August 26, 2013

The Honorable Julie Harhart
Pennsylvania House of Representatives
313 Main Capitol Building
PO Box 202183
Harrisburg, PA 17120-2183

Dear Representative Harhart:

ASET – The Neurodiagnostic Society is the largest national professional association in the United States for individuals involved in the study and recording of electrical activity in the brain and nervous system. Our over 4,000 members include technologists, students, physicians and institutions involved in neurodiagnostics, which includes but is not limited to Electroencephalography (EEG), Evoked Potentials (EP), Nerve Conduction Studies (NCS), Polysomnography/Sleep Technology, Intraoperative Neurophysiological Monitoring (IONM), Long Term Monitoring (LTM), and Intensive Care Unit Continuous EEG Monitoring (ICU/cEEG).

We are writing to share our opposition to part of Senate Bill 137, the Speech-Language and Hearing Licensure Act. Specifically, we are concerned about language in the section on "Practice of audiology" which states:
"Areas of audiology practice include the following: ...

Section 3 (13) administration of electrophysiologic measures of neural function, including, but not limited to, sensory and motor-evoked potentials, preoperative and postoperative evaluation of neural function, neurophysiologic intraoperative monitoring of the central nervous system, spinal cord and cranial nerve function;"

Where others, such as audiologists, might be able to perfect <u>some</u> of the skills needed to perform <u>some</u> of these studies, these procedures are the primary focus of Neurodiagnostic professionals who are specifically educated, trained, skilled, and in many cases registered to perform Evoked Potentials (EP), Nerve Conduction Studies (NCS) and/or Intraoperative Neurophysiological Monitoring (IONM) in the operating room. Please refer to the attached national competency skill standards. IONM specifically requires a high degree of training and education in Neurology and Neurophysiology, particularly with regard to the interpretation of these studies. It is in the patients' best interest that only well qualified professionals conduct and monitor – and that interpretation of such neurodiagnostic testing remain the sole domain of the physician neurologists – in order to minimize devastating neurological surgical outcomes. The scope of practice for Audiology vis a vis neurophysiology intraoperative monitoring should only be to establish a base line electrical state and monitor whether that state remains unchanged over the course of surgery, providing the Audiologists is specifically trained in IONM.

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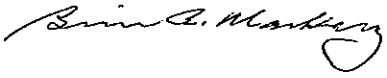
Section 3 (13) is overly broad. It includes a very broad array of techniques, and allows for audiologists to carry out independently a very broad set of medical tests. It would allow for persons to perform testing with far less skills, knowledge, abilities, training, and experience than the physicians they would be replacing. It establishes no clear minimum standards for the audiologists. Many could be trained to perform certain procedures, but licensed to perform a broad range of other medical procedures. Audiologists want to be trained to perform electromyography of the legs for lumbar spine surgery, which constitutes 40% of current intraoperative monitoring. Yet the same person would become licensed to guide a neurosurgeon during removal of cerebral cortex for epilepsy surgery, protecting the brain during open heart surgery, and giving medical advice during complications of any surgery. The section 3 (13) is overly broad, would allow audiologists to perform services far beyond the range of hearing and communications disorders, and beyond what any brand new type of allied health training program has been shown to accomplish.

Therefore, it is our position that IONM techniques should be restricted to persons, who have sufficient skills, knowledge, and abilities, based upon years of formal education, supervised training and experience. We ask that you consider amending Senate Bill 137 by removing the section described above before the final passage.

Thank you for your consideration of our request.

Sincerely,



Brian Markley, R. EEG/EP T., R.NCS.T.
President

BM/bh

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NATIONAL COMPETENCY SKILL STANDARDS FOR PERFORMING INTRAOPERATIVE NEUROPHYSIOLOGIC MONITORING

Intraoperative Neurophysiologic Monitoring (IONM) providers practice in accordance with the facility policy and procedure manual which details every aspect and modality of testing.

The ASET-The Neurodiagnostic Society presents this document to provide national criteria for evaluating competencies for performing intraoperative neurophysiologic monitoring (IONM).

Intraoperative neurophysiologic monitoring is an advanced level of practice in the neurodiagnostic field. Training and education should reflect this advanced level and achievement of recognized professional credentials should be accomplished.

These national competencies were established following analysis of survey data collected July thru August 2003, with tabulation completed by the ASET Executive Office. This document was updated according to nationally recognized and accepted criteria and approved by ASET's Board of Trustees in March 2011.

Basic knowledge and technical performance, as well as quality patient care and patient interaction, were considered. The technical components include standards of practice defined in the publications of the American Clinical Neurophysiology Society (ACNS) and the American Society of Neurophysiological Monitoring (ASNM). These resources are found on their respective websites: ACNS– www.acns.org; ASNM – www.asnm.org.

Section I: Intraoperative Neurophysiologic Monitoring Core Knowledge

Pre-surgical considerations

The IONM technologist:

- confirms procedure orders for surgical monitoring requested
- obtains relevant patient history
- verifies patient identity according to The Joint Commission Standards
- explains IONM procedure to the patient
- obtains or verifies informed consent for IONM
- reviews all IONM contraindications based on patient history and surgeon orders
- establishes and confirms an online HIPPA-compliant connection with the attending neurophysiologist
- determines monitoring and anesthetic preferences of attending neurophysiologist
- initiates pre-surgical communications with anesthesia team regarding these preferences
- selects montage(s) appropriate for surgical procedure being performed.

Select the appropriate instrumentation and settings
The IONM technologist:
•maintains equipment in good working order and confirms bi-annual maintenance checks have been performed according to the hospital's biomedical standards
•if using preprogrammed templates, is sure that the template for the selected surgery to be performed has appropriately set parameters
•ensures that averager and stimulator are functioning appropriately
•ensures that all stimulators are delivering expected stimuli to the correct site.

Operating room environment
The IONM technologist:
•follows standard precautions for infection control per facility policy and procedures
•avoids contamination of sterile drapes, personnel, instruments, etc.
•passes sterile electrodes to the surgical personnel in an approved sterile fashion
•places bloody or contaminated items in biohazard containers and sharps in a sharps container
•follows hazardous material management guidelines
•observes electrical and general safety precautions in connecting the patient to equipment by arranging cables and equipment to prevent injury.

Intraoperative Neuromonitoring
The IONM technologist:
•confers with the surgeon regarding structures at risk, modalities to be monitored, and documents the conversation
•communicates the IONM preferences of surgeon to the attending neurophysiologist and confirms the appropriateness of modalities to be monitored
•communicates IONM preferences to the anesthesia team and other operating room personnel in a clear, definite, and collegial manner and documents conversation(s)
•before the patient enters the operating room suite, and/or during intubation and prepping:
- sets up and confirms proper operation of all equipment
- applies electrodes (primary and backup) and secures placement
- tests equipment and checks integrity of electrodes by checking and documenting impedances
- arranges head box, cables, and electrodes for minimization of artifacts and electrical hazards preventing electrodes from being dislodged, dried out, or contaminated with fluids

•obtains initial responses and obligate peaks after induction and prior to incision and sets baselines as appropriate to the procedure; marks waveforms and calculates the absolute latencies, amplitudes, or inter-peak intervals at baseline
•sets or resets baselines as appropriate to the surgical procedure according to the facility policy and procedures, but in all cases prior to any part of the surgery that puts neural tissue at risk

•obtains an interpretation of baselines from the attending neurophysiologist and communicates the information to the surgeon
•throughout the surgery, reports any change in data which meets the alarm criteria outlined in the facility policy and procedure manual
•during the recording, changes methods of data collection as needed according to facility policies and procedures including:

- o adjusting stimulus rate as needed to reduce time-locked artifacts
- o establishing and documenting that stimulating parameters are within safe limits
- o recording from additional electrode derivations in case of technical problems in order to allow continuous recording
- o using a montage that records obligate peak responses from peripheral nerve, spinal cord, subcortical structures, and the cerebral cortex as appropriate.

•at the end of the procedure, removes and discards disposable supplies, especially sharps and contaminated items according to facility policies and procedures; cleans and disinfects equipment, cables, etc.

<u>During and throughout the procedure</u>
The IONM technologist documents:
•procedure
•modalities performed and areas monitored
•surgical maneuvers and events
•levels of inhaled anesthetics, dosage of intravenous anesthetics, and use of muscle relaxants
•blood pressure, temperature, and other physiologic parameters as appropriate
•any and all communications or warnings relevant to patient care:

- o with attending surgeon, surgeon replies, and corrective action taken
- o with attending neurophysiologist
- o with anesthesia team and/or other operating room personnel

•all technical problems and corrective troubleshooting steps performed
•and saves all data according to the practice of medical records retention in the state in which the surgery was performed
•exact time, obligate waveform labels, latencies, and amplitudes for all printed traces as detailed in the facility policy and procedures
•and prepares the documentation for the attending neurophysiologist according to facility policy and procedures.

<u>Intraoperative Communications/Data Analysis</u>
The IONM technologist:
•recognizes significant changes, according to facility alarm criteria, and alerts the surgeon and attending neurophysiologist as detailed in facility policy and procedures

- o if needed, notifies the surgeon that monitoring is momentarily interrupted for troubleshooting

•prepares technologist report of case for the attending neurophysiologist according to facility policy and procedures.

Section II: Knowledge and Skills

The IONM technologist understands:

•critical periods during the surgery when iatrogenic injury is most likely to occur and other points in surgery that could cause possible data changes.
•blood pressure and other physiologic factors
•surgical procedure being performed
•structures at risk
•unique surgical instruments and the effects of their use
•effects of corrective forces exerted by implanted instrumentation
•anatomy of monitored pathways, source of blood supply, electrode derivations, and generators of components and obligate waveforms
•pre-operative deficits, intraoperative injuries, and possible post operative outcomes
•waveform changes generated by ischemia, blood pressure, oxygen saturation, core and limb temperature
•how anesthetic and physiological changes affect desired patient data per modality including:

- o changes in concentration of volatile agents (MAC)
- o interactions between nitrous oxide and potent volatile anesthetics
- o unstable physiological factors such as changes in CO, Hemo/Hemato, blood pressure, and metabolic rates

•how the method of delivering anesthetics (inhalation, infusion, bolus injection, low flow inhalation, total intravenous) affects data
•modalities being performed and how to obtain desired data relative to anesthesia
•operating room etiquette in the following areas:

- o use of collodion, acetone, or other flammable materials
- o potentially bio-hazardous material
- o use of sharp electrodes
- o electrical safety issues related to:
  - types of recording and stimulating electrodes
  - cautery units and return grounding pads
  - other instruments that are connected to the patient
  - simultaneous multiple earth grounds and how equipment in the OR can create ground loops
  - use of new equipment in the OR (bio-med checks at individual hospitals)
  - placement of other equipment (blood warmers, microscopes, etc.) effects on the quality of the intraoperative recording
  - placement of power cords relative to other equipment.

The IONM technologist maintains and improves knowledge, skills, and professional stature by any or all of the following:
•hospital in-service programs, especially post-operative review of monitored surgical cases with attending neurophysiologist
•reading books and journal articles
•attending professional meeting, seminars, and online education opportunities
•providing education to staff members
•participating in research activities
•other educational opportunities that become available
•achieving intraoperative neuromonitoring certification and meeting recertification requirements.

Section III: Modalities

As detailed in the facility policy and procedure manual, during the intraoperative neurophysiological monitoring, the IONM technologist:
•discusses anesthetic recommendations for monitoring, in a definitive but cordial manner, with anesthesia staff
•ensures that the data collection portion of the IONM instrument and stimulators are correctly synchronized
•ensures that all stimulators are correctly delivering expected stimuli to the selected side
•chooses the appropriate stimulus rate and adjusts as needed to reduce time-locked artifacts
•has knowledge of stimulation rate and number of averages to obtain the greatest amount of data in the shortest amount of time
•establishes and documents that stimulating parameters are within safe limits
•recognizes, documents, and attempts to eliminate or reduce all artifacts
•establishes baseline values prior to induction of anesthesia and positioning of the patient, if appropriate (as in cases of unstable cervical spine)
•reestablishes baselines accordingly to facility policy and procedures
•performs electrographic measurement of muscle relaxant agents on compound muscle action potentials with techniques used in peer-reviewed scientific literature to ensure that levels are adequate for monitoring motor pathways
•monitors continuously during critical periods of the procedure, documents evoked potential tracings at frequent intervals as directed by facility policy and procedures
•archives data:
- o preserves and archives data based on the facility policy and procedures
- o makes electronic as well as hard copy print outs of data for documentation purposes

- o even in the absence of significant changes, documents waveforms along with descriptions of surgical events.

Intraoperative electroencephalography (EEG)
The IONM technologist:
•selects montage(s) appropriate for surgical procedure being performed according to facility policy and procedures
•selects the appropriate instrumentation settings according to facility policy and procedures and makes instrument changes as appropriate
•recognizes, documents, and attempts to eliminate or reduce all artifacts
•monitors appropriate evoked potential modalities and physiological characteristics appropriate to the EEG monitoring
•understands necessity of recording activity pre-position and post-position of the patient's head
•establishes a preoperative post-anesthetic baseline prior to incision and re-establishes that baseline if necessary
•recognizes and documents all EEG patterns during the monitoring and explains the relevance of the underlying patterns to the performance of IONM monitoring
•recognizes significant EEG changes, according to facility alarm criteria, and alerts the surgeon and attending neurophysiologist as detailed in facility policy and
•procedure documents warnings to surgeon and surgeon's response, as well as any corrective action and/or recovery, following facility policy and procedures.

Spontaneous or evoked electromyography (EMG)
The IONM technologist:
•has knowledge of anesthetic techniques preventing inhibition of neuromuscular junction transmission
•performs electrographic measurement of muscle relaxant agents on compound muscle action potentials with techniques used in peer-reviewed scientific literature to ensure that levels are adequate for monitoring motor pathways
•selects appropriate recording parameters and montage for EMG
•is aware of the resistance to neuromuscular blockade relative to body location
•is aware of the effects of other nonmuscle relaxing agents such as some vancomycin, blood pressure lowering agents, and magnesium
•understands anatomy and physiology of muscles relative and at risk to surgery performed
•understands the appropriate use and safety issues related to subdermal needle electrodes
•recognizes significant EMG activity and alerts the surgeon and attending neurophysiologist according to facility policy and procedures
•understands rate of stimulation relative to neuromuscular blockade during evoked EMG
•uses safety precautions with regard to duration and intensity when performing direct nerve stimulation.

Motor cranial nerve recording
The IONM technologist:
•selects appropriate recording parameters and montage for EMG
•applies needle, adhesive electrodes, or hook-wire recording electrodes to the appropriate muscles to record spontaneous and evoked EMG responses from the specific nerves
•tests impedance and recording function prior to prepping and draping
•performs electrographic measurement of muscle relaxant agents on compound muscle action potentials with techniques used in peer-reviewed scientific literature to ensure that levels are adequate for monitoring motor pathways
•ensures neuromuscular blockade level complies with facility policy and procedures
•monitors the ongoing EMG through a loudspeaker or earphone which provides continuous auditory feedback
•provides an appropriate sterile stimulating probe according to the surgeon's preference
•selects appropriate stimulus intensity, duration, and polarity to produce an appropriate muscle response from the cranial nerve being stimulated while being cognizant of patient safety issues
•records spontaneous free-running EMG, signal-triggered EMG, and evoked CMAPs
•informs the attending surgeon of spontaneous activity, mechanical stimulation of the nerve and results of nerve stimulation
•recognizes significant EMG changes, according to facility alarm criteria, and alerts the surgeon and attending neurophysiologist as detailed in the facility policy and procedures
•documents surgical events, warnings to surgeon, etc., as stated in the facility policy and procedures.

Spinal Screw and Direct Nerve Stimulation – Threshold Testing
The IONM technologist:
•selects appropriate recording parameters and montage for EMG
•applies needle, adhesive electrodes, or hook-wire recording electrodes to the appropriate muscles to record spontaneous and evoked EMG responses from the specific nerves
•tests impedance and recording function prior to prepping and draping
•performs electrographic measurement of muscle relaxant agents on compound muscle action potentials with techniques used in peer-reviewed scientific literature to ensure that levels are adequate for monitoring motor pathways
•ensures neuromuscular blockade level complies with facility policy and procedures
•monitors the ongoing EMG through a loudspeaker or earphone which provides continuous auditory feedback

•provides an appropriate sterile stimulating probe according to the surgeon's preference
•selects appropriate stimulus intensity, duration, and polarity to produce an appropriate muscle response from the screw or nerve being stimulated while being cognizant of patient safety issues
•is aware of how excessive fluid in the sterile field can cause stimulus shunting and the effect it may have on threshold levels
•records spontaneous free-running EMG, signal-triggered EMG, and evoked CMAPs
•informs the attending surgeon of spontaneous activity, mechanical stimulation of the nerve and results of nerve stimulation
•documents surgical events, screw threshold levels, warnings to surgeon, etc., as stated in the facility policy and procedures.

Intraoperative somatosensory evoked potential (SSEP)
The IONM technologist:
•maintains appropriate stimulating electrode impedance and assures proper stimulation by decreasing stimulus artifact
•maintains appropriate recording electrode impedance, relatively balanced and below 5000 Ohms to ensure properrecording and decrease artifact
•uses a montage that records obligate peak responses from peripheral nerve, spinal cord, subcortical structures, and the cerebral cortex as appropriate
•records from electrodes overlying the scalp surface, peripheral sites of mixed nerves, and from electrodes placed in the spinous process or epidural spaces
•marks waveforms and calculates the absolute latencies, amplitudes, and/or inter-peak intervals at baseline and throughout the monitoring procedure
•is prepared to use alternative stimulating or recording paradigms in order to compensate for complex technical problems.

Localization of sensorimotor cortex
The IONM technologist:
•obtains a relevant patient history
•obtains a pre-incision baseline with surface electrodes to confirm function of the somatosensory pathway and approximate latency of the N20 peak
•selects appropriate timebase, sensitivity, and band pass settings
•selects the appropriate stimulation site (normally, contralateral median nerve)
•uses appropriate electrodes placed or manipulated by surgeon
•prepares stimulus site to reduce stimulating electrode impedance
•monitors subcortical peripheral nerve site to verify stimulus effect
•uses a referential and bipolar montage that records direct cortical responses and allows identification a "phase reversal" and amplitude gradients
•obtains adequate resolution of the obligate waveform components
•records from multiple cortical sites inorder to obtain adequate localization

•prints out a hard copy of simultaneous or sequentially recorded SSEPs for the purpose of studying the amplitude gradient and polarity of the responses in relation to the location of the gyri.

Intraoperative brainstem auditory evoked potential (BAEP)
The IONM technologist:
•establishes hearing threshold and documents any existing hearing loss or condition of ear structures
•uses molded ear speakers or insert transducers to avoid contamination of the surgical field
•uses waterproof adhesive tape, Tegaderm™, and/or bone wax to protect the ear speaker and ear canal from blood or fluids
•chooses the appropriate montage, timebase, number of stimuli, sensitivity, and band pass settings
•understands use of condensation, rarefaction, and alternating click to obtain best response as appropriate
•uses an appropriate stimulus intensity based on facility policy and procedures and adjusts intensity based on patient hearing assessment
•has knowledge of the adverse effects on peak components that changing the stimulus rate has and can only adjust the stimulus rate according to facility policy and procedures
•uses an appropriate stimulus rate to resolve the most important BAEP components and maintains the same rate throughout that obtains the most data in the shortest amount of time
•obtains adequate resolution of obligate component(s) waves I, III, and V
•measures and calculates the absolute latencies, amplitudes and inter-peak intervals of obligate peaks at baseline and throughout monitoring
•masks the contralateral ear with appropriate white noise intensity
•continuously monitors the ear ipsilateral to surgical intervention (contralateral ear monitoring is also appropriate for large posterior fossa tumors, or as a control)
•during certain posterior fossa procedures, records direct nerve action potentials from the 8th cranial nerve simultaneously with the BAEPs by:

- providing the surgeon with a sterile direct nerve electrode for placement on the exposed 8th cranial nerve
- communicates to the surgeon the correct placement of the recording electrodes
- using the same auditory clicks to stimulate the ipsilateral ear at the same intensity and stimulus rate as that used with the BAEPs
- using a montage referencing the direct nerve electrode to the ipsilateral ear
- selecting appropriate timebase and recording sensitivity to record these high amplitude responses

- o reporting significant changes in morphology, latency and amplitude of these responses as outlined in the facility policy and procedures.

Intraoperative transcranial electrical motor evoked potentials (TCeMEP)
The IONM technologist:
•reviews the patient's history/physical checking for medical conditions which may contraindicate the use of TCeMEPs; reviews these findings with the attending neurophysiologist
•chooses the appropriate stimulation sites by measuring the head using the International 10–20 System of electrode placement
•applies stimulating electrodes that are below 5000 Ohms and balanced
•chooses the appropriate muscles to be monitored based on the surgical procedure being performed
•securely applies recording electrodes that are below 5000 Ohms and balanced to ensure proper recording of the muscle activity
•collaborates with the anesthesia team to ensure the proper anesthetic regimen for protocol being used
•collaborates with the anesthesia team to ensure that appropriate mouth and tongue protection is in place according to facility policy and procedures
•chooses the appropriate stimulation parameters including, intensity, duration, and frequency of stimulation delivery
•recognizes significant change, according to facility alarm criteria, and alerts the surgeon and attending neurophysiologist as detailed in the facility policy and procedures.

-- Approved by ASET Board of Trustees, March 2011