  - B. All laboratory appeal requests have been exhausted.
  - C. Grounds for adverse action exist as described in subsection 2 of Section XIII, Grounds & Procedure for Adverse action Against Accreditation.
4. **Notification of Accreditation Decisions.**
  - A. The IAC will receive notification within four weeks after the Division Board issues its decision. Notification letters contain the following information:
    - i. **Granted:** A letter of notification is included in a portfolio that contains a certificate for or listing of each area of testing in which the accreditation is

granted, a press release, a CD containing the applicable IAC logo and in most cases a CD containing the laboratory's Application Review Findings Summary.

**ii.** Delayed: The letter of notification will outline the deficiencies identified during the application review (and site visit, if applicable) and the additional information requested by the Division Board.

**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 applicable IAC Division 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 additional delay material submissions to demonstrate compliance;
- (5) if continued noncompliance 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 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).

**iii.** Site Visit: The laboratory will be notified that a site visit is required and will be completed on an undisclosed date within a two to three month timeframe.

**a.** Site Visits required as a result of the application review must be completed within one year of notification or the laboratory will be required to resubmit an entire accreditation application and application fees. Accreditation will expire three years from the initial date that the Division Board rendered the site visit decision.

**B.** Notification letters, accreditation portfolios, and certificates are sent to the attention of the Technical Director at the main laboratory address listed in the application. These materials are sent via a delivery service that provides a tracking mechanism. The Medical Director will be sent a copy of the notification letter by first class mail.

**5. Application Review Findings Summary.**

**A.** The Application Review Findings Summary (ARF) is provided to laboratories following the accreditation decision. The ARF is meant to provide the laboratory feedback regarding the review of their application and is designed as an educational tool for evaluating and improving the overall quality of the laboratory. The ARF CD is generally included with the initial notification letter or in the accreditation portfolio after all areas applied for have been granted accreditation. If not included in the accreditation portfolio, the ARF will be sent separately as soon as possible.

**B.** The ARF document is a compilation of the combined answers from the reviewers to each review question and represents their findings based on the review of the original application material. Whenever possible, comments from the review of additional material are also included.

**C.** Areas of compliance are generally indicated by a “Yes” or “Meets Standard”, and areas of noncompliance are most often indicated by “No” or “Unacceptable”. In addition, there may be other subjective comments provided by the reviewers as suggestions for improvement. All comments are meant to be constructive rather than critical in an effort to improve the laboratory performance.

**D.** When applying for reaccreditation, laboratories will need to demonstrate that they have addressed the issues raised in the previous Application Review Findings Summary as well as that they are currently in compliance to the *Standards*.

**6. Decision Appeals Process.**

**A.** Only “Denial” or “Delayed” decisions can be appealed. “Site Visit” decisions can not be appealed.

**B.** A laboratory’s failure to comply with any IAC deadline may **not** be appealed.

**C.** A laboratory may request an appeal within thirty (30) calendar days after receipt of the decision letter. After this time, the laboratory may not request an appeal.

**D.** All appeal requests and supporting information must be submitted in writing and sent to the IAC by traceable mail or delivery service.

**E.** The appeal must specify a valid basis for the appeal.

**F.** Written briefing may be submitted within sixty (60) days after receipt of the appeal request by the IAC.

**G.** The Chief Executive Officer will appoint an Appeal Committee composed of three members selected from the Division Board. Appeal Committee members may not: (a) be the same individuals who initially reviewed the application, (b) review any matter in which their impartiality might reasonably be questioned, (c) review any matter involving a laboratory located within 50 miles of where the member lives or works, or (d) review any matter which presents an actual, apparent, or potential conflict of interest. When a committee member is unavailable, the Chief Executive Officer will designate another individual to serve as an interim member. Committee action is determined by majority vote.

**H.** The IAC may file a written response to the appeal request.

**I.** The Appeal Committee will render a decision based on the written record. Documentation not previously submitted to the IAC will not be considered. An oral hearing is not permitted.

**J.** In order to overturn the decision, the laboratory must demonstrate that the decision was arbitrary or capricious. Proof is by preponderance of the evidence.

**K.** The decision of the Appeal Committee is final.

**L.** The laboratory will be notified in writing of the decision.

**M.** Only one appeal per application is permitted. If that appeal upholds the original denial, the laboratory must complete and submit a new application in order to seek accreditation at another time.

**N.** The laboratory is responsible for all expenses incurred by it related to the appeal. In addition, it must pay the appeal fee listed in the Accreditation Agreement.

## **IX. Site Visits & Audits**

The IAC may conduct random or investigative on-site visits or random audits as part of the application review process or during the period of accreditation. The IAC will determine when a visit or audit is necessary.

**1. Random Site Visits.** Random site visits are the IAC's means to assess compliance to the *Standards*. A computerized program selects laboratories to receive random site visits.

**A.** The IAC will conduct a random site visit at no charge to the laboratory.

- B.** Laboratories selected for random site visits are notified in writing and the site visit will be performed on an undisclosed date within a two to three month timeframe provided to the laboratory.
- C.** One week after the written notification has been sent, an IAC staff member will contact the laboratory to confirm that the notification was received. At this time, the appropriate laboratory contact person is established and any questions regarding selection for the site visit are addressed and clarified.
- D.** One site visit representative will be sent to conduct the site visit.
- E.** The date of the site visit will be determined by the IAC staff and site visitor.
- F.** The laboratory will receive the agenda for the site visit day and blank copies of the site visit forms to be used by the site visit representative in assessing the laboratory.
- G.** Whenever possible the Medical Director and Technical Director must be available during the site visit to answer specific questions.
- H.** Patient testing will be observed as part of the site visit.
- I.** All records must be easily accessible in the laboratory for review by the site visit representative.
- J.** The site visit findings and application review findings are reported to the Division Board at their next scheduled meeting.
- K.** Laboratories are sent a site visit representative evaluation form to complete and return to the IAC. This information assists the IAC in assessing site visit representatives, the site visit process, and IAC staff members.

**2. Random Audits.** Random Audits are the IAC's means to further assess continued compliance to the IAC *Standards*, policies and procedures, and may occur at anytime during the application review period or the Laboratory's accreditation period (if granted).

- A.** Laboratories selected for audit are notified of the audit requirements in writing.
- B.** Audit materials may be audited by IAC staff or by application reviewers.
- C.** If audited at the time of application submission, applications will not be reviewed until the audit materials are submitted.
- D.** The audit materials must be received by the IAC within thirty (30) days after the laboratory receives the audit notice.
- E.** If audit materials are not submitted within thirty days, the application will be returned to the laboratory and it will be necessary to reapply for accreditation; additional fees will apply.

**3. Required Site Visits.** The IAC may also conduct an on-site visit for cause (an "investigative site visit"). "Cause" to conduct an on-site visit includes (but is not limited to): (a)

the IAC is unable to make an accreditation determination based on the written information submitted by a laboratory, and (b) the IAC is investigating a complaint that a laboratory has failed to adhere to IAC *Standards*, policies, and procedures.

**A.** When a site visit is required related to an application, the laboratory is generally notified of the necessity of the site visit in writing within two weeks after the Division Board meeting where the application was reviewed. If the site visit is requested after additional material is submitted due to a delay decision, the laboratory is notified within two to four weeks after the additional material submission and review. If a complaint has been received, it will be handled in accordance with Section XIII, Grounds & Procedure for Adverse action Against Accreditation.

**B.** An investigative site visit will be completed on an undisclosed date within a two to three month timeframe.

**C.** IAC staff members and/or site visit representatives make the arrangements for the site visit.

**D.** Investigative site visit fees are listed in the Accreditation Agreement. Accreditation decisions will not be released until site visit costs have been paid by the laboratory.

**E.** The laboratory will receive the agenda for the site visit day and blank copies of the site visit forms to be used by the site visit representative in assessing the laboratory.

**F.** For investigative site visits, two site visit representatives will be used.

**4. Findings.** If the IAC discovers a possible violation of IAC rules during a site visit or audit, the matter will be handled in accordance with the policy on Grounds & Procedure for Adverse Action Against Accreditation below.

## **X. Site Visit Representatives**

**1.** To be eligible to serve as a site visit representative, an individual must meet the following requirements:

**A.** Employment in an accredited laboratory (Note: recently-formed Divisions may have site visitors that are working in laboratories not currently accredited by the IAC, but they must meet this requirement within one year.);

**B.** Appropriate technical credentials and/or medical experience and training as required by the *Standards*;

**C.** A minimum of five years full-time experience within the specialty field specific to the Division; and

**D.** Familiarity with the accreditation process and *Standards*.

2. Site visit representatives must complete an IAC training course prior to conducting any site visit.
3. Site visit representatives must sign an engagement agreement and abide by IAC requirements regarding conflicts of interest, confidentiality, and HIPAA compliance. (Please see the agreement form for further information.)
4. Site visit representatives receive an honorarium for their participation. The amount is established by the Division Board of Directors.

## XI. Reporting Changes

1. If there is any change in an accredited laboratory's operations that might have a bearing upon the laboratory's accreditation, the laboratory must notify the IAC within thirty (30) calendar days after the change. The notice must be in writing and must include the information requested by the IAC. Instructions and sample forms are available from the IAC websites.
2. Changes which must be reported include (but are not limited to):
  - A. the departure of the individual serving as Medical Director or Technical Director;
  - B. a new permanent site;
  - C. a new mobile service or mobile location;
  - D. a change in the laboratory's name or contact information;
  - E. ceasing to do business;
  - F. discontinuation of an accredited service;
  - G. change in ownership;
  - H. the commencement of legal action (civil or criminal) against the laboratory, its directors, officers, employees, and/or agents; and
  - I. other change that results in the laboratory no longer meeting IAC *Standards*, policies, and procedures.
3. The IAC will review the change. If the IAC determines that the change has a significant impact on the laboratory's operations, the IAC may require the laboratory to submit additional evidence of continuing compliance with IAC *Standards*, policies, and procedures. An opinion letter from legal counsel may be required. Additional fees may apply.
4. If ownership of a laboratory changes, the IAC will determine whether the laboratory must apply for accreditation as a new facility, or if the laboratory's existing accreditation remains valid. **Accreditation cannot be transferred without written approval from the IAC.**
5. Accreditation is awarded to the listed laboratory, permanent sites, and mobile services as a whole. An accreditation award may not be divided or shared following a sale, dissolution, or other change in ownership or legal structure. The parties to the sale, dissolution, or other change in a laboratory's ownership or legal structure must determine, among themselves, the one party who will continue to own the accreditation. That one party must then notify the IAC and submit

an opinion letter from legal counsel confirming that the party has the right to continue to hold the accreditation. If the new and former owners/partners/etc. are unable to reach an agreement regarding which one party among them will own the accreditation award, the accreditation award will be terminated and all parties seeking accreditation will be required to submit new applications.

**6.** If there is a change in the Medical or Technical Directors and a replacement has not been appointed within the first thirty days, notification must still be submitted to the IAC. The laboratory then has an additional thirty days (total of sixty days) to notify the IAC of the individual appointed to the position. If the newly appointed person was not included in the most recent accreditation application, it will be necessary to re-submit the pages of the application applicable to the position and additional case studies may be requested.

**7.** It is not necessary to provide interim information regarding any addition or deletion of medical or technical staff, equipment, changes in protocols or policies, or response to the application review findings document. These will be required in the reaccreditation application.

## **XII. Use of IAC Trademarks**

**1. Ownership.** The IAC “Accredited Laboratory” logo is the sole and exclusive property of the IAC and is subject to all applicable trademark and other rights of the IAC as owner under United States intellectual property law and international conventions. Accredited laboratories shall not use the logo, or any other intellectual property owned by the IAC, except as expressly authorized in this policy or otherwise authorized in advance and in writing by the IAC.

**2. License.** For the duration of accreditation, the IAC will permit an accredited laboratory to use the logo for the sole purpose of indicating accreditation by the IAC. All goodwill associated with the logo as used by accredited laboratories inures solely to the benefit of the IAC.

### **3. Conditions of Use.**

**A.** Any use of the logo must be accurate and supportive of IAC objectives, and must do so in a manner that is compatible with the mission of the IAC.

**B.** All use of the logo must be truthful and not misleading. Specifically, laboratories shall **not**:

- i.** use the logo unless the IAC has made an official accreditation decision;
- ii.** use the logo on reports or correspondence for areas of testing in which they are not accredited;
- iii.** use the logo without the words “Accredited Laboratory” (this logo is for IAC use only);

- iv. use the logo (or a word or design that is confusingly similar to the IAC name or logo) as part of the laboratory's name, logo, domain name, or product or service name;
- v. use the logo in any manner that reflects negatively on the IAC or its activities;
- vi. use the logo in any manner that conflicts with IAC *Standards*, policies and procedures;
- vii. suggest or imply that the laboratory has any relationship with the IAC other than as an accredited laboratory; or
- viii. suggest or imply that the IAC is endorsing or guaranteeing any product or service offered by the laboratory.

**C.** Laboratories will be provided with a CD that contains a digital version of the logo. Laboratories must use the logo in its exact form with the surrounding words "Accredited Laboratory"; only changes in size and color are permitted.

**D.** All use of the logo must (i) conform to the design standards issued by the IAC (a current copy of which will be provided), and (ii) be appropriate and dignified as befits the public image of the IAC.

**E.** The logo may not be the most prominent visual element on the laboratory's promotional materials. The laboratory name and/or logo, product or service name, and graphics should be significantly larger than the reference to the IAC logo.

**F.** Upon the termination or expiration of accreditation, or for the duration of any probation or suspension regarding accreditation, the laboratory:

- i. shall cease use of the logo;
- ii. shall destroy all print and electronic artwork materials provided by the IAC, without retaining copies; and
- iii. shall not distribute any materials containing the logo that it might already have prepared.

**G.** The laboratory is responsible for correcting (at the laboratory's expense) any outdated or otherwise inaccurate use of the logo or other IAC intellectual property.

**4. Quality Control.** The IAC has the right to control the quality of all materials on which the logo is used. The IAC will have access to the materials which the laboratory makes publicly available (such as business cards, letterhead, etc.). Also, the laboratory shall submit samples of its materials if requested by the IAC. If the IAC determines that the laboratory is not meeting the requirements of this policy, the IAC will notify the laboratory and provide an explanation. The laboratory shall correct the violation within thirty (30) calendar days after receipt of the notice. The IAC is the final judge as to whether any use of the logo is consistent with this policy.

**5. Consequences of Misuse.** The IAC is committed to protecting its intellectual property for the benefit of all accredited laboratories and the general public as consumers. If a laboratory

fails to comply with this policy, the IAC may revoke or take other adverse action with regard to the laboratory's accreditation.

**6. Further Information.** If a laboratory has a question regarding proper use of the logo, and for permission to use the logo on materials other than those listed above, it should contact the IAC.

### **XIII. Grounds & Procedure for Adverse Action Against Accreditation**

This policy has been adopted to establish a fair process for addressing noncompliance with IAC *Standards*, policies, and procedures. Matters are investigated by IAC staff and presented for judgment before a Compliance Monitoring Committee. An Appeals Body is available to hear appeals of Compliance Monitoring Committee decisions, and is the final decision-maker on behalf of the IAC.

**1. General Principles.** Laboratories and their staff must:

- A. be truthful, forthcoming, and cooperative in their dealings with the IAC;
- B. be in continuous compliance with IAC *Standards*, policies, and procedures (as amended from time to time by the IAC);
- C. respect IAC intellectual property rights;
- D. abide by laws related to the profession and to general public health and safety; and
- E. carry out their professional work in a competent and objective manner.

**2. Grounds for Adverse Action.** The IAC may deny, suspend, revoke, or take other action regarding an application or accreditation if a laboratory is not in compliance with the *Standards* relevant to its accreditation. Grounds for adverse action also include (but are not limited to):

- A. Providing fraudulent or misleading information;
- B. Failure to pay fees when due;
- C. Unauthorized possession or misuse of IAC accreditation marks and other intellectual property;
- D. Misrepresentation of accreditation status;
- E. Refusal to allow the IAC to conduct an on-site visit;
- F. Failure to provide requested information in a timely manner;
- G. Failure to inform the IAC as required by the Reporting Changes policy;
- H. Noncompliance with laws related to the laboratory's business or to general public health and safety;
- I. Adverse action by an accreditation or professional organization other than the IAC; and
- J. Other failure to maintain continuous compliance with IAC *Standards*, policies, and procedures.

**3. Compliance with IAC *Standards*, Policies and Procedures.** A laboratory must be in

continuous compliance with all IAC *Standards*, policies, and procedures. Each laboratory bears the burden for demonstrating and maintaining compliance at all times.

**4. Sanctions.** The IAC may impose one or more of the following sanctions for failing to adhere to the IAC *Standards*, policies, and procedures:

- A. Denial of accreditation;
- B. Revocation of accreditation;
- C. Non-renewal of accreditation;
- D. Suspension of accreditation;
- E. Reprimand; or
- F. Other corrective action.

**5. Complaints.** Persons concerned with possible violation of IAC *Standards*, policies, and procedures are encouraged to contact the IAC. The person should submit a written statement identifying the persons alleged to be involved and the facts concerning the alleged conduct in detail, and the statement should be accompanied by any available documentation. The statement should also identify others who may have knowledge of the facts and circumstances concerning the alleged conduct. The person making the complaint should identify him-/herself by name, address, and telephone number. If requested, the IAC will make efforts to protect the identity of the person filing the complaint. The IAC will also consider anonymous complaints.

**6. Compliance Monitoring Procedures.**

**A. Initial Evaluation.**

- i. Upon receipt of a complaint or a change notice, the Chief Executive Officer will confer with the Division Board President and IAC Chairman. They may request supplemental information.
- ii. If they determine that the complaint is frivolous or that the change is not relevant to accreditation program compliance, no further action will be taken.
- iii. If they determine that the complaint is not frivolous or that the change may be relevant to accreditation program compliance, IAC staff will be assigned to investigate.
- iv. Laboratories submitting change notices and persons submitting complaints will be notified of the decision of the Chief Executive Officer, Division Board President, and IAC Chairman.

**B. Audits.** The IAC may conduct one or more compliance audits. If the IAC discovers a possible violation of IAC rules, the Chief Executive Officer will confer with the Division Board President and IAC Chairman to determine whether IAC staff will continue to investigate the allegation.

**C. IAC Staff Investigation.**

**i.** The Chief Executive Officer will assign one or more staff members to investigate the complaint or change notice. An IAC staff member may not: (a) review any matter in which his or her impartiality might reasonably be questioned, or (b) review any matter which presents an actual, apparent, or potential conflict of interest.

**ii.** Staff will investigate the matter upon assignment by the Chief Executive Officer. Staff may conduct an investigative site visit. If the staff member(s) determine after the investigation that the facts are inadequate to sustain a finding of a violation of IAC rules, no further action will be taken. Laboratories submitting change notices and persons submitting complaints will be notified of this decision.

**iii.** If the staff member(s) find that good cause exists to question whether a violation of an IAC rule has occurred, the staff member(s) will transmit a statement of allegations to the laboratory by certified mail, return receipt requested, setting forth the applicable rule and a statement:

- a.** of the facts constituting the alleged violation;
- b.** that the laboratory may request an oral hearing (in person or by phone) or a review by written briefing for the disposition of the matter, with the laboratory bearing its own expenses;
- c.** that the laboratory has thirty (30) days after receipt of the statement to notify the IAC if it disputes the allegations, has comments on available sanctions, and/or requests a review of the written record, an oral hearing in person, an oral hearing by phone, or a review by written briefing;
- d.** that, in the event of an oral hearing, the laboratory may appear in person with or without the assistance of counsel, may examine and cross-examine any witness under oath, and produce evidence on its behalf;
- e.** that the truth of allegations or failure to respond may result in sanctions including revocation; and
- f.** that if the laboratory does not dispute the allegations or request a review or hearing, the laboratory consents to the Chief Executive Officer rendering a decision on the evidence before him/her and applying available sanctions.

**iv.** If the laboratory disputes the allegations or available sanctions, the Chief Executive Officer may offer the laboratory the opportunity to negotiate a specific sanction in lieu of proceeding with the requested written review or hearing. Any agreed-upon sanction must be documented in writing and signed by the IAC and the laboratory. If the laboratory is unwilling to accept the Chief Executive Officer's offer, the requested review or hearing will proceed as provided below.

**D. Compliance Monitoring Committee.**

**i.** The IAC Board of Directors will appoint a standing Compliance Monitoring Committee to consider allegations. This Committee is composed of one member from each Division Board. A Compliance Monitoring Committee member may not: (a) review any matter in which his or her impartiality might reasonably be questioned, (b) review any matter involving a laboratory located within 50 miles of where the member lives or works, or (c) review any matter which presents an actual, apparent, or potential conflict of interest. When a committee member is unavailable, the IAC Board of Directors will designate another individual to serve as an interim member. Committee action is determined by majority vote.

**ii.** Written Review. If the laboratory requests a written review, the Chief Executive Officer will forward the allegations and response of the laboratory to the Compliance Monitoring Committee. Written briefing may be submitted within thirty (30) days following receipt of the written review request by the Compliance Monitoring Committee. The Compliance Monitoring Committee will render a decision based on the record below and written briefs (if any) without an oral hearing.

**iii.** Oral Hearing. If the laboratory requests a hearing:

**a.** The Chief Executive Officer will:

(1) forward the allegations and response of the laboratory to the Compliance Monitoring Committee; and

(2) designate one staff member to present the allegations and any substantiating evidence, examine and cross-examine witnesses, and otherwise present the matter during the hearing.

**b.** The Compliance Monitoring Committee will:

(1) schedule a hearing after the request is received, allowing for an adequate period of time for preparation; and

(2) send by certified mail, return receipt requested, a Notice of Hearing to the laboratory. The Notice of Hearing will include a statement of the time and place selected by the Compliance Monitoring Committee. The laboratory may request modification of the time and place for good cause. Failure to respond to the Notice of Hearing will be deemed to be the laboratory's consent for the Chief Executive Officer to administer any sanction which he/she considers appropriate.

- c.** The Compliance Monitoring Committee will maintain a verbatim oral or written transcript.
  - d.** The IAC and the laboratory may consult with and be represented by counsel, make opening statements, present documents and testimony, examine and cross-examine witnesses under oath, make closing statements and present written briefs as scheduled by the Compliance Monitoring Committee.
  - e.** The Compliance Monitoring Committee will determine all matters related to the hearing.
  - f.** Formal rules of evidence do not apply. Relevant evidence may be admitted. Disputed questions will be determined by the Compliance Monitoring Committee.
  - g.** In all written reviews and oral hearings:
  - h.** Proof is by preponderance of the evidence.
  - i.** The Compliance Monitoring Committee will issue a written decision following the review or hearing and any briefing. The decision will contain factual findings, conclusions of law, and any sanctions applied. It will be mailed promptly by certified mail, return receipt requested, to the laboratory.
- E.** If the decision rendered by the Compliance Monitoring Committee finds that the allegation is not established, no further action on the matter will occur.
- F.** If the decision rendered by the Compliance Monitoring Committee is not favorable to the laboratory, the laboratory may appeal the decision to the Appeals Body.
- G.** Laboratories submitting change notices and persons submitting complaints will be notified of the decision of the Compliance Monitoring Committee.

**7. Appeals Body.**

- A.** The IAC Chairman will appoint an Appeals Body to consider the appeal. The Appeals Body is composed of three (3) members drawn from the IAC Board of Directors. An Appeals Body member may not: (a) have participated in the initial hearing as part of the Compliance Monitoring Committee, (b) review any matter in which his or her impartiality might reasonably be questioned, (c) review any matter involving a laboratory located within 50 miles of where the member lives or works, or (d) review any matter which presents an actual, apparent, or potential conflict of interest. When an Appeals Body member is unavailable, the IAC Chairman will designate another individual to serve as an interim member. Appeals Body action is determined by majority vote.

- B.** The laboratory may request an appeal within thirty (30) calendar days after its receipt of the Compliance Monitoring Committee's decision. After this time, the laboratory may not request an appeal.
  - C.** All appeals must be submitted in writing and sent to the IAC by traceable mail or delivery service.
  - D.** The appeal must specify a valid basis for the appeal.
  - E.** The IAC may file a written response to the appeal request.
  - F.** Written briefing may be submitted within thirty (30) days following receipt of the appeal request by the Appeals Body.
  - G.** The Appeals Body will render a decision based on the record below and written briefs (if any) without an oral hearing. Alternatively, the Appeals Body may choose to conduct a de novo written review.
  - H.** In all reviews:

    - i.** In order to overturn a decision of the Compliance Monitoring Committee, the laboratory must demonstrate that the Committee's decision was arbitrary or capricious. Proof is by preponderance of the evidence.
    - ii.** The Appeals Body will issue a written decision following the review and any briefing. The decision will contain factual findings, conclusions of law, and any sanctions applied. It will be mailed promptly by certified mail, return receipt requested, to the laboratory.
  - I.** A decision rendered by the Appeals Body is final.
  - J.** Laboratories submitting appeals and persons submitting complaints will be notified of the decision of the Appeals Body.
- 8. Summary Procedure.** If the Chief Executive Officer, Division Board President, and IAC Chairman determine that there is cause to believe that a threat of immediate and irreparable injury to the public exists, they will forward the allegations to the IAC Board of Directors. The Board of Directors will review the matter immediately, and provide telephonic or other expedited notice and review procedures to the laboratory. If the Board of Directors determines (following this notice and opportunity to be heard) that a threat of immediate and irreparable injury to the public exists, accreditation may be suspended for up to ninety (90) days pending a full review as provided above.
- 9. Reinstatement of Eligibility.** Following a period of ineligibility based on noncompliance with IAC *Standards*, policies, and procedures, the laboratory may apply for

reinstatement of eligibility by demonstrating that it has taken corrective action. Unless and until clear and convincing evidence is submitted, the laboratory will remain ineligible.

**10. Continuing Jurisdiction.** The IAC retains jurisdiction to review and issue decisions regarding any matter which occurred prior to the termination or expiration of accreditation.

#### **XIV. Release of Information**

**1.** Information regarding Division Board accreditation decisions must not be disclosed until written notice of that decision has been mailed to the laboratory's Medical Director. This information will not be released by phone without express written permission from the Medical Director. Also, this information will not be released to a laboratory's accreditation consultant without express written permission from the Medical Director.

**2.** If accreditation is granted, the IAC will publish the laboratory's accreditation status and the effective date in a directory of accredited laboratories. The IAC may also post a link on the IAC website to the laboratory's website.

**3.** Upon inquiry, the IAC will release the following information to third parties:

- A.** whether a laboratory's application is pending;
- B.** whether a laboratory is among the laboratories granted accreditation or re-accreditation; and
- C.** whether any adverse action has been taken regarding a laboratory, such as revocation or suspension of accreditation.

**4.** Regarding adverse actions, the IAC will release the effective date of the action and a summary of the reasons for the action. Information regarding adverse actions is released only after the laboratory's right of appeal has been exhausted.

**5.** CMS requires certain information be provided to it by approved accreditation organizations for advanced diagnostic imaging services. The IAC will provide CMS, on an ongoing basis, the information listed below regarding laboratories that are Medicare suppliers.

- A.** Copies of all accreditation surveys, together with any survey-related information that CMS may require (including corrective action plans and summaries of findings with respect to unmet CMS requirements);
- B.** Notice of all accreditation decisions;
- C.** Notice of all complaints related to the suppliers;
- D.** Information about all accredited suppliers against which the IAC has taken remedial or adverse action, including revocation, withdrawal, or revision of the supplier's accreditation (with notice given in writing within thirty [30] calendar days of any such action being taken);
- E.** Information about any deficiency that poses an immediate jeopardy to the laboratory's beneficiaries or a hazard to the general public (with notice given in writing

[electronically or hard copy] within two [2] business days of the IAC's discovery of the deficiency); and

**F.** Summary data specified by CMS that relates to the past year's accreditations and trends (provided on an annual basis).

**6.** The IAC rents its mailing list to organizations and companies who offer products that might be of interest to accredited laboratories. A laboratory may opt-out of this use by completing an opt-out form available from the IAC.

**7.** The IAC shares aggregated, anonymous data about laboratories for research purposes. No identifiable information is provided. A laboratory may opt-out of this use by completing an opt-out form available from the IAC.

**8.** The identity of application reviewers is never disclosed and is not released under any circumstances. The only information released regarding site visit representatives is name and place of employment. Only the names of Directors and Division Board members may be released, unless the individual has given express written permission to release any additional information. However, the IAC will permit its representatives to serve as witnesses if CMS takes an adverse action based on accreditation findings.

**9.** All other laboratory and IAC information is treated as confidential and privileged. However, the IAC must release information as required by law or court order, and will notify governmental agencies if it discovers a performance deficiency that violates federal, state, or local laws.