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LAB - LTM

ABRET LTM LABORATORY ACCREDITATION

Epilepsy and Critical Care EEG Monitoring

INTRODUCTION & STANDARDS

9/2024

General Information

The Laboratory Accreditation Board of ABRET (LAB of ABRET) is a separate board functioning under ABRET, Inc., a not-for-profit, 501 (c)(6) corporation.

The Long-term monitoring (LTM) Board of ABRET accredits (1) Epilepsy monitoring programs (EM) and (2) Critical Care EEG monitoring programs (CC-EEG). An additional designation will be given for laboratories performing invasive Epilepsy Monitoring (EM+). Facilities with Adult and Pediatric LTM programs must apply for each program separately.

Eligibility

Any laboratory performing long-term EEG monitoring (24 hour) with minimum of 2 dedicated beds or 2 acquisition units may apply for accreditation.

Studies must be interpreted by licensed physicians (M.D. or D.O.). The Medical Director must have one year of formal neurophysiology training or neurophysiology board certification.

At least one of the staff technologists must be an R. EEG.T., with CLTM preferred.

The technical director is expected to have a CLTM credential. The technical director oversees the technologists and technical aspects of monitoring.

A minimum of 50 cases over the last four years per LTM category (Epilepsy Monitoring and Critical Care EEG) is required.

For Epilepsy Monitoring *plus accreditation for extraoperative invasive recordings*, the lab must have performed at least three cases of extraoperative invasive recordings (including ECOG cases) within the last three years.

Accreditation

LTM-Lab accreditation by ABRET requires a formal review of EEG data, Policies & Procedures. A site visit may be required.

Accreditation will be valid for 5 years.

A list of ABRET accredited laboratories will be published. Successful laboratories will receive a framed certificate, press release and a digital badge for use on the organization's website or in email signatures.

PROCESS FOR LTM LABORATORY ACCREDITATION

STEP ONE

Please send:

- 1. A complete Part I application form (Sections I–IV) with CV forms (Appendices 1–2). An online version will soon be available at www.abret.org.
- Signed Application Agreement (sign/complete pages 7 & 9 of this document and provide initials on page 8, Sections 4.C.i–iv, attesting that you have read ABRET policies contained in this document).
- 3. An initial Processing fee of \$100.00 payable to ABRET (<u>pay online here</u> or refer to the Fees section on page 3 below). Contact <u>Anna@abret.org</u> if you require an invoice or W-9 for processing.

STEP TWO

Once the Part I application form has been accepted (*Step One*), <u>ABRET will contact the lab</u> to request the following items for submission based on application type (per step 2 below):

- 1. **Policies** in electronic format. Include a Table of Contents with page numbers. *Please do not include extraneous/additional information that is not included in the list of requested policies found on pages 4-6 of this document.*
- 2. Recordings (Expected Technical Requirements are found on page 4):

For Epilepsy Monitoring (4-5) (provide an official report with each submitted record)

- Submit three recordings (individual patients, complete 12–24-hour continuous EEG segments including annotations and audio/video of the clinical events) for the Epilepsy Monitoring application. All records must have clinical events, at least 2 should demonstrate clinical and/or electrographic seizures.
 - Accreditation of Pediatric Programs One of the three records must be a vEEG on a patient under the age of 2 years.
- The LAB-LTM Board will request **one** additional archived recording by a randomly selected date. Random files do not need to be continuous or contain audio/video <u>unless</u> there are clinical events.
- <u>Laboratories performing extraoperative invasive recordings</u> (including all designated Level 4 NAEC centers) should submit **one** additional 12–24-hour invasive recording showing clinical and electrographic seizures with video.
 - Clipped and archived recordings are allowed but the submitted record should be from a 24-hour continuous segment. An invasive map (manual, pictures, or image co-registration) and list of implanted electrodes with names and locations should be included.

For Critical Care EEG Monitoring (3) (provide an official report with each submitted recording)

• Submit **two** recordings (individual patients, continuous 12–24-hour EEG segments including annotations and audio/video clips of the clinical events) for the ICU/Critical Care EEG Monitoring application. These records must have electrographic seizures with or without clinical correlation.

- The LAB-LTM Board will request **one** additional archived recording for ICU/Critical Care EEG by a randomly selected date. Random files do not need to be continuous or contain audio/video unless there are clinical events.
- 3. Send two complete copies of EEGs on portable hard drives, encrypted according to institutional policies. Please organize patient files in folders and if clipped, recordings must be listed in the order of recording. Include reading software and all montages typically used in the laboratory. Patient identifying information should be removed. Data will only be used for evaluation and will be destroyed or returned upon completion of the evaluation. Complete the attached Recording ID Forms found on pages 23–24.
- **4.** A Business Associate Agreement must be completed to satisfy HIPAA requirements. Either send a signed copy of your institutional agreement form or complete/sign the template located on the ABRET website and return it to anna@abret.org. Data will only be used for evaluation and destroyed or returned upon completion of the evaluation.

LAB-LTM Fees

Processing Fee*: \$100 (For labs with additional programs, such as Adult and Pediatric or satellite labs that fall under the same health system, additional processing fees are waived)

Accreditation Fees

- For one (Epilepsy Monitoring/EM or Critical Care/CC): \$1,500
- For both (EM & CC): \$2,500
- Epilepsy Monitoring with Invasive/EM+ (NAEC Level IV): \$2,500
- For both (EM+ & CC): \$3,000
- Satellite or related labs may be recognized under the same application for a discounted fee if the staff, medical director, and policies are the same. The first lab will be full price (\$1,500), and subsequent labs will be discounted 20% (i.e., \$1500 x 20% = \$1,200)
- Centers with both Adult and Pediatric programs should submit separate applications (NAEC considers the programs separately). The first program is full price with the additional program discounted 20%.
 - Adult/Ped EM: \$2,700 =\$1500 + \$1200 (i.e., \$1500 x 20%)
 - o Adult/Ped EM+: \$4,500 =\$2500 + \$2000 (i.e., \$2500 x 20%)
 - Adult/Ped EM & CC: \$4,500 =\$2500 + \$2000 (i.e., \$2500 x 20%)
 - o Adult/Ped EM+ & CC: \$5,400 =\$3000 + \$2400 (i.e., \$3000 x 20%)

Pay online here: **LAB-LTM Fees** or make check payable to ABRET LAB-LTM and mail to:

ABRET Executive Office
111 E. University Drive, Ste. 05–355
Denton, TX 76209

Contact anna@abret.org if you require an invoice or W-9 for processing.

Mail two (2) copies of all other materials on CD, DVD, flash drive, or portable hard drives to:

ABRET LAB – LTM c/o Anna M. Bonner 2054 Kildaire Farm Road, #431 Cary, NC 27518

Unsuccessful laboratories may reapply in one year.

EXPECTED TECHNICAL STANDARDS FOR RECORDINGS

- 1. All recordings must be interpretable (provide ancillary material as needed, e.g. event log, electrode map and montages).
- 2. All submitted records must have been recorded within twelve months of the application.
- 3. Every record must contain a minimum of sixteen EEG electrodes for ICU and twenty-one for EMU recordings.
- 4. Every record must contain an EKG channel.
- 5. All inter-electrode impedances (not greater than 10,000 ohms) should be balanced and documented at least once a day.
- 6. Patient age, Date, Technologist's name, or ID.
- 7. Required documentation in the report: Time of recording, Time and description of Symptoms or Events, Behavioral state of patient, Medication, Summary of relevant medical history.
- 8. If meaningful calibration is not available, ideally the first 30 seconds of the recording should be observed by the technologist using the primary system reference montage.
- 9. Scalp recording standards:
 - a. Sensitivity of 5-10 μv/mm is required and should be adjusted as needed.
 - b. Low frequency (high-pass) filter 1 Hz or lower (time constant of not <0.16 seconds) is required and should be adjusted as needed.
 - c. High frequency (low-pass) filter greater than or equal to 70 Hz is required and should be adjusted as needed.
- 10. Intracranial recordings:
 - a. Low frequency (high-pass) filter 0.5 Hz or lower;
 - b. high frequency (high-pass) filter 70 Hz or higher.
- 11. The notch filter should **not** be defaulted to "on".
- 12. Any artifacts should be corrected or monitored, as necessary.
- 13. For epilepsy monitoring:
 - a. If hyperventilation is performed, effort should be noted.
 - b. If photic stimulation is performed, stimulus frequency and effect should be documented.
- 14. Visual, auditory, somatosensory stimulation or noxious stimulation should be used and documented, as appropriate. Clear documentation of the patient's maximal level of alertness must take place at some time during recording.
- 15. Before submitting data, verify it is viewable on a generic PC running Windows with the reading software you included, and not just on your review station. Provide additional information/instructions as to how to use your particular reading software and video files, and if there are any nuances to facilitate the process, such as passwords.

Reference: American Clinical Neurophysiology Society Guidelines in Electroencephalography (www.acns.org)

Policies and Procedures

Provide a Table of Contents of your Policy and Procedure Manual (Please do not include additional policies or extraneous information)

- 1. Staffing policies (Job descriptions/Competencies)
- 2. Infection Control
- 3. Electrical Safety
- 4. Patient safety

- Role of technologists, nurses, house staff
- Monitoring Environment
- Out of bed policy (including bathroom safety)
- 5. Quality Improvement
- 6. Continuing Education Requirements
- 7. Emergency Coverage
- 8. HIPAA:
 - Hospital or departmental patient authorization for usage of identifiable material (audio, video) for patient care.
 - For teaching institutions, provide additional patient authorization for educational usage of identifiable audio-video material within the institution.

9. Archiving:

- Data retention policy (storage media, security, duration)
- Archiving procedure (auto-editing/manual clipping, quality control) for:
 - o Epilepsy Monitoring
 - Critical Care EEG

10. Procedural policies**:

- Epilepsy Monitoring
- Epilepsy Monitoring with Invasive
- Pediatric Epilepsy Monitoring (if applicable)
- Critical Care EEG
- **Please address the following elements in each Procedural Policy:
 - Information including patient's name, age, record ID, inpatient or outpatient date, and name of technologist
 - Patient preparation
 - Patient history
 - Electrode placement and application standards
 - Electrode impedance standards
 - Recording protocols including calibration, montages, activation, length of record, instrument adjustment and record annotation
 - Monitoring for scalp breakdown
 - Event annotation, testing, documentation, and notification standards
 - Documentation of daily medication changes, changes in clinical status, other diagnostic tests, and monitoring procedures
 - Monitoring Protocol: If not already included in the policies, provide a narrative addressing:
 - Epilepsy Monitoring: type of personnel, hours and days of coverage, backup monitoring plan during breaks, review of raw data, utilization of seizure and spike detection software, access for physicians to review after hour recordings, response to critical results, standard montages available for review.
 - o **Epilepsy Monitoring with Invasive** (if applicable)
 - o **Pediatric Epilepsy Monitoring** (if applicable)
 - Critical Care EEG: review and report of ongoing studies, weekend and overnight coverage, utilization of seizure detection software and quantitative EEG, standards for emergency hookup and reporting, access for physicians to review after hour recordings, response to critical results.
 - Use of specialized electrodes
 - Epilepsy Monitoring: For extraoperative recording and mapping

- Critical Care EEG: Imaging compatible electrodes, needle, subdermal electrodes
- Information Technology:
 - Protocol for equipment and network dysfunction (during and after working hours).
 Include your contingency plan if remote monitoring is not available.

REFERENCES

- 1. American Clinical Neurophysiology Society Guidelines (www.acns.org)
 - a. Minimal Technical Requirements for Performing Clinical Electroencephalography, Guideline 1
 - b. Recording Clinical EEG on Digital Media, Guideline 4
 - c. Minimal Technical Standards for Pediatric Electroencephalography, Guideline 5
 - d. Standards for Long Term Monitoring for Epilepsy, Guideline 12
 - e. Guideline on Continuous EEG Monitoring in Neonates, Guideline 13
 - f. Standardized Critical Care EEG Terminology, Guideline 14
- 2. ASET: The Neurodiagnostic Society (www.aset.org)
 - a. LTME National Competencies
 - b. cEEG Competencies
 - c. Policy & Procedures for the Neurodiagnostic Department: Reference Manual
- 3. National Association of Epilepsy Centers, "Guidelines for Essential Services, Personnel, and Facilities in Specialized Epilepsy Centers". (www.naec-epilepsy.org)
- 4. The Joint Commission, "National Patient Safety Standards" (www.jointcommission.org)

2/2024

Accreditation Application Agreement Facility Owner's Name ("Facility"): Facility Name (if different): Address: Legal Structure (check one): ____ corporation ____ limited liability company

other (specify):

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. Fees**. ABRET's current application fee is \$100. Facility shall pay this fee at the time Facility submits its application. This fee is not refundable.
- **Term**. 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.

4. Responsibilities of Facility.

- A. <u>Cooperation</u>. 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.** Compliance with ABRET Rules. 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). Please initial below, attesting you have been provided with the following ABRET policies:

i.	APPLICATION REVIEW AND APPEAL POLICY (page 10);
ii.	RELEASE OF INFORMATION POLICY (page 12);
iii.	REPORTING CHANGES POLICY (page 13); and
iv.	ADVERSE ACTION POLICY (page 16).

- **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.
- **5. 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.

6. 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.
- **8. Governing Law**. This Agreement is governed exclusively by the laws of the State of Texas, without reference to its choice of law doctrine.

- **9.** <u>Dispute Resolution</u>. The sole jurisdiction and venue for any litigation arising from this Agreement is the appropriate federal court for the Eastern District of Texas or state court located in Denton County, Texas. 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.
- **10. No Assignment**. Facility shall not assign any of its rights or obligations under this Agreement without the prior written consent of ABRET.
- **11. Successors**. This Agreement will be binding upon, and will inure to the benefit of, the parties and their respective permitted successors and assigns.
- **12. Sole Agreement**. 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.
- **13.** <u>Amendment</u>. No amendment of this Agreement will be valid unless in writing and signed by ABRET.
- **14.** <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.
- **15. 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.
- **16. 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".
- **17.** <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:Signature	By: Signature
Name:	Name:
Title:	Title:

ABRET ACCREDITATION POLICIES

ACCREDITATION DECISION REVIEW & 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 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.

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.

ABRET LAB 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.

ACCREDITATION TRADMARK 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.
- **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:
 - **A.** letterhead and business cards;
 - **B.** websites; and
 - **C.** advertisements, brochures, and other promotional materials.

4. Conditions of Use.

- **A.** 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.
- **B.** 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.
- **C.** 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.
- **D.** 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.

- E. 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.
- **F.** If accreditation ends, then the facility shall:
 - 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.
- **G.** The facility is responsible for correcting (at its expense) any outdated or otherwise inaccurate reference to active ABRET accreditation.
- 5. 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.
- 6. 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.
- **7. Further Information**. If an individual has a question regarding use of these marks, please contact ABRET.

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;
 - 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
 - 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.



ABRET LABORATORY ACCREDITATION LTM RECORD ID SHEET Epilepsy Monitoring

Date	
Hospital/Institution	
City, State	

Please complete the following information and submit the ID form with your recordings.

RECORD #:	Identifying number	Date(s) performed
1 – Long Term/EMU EEG With clinical events; clinical & electrographic seizures.		
2 - Long Term/EMU EEG With clinical events; clinical & electrographic seizures.		
3 – Long Term/EMU EEG With clinical events; clinical & electrographic seizures.		
4 – Random Recording Selected by ABRET Date requested:		
5 – Invasive Recording* With clinical and electrographic seizures.		

Pediatric Centers: One of the 1-3 records should be a vEEG on a patient under the age of 2 years.

*Invasive: The submitted record should be from a 24-hour continuous segment. An invasive map (manual, pictures, or image co-registration) and list of implanted electrodes with names and locations should be included.

Please double check and verify that your data is viewable before submission = i.e., you should run each study on a generic, Windows-based PC (not just on your review station). Make sure the review software opens the records properly, and that the software displays the data including instrument settings, impedances, montages, and all tech comments and annotations, or please include screenshots of each as necessary.

Please provide additional information/instructions as to how to use your particular reading software and if there are any nuances reviewers need to be aware of (passwords, etc.)

Please LABEL each Hard Drive/USB/DVD with your hospital's name.



ABRET LABORATORY ACCREDITATION LTM RECORD ID SHEET CC-EEG/ICU

Date	
Hospital/Institution	
State	

Please complete the following information and submit the ID form with your recordings.

RECORD #:	Identifying number	Date(s) performed
1 – ICU/CC EEG With electrographic seizure, with or without clinical correlate.		
2 - ICU/CC EEG With electrographic seizure, with or without clinical correlate.		
3 – Random Recording Selected by ABRET		
Date requested:		

Please double check and verify that your data is viewable before submission = i.e., you should run each study on a generic, Windows-based PC (not just on your review station). Make sure the review software opens the records properly, and that the software displays the data including instrument settings, impedances, montages, and all tech comments and annotations, or please include screenshots of each as necessary.

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