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ABRET NIOM LABORATORY ACCREDITATION

Neurophysiologic Intraoperative Monitoring

Instruction Manual for LAB-NIOM Accreditation

General Information

The Neurophysiologic Intraoperative Monitoring Laboratory Accreditation Board (LAB-NIOM) of ABRET is a separate board functioning under ABRET, Inc., a not-for-profit, 501 c6 corporation. Through evaluation of practices and policies of NIOM laboratories, LAB-NIOM will accredit laboratories meeting its standards. These standards are based on guidelines for performance, interpretation, and billing established by CMS, AAN, ACNS, ABCN, AANEM, and ASET.

Hospitals performing NIOM studies may apply for accreditation. The staff performing NIOM studies do not need to be employees of the hospital. NIOM laboratories wanting to become accredited by the LAB-NIOM must complete an application that can be downloaded from the ABRET website (www.abret.org). Prior to completion of the application, it is strongly advised that this instruction manual and references cited herein be reviewed.

The accreditation process will involve completing and submitting the Program Evaluation Document and Appendices with appropriate fees to the ABRET executive office. Upon receipt of the requisite documents, two members of the LAB-NIOM will review the application. Disagreements between the primary reviewers will be resolved by further review. A site visit will not be conducted.

One of four decisions is possible after review of the application: 1) Accredited; 2) Accredited with provisions; 3) Decision deferred; 4) Rejected. A laboratory accredited with provisions will be required to respond to the provisions within 60 days of notification. Upon receipt of the response to the provisions, the accreditation certificate will be sent. The decision to accredit will be deferred the application is missing critical parts of the application. The laboratory will have 60 days to resubmit the application. If the laboratory does not submit responses within 60 days, the accreditation process will be deemed terminated by the application laboratory. In case of a negative decision, recommendations on improvement will be provided. Such laboratories will be eligible for reapplication after six months.

After notification of a successful review of the application, the NIOM laboratory will be sent a framed certificate of accreditation and a packet of material outlining the value of accreditation. Accreditation will be for 5 years. Names of all accredited NIOM laboratories will be published on the ABRET website. When laboratories reaccredit, special attention will be paid to whether provisions (if any) that were noted in the previous application have been resolved.

All accredited NIOM laboratories are responsible for meeting federal, state, and local regulations relevant to operating a medical practice. These include regulations regarding professional practice acts, waste management, patient confidentiality, infection control, and electrical safety. Additionally, national and local standards for the practice of NIOM should be followed. The Code of Medical Ethics of the American Medical Association must be followed. (AMA 2008)

In this instruction manual each question of the Program Evaluation Document is discussed. When appropriate, references are noted to provide additional references and reading sources. If after review of this instruction manual, it is felt that the NIOM laboratory is ready to apply for accreditation, the Program Evaluation Document should be submitted to the LAB-NIOM.

ABRET encourages labs to upload their application materials via Citrix ShareFile. Email ABRET for a secure upload link. If mailing a PDF on DVD or CD, please send two copies. If submitting a paper application and exhibits, please send two sets.

Satellite Labs

LAB-NIOM recognizes that there are some NIOM programs operating under the same leadership in a secondary location. Hospital systems wishing to accredit multiple labs must meet specific criteria and complete the Satellite Lab Application. Related or satellite laboratories applying for accreditation are eligible if they utilize the same monitoring technologists, are under the same medical director, and involve the same interpreting physicians. The satellite application must be submitted with the primary application. Both sites must be successful in earning accreditation. If one site fails, neither site will be accredited. The discount for the second site will be 50%. Both sites will receive recognition and a framed certificate.

I. Program Overview

The Program Overview requests general information about the hospital and the NIOM laboratory. Names of the person completing the application, the Medical and Technical Directors, and the Administrator should be included in this section. Email addresses will allow easy communication. The Medical and Technical Directors do not necessarily have to be employees of the applicant hospital, but must have a contractual agreement with the hospital. Further information about both these positions is discussed below. It is expected that the Administrator overseeing the program will be an employee of the hospital. It is very important to identify an individual who will be responsible for communicating with LAB-NIOM about the application. Outcome of the application review by LAB-NIOM will only be discussed with this individual.

II. Brief History of the NIOM Program

LAB-NIOM is interested in when the NIOM program was started in the applicant hospital and how it has evolved. Important to discuss is how services have expanded (i.e. what types of surgeries are monitored, how staffing has changed, and how the medical leadership has evolved). Significant milestones in the history of the program should also be noted, especially those with regional or national impact.

III. Hospital Information

A. Number of beds

The number of inpatient beds should be noted.

B. Joint Commission certification

It is expected that the applicant hospital will be accredited. If it is not, a detailed explanation about why it is not and what steps are being taken to obtained accreditation should be provided. An expected data of accreditation should be provided. Similarly, if the hospital has provisional accreditation, discuss what these provisions are and how they are being addressed. An expected date of removal of these provisions should be provided.

C. Type of hospital

Whether the applicant hospital is an academic (teaching hospital of a university), a tertiary care private (large referral hospital without primary university affiliation), a community (smaller hospital with limited specialties, private or public), or Veterans Administration hospital should be noted. If the hospital does not fall into any of the above classifications, "Other" should be selected and the hospital type should be described.

D. Surgical subspecialties

Circle the surgical subspecialties available at the applicant hospital. Circle only those for which NIOM is performed. If NIOM is provided for surgical subspecialties other than the ones listed, those should be listed under "Other".

IV. Medical Director

A. Name

Provide full name of the Medical Director and highest academic degree (i.e. M.D., D.O.). It is recognized that some laboratories may use a different title than Medical Director. The person who provides medical leadership and direction to the laboratory should be listed here.

B. Is the Medical Director is full time?

It is not necessary that the Medical Director be an employee of the applicant hospital. However, the Medical Director must work at least part time at the applicant hospital. If the Medical Director is not at the applicant hospital full time, note the percent of time the Medical Director spends at the hospital. For part time Medical Directors, also discuss their other responsibilities, in particular if they direct other NIOM laboratories.

C. Is the Medical Director an interpreting physician?

It is expected that the Medical Director will be an interpreting physician. If the Medical Director is not involved in interpreting NIOM studies, discuss why this is the case. Describe who interprets these studies. Also discuss why one of the interpreting physicians is not the Medical Director.

D. Time Medical Director devotes to NIOM program

Note the percentage of time and the number of hours per week the Medical Director devotes leadership, direction, and monitoring of the NIOM program. Do not include the hours devoted to interpretation of NIOM studies.

E. Medical Director's licensure

It is expected that the Medical Director will have an unrestricted license to practice medicine in the state of the applicant hospital. If the Medical Director is not licensed as noted above, discuss why not and how this will be rectified.

F. Hospital privileges

It is expected that the Medical Director will have privileges at the applicant hospital. It is not necessary to have admitting privileges, however, at least courtesy (i.e. ability to perform/interpret procedures but not admit patients) privileges should be maintained.

G. Duration Medical Director has been in current position

Note the number of years and months that the Medical Director has been in current position.

H. Duration Medical Director has been in NIOM field

Note the number of years and months that the Medical Director has been involved with NIOM in any capacity.

I. Responsibilities of Medical Director

Provide a narrative description of the Medical Director's responsibilities as they relate to the NIOM laboratory. Specifically comment on oversight responsibilities, role in developing protocols for monitoring, training, and educational responsibilities. Also comment on whether the Medical Director oversees the medical billing of the laboratory.

J. CV of Medical Director

Complete the CV form provided in Appendix 1. Do not include a separate CV document. Complete all sections of the form; if a section does not apply, please indicate as such. Especially important is the training and certification in NIOM. Include in this list courses taken as part of training in NIOM. It is expected that the Medical Director will have board certification in clinical neurophysiology or equivalent. A minimum of 10 weeks of supervised training in NIOM is strongly recommended. Do not include all publications, rather only the last 10 publications should be listed. Papers under preparation or consideration should not be listed. Those papers that have been accepted but not published can be included.

V. Interpreting Physicians

A. List of interpreting physicians

In the table provided, list names (last, first) of all interpreting physicians. Include the Medical Director in the table if he/she interprets NIOM data. Also, answer all questions listed in the table for the interpreting physicians. Indicate whether the physician interprets NIOM data at other hospitals. Whether the physician is employed by the hospital or provides a professional fee for service should be noted. The number of cases monitored is only at the applicant hospital; do not include cases he/she monitored at other hospitals. Issues about hospital privileges and state medical license are the same as noted for the Medical Director.

B. CV of interpreting physicians

Complete the CV forms provided in Appendix 2 for each interpreting physician listed in Section V.A. If the Medical Director is also listed in Section V.A., do not include his/her CV again. Do not include a separate CV document. Complete all sections of the form; if a section does not apply, please indicate as such. Especially important is the training and certification in NIOM. It is expected that the interpreting physicians will have board certification in clinical neurophysiology or equivalent. A minimum of 10 weeks of supervised training in NIOM is strongly recommended. Do not include all publications, rather only the last 10 publications should be listed. Papers under preparation or consideration should not be listed. Those papers that have been accepted but not published can be included.

C. Monitoring qualifications and competencies of interpreting physicians

It is expected that the applicant hospital will have a criteria for granting privileges to physicians for interpreting NIOM studies. Such criteria are often used by hospitals to grant medical staff privileges to perform studies or procedures in which they have expertise. It is expected that the criteria for NIOM interpreting physicians will include training, certification, scholarship, and/or experience in clinical neurophysiology with an emphasis on NIOM. The applicant hospital should have a method of determining if interpreting physicians are obtaining continuing education in NIOM. Continuing education can be in form of attending national conferences or seminars, taking board examinations, writing and reading scholarship, and participating in other CME activities. Transcript of such activities should be maintained by the applicant hospital and do not need to be submitted with the application. However, LAB-NIOM reserves the right to audit applicant hospitals to monitor compliance.

D. Physician involvement in continuing education of technologists

Training technologists is an important, though not mandatory, part of the NIOM laboratory. It is expected that the interpreting physicians conduct reading sessions, lectures, small discussion groups, and/or didactic sessions with technologists. If such discussion/training does not occur, explain why not.

E. Contacting the interpreting physician in case of emergency

Describe the method(s) for contacting the interpreting physician in case of emergency. If more than one method is used, discuss all. The emergency may be to discuss adding an emergent case to the work load or a sudden change in NIOM data. Discuss the next step if above techniques do not work.

F. Emergency physician coverage

Discuss the protocol of the NIOM laboratory for accepting emergency surgeries for NIOM.

G. Physician coverage for cases extending beyond expected completion time

Discuss how interpreting physician coverage is arranged if the surgery continues after regular business hours.

VI. Technical Director

A. Name

Provide full name of the Technical Director and highest academic degree (i.e. B.A., M.A., PhD.) and board registration/certification status (i.e. R. EEG T., R. EP T., CNIM, CLTM, D.ABNM). It is recognized that some laboratories may use a different title than Technical Director. The person who provides technical leadership and direction to the laboratory should be listed here.

B. Is the Technical Director is full time?

It is not necessary that the Technical Director be an employee of the applicant hospital. However, the Technical Director must be intimately involved with the day-to-day functioning of the

NIOM laboratory. If the Technical Director is not at the applicant hospital full time, note the percent of time the Technical Director spends at the hospital. For part time Technical Directors, also discuss their other responsibilities, in particular if they direct other NIOM laboratories.

C. Is the Technical Director an NIOM technologist?

It is expected that the Technical Director is responsible for the day to day function of the laboratory and will be an NIOM technologist. If the Technical Director is not a credentialed NIOM technologist, describe why not. Important to discuss is the administrative structure of the NIOM laboratory. Discuss why one of the NIOM technologists is not the Technical Director.

D. Time Technical Director devotes to NIOM program

Note the percentage of time and the number of hours per week the Technical Director devotes leadership, direction, and monitoring of the NIOM program. Do not include the hours devoted to performing NIOM studies.

E. Duration Technical Director has been in current position

Note the number of years and months that the Technical Director has been in current position.

F. Duration Technical Director has been in NIOM field

Note the number of years and months that the Technical Director has been involved with NIOM in any capacity (i.e. as a staff technologist, supervisor, administrator, etc. for NIOM services).

G. Responsibilities of Technical Director

Provide a narrative description of the Technical Director's responsibilities as they relate to the NIOM laboratory. Specifically comment on oversight responsibilities, role in developing protocols for monitoring, training, and educational responsibilities.

H. CV of Technical Director

Complete the CV form provided in Appendix 3. Do not include a separate CV document. Complete all sections of the form; if a section does not apply, please indicate as such. Especially important is the training and certification in NIOM. It is expected that the Technical Director will have CNIM certification or equivalent. If this registration not available, discuss on the CV form how this will be rectified in the future.

VII. Technologists

A. List of technologists

In the table provided, list names (last, first) of all NIOM technologists. Only those individuals fully trained in NIOM and capable of working independently should be included in this list. Include the Technical Director in the table if he/she performs NIOM. Also, answer all questions listed in the table for

the technologists. Indicate whether the technologist performs NIOM studies at other hospitals. Experience of the technologists in NIOM should be noted. The number of cases in the last calendar year for which the technologist was primarily responsible should be noted. If the technologist participated by providing breaks to another technologist, the first technologist should not count that case. It is expected that only one technologist would list their names for each case, even if more than one technologist was involved; the person most involved should get credit for the case. Whether the technologist is employed by the hospital or is a contractual employee should be noted. If the applicant hospital uses both employed and contractual technologists, all should be listed here.

B. CV of technologists

Complete the CV form provided in Appendix 4 for all technologists listed in Section VII.A. If the Technical Director is also listed in Section VII.A., do not include his/her CV again. Do not include a separate CV document. Complete all sections of the form; if a section does not apply, please indicate as such. Especially important is the training and certification in NIOM.

C. Which technologist will cover which case and who decides?

Discuss the process by which decisions are made regarding which technologists will cover which case. Important to note is whether there are restrictions for certain types of NIOM cases that some technologists are able to perform. Also note who decides how cases are allocated to technologists.

D. Monitoring qualifications and competencies of technologists

It is expected that the NIOM laboratory will have a criteria for allowing technologists to perform NIOM studies. Such criteria should include training, certification, and/or experience in NIOM.

E. Continuing education

The applicant hospital should have a method of determining if technologists are obtaining continuing education in NIOM. Continuing education can be in form of attending national conferences or seminars, taking board examinations, writing and reading scholarship, and participating in other CE activities. It is expected that each technologist will have at least 10 CEUs per year. Transcript of such activities should be maintained by the applicant hospital and do not need to be submitted with the application. However, LAB-NIOM reserves the right to audit applicant hospitals to monitor compliance. If the applicant hospital uses contract employees as technologists, specify if the same criteria for monitoring qualifications and credentials is used for them.

F. Process of ensuring breaks for technologists

Discuss the process by which the NIOM laboratory ensures that technologists are allowed adequate breaks during long surgical cases. Important to note is whether another technologist or the interpreting physician performs the monitoring or whether breaks are timed to coincide with periods during surgery when neural tissue is not at significant risk. If the latter is used, confirm whether the

interpreting physician and surgeon are aware that monitoring is suspended. State the frequency and duration of such breaks.

G. How are unexpectedly long surgical cases handled?

When surgery continues longer than expected, especially when it continues after hours, how is technologist coverage handled? Also discuss how technologists breaks are handled in these situations (refer to discussion in Section VII.E).

H. Emergency NIOM coverage

Discuss if after hours and weekend NIOM coverage is available at the applicant hospital. If so, discuss how it is staffed. Discuss how it is decided whether NIOM will be performed for an emergency surgery and how the technologist and interpreting physician are made aware of the case. Also discuss the method of providing breaks to technologists during the surgery (refer to discussion in Section VII.E).

VIII. Other Monitoring Personnel

A. Staff other than interpreting physicians and technologists involved in NIOM

State whether or not other individuals are involved with NIOM at the applicant hospital. Examples would include mid-level providers, PhD neurophysiologists, experienced technologists who oversee multiple cases, etc. If such staff is not used at the applicant hospital, indicate this by noting "N/A".

B. List of other staff

In the table provided, list names (last, first) of all other staff members. Also answer all questions listed in the table for the staff members. Indicate whether other monitoring staff performs NIOM studies at other hospitals. Experience of the staff member in NIOM should be noted. The number of cases in the last year for which the staff member was primarily responsible should be noted. Whether the staff member is employed by the hospital or is a contractual employee should be noted. Especially important to discuss are the responsibilities of each staff member listed (i.e. technical performance of studies, interpretation, etc.).

C. CV of other staff

Complete the CV form provided in Appendix 5 for all technologists listed in Section VIII.B. Do not include a separate CV document. Complete all sections of the form; if a section does not apply, please indicate as such. Especially important is the training and certification in NIOM. Do not include all publications, rather only the last 10 publications should be listed. Papers under preparation or consideration should not be listed. Those papers that have been accepted but not published can be included.

D. Responsibilities of other monitoring staff

Describe responsibilities for all staff members listed in item VIII.B. Discuss if they are responsible for hook-up, break down, supervision, or interpretation of cases. It is important to mention their relationship/interaction with technologists and interpreting physicians.

E. Monitoring qualifications and competencies of other staff

It is expected that the NIOM laboratory will have a criteria for allowing other staff members to participate in NIOM studies. Such criteria should include training, certification, scholarship, and/or experience in NIOM.

F. Continuing education

The applicant hospital should have a method of determining if other monitoring staff members are obtaining continuing education in NIOM. Continuing education can be in form of attending national conferences or seminars, taking board examinations, writing and reading scholarship, and participating in other CE activities. It is expected that each other monitoring staff member will have at least 10 CEUs per year. Transcript of such activities should be maintained by the applicant hospital and do not need to be submitted with the application. However, LAB-NIOM reserves the right to audit applicant hospitals to monitor compliance. If the applicant hospital uses contract employees as technologists, specify if the same criteria for monitoring qualifications and credentials is used for them.

G. Supervision

Discuss who supervises the other monitoring personnel. Specifically note if they are supervised by the interpreting physician and how the supervision occurs. If they are not supervised by the interpreting physician, discuss their role versus that of the interpreting physician.

IX. Administrator

A. Name and title

Note the name and hospital title of the administrator in charge of overseeing the NIOM laboratory. It is recognized that some laboratories may use a different title than Administrator. The person who provides administrative leadership and direction to the laboratory should be listed here. This person is usually involved in the finances of the NIOM laboratory as well.

B. Is the Administrator full time?

It is expected that the Administrator will be a full time employee of the applicant hospital. However, the Administrator may or may not be associated with the NIOM laboratory full time. It is this latter issue that full time question refers to with respect to the Administrator. If the Administrator is not associated with the NIOM laboratory full time, what other responsibilities does he/she have within the applicant hospital?

C. Time Administrator devotes to NIOM program

Note the percentage of time and the number of hours per week the Administrator devotes leadership, direction, and monitoring of the NIOM program.

D. Duration Administrator has been in current position

Note the number of years and months that the Technical Director has been in current position.

E. Financial support from the hospital for NIOM program

Discuss the support from the applicant hospital towards the NIOM program in supporting day-to-day operations. Note also if purchase of supplies and equipment is handled by the hospital. Also note if the hospital provides funding towards education and continuing education of technologists and other staff.

F. Responsibilities of Administrator

Provide a narrative description of the Administrator's responsibilities as they relate to the NIOM laboratory. Specifically comment on oversight, quality improvement, and management responsibilities.

G. Letter of support

A letter from the applicant hospital's administration detailing its support for the NIOM laboratory should be included as Appendix 6. This letter should detail the financial commitment to the NIOM laboratory including support of the professional and technical staff.

X. Facility

A. NIOM laboratory space

Describe the space allocated to the NIOM laboratory. This is the space used by technologists to complete paperwork and other responsibilities. Include the approximate square footage of this space. It is expected that the NIOM laboratory space will be more than storage space in the operating room.

B. Resources available in the NIOM laboratory

Indicate which of the listed objects in the PED is available in the NIOM laboratory. For those things not available, describe how those services are provided to the laboratory.

C. NIOM equipment

Indicate the NIOM equipment used by the laboratory. It is important to note which NIOM modalities the equipment is used to monitor. If the machine is used for multimodality monitoring, indicate all the modalities that the laboratory uses. If a machine has capabilities that are not used by the laboratory, do not list those. Also describe the schedule for inspection of the machines by the BME department of the applicant hospital and date that machine was last inspected. Add additional lines for more equipment if needed.

D. Storage of records

Describe how NIOM records are stored. Particularly important is how continuous recordings such as EEG and free running EMG (if these studies are performed) data is stored. Also note how long the records are kept.

XI. Case Load

A. NIOM modalities performed

Note which NIOM modalities are performed by the laboratory. For modalities that are performed, complete the additional information. It is expected that guidelines for performing NIOM studies issued by the ACNS where applicable will be followed. (ACNS 1994) Deviations from these guidelines are acceptable if adequate explanation is provided. Note the exact number of studies performed for each type of monitoring. If multimodality monitoring is used for a case, that case should be counted in each of the modalities. The stimulating and recording montages and filter settings should be noted. For those modalities that require averaging, note the number of responses averaged per trial. Also note the criteria used for raising an alert to the surgeon for each modality that the laboratory monitors. If other types of monitoring is performed which is not listed in the table, include it in the "Other" category. Add additional lines if necessary. Cranial nerve monitoring, brain mapping, and movement disorder surgery monitoring should not be included as it is covered in subsequent sections. For any of the responses, if additional information is required, include in the section provided.

B. Cranial nerve monitoring

If cranial nerve monitoring other than BAEP and facial nerve EMG is performed, describe it here. Discuss the stimulating and recording montages, filter settings, whether averaging is used, and criteria for raising a surgical alert. Additionally, the number of cases performed in the last year should be noted.

C. Functional cortical localization

If brain monitoring is performed, describe it here. Discuss the stimulating and recording techniques, filter settings, and interpretation criteria. If specialized equipment is used, describe it here (also make sure this equipment is listed in Section X.C. Additionally, the number of cases performed in the last year should be noted.

D. Movement disorder surgery

If movement disorder surgery is performed, describe it here. Discuss the recording techniques, filter settings, and interpretation criteria. If specialized equipment is used, describe it here (also make sure this equipment is listed in Section X.C. Additionally, the number of cases performed in the last year should be noted.

E. Types of surgeries performed

Note whether NIOM is used for the types of surgeries listed. For the surgeries that are performed, note the number of such surgeries that utilized NIOM in the last year. If other types of surgeries are performed at the applicant hospital that are not listed, specify them in the "Other" section. Add additional lines if necessary.

XII. Interpretation

A. Interpretation of NIOM cases

It is expected that all NIOM cases will be interpreted by a physician interpreter. If someone other than an interpreting physician provides interpretation, explain the qualifications of this person. In such situations explain how the physician interpreter is involved.

B. When interpreting physician reviews a case

It is expected that all NIOM interpretations will be provided "real time", i.e. as the surgery is ongoing. This requires the physician interpreter to review the data from the start to the termination of the monitoring. If the interpreting physician reviews data at some other time, explain how they are involved with the care of the patient during the monitoring. This does not include report generation, which may be done after the case is completed.

C. Method of data review by interpreting physician

Discuss the method by which the interpreting physician reviews the NIOM data. It is expected that this will be done either by being in the operating room in person or in a location from where the NIOM data can be viewed remotely. If remote monitoring is utilized by the interpreting physician, note the program that is used. If the interpreting physician is required to be in the operating room for some types of surgeries, specify the type and why presence in the operating room is required.

D. Communicating an alert to the surgeon

Discuss how and when the surgeon is notified of an alert. Specifically note how the interpreting physician communicates with the surgeon if he/she is viewing the data remotely. Also discuss the process of alerting the surgeon if the change in waveforms is noticed first by the technologist.

E. Simultaneous cases being monitored

If the interpreting physician monitors a number of cases at one time, note the maximum number of cases they can be involved with simultaneously. Discuss the rationale for using this number. If the greater than the maximum number of cases is on-going at a given time, how are these additional case(s) monitored? Specifically, is another interpreting physician used in such situations? Applicants are encouraged to review the AAN's model medical policy on NIOM.(AAN 2008), and the American Clinical Neurophysiology Society Guideline 11A on NIOM personnel (ACNS 1994)

F. Medicare rules and regulations regarding NIOM

CMS has issued guidelines for NIOM. Discuss whether the local Medicare carrier uses these guidelines. If these guidelines are used, mention what they are and how the NIOM laboratory fulfills these regulations. A reference of sample Medicare NIOM guidelines for North Carolina is provided.(Anonymous 2006) Be certain to review Medicare guidelines for the state in which the applicant hospital is located.

XIII. Documentation

A. Process of creating NIOM report

Discuss the process of creating the NIOM report, its transcription, and posting in the patient's chart. Note who creates the reports. Also note if the interpreting physician signs the report.

B. Turn around time for NIOM reports

Discuss how quickly after surgery, NIOM reports are available on the patients' charts.

C. Number of hours of interpreting physician and technologist time

Note whether the number of hours spent on monitoring for the technologist and interpreting physicians is noted on the NIOM report. If not, explain. It is expected that technologists will be involved with the surgery longer than the interpreting physician as the former are responsible for set-up and the termination of surgery.

D. NIOM event case log

Communication between the NIOM team and the surgeon and anesthesiologist is important. Discuss the events that are typically noted in the event case log. Specifically state if surgical alerts are noted in the case log.

XIV. Education and Scholarship

A. Available educational activities

Discuss the educational activities available for technologists, interpreting physicians, and other staff. Include how often these conferences occur and who presents in the conferences. All Neurodiagnostic related conferences can be mentioned in this section. Provide a list of topics (if applicable) for the last one year in Appendix 7.

B. CME for interpreting physicians

Describe how interpreting physicians obtain CME in clinical neurophysiology and NIOM. If this is obtained through attending conferences, mention the names of the meetings. If it is through giving lectures and reading journals, describe the lectures and list the journals read. CME may also be by taking board examinations; if this has happened in the last one year, list the board examination.

C. CE for technologists and other monitoring staff

Describe how technologists and other monitoring staff obtain continuing education. If this is obtained through attending conferences, mention the names of the meetings. If it is through giving lectures and reading journals, describe the lectures and list the journals read. CEUs may also be by taking board examinations; if this has happened in the last one year, list the board examination. Also note if the applicant hospital provides funds for obtaining CEUs.

D. New NIOM techniques and staff training

Discuss how the technologists are taught new NIOM techniques. Examples would include when a new type of surgery will be monitored. This training may be in the form of in-services, didactic lectures, group demonstrations, etc. This is particularly important if contract technologists are used.

E. Training for new NIOM equipment

Discuss how technologists are taught the functioning of new NIOM equipment. This training may be in the form of in-services, didactic lectures, group demonstrations, etc. This is particularly important if contract technologists are used.

XV. Trainee Technologists

A. Current trainees

A trainee technologist is one who has not completed training in NIOM. This person is not able to function independently in the operating room. A technologist may have other certification or registration, such as R. EEG T. or R. EP T., but if they are not fully trained in NIOM, they are considered a trainee for the purpose of this application. If the NIOM laboratory has trainees, list them in the table provided. Also list their degree, dates of start and expected termination of training, and number of cases monitored at the time of the application. Add lines if necessary. Though it is encouraged, it is not necessary that student technologists be enrolled in a formal training program.

B. Previous trainees

List the technologists (if any) trained by the NIOM laboratory in the last three years in the table provided. Also note the dates of training and number of cases completed. Particularly important is whether the trainees took and passed relevant board examinations and their current employment status.

C. Trainees not completing training

List the trainees who started but did not complete the training in the last three years in the table provided. Also note the dates of training and number of cases completed before leaving training. Particularly important to note is the reason for leaving the training.

D. Prerequisites for training

List any prerequisites for entering training. This can include degrees, previous board certification, training, experience, etc.

E. Duration of training

Note the duration of the training program. If the program is not a formal program, discuss how the duration of training is determined (i.e. competency check-off, number of cases completed, etc.).

F. Role of trainees in operating room

Discuss the role of trainees in performing clinical studies. List the functions they can perform in the operating room. Note if trainees are responsible for giving breaks to staff technologists.

G. Role of trainees in setup and break down of case

Discuss how the trainees are involved with setting up and terminating an NIOM case. Important to note is if they are alone during either of these time periods.

H. Supervision while in the operating room

Discuss who supervises trainees while they are in the operating room. Note if the supervisor is present in the operating room as well. Describe how the student is given gradually increasing responsibilities for NIOM.

I. Criteria for completion of training

List the criteria for completion of program. This may include completion of formal coursework, performance of a certain number of NIOM studies, experience, etc. It is expected that the same criteria will be used for all trainees.

J. Formal coursework

Though formal coursework is not mandatory for the education of technologists, it is highly encouraged. If such coursework is used, describe it here. If online course or courses from professional societies is used, mention the name.

XVI. Policies and Procedures

A. Policies and procedures manual

It is strongly advised that the NIOM laboratory have a policies and procedures manual. If such a manual is not available, provide an explanation and how this will be rectified. Some laboratories may have manuals (Scope of Service manual) that may serve the same purpose as the Policy and Procedures manual. If so, please note this.

B. Frequency of updating policies and procedures manual

It is expected that the policies and procedures manual will be periodically reviewed and updated. Provide a frequency of how often this is done.

C. Quality improvement

Discuss the current QI project and how it is expected to improve patient care. Also describe one other QA project undertaken in the last three years and how its results affected patient care.

D. How are staff trained on new NIOM techniques?

How is this documented?

E. How are staff trained on new equipment?

How is this documented?

F. Table of contents for policies and procedures manual

Provide a copy of the table of contents of the policies and procedures manual in Appendix 8.

G. Copies of policies

It is strongly encouraged that every NIOM laboratory has policies listed in Section XVI. E. In Appendix 9 reproduce the listed policies. If a listed policy is not available, provide an explanation for why it is not present.

XVII. Plans for Program Development and Improvement

A. Plans for improving NIOM services

Discuss the short and long term plans for improving the NIOM services at the applicant hospital. This may involve increasing the surgeons to whom the service is available, introduction of other monitoring modalities, or adding additional staff. If additional equipment is to be purchased, mention that as well.

B. Anticipated changes

Discuss anticipated changes in management, staffing, equipment, and facility of the NIOM laboratory in the next 3 years. Particularly important are changes in personnel. If personnel are expected to leave, discuss plans for replacement.

XVIII. Signature Page

The Program Evaluation Document (PED) must be signed by the individual completing the application. Additionally, the PED must be signed by the Medical Director, Technical Director, and Administrator as having verified that the information provided is correct.

Appendices

Appendix 1: See section IV.J.

Appendix 2: See section V.B.

Appendix 3: See section VI.H.

Appendix 4: See section VII.B

Appendix 5: See section VIII.C.

Appendix 6: See section IX.G.

Appendix 7: See section XIV.A.

Appendix 8: See section XVI.C.

Appendix 9: See section XVI.E.

References

- 1. AAN (2008). "Principles of coding for intraoperative neurophysiologic monitoring (IOM) and testing." Retrieved Feb. 14, 2009.
- 2. ACNS (1994). "Guideline eleven: guidelines for intraoperative monitoring of sensory evoked potentials. American Electroencephalographic Society." J Clin Neurophysiol **11**(1): 77-87.
- 3. AMA (2008). <u>Code of medical ethics of the American Medical Association: 2008-2009 edition</u>. Chicago, American Medical Association Press.
- 4. Anonymous (2006). "LCD for neurophysiologic intraoperative monitoring." Retrieved Feb 14, 2009, from http://www.cignagovernmentservices.com/partb/coverage/lcd/nc/drafts/L24058.html.

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ACCREDITATION POLICIES FOR APPLICANT LABS

<u>LAB APP – 1</u>

Accreditation Application Agreement

Facility Owner's Name ("Facility"):	
Facility Name (if different) & Address:	
Facility Employer Identification Number:	
Legal Structure (check one):	corporation
	limited liability company
	other (specify):
Date:	

Facility and ABRET Neurodiagnostic Credentialing and Accreditation ("ABRET") agree as follows:

1. Application.

- **A.** Facility requests accreditation as indicated on its application. The facility hereby authorizes ABRET and its officers, directors, employees, and agents (collectively, "ABRET") to review its application and to determine its eligibility for accreditation. This authorization includes (but is not limited to) permission for ABRET to contact state and federal authorities, licensing boards, nongovernmental accreditation and certification bodies, and others for the purpose of verifying the information provided by Facility.
- **B.** Through its accreditation application review process, ABRET will determine whether a Facility's performance meets ABRET's current Standards, policies and procedures. ABRET may amend these Standards, policies, and procedures from time to time, and updated information will be made available through the ABRET website.
- **C.** ABRET will make efforts to review a Facility's application at the earliest date possible, but it cannot guarantee the timing of the completion of any review.
- **D.** The provisions of the attached Business Associate Agreement are a part of this Agreement and are incorporated by reference.
- **2.** <u>Term.</u> This Agreement will become effective on the date of signature by ABRET and will remain in effect for the duration of the application review process. If accreditation is granted, this Agreement will automatically continue in effect for the duration of that accreditation award.

3. Responsibilities of Facility.

- **A.** Cooperation. Facility agrees to cooperate promptly and fully with ABRET.
- **B.** Submission of Materials.
 - **i.** Facility shall complete its application in a manner that presents an accurate, true and complete description of the services provided by Facility.
 - **ii.** Facility agrees to submit any additional information requested by ABRET.
 - **iii.** All information must be produced in a timely manner and in the format requested by ABRET.
- **C.** <u>Compliance with ABRET Rules</u>. Facility has read, accepts, and agrees to abide by ABRET's Standards, policies, and procedures, including but not limited to those listed below. Facility must read and keep up-to-date with these rules. Facility bears the burden of showing and maintaining compliance during the application review period and for the duration of accreditation (if granted).

i.	_[APPLICATION REVIEW AND APPEAL POLICY]_;
ii.	_[RELEASE OF INFORMATION POLICY];
iii.	[REPORTING CHANGES POLICY];
iv.	[TRADEMARK POLICY]; and
v.	[ADVERSE ACTION POLICY]

- **D.** On-site Visits. Facility hereby consents to one or more on-site visits by ABRET.
- E. Affiliates and Subsidiaries. If Facility includes in its application one or more sites owned or otherwise operated by independent physicians, companies, or other third parties, then Facility is responsible for managing their participation in ABRET's accreditation program. Facility represents that it has the authority to bind each entity to the provisions of this Agreement as if the entity were Facility. Facility hereby agrees to take all reasonable measures to assure that each entity complies with this Agreement. Further, Facility shall be liable for each entity's participation in the accreditation process as provided in the Section titled "Waiver of Claims & Indemnification". ABRET may bring a separate action against any one or more entities under this Agreement and may elect to recover from any one or more entities the full amount of any unpaid fees or other collective liability. If one entity violates this Agreement, then ABRET may take adverse action against Facility and one or more entities.
- **4. No Warranty.** A grant of accreditation by ABRET is recognition of Facility's performance at the time of application; accreditation does not constitute a warranty of complete or continuous compliance. Facility is solely responsible for ensuring the quality and safety of its services.

5. Waiver of Claims & Indemnification.

- A. Facility hereby waives all claims against ABRET and assumes full responsibility for all expenses which Facility may incur arising out of this Agreement and/or Facility's participation in the ABRET accreditation program, including (but not limited to) those arising out of ABRET's decisions regarding Facility's grant or denial of accreditation, publication of these decisions, publication of the accreditation status of Facility, and third party actions based on the accreditation program or Facility's accreditation status.
- **B.** Facility shall defend and indemnify ABRET against all claims, liabilities, damages and expenses (including but not limited to reasonable attorney's fees) arising out of this Agreement and Facility's participation in the ABRET accreditation program, including (but not limited to) those arising out of ABRET's decisions regarding Facility's grant or denial of accreditation, publication of these decisions, publication of the accreditation status of Facility, and third party actions based on the accreditation program or Facility's accreditation status.
- **C.** The provisions of this Section do not extend to claims, liabilities, damages and expenses arising out of the gross negligence or willful misconduct of ABRET.
- **Notice**. Any notice that either party is required or may desire to serve upon the other party must be in writing. Notice must be served (i) by overnight delivery by a nationally recognized express transportation company (with confirmed delivery, charge prepaid or billed to shipper), or (ii) by depositing the same in the mail (first class postage prepaid, certified and return receipt requested) with notice also required to be given by electronic mail on the same date as deposited in the mail. Notice given by mail or electronic mail alone is not sufficient. Notices to the Facility are to be sent to the address shown on page one of this Agreement.
- 7. <u>Governing Law</u>. This Agreement is governed exclusively by the laws of the State of Illinois, without reference to its choice of law doctrine.
- **8.** <u>Dispute Resolution</u>. The sole jurisdiction and venue for any litigation arising from this Agreement is the appropriate federal court for the Central District of Illinois or state court located in Sangamon County, Illinois. The parties hereby waive trial by jury in any action arising out of this Agreement. If a dispute arises, the parties shall make a good faith attempt to resolve the dispute through dialogue and negotiation for a period of sixty (60) calendar days prior to pursuing court action.
- **9. No Assignment**. Facility shall not assign any of its rights or obligations under this Agreement without the prior written consent of ABRET.
- **10.** <u>Successors</u>. This Agreement will be binding upon, and will inure to the benefit of, the parties and their respective permitted successors and assigns.
- 11. <u>Sole Agreement</u>. This Agreement contains the entire agreement between the parties concerning Facility's application and accreditation. It supersedes all prior and contemporaneous oral and written understandings.

- **12.** <u>Amendment</u>. No amendment of this Agreement will be valid unless in writing and signed by ABRET.
- 13. <u>Waiver</u>. No waiver will be effective unless it is in writing and signed by the party granting the waiver. If a party excuses the other party's failure to perform a term of this Agreement in one instance, then that waiver does not excuse any subsequent non-performance of the same term.
- **14. Severability**. If any provision of this Agreement is held to be invalid, the remaining provisions of this Agreement are not to be affected and will continue in effect. The invalid provision is to be deemed modified to the least degree necessary to remedy the invalidity.
- **15. Survival.** The obligations and rights of the parties which by their nature would continue beyond the termination of this Agreement will survive beyond the termination of this Agreement and remain in full force and effect. These obligations and rights include (without limitation) those set forth in Sections titled "Waiver of Claims & Indemnification".
- **16.** <u>Independent Contractors</u>. The relationship between the parties to this Agreement is that of independent contractors. This Agreement is not intended to create any association, partnership, joint venture or agency relationship between the parties.

In Witness Whereof, the parties are signing this Agreement as of the date indicated on the first page.

ABRET	Facility
By:	By:
Name:	Name:
Title:	Title:

LABAPP - 2

ABRET LAB ADVERSE ACTION POLICY

ABRET has developed this Adverse Action policy to articulate standards of conduct for eligibility for accreditation and continued accreditation. This policy was also adopted to establish a fair process for addressing noncompliance with ABRET Standards, policies, and procedures.

1. General Principles. Facilities and their staff must:

- **A.** be truthful, forthcoming, prompt, and cooperative in their dealings with ABRET;
- **B.** be in continuous compliance with ABRET's Standards, policies, and procedures (as amended from time to time by ABRET);
- **C.** respect ABRET's 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. Grounds for adverse action include:

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

3. Sanctions.

- **A.** ABRET may impose one or more of the following sanctions for failing to adhere to ABRET Standards, policies, and procedures:
 - **i.** Denial of accreditation:
 - ii. Revocation of accreditation:
 - iii. Non-renewal of accreditation;
 - iv. Suspension of accreditation for a specific period of time;
 - v. Reprimand;
 - vi. Notification of other legitimately interested parties; or
 - vii. Other corrective action.

- **B.** The sanction must reasonably relate to the nature and severity of the violation, focusing on reformation of the conduct of the facility and deterrence of similar conduct by others. The sanction decision may also take into account aggravating circumstances, prior adverse action history, and mitigating circumstances. No single sanction will be appropriate in all situations.
- 4. Compliance with ABRET Standards, Policies, and Procedures. A facility must be in continuous compliance with all ABRET Standards, policies, and procedures. Each facility bears the burden for demonstrating and maintaining compliance at all times.
- **5. Non-Payment of Fees.** Failure to pay fees when due results in automatic suspension of accreditation. Accreditation may be reinstated if the facility pays all fees within thirty (30) days after the original due date. Failure to pay fees within this time period results in automatic termination of accreditation.

6. Complaints.

- **A.** Persons concerned with possible violation of ABRET rules are encouraged to contact ABRET. The person should submit a written statement identifying the facility 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, email address, and telephone number. However, ABRET will consider anonymous complaints as long as sufficient information is provided to enable ABRET to conduct an appropriate investigation.
- **B.** Actions taken under this Policy do not constitute enforcement of the law. Individuals bringing complaints under this Policy are not entitled to any relief or damages by virtue of this process.
- **7. Pending Allegations**. ABRET may place an application on hold while allegations of misconduct are pending.

8. Establishment of Review Committee and Hearing Committee.

- **A.** The ABRET President will appoint a Review Committee and a Hearing Committee on an ad hoc basis as needed to consider alleged violations of ABRET Standards, policies, and procedures.
- **B.** Each of these Committees will be composed of five members drawn from current or former ABRET volunteers.
- C. A committee member may not simultaneously serve on more than one committee and may not serve on any matter in which his or her impartiality might reasonably be questioned, or which presents an actual or apparent conflict of interest.
- **D.** At all times during ABRET's handling of the matter, ABRET must exist as an impartial review body.
 - **i.** In order to avoid actual, apparent, or perceived conflicts of interest, no member is permitted to serve on the Review Committee or the Hearing Committee whenever:

- **a.** A member has formed an opinion on the matter; or
- **b.** A member is or has been employed by the facility that is the subject of the allegation; or
- **c.** The member has special knowledge that could bias his/her decision relative to either the facility or ABRET.
- **ii.** If anyone identifies a situation where the impartiality of a Committee member might reasonably be questioned, or which presents an actual or apparent conflict of interest:
 - **a.** The member shall make full disclosure of such matter by reporting the possible conflict or bias immediately to the Committee chair; and
 - **b.** The Board of Directors shall determine whether the member is permitted to continue to participate as a Committee member.
- **E.** Each Committee shall elect its own Chair.
- **F.** Committee action shall be determined by majority vote.
- **G.** When a committee member is unavailable to serve by resignation, disqualification or other circumstance, the President of ABRET shall designate another individual to serve as an interim member.

9. Review Procedures.

A. Initial Evaluation by President.

- **i.** Upon receipt of a complaint or a change notice, the Executive Director will confer with the President. The President or the Executive Director may request supplemental information.
- **ii.** If the Executive Director and President determine that the complaint is frivolous or that the change is not relevant to certification, no further action will be taken.
- **iii.** If the Executive Director and President determine that ABRET lacks jurisdiction over the complaint or the facility that is the subject of the complaint, then they may refer the matter to the appropriate governmental agency or another entity engaged in the administration of law.
- **iv.** If the Executive Director and President determine that the complaint is not frivolous or that the change may be relevant to certification, it will be forwarded to the Review Committee for investigation.
- **v.** Facilities submitting change notices and persons submitting complaints will be notified of the decision of the Executive Director and President.
- **B.** Audits. ABRET may conduct one or more compliance audits. If ABRET discovers a possible violation of ABRET rules, the Executive Director will confer with the President to determine whether the allegation will be forwarded to the Review Committee for investigation.

C. Procedures of the Review Committee.

- i. The Review Committee will investigate the allegations. The Review Committee may contact the individual who submitted the complaint, the facility in question, and others who may have knowledge of the facts and circumstances surrounding the allegations. They may conduct an investigative site visit.
- **ii.** If the Committee determines that the facts are inadequate to sustain a finding of a violation of ABRET rules, no further action will be taken. Facilities submitting change notices and persons submitting complaints will be notified of this decision.
- **iii.** If the Committee finds that good cause exists to question whether a violation of an ABRET rule has occurred, the Committee will transmit a statement of the following information to the facility by traceable delivery service, signature required:
 - **a.** the applicable rule;
 - **b.** the facts constituting the alleged violation;
 - **c.** that the facility may request an oral hearing (in person or by phone) or a review by written briefing for the disposition of the matter, with the facility bearing its own expenses;
 - **d.** that the facility has thirty (30) days after receipt of the statement to notify the President and the Committee if it disputes the allegations, has comments on available sanctions, and/or requests an oral hearing in person, an oral hearing by phone, or a review by written briefing;
 - **e.** that, in the event of an oral hearing, the facility 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;
 - **f.** that the truth of the allegations or failure to respond may result in sanctions including revocation; and
 - **g.** that if the facility does not respond, or if the facility responds but does not dispute the allegations, comment on available sanctions, or request a review or hearing, then the facility waives its right to further review and appeal, and consents to the Review Committee rendering a final decision on the evidence before it and applying available sanctions.
- **iv.** The Review Committee may offer the facility the opportunity to negotiate a specific sanction. Any agreed-upon sanction must be documented in writing and signed by ABRET and the facility.

D. Procedures of the Hearing Committee.

i. Written Review. If the facility requests a review by written briefing, the Review Committee will forward the allegations, the record of the investigation, the determination of a violation, the recommendation regarding sanction(s), and the response of the facility to the Hearing Committee. Written briefing may be submitted within thirty (30) days following receipt of the written review request by the Hearing Committee. The Hearing Committee will render a decision based on the record below and written briefs (if any) without an oral hearing.

- **ii.** Oral Hearing. If the facility requests a hearing:
 - **a.** The Review Committee will:
 - (1) forward the allegations, the record of the investigation, the determination of a violation, the recommendation regarding sanction(s), and the response of the facility to the Hearing Committee; and
 - (2) designate one of its members to present the allegations and any substantiating evidence, examine and cross-examine witnesses and otherwise present the matter during the hearing.
 - **b.** The Hearing Committee will:
 - (1) schedule a hearing after the request is received, allowing for an adequate period of time for preparation; and
 - (2) send by traceable delivery service, signature required, a Notice of Hearing to the facility. The Notice of Hearing will include a statement of the time and place selected by the Hearing Committee. The facility 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 facility's consent for the Review Committee to administer any sanction which it considers appropriate.
 - **c.** The Hearing Committee will maintain a verbatim oral or written transcript.
 - **d.** ABRET and the facility 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 Hearing Committee.
 - **e.** The Hearing Committee shall determine all matters relating to the hearing.
 - **f.** Formal rules of evidence do not apply. Relevant evidence may be admitted. Disputed questions will be determined by the Hearing Committee.
 - **g.** The right to the hearing may be forfeited if the facility fails to appear without good cause.
- iii. In all written reviews and oral hearings:
 - **a.** The Hearing Committee may accept, reject, or modify the recommendation of the Review Committee, either with respect to the determination of a violation or the recommended sanction.

- **b.** Proof is by preponderance of the evidence.
- **c.** The Hearing Committee will issue a written decision following the review or hearing and any briefing. The decision will contain factual findings, conclusions regarding ABRET's rules, and any sanctions applied. It will be mailed promptly by traceable delivery service, signature required, to the facility.
- **E.** If the decision rendered by the Hearing Committee finds that the allegations are not established, no further action on the matter will occur.
- **F.** If the decision rendered by the Hearing Committee is not favorable to the facility, the facility may appeal the decision to the ABRET Board of Directors.
- **G.** Facilities submitting change notices and persons submitting complaints will be notified of the decision of the Hearing Committee.

10. Appeal to the Board of Directors.

- **A.** A Director may not review any matter in which his/her impartiality might reasonably be questioned, or review any matter which presents an actual, apparent, or potential conflict of interest.
- **B.** The facility may request an appeal within thirty (30) calendar days after its receipt of the Hearing Committee's decision. After this time, the facility may not request an appeal.
- **C.** All appeals must be submitted in writing and sent to ABRET by traceable mail or delivery service.
- **D.** The appeal must specify a valid basis for the appeal. If the President determines that the request is frivolous, then the appeal will not proceed.
- **E.** The Review Committee 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 Board of Directors.

G. The Board of Directors will render a decision based on the record below and written briefs (if any) without an oral hearing. Alternatively, the Board of Directors may choose to conduct a new in-depth review of all the facts and rules (a "de novo" review). Only facts and conditions up to and including the time of the Hearing Committee's determination are considered during an appeal.

H. In all reviews:

- i. In order to overturn a decision of the Hearing Committee, the facility must demonstrate that the Hearing Committee's decision was inappropriate because of (a) material errors of fact, or (b) failure to conform to ABRET's rules. Proof is by preponderance of the evidence.
- **ii.** The Board of Directors may accept, reject, or modify the recommendation of the Hearing Committee, either with respect to the determination of a violation or the recommended sanction. The Board of Directors will issue a written decision following the review and any briefing. The decision will contain factual findings, conclusions regarding ABRET's rules, and any sanctions applied. It will be mailed promptly to the facility by traceable delivery service, signature required.
- **I.** A decision rendered by the Board of Directors is final.
- **J.** Facilities submitting appeals and persons submitting complaints will be notified of the decision of the Board of Directors.
- 11. **Permanent Record.** All decisions of the Hearing Committee and/or Board of Directors shall be filed as a part of a facility's accreditation record with ABRET.
- 12. Summary Procedure. If the Executive Director determines that there is cause to believe that a threat of immediate and irreparable harm to the public exists, the Executive Director shall forward the allegations to the ABRET Board of Directors. The Board shall review the matter immediately, and provide telephonic or other expedited notice and review procedure to the individual. If the Board 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 herein.
- 13. Reinstatement of Eligibility. Following a period of ineligibility based on noncompliance with ABRET Standards, policies and procedures, the facility may apply for reinstatement of eligibility by demonstrating that it has taken corrective action. Unless and until clear and convincing evidence is submitted, the facility will remain ineligible.
- **14. Continuing Jurisdiction.** ABRET may take action under this Policy during the time when a facility's application is pending and at any time during accreditation. In addition, ABRET retains jurisdiction to review and issue decisions regarding any matter which occurred prior to the expiration, or relinquishment of accreditation.

LABAPP-3

Accreditation Decision Review and Appeal Policy

ABRET has adopted this policy to establish a fair process for addressing application issues.

- 1. **Initial Review.** ABRET will determine whether a facility has met the requirements for accreditation. It may decide: (i) to grant accreditation, or (ii) to require the facility to submit additional evidence of compliance. Additional evidence of compliance may include a site visit. The timeframe and other conditions for further review will be provided by ABRET in writing.
- **2. Adverse Action Allegations**. ABRET may place an application on hold while allegations of misconduct are pending.
- **3. Denial**. Accreditation may be denied for reasons that include (but are not limited to) the following:
 - **A.** failure to truthfully complete and sign an application in the form provided by ABRET;
 - **B.** failure to pay the required fees;
 - **C.** failure to provide additional information as requested;
 - **D.** refusal to allow a site visit:
 - **E.** the facility has submitted the maximum of three supplemental information responses and ABRET remains unable to confirm that the facility meets the requirements for accreditation; and
 - **F.** grounds exist for adverse action as described in the ABRET LAB ADVERSE ACTION POLICY.
- **4. Notification**. ABRET will notify the facility within 30 calendar days after it makes its decision.
- 5. Decision Appeals Process.
 - **A.** Only "Denial" decisions can be appealed.
 - **B.** A failure to comply with any ABRET deadline may not be appealed.
 - **C.** A facility may request an appeal within 30 calendar days after notification of the denial decision. After this time, the facility may not request an appeal.

- **D.** Appeal requests must be submitted in writing and sent to ABRET by traceable mail or delivery service.
- **E.** The appeal must specify a valid basis for the appeal. If ABRET determines that the request is frivolous, then the appeal will not proceed.
- **F.** ABRET may file a written response to the appeal request.
- G. ABRET will appoint an Appeal Committee to consider the appeal. The Appeal Committee is composed of three members selected from the ABRET Board of Directors. 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, or (c) review any matter which presents an actual, apparent, or potential conflict of interest. Committee action is determined by majority vote.
- **H.** The Appeal Committee will render a decision based on the written record. Documentation not previously submitted to ABRET will not be considered. An oral hearing is not permitted.
- **I.** The Appeal Committee may accept, reject, or modify the denial decision. In order to overturn the decision, the facility must demonstrate that the denial decision was inappropriate because of: (a) material errors of fact, or (b) failure to conform to ABRET's rules.
- **J.** The decision of the Appeal Committee is final.
- **K.** ABRET will notify the facility of the decision of the Appeal Committee in writing.
- L. Only one appeal per application is permitted. If that appeal upholds the original denial, then the facility must complete and submit a new application in order to seek accreditation at another time.
- **M.** The facility is responsible for all expenses incurred by it related to the appeal and must pay any administrative appeal fee charged by ABRET.
- **6. Reinstatement of Eligibility**. Following a denial based on this policy or other noncompliance with ABRET Standards, policies, and procedures, a subsequent application will not be reviewed unless the facility demonstrates that it has undertaken corrective action.

LAB APP - 4

Reporting Changes Policy

ABRET has adopted this policy to provide guidance to accredited facilities regarding when and how to report changes to ABRET.

1. Changes to the ABRET Standards, Policies, and Procedures. Accredited facilities are expected to maintain continuous compliance with the Standards and other ABRET policies and procedures, including changes to the Standards that occur during the five-year accreditation period. Facilities will be notified of changes, and revised Standards, policies, and procedures will also be published on the ABRET website.

2. Facility Changes.

- **A.** Accreditation is awarded to the facility as its operations are described on its application. A facility shall report to ABRET any change regarding the facility's operations or other development that is related to accreditation. Facilities are expected to notify ABRET in writing within 90 calendar days after the facility first learns of the development, and must provide documentation of the resolution of the matter within 90 calendar days after resolution. Examples of information that must be reported include (but are not limited to):
 - i. contact information changes;
 - ii. personnel changes, including medical director;
 - iii. changes in the facility's address or the location(s) where services are provided;
 - iv. changes in ownership or management of the facility;
 - **v.** discontinuing a service or ceasing to do business;
 - **vi.** being investigated or sanctioned for fraud or other misconduct by a government agency; and
 - **vii.** being sued by a patient.
- **B.** Regarding personnel changes, the facility shall notify ABRET of the departure of personnel and shall submit a replacement plan within 30 calendar days.
- **C.** Regarding ownership changes, accreditation cannot be transferred without written approval from ABRET. Accreditation may not be divided or shared following a sale, dissolution or other change in ownership or legal structure.
- **D.** ABRET will review the change to determine whether the facility's existing accreditation remains valid following the change or if the change requires the facility to re-apply for

accreditation. ABRET may require the facility to submit additional evidence of continuing compliance.

LAB APP – 5 Release of Information Policy

ABRET has adopted this policy to inform applicants and accredited facilities of how information may be released.

- **1.** Interested parties may request verification of accreditation.
 - **A.** Requests may be made to the Executive Office.
 - **B.** Accreditation verification forms are available from the office or website.
 - **C.** Accreditation may be verified online on the ABRET website. If accreditation is granted, ABRET will publish the facility's accreditation status and the expiration date in a directory of accredited laboratories.
- **2.** Appropriate information must be provided for the verification.
 - **A.** The request must include the name and address of the facility.
 - **B.** The Executive Director sends a confirmation of accreditation along with the date of accreditation and expiration to the requesting party.
 - **C.** If the Executive Director experiences a conflict or is unclear of the facility's status, additional information is requested.
- **3.** ABRET does not release information on the status of a pending application. The Executive Director may, however, upon written authorization from the facility, confirm or deny that a facility has a pending application.
- **4.** Accreditation decisions will not be disclosed until written notice of that decision has been sent to the facility.
- **5.** ABRET may also publish whether any adverse action has been taken regarding a facility, such as revocation or suspension of accreditation. Regarding adverse actions, ABRET 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 facility's right of appeal has been exhausted.

- **6.** ABRET rents its mailing list to organizations and companies who offer products that might be of interest to facilities. A facility may opt-out of this mailing list by contacting ABRET.
- **7.** ABRET shares data about facilities for research purposes. No patient identifiable information is provided. A facility may opt-out of data sharing by contacting ABRET.
- **8.** As a general policy, all other facility and ABRET information is treated as confidential and privileged. ABRET will, in its discretion, exercise sound judgment with respect to assistance in investigations by other parties, such as a regulatory agency, another accreditation organization, or a payer. However, ABRET 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 or otherwise presents a threat to the public.

LAB APP - 6

Accreditation Trademark Policy

ABRET permits laboratories and other facilities to use the ABRET name to state the fact of accreditation in accordance with this policy as long as active accreditation is maintained.

- 1. **Ownership.** The acronym "ABRET", the name "ABRET Neurodiagnostic Credentialing and Accreditation," and the accreditation certificates and other emblems of ABRET are the sole and exclusive property of ABRET and are subject to all applicable trademark and other rights of ABRET as owner under United States intellectual property law and international conventions. Facilities shall not use these items, or any other intellectual property owned by ABRET, except as expressly authorized in this policy or otherwise authorized in advance and in writing by ABRET.
- 2. **License.** For the duration of accreditation, ABRET will permit an accredited facility to use the ABRET name and accreditation certificate for the sole purpose of indicating accreditation by ABRET. All goodwill associated with these items as used by accredited facilities inures solely to the benefit of ABRET.
- 3. **Permitted Uses.** Facilities may display the accreditation certificate at its accredited location(s). Facilities may use the ABRET name on:
 - **B.** letterhead and business cards:

- C. websites; and
- **D.** advertisements, brochures, and other promotional materials.

1. Conditions of Use.

- b. All use of the ABRET name must be accurate and supportive of ABRET objectives, and must do so in a manner that is compatible with the mission of ABRET.
- c. All use of the ABRET name must be truthful and not misleading. Specifically, a facility shall not use this name:
 - i. unless ABRET has made an official accreditation decision:
 - ii. in connection with services or testing areas in which the facility is not accredited;
 - iii. in any manner that reflects negatively on ABRET or its activities;
 - iv. in any manner that conflicts with ABRET policies and procedures;
 - v. to state or imply that the facility has any relationship with ABRET other than as an accredited facility; or
 - vi. to state or imply that ABRET is endorsing or guaranteeing any product or service offered by the facility.
- d. Facilities shall not use the ABRET name (or a word or design that is confusingly similar to an ABRET trademark) as part of the facility's business name, logo, domain name, or product or service name.
- e. The ABRET name may not be the most prominent visual element on the facility's promotional materials. The facility's business name and/or logo, product or service name, and graphics should be significantly larger than the reference to ABRET accreditation.
- f. If space permits, then use of the ABRET name must be accompanied by an acknowledgement of ABRET ownership. This acknowledgement should appear as a footnote with the copyright notice, at the end of a printed document, or at the bottom of a webpage. Please include the following acknowledgement: The ABRET name is a registered trademark owned by ABRET Neurodiagnostic Credentialing and Accreditation and is used by permission.
- g. If accreditation ends, then the facility shall:
 - i. cease use of any statement that indicates active ABRET accreditation;

- ii. return all certificates and other items provided by ABRET, without retaining copies; and
- iii. not distribute any materials containing a statement of active ABRET accreditation that the facility might already have prepared.
- h. The facility is responsible for correcting (at its expense) any outdated or otherwise inaccurate reference to active ABRET accreditation.
- 1. Quality Control. ABRET has the right to control the quality of all materials on which its name is used in a statement indicating active ABRET accreditation. ABRET will have access to the materials which the facility makes publicly available (such as business cards, letterhead, etc.). Also, the facility shall submit samples if requested by ABRET. If ABRET determines that the facility is not meeting the requirements of this policy, ABRET will notify the facility and provide an explanation. The facility shall correct the violation within 30 calendar days after receipt of the notice. ABRET is the final judge as to whether any use of the ABRET name is consistent with this policy.
- 2. Consequences of Misuse. ABRET is committed to protecting its intellectual property for the benefit of all accredited facilities and the general public as consumers. If a facility fails to comply with this policy or otherwise misuses an accreditation certificate, the ABRET name, or other intellectual property of ABRET, then ABRET may revoke or take other action with regard to the facility's accreditation status in accordance with the ABRET ACCREDITATION ADVERSE ACTION POLICY. If the facility is not accredited by ABRET at the time of the misuse, then ABRET will require corrective action as a condition of eligibility for accreditation should the facility seek accreditation at a later time. In addition, ABRET may pursue other remedies that may be legally available.
- 3. **Further Information**. If an individual has a question regarding use of these marks, please contact ABRET.