COLORADO

Department of Regulatory Agencies

Colorado Office of Policy, Research & Regulatory Reform

2023 Sunrise Review

Intraoperative Neurophysiological Monitoring Technologists

June 30, 2023

COLORADO
Department of Regulatory Agencies
Executive Director's Office

June 30, 2023

Members of the Colorado General Assembly
c/o the Office of Legislative Legal Services
State Capitol Building
Denver, Colorado 80203

Dear Members of the General Assembly:

The General Assembly established the sunrise review process in 1985 as a way to determine whether regulation of a certain profession or occupation is necessary before enacting laws for such regulation and to determine the least restrictive regulatory alternative consistent with the public interest. Pursuant to section 24-34-104.1, Colorado Revised Statutes (C.R.S.), the Colorado Office of Policy, Research and Regulatory Reform (COPRRR) at the Department of Regulatory Agencies (DORA) undertakes a robust review process culminating in the release of multiple reports each year on June 30 and December 31.

A national leader in regulatory reform, COPRRR takes the vision of their office, DORA and more broadly of our state government seriously. Specifically, COPRRR contributes to the strong economic landscape in Colorado by ensuring that we have thoughtful, efficient and inclusive regulations that reduce barriers to entry into various professions and that open doors of opportunity for all Coloradans.

As part of this year's review, COPRRR has completed its evaluation of the sunrise application for the regulation of Intraoperative Neurophysiological Monitoring technologists and is pleased to submit this written report.

The report discusses the question of whether there is a need for regulation in order to protect the public from harm, whether regulation would serve to mitigate the harm and whether the public can be adequately protected by other means in a more cost-effective manner.

To learn more about the sunrise review process, among COPRRR's other functions, visit coprrr.colorado.gov.

Sincerely,

Patty Salazar
Executive Director

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Background

Sunrise Process

Colorado law, section 24-34-104.1, Colorado Revised Statutes (C.R.S.), requires that individuals or groups proposing legislation to regulate any occupation or profession first submit information to the Department of Regulatory Agencies (DORA) for the purposes of a sunrise review.

The intent of the law is to impose regulation on occupations and professions only when it is necessary to protect the public health, safety, or welfare. DORA's Colorado Office of Policy, Research and Regulatory Reform (COPRRR) must prepare a report evaluating the justification for regulation based upon the criteria contained in the sunrise statute:[1]

> (I) Whether the unregulated practice of the occupation or profession clearly harms or endangers the health, safety, or welfare of the public;
>
> (I.5) Whether the practitioners of the profession or occupation exercise independent judgment, and whether the public can reasonably be expected to benefit from the direct regulation of the profession or occupation if a practitioner's judgment or practice is limited or subject to the judgment or supervision of others;
>
> (II) Whether the public needs, and can be reasonably expected to benefit from, an assurance of initial and continuing professional or occupational competence;
>
> (III) Whether the public can be adequately protected by other means in a more cost-effective manner; and
>
> (IV) Whether the imposition of any disqualifications on applicants for licensure, certification, relicensure, or recertification based on criminal history serves public safety or commercial or consumer protection interests.

Any professional or occupational group or organization, any individual, or any other interested party may submit an application for the regulation of an unregulated occupation or profession. Applications must include a description of the proposed regulation and justification for such regulation.

Methodology

During the sunrise review, COPRRR staff performed a literature search, interviewed the sunrise applicant, contacted regulators in Colorado, contacted state and national associations, reviewed laws in other states, and interviewed stakeholders.

[1] § 24-34-104.1(4)(b), C.R.S.

Profile of the Profession

What is Intraoperative Neurophysiological Monitoring?

Intraoperative Neurophysiological Monitoring (IONM) is a technique that provides monitoring of a patient's nervous system during a variety of surgical procedures.[2] The purpose behind the use of IONM is the prevention or reduction of neurological damage to a patient's nervous system using early intervention when a signal change is detected,[3] and the utilization of IONM in surgical procedures has continued to grow over the past few decades to more than 500,000 cases per year.[4]

IONM is currently used in surgeries in which the nervous system may potentially be impacted, including:[5]

- Spine and spinal cord surgeries,
- Brain and brain stem surgeries,
- Cerebrovascular surgeries,[6]
- Thyroid surgeries, and
- Nerve repair surgeries.

Additionally, IONM may be utilized in a variety of other procedures including vascular, orthopedic, and cardiothoracic[7] surgical procedures.[8]

Examples of neurological damage that may occur in surgeries where nerves may be impacted include, but are not limited to, hearing loss, muscle weakness, and paralysis.[9] Additionally, reduced functioning in facial nerves can cause a reduced ability to speak, or the inability to blink or produce tears.[10]

[2] Jay L. Shils, PhD, DABNM, FASNM, FACNS, et al., (2015), "Intraoperative Neuromonitoring," *International Anesthesiology Clinics*, 53 (1), p. 53.
[3] Dipti Ghatol, et al., *Intraoperative Neurophysiological Monitoring*, StatPearls Publishing (2023), p. 1.
[4] Stan Skinner, MD, et al., (2017), "Communication and Collaboration in Spine Neuromonitoring: Time to Expect More, a Lot More, from the Neurophysiologists," *Journal of Neurosurgery Spine*, 27, p. 3.
[5] Dipti Ghatol, et al., *Intraoperative Neurophysiological Monitoring*, StatPearls Publishing, (2023), p. 3.
[6] Cerebrovascular surgical procedures relate to blood vessels that supply oxygen to the brain.
[7] Cardiothoracic surgical procedures are performed on organs in the chest cavity, including the heart.
[8] Eva Katharina Ritzl, MD, FRCP, (2012), "Is Intraoperative Neuromonitoring a Good Idea in My Practice?" *Neurology Clinical Practice*, 2 (2), p. 2.
[9] University of Texas at Dallas. *Frequently Asked Questions about the: "Neurological Diagnosis and Monitoring Specialization Area."* Retrieved May 2, 2023, from personal.utdallas.edu/~golden/ionm/
[10] Taemin Oh, BA, et al., (2012), "Intraoperative Neuromonitoring Techniques in the Surgical Management of Acoustic Neuromas," *Neurosurg Focus*, 33 (3), p. 2.

During IONM-related procedures, IONM technologists perform their work under the supervision of an IONM-trained physician such as a neurologist or physiologist[11] and are required to function on an IONM team in tandem with the entire intraoperative team, including the surgeon, the anesthesia team, and other operating room personnel.[12]

In the operating room setting, effective communication and collaboration between the IONM technologist, the supervising physiologist or neurologist, the surgery team, and the anesthesiology team is critical during the surgical procedure.[13] Any signal loss in the nerves being monitored requires quick and effective troubleshooting and communication to prevent neurologic damage.[14]

Prior to the surgical procedure, the IONM team discusses the IONM monitoring process as well as any risks associated with the IONM monitoring procedure with the patient. The IONM team also discusses the plan related to anesthesia with the anesthesia team and sets up the IONM monitoring equipment in the operating room prior to the arrival of the patient.[15]

The IONM monitoring systems contain different channels that allow for different types of monitoring, depending upon what is needed for the specific procedure. When in use, the monitoring system relays a constant stream of data and records the neurologic signals being monitored in the form of waveforms. The IONM monitoring system can also stimulate specific muscles and nerves.[16]

When the operating room setup occurs, the IONM technologist typically attaches electrodes to the anesthetized patient, and then the electrodes are attached via corresponding wires to the appropriate inputs in the IONM monitoring equipment.

Several types of electrodes may be utilized to monitor specific nerves and muscles. Depending on the type of IONM being performed and the location on the body where the electrodes are being attached, an invasive procedure may be required to attach them. For example, needle electrodes may be inserted into a muscle to monitor that specific muscle's activity, and electrodes shaped like a small corkscrew may be inserted into the scalp for certain procedures.

[11] University of Texas at Dallas. Frequently Asked Questions about the: "Neurological Diagnosis and Monitoring Specialization Area." Retrieved May 2, 2023, from personal.utdallas.edu/~golden/ionm/
[12] Dipti Ghatol, et al., *Intraoperative Neurophysiological Monitoring*, StatPearls Publishing, (2023), p. 5.
[13] Dipti Ghatol, et al., *Intraoperative Neurophysiological Monitoring*, StatPearls Publishing, (2023), p. 8.
[14]Eva Katharina Ritzl, MD, FRCP, (2012), "Is Intraoperative Neuromonitoring a Good Idea in My Practice?" *Neurology Clinical Practice*, 2 (2), p. 4.
[15] Dipti Ghatol, et al., *Intraoperative Neurophysiological Monitoring*, StatPearls Publishing, (2023), p. 5.
[16] Dipti Ghatol, et al., *Intraoperative Neurophysiological Monitoring*, StatPearls Publishing, (2023), pp. 4-5.

IONM Monitoring and Anesthesia

The IONM team and the anesthesia team collaborate throughout the procedure, and often rely on information from one another to deliver care.

For example, anesthesia doses can be adjusted to support the optimization of IONM signals.[17]

Since anesthesia can change a variety of physiological states in the patient—such as intracranial pressure, cerebral blood flow, or blood pressure—it is important that the IONM team and the anesthesia team communicate effectively at the beginning of the procedure regarding the anesthesia that will be utilized.[18]

Supervision of the IONM Technologist

During the procedure, the IONM technologist and the supervising IONM-trained physician are constantly monitoring and communicating with one another regarding the signals received from the monitored nerves and muscle groups, looking for any changes in signal strength which could potentially indicate a problem.

Further, the IONM technologist must be present in the operating room for the entire length of the procedure under continuous supervision of the IONM-trained physician.[19]

The IONM-trained physician may be located on-site where the procedure is being performed or may be engaged remotely at an off-site location. However, the IONM-trained physician must be able to consistently communicate with the IONM technologist for the duration of the procedure.[20] Additionally, a supervising physician may be able to monitor several procedures simultaneously in real time,[21] and off-site monitoring of multiple cases at one time is often the way in which an IONM-trained physician provides IONM monitoring supervision.[22] If not physically present for the procedure, supervision may occur via an on-site intranet or through a web-based connection.[23]

[17] Dipti Ghatol, et al., *Intraoperative Neurophysiological Monitoring*, StatPearls Publishing, (2023), p. 8.
[18] Jay L. Shils, PhD, DABNM, FASNM, FACNS, et al., (2015), "Intraoperative Neuromonitoring," *International Anesthesiology Clinics*, 53(1), p.54.
[19] Eva Katharina Ritzl, MD, FRCP, (2012), "Is Intraoperative Neuromonitoring a Good Idea in My Practice?" *Neurology Clinical Practice*, 2 (2), p. 5.
[20] Eva Katharina Ritzl, MD, FRCP, (2012), "Is Intraoperative Neuromonitoring a Good Idea in My Practice?" *Neurology Clinical Practice*, 2 (2), p. 5.
[21] Eva Katharina Ritzl, MD, FRCP, (2012), "Is Intraoperative Neuromonitoring a Good Idea in My Practice?" *Neurology Clinical Practice*, 2 (2), p. 2.
[22] Stan Skinner, MD, et al., (2017), "Communication and Collaboration in Spine Neuromonitoring: Time to Expect More, a Lot More, from the Neurophysiologists," *Journal of Neurosurgery Spine*, 27, p. 1.
[23] Stan Skinner, MD, et al., (2017), "Communication and Collaboration in Spine Neuromonitoring: Time to Expect More, a Lot More, from the Neurophysiologists," *Journal of Neurosurgery Spine*, 27, p. 3.

While IONM technologists are looking for any change in the signal that might indicate a reduction in signal strength or loss of signal, they are not permitted to interpret what the change of signal may mean; this is the role of the supervising physician.[24]

Common Types of IONM Monitoring

The most common types of IONM monitoring include: [25]

- Electromyography (EMG),
- Somatosensory sensory evoked potential (SSEP), and
- Motor-evoked potential (MEP).

EMG may be used to monitor functioning of the cranial nerve, spinal cord, or nerve roots, and may be utilized in procedures, including spinal surgeries, skull base tumors, and neck surgeries including thyroid surgery.[26]

SSEP and MEP may be used in a variety of procedures, including, spine and spinal cord surgeries, brain and brainstem surgeries, cerebrovascular surgeries, thyroid surgeries, and pelvic fracture surgeries.[27]

Additionally, MEP testing uses an electrical stimulus at a low amplitude to receive a neuronal response.[28] When utilized, MEPs may provide feedback in real-time, which can be used to alert anesthesia and operative staff regarding the potential of neurological injury. Further, surgeons often request that MEP tests be performed to detect any changes in the monitored signals.[29]

In general, IONM monitoring during the procedure may focus on three specific elements of the signals produced:[30]

- The height or amplitude of the response received in comparison with the baseline or between the highest and lowest recorded points;
- The latency, or length of time to receive a response; and
- The shape of the wave being monitored.

IONM Technologist Certification

Non-certified IONM technologists predominantly receive on-the-job training from the company that hires them, and the depth and quality of the training received may vary.

[24] University of Texas at Dallas. *Frequently Asked Questions about the: "Neurological Diagnosis and Monitoring Specialization Area."* Retrieved May 2, 2023, from personal.utdallas.edu/~golden/ionm/
[25] Dipti Ghatol, et al., *Intraoperative Neurophysiological Monitoring*, StatPearls Publishing, (2023), p. 5.
[26] Dipti Ghatol, et al., *Intraoperative Neurophysiological Monitoring*, StatPearls Publishing, (2023), p. 4.
[27] Dipti Ghatol, et al., *Intraoperative Neurophysiological Monitoring*, StatPearls Publishing, (2023), p. 3.
[28] Dipti Ghatol, et al., *Intraoperative Neurophysiological Monitoring*, StatPearls Publishing, (2023), p. 5.
[29] Alexander Doyal, et al., *Motor Evoked Potential*, StatPearls Publishing, 2023, p. 3.
[30] Jay L. Shils, PhD, DABNM, FASNM, FACNS, et al., (2015), "Intraoperative Neuromonitoring," *International Anesthesiology Clinics*, 53 (1), p. 54.

The American Board of Registration of Electroencephalographic and Evoked Potential Technologists (ABRET) offers a certification for IONM technologists, referred to as the Certification for Neurophysiologic Intraoperative Monitoring (CNIM).

This certification is designed for technologists in the neurodiagnostic field and also for those technologists who are formally trained and already working within the field of IONM.[31]

CNIM certification may be obtained utilizing one of four different pathways that combine examination, education, and experience:[32]

- Pathway 1 – A diploma is required from a health-related educational program accredited by the Commission on Accreditation of Allied Health Education Programs. Additionally, the candidate must supply documentation of 100 IONM cases and be certified in Cardiopulmonary Resuscitation (CPR) or Basic Life Support (BLS);
- Pathway 2 - Current certification as an Electroencephalographic Technologist or as an Evoked Potential Technologist is required. Additionally, the candidate must supply documentation of 150 IONM cases and must be certified in CPR or BLS;
- Pathway 3 – This pathway requires a bachelor's degree or higher in addition to the documentation of 150 IONM cases. Further, the candidate must complete 30 intraoperative monitoring educational hours, which must be obtained through the American Society of Electroencephalographic Technicians (ASET), the American Society of Neurophysiological Monitoring (ASNM), or the American Clinical Neurophysiology Society (ACNS). Additionally, the candidate must be certified in CPR or BLS; or
- Pathway 4 - This pathway requires a certificate of completion from an ABRET-recognized program, as well as the documentation of 150 IONM cases. Additionally, the candidate must be certified in CPR or BLS.

Each pathway listed above requires documentation of a varying number of IONM cases that must be completed in order to receive certification. ABRET requires that in each case submitted for documentation, the candidate must be the primary technologist establishing the setup, monitoring, and troubleshooting, although oversight is typically provided by another, more experienced IONM technologist in a supportive role.

Additionally, intraoperative monitoring educational hours are required for those who pursue entry into the profession utilizing Pathway 3.

[31] *Handbook for Candidates: Certification for Neurophysiologic Intraoperative Monitoring – CNIM*, ABRET Neurodiagnostic Credentialling and Accreditation (2023), p. 1. Retrieved January 9, 2023, from abret.org/resources/handbooks/

[32] *Handbook for Candidates: Certification for Neurophysiologic Intraoperative Monitoring – CNIM*, ABRET Neurodiagnostic Credentialling and Accreditation (2023), p. 2. Retrieved January 9, 2023, from abret.org/resources/handbooks/.

In order to begin the application process, the candidate must provide an application to ABRET and must indicate the educational pathway under which the candidate is applying. Further, the candidate must pay the examination fee of $700.[33] Once ABRET determines that application and eligibility requirements have been met, registration for the candidate's examination will be sent to Prometric which administers the examination for CNIM certification.[34]

Additionally, there are several other certification types available to professionals who work in specialized areas relating to IONM. These specialty certifications may also allow the practitioner to perform work as an IONM technologist. However, stakeholders have indicated that the CNIM is widely considered the standard for evaluating technical competency and is also considered the baseline certification for IONM technologists.

Although there are several non-accredited training programs for IONM in Colorado, there are no accredited schools for IONM located within the state.

Certification Examination Content

The certification examination for the CNIM is multiple-choice and computer-based, with a total testing time of approximately four hours. Content areas of the examination are focused on the following categories:[35]

- Preparation and Application of Fundamental Concepts – 25 percent;
- Intraoperative Phase – 25 percent;
- Post-operative Phase – 13 percent;
- Provider Communication and Documentation – 27 percent; and
- Safety and Ethics – 10 percent.

Upon passing the required examination, the candidate will be awarded the CNIM certification. Once certified, renewal is required every five years,[36] and the cost of recertification is $100.[37]

[33] *Handbook for Candidates: Certification for Neurophysiologic Intraoperative Monitoring – CNIM*, ABRET Neurodiagnostic Credentialling and Accreditation (2023), p. 4. Retrieved January 9, 2023, from abret.org/resources/handbooks/
[34] *Handbook for Candidates: Certification for Neurophysiologic Intraoperative Monitoring – CNIM*, ABRET Neurodiagnostic Credentialling and Accreditation (2023), p. 4. Retrieved January 9, 2023, from abret.org/resources/handbooks/
[35] *Handbook for Candidates: Certification for Neurophysiologic Intraoperative Monitoring – CNIM*, ABRET Neurodiagnostic Credentialling and Accreditation (2023), p. 9. Retrieved January 9, 2023, from abret.org/resources/handbooks/
[36] *Handbook for Candidates: Certification for Neurophysiologic Intraoperative Monitoring – CNIM*, ABRET Neurodiagnostic Credentialling and Accreditation (2023), p. 2. Retrieved January 9, 2023, from abret.org/resources/handbooks/
[37] ABRET – The Neurodiagnostic Society. *Recertification FAQs.* Retrieved May 12, 2023, from abret.org/recertification/recertification-faq/

Recertification

Renewal for CNIM certification takes place every five years, and the certified IONM technologist must complete certain requirements prior to applying for recertification.

Two pathways exist for recertification:[38]

1. Continuing Education – The certified IONM technologist must submit evidence of the completion of 50 hours of continuing education by the fifth year of their certification; or
2. Examination – Certified IONM technologists may elect to complete the examination application, pay the examination fee, and retake the CNIM examination while the certified IONM technologist is still within the recertification grace period, prior to January 31.

CNIM Disciplinary Process

ABRET has established a code of ethics, referred to as principles, for all of ABRET's credentialled professions, including CNIM-certified IONM technologists. The principles provided by ABRET include:[39]

- Remaining up to date on current technology and learning about and applying scientific advancements in the relevant field of study;
- Refusing primary responsibility for the *interpretation* [emphasis added] of testing or monitoring relating to functions including Neurophysiologic Intraoperative Monitoring;
- Abiding by any laws relating to the profession or public health and safety, and avoiding dishonest, illegal, or unethical practices; and
- Remaining in compliance with ABRET's rules.

ABRET also has an established complaint process for CNIM-certified IONM technologists. Further, ABRET may suspend, deny, revoke, or take additional disciplinary actions regarding an application or certification, and grounds for discipline include, but are not limited to:[40]

- Misrepresenting certification status;
- Failing to provide any requested information in a timely manner;
- Failing to inform ABRET regarding any changes or adverse actions;
- Being impaired while working due to habitual use of drugs, alcohol, or any other substance, or impairment of professional performance due to any mental or physical condition;
- Engaging in gross or repeated negligence or malpractice in professional work;

[38] *Recertification Handbook*, ABRET Neurodiagnostic Credentialling and Accreditation (2019), pp. 3-5. Retrieved May 12, 2023, from abret.org/recertification/
[39] ABRET Diagnostic Credentialing and Accreditation. *Principles.* Retrieved May 18, 2023, from abret.org/about/principles/
[40] ABRET Diagnostic Credentialing and Accreditation. *Ethics and Professional Conduct.* Retrieved May 18, 2023, from abret.org/about/ethics-professional-conduct/

- Failing to comply with laws regarding the profession or the public health and safety;
- Accepting primary responsibility for the interpretation of monitoring to provide a clinical diagnosis and/or treatment;
- Being convicted of, or pleading guilty or *nolo contendere* to a felony or misdemeanor related to public health and safety, or to the profession; and
- Having any disciplinary action from any licensing board or professional organization other than ABRET.

ABRET has provided information regarding violations that occurred recently relating specifically to IONM technologists. These violations include:

- Taking pictures in the operating room,
- Falsifying documentation,
- Fraudulently using the CNIM credential, and
- Being Intoxicated.

According to ABRET, none of these recent disciplinary actions involved CNIMs with a Colorado address, nor were any complaints received in the past year related to CNIM-certified IONM technologists with Colorado addresses.

Discipline by ABRET does not directly impact the ability of an IONM technologist to continue to work in the field. Discipline only impacts their status as a certificate holder.

CNIM Certification in Colorado

The number of IONM technologists that are not certified and perform IONM work within the state of Colorado is unknown.

However, according to ABRET, 5,249 CNIM certifications have been awarded nation-wide, and there are currently a total of 166 CNIM-certified IONM technologists with Colorado addresses. It should be noted that IONM companies often operate in several, or even many states. Therefore, it is unknown if the number of reported CNIM-certified IONM technologists with Colorado addresses actually perform work within the state.

Conversely, the number of IONM technologists who do not reside in Colorado but perform IONM work within the state is also unknown.

Proposal for Regulation

Assure Neuromonitoring (sunrise applicant) submitted a sunrise application to the Colorado Office of Policy, Research and Regulatory Reform in the Department of Regulatory Agencies for review consistent with section 24-34-104.1, Colorado Revised Statutes (C.R.S.). The application identifies licensure of Intraoperative Neurophysiological Monitoring (IONM) technologists as the appropriate level of regulation. The sunrise applicant further proposes that certification by the American Board of Registration of Electroencephalographic and Evoked Potential Technologists (ABRET) be required as a condition of licensure.

Additionally, the sunrise applicant has proposed that a limited "grandfather clause" be included in order to allow licensure for IONM technologists with substantial pre-existing experience.

According to the sunrise applicant, IONM technologists provide critical services during surgical procedures that utilize IONM, which are often high-risk in nature. The sunrise applicant further states that a lack of competent training can lead to catastrophic outcomes for a patient, which may include nerve damage, paralysis, and death.

The sunrise applicant maintains that licensing IONM technologists and requiring that each licensee be certified by ABRET would help to ensure that all practitioners of the profession would be duly qualified to perform IONM, and may increase the supply of IONM technologists, since more individuals may choose to enter the profession once it is a licensed profession.

Further, the sunrise applicant states that providing a pathway to licensure would allow IONM technologists to receive uniform training to ensure that practitioners can perform their duties with minimal competency.

Summary of Current Regulation

Federal Laws and Regulations

Currently, there are no federal laws requiring Intraoperative Neurophysiological Monitoring (IONM) technologists to be licensed, certified or registered, and no regulations are known to be specifically applicable to this profession.

However, stakeholders have indicated that third party payors may have requirements regarding the utilization of a supervising physician or credentialling in some instances.

The Colorado Regulatory Environment

The State of Colorado does not currently regulate IONM technologists, although the state does regulate many of the professionals with whom IONM technologists work, including supervising physicians, as well as many of the facilities in which they work.

Regulation in Other States

No other states currently regulate IONM technologists.

Analysis and Recommendations

Public Harm

Sunrise criterion I asks:

> Whether the unregulated practice of the occupation or profession clearly harms or endangers the health, safety, or welfare of the public.

In order to determine whether the regulation of Intraoperative Neurophysiological Monitoring (IONM) technologists is necessary, the Colorado Office of Policy, Research and Regulatory Reform (COPRRR) staff requested that the Assure Neuromonitoring (sunrise applicant) and other stakeholders provide specific examples of harm.

Due in part to the privacy requirements of the Health Insurance Portability and Accountability Act (HIPAA), some of the examples were anecdotally provided to protect the anonymity of the patient. Additionally, stakeholders who provided examples had first-hand knowledge in some instances. Other examples were provided in a variety of formats, including literature reviews, legal cases, and medical journals. Additionally, some examples were located through COPRRR's own research, and the narrative that follows is a compilation of evidence obtained from multiple sources.

In general, all of these examples can be categorized into groups of similar cases, relating to:

- Lack of communication during the procedure in which IONM was utilized,
- Lack of documentation regarding the IONM monitoring,
- Lack of supervision of IONM technologists during a surgical procedure,
- Improper set up of IONM equipment, and
- Billing issues related to IONM services.

Lack of Communication

Two specific cases are offered in consideration of this type of harm, as well as additional anecdotal evidence.

Example #1

In California, a patient was paralyzed following a spinal surgery in which new hardware was inserted into the spinal cage to stabilize the spine. During the procedure, IONM monitoring was performed by two employees of an IONM company, along with a supervising physician to remotely interpret the monitored data. The neurologist was not able to log into the system during the procedure, and the surgeon was not informed of this by the IONM technologists. IONM signals were lost during the procedure, which was not appropriately communicated to the surgeon, and the loss of signal was

incorrectly attributed to malfunctioning equipment. Despite attempts to repair the damage, the patient was permanently paralyzed. A lawsuit was subsequently filed, the patient was ultimately awarded approximately $20 million dollars,[41] and the IONM employees were found to be 80 percent at fault.[42]

Analysis

Several occurrences were cited in this example as contrary to generally accepted processes and procedures. Namely, no supervising physician was present for the surgery, and clear communication was not provided by the IONM technologists regarding the lack of supervision, nor the loss of signal.

It is unknown why the remote supervising physician was not able to log into the system to view the IONM signals, nor is it known if there could have been another way in which the supervising physician could have made sure that the surgeon was aware that they were not overseeing the procedure, such as calling hospital administration or reaching out to the operating room staff directly. However, it appears from this example that the surgeon was not informed, and ultimately, the two IONM technologists proceeded with IONM without informing the surgeon.

Additionally, the loss of signal was not communicated to the surgeon. Typically, when a loss of signal occurs, this information would be discussed between the IONM technologist and the supervising physician since the IONM technologist is viewing the signal for any changes, and the supervising physician is responsible for interpretation of signal changes. Once a change in signal is confirmed, this information should be quickly communicated to the surgeon during the procedure to prevent damage.

However, since no supervising physician was present and the IONM technologists were aware of this fact, they did not relay this information to the surgeon on their own, and apparently blamed the lack of warning on faulty equipment. It is also unknown if their claim that the equipment was faulty was expressed during the procedure, or after the fact.

Example #2

A medical journal review of 17,273 surgical procedures utilizing Transcranial Motor Evoked Potentials (TcMEP) from 307 hospitals, determined that 111 bite injuries occurred in a total of 109 patients. These included 88 tongue injuries, 22 lip injuries, as well as 1 broken tooth. Additionally, several patients experienced multiple injuries. Of all of the injuries reviewed, the severity ranged from minor bruising to deep

[41] Michels & Lew. *$20 Million Trial Verdict for a Woman Who Sustained Permanent Paralysis Due to Faulty Monitoring of Brain Function During Surgery.* Retrieved March 16, 2023, from michels-lew.com/about/results/brain-damage-20-million-verdict/

[42] Law.com Verdict Search. *Suit: Failure to notify surgeon of signal loss resulted in paralysis.* Retrieved March 16, 2023, from verdictsearch.com/verdict/suit-failure-to-notify-surgeon-of-signal-loss-resulted-in-paralysis/

lacerations that required stitches (25 patients suffered deep lacerations).[43] Additionally, this study reviewed comments from surgical incidence reports. Of the cases reviewed in which injury occurred, it was noted that in two instances, the IONM technologist failed to communicate with the anesthesiologist regarding the placement of bite blocks, and no bite blocks were inserted into the patients' mouths to protect them during the procedure.[44]

Analysis

This study evaluated the occurrences of bite injuries caused by TcMEP—a form of Motor Evoked Potential (MEP) that uses electrical stimulus to generate a neural response, which can cause a patient to involuntarily bite down. It is unknown where the hospitals that were evaluated were located, and whether any of the hospitals are in Colorado.

The study concluded that—although incidents of harm are very low—injury can be caused by this type of IONM procedure. Additionally, in two instances where harm resulted, the incident report indicated that the IONM technologist had not relayed important information to the anesthesiologist regarding the risks of TcMEP, nor had they relayed that bite blocks needed to be placed in the patient's mouth to prevent injury. Therefore, these two patients did not receive bite blocks as a preventative measure and injuries occurred.

Additionally, another case was provided anecdotally by stakeholders involving a lack of communication on the part of the IONM technologists. In Illinois, IONM was utilized during a spinal surgery. Changes in the signals occurred that demonstrated a risk of damage to the spinal cord, but the IONM technologist did not communicate this information to the supervising physician who was participating remotely, and the supervising physician did not alert the surgeon since they were not aware of a problem. The patient woke up with paralyzed legs.

Lack of Documentation

One specific case is offered as an example of this type of harm.

Example #3

In Texas (2016), a patient was experiencing pain in her lower legs, and consulted a doctor who diagnosed the patient with several back conditions and the doctor prescribed physical therapy and medication. Six months later—when no improvement was demonstrated—the doctor recommended surgery. The patient consented to undergo two separate spinal fusion surgeries. During the second surgery, several of the

[43] Arvydas Tamkus, MD, PhD, DABNM, et al., (2023), "The Incidence of Bite Injuries Associated with Transcranial Motor-Evoked Potential Monitoring," *Anesthesia and Analgesia*, 115 (3), pp. 2-3.
[44] Arvydas Tamkus, MD, PhD, DABNM, et al., (2023), "The Incidence of Bite Injuries Associated with Transcranial Motor-Evoked Potential Monitoring," *Anesthesia and Analgesia*, 115 (3), p. 6.

screws were misplaced into nerves in the spine. After the surgery, the patient reported extreme pain, numbness, and weakness. Surgery was performed the next day to address the screw misplacement, but the patient's symptoms did not subside, and the patient filed suit for medical negligence in 2019. The patient later amended the suit to include the IONM supervising physician and the IONM technologist that participated in the procedure. Further, the patient stated that the IONM reports concluded that the patient's responses were normal throughout the procedure, but the patient alleged that the reports must have been incorrect, since the screws had been inappropriately placed and should have shown a change in IONM signals; the patient alleged negligence in the monitoring, a failure to notify the surgeon of changes, and failure to properly document and preserve monitoring data. Additionally, reports submitted by other experts indicated that the monitoring documentation may have been incomplete, since changes in signals should have been observable as the surgeon was placing screws in the spinal nerves. Further, one expert expressed that some of the IONM reports were missing. The second expert's report also discussed whether the IONM monitoring was actually beneficial or useful in this case and indicated that the surgeon was responsible for placing the screws, regardless of what the EMG monitoring showed.[45]

Analysis

The patient alleged that the IONM technologist did not inform the surgeon of changes in IONM signals. However, the reports indicated that no signal change occurred. Further, it was alleged by the patient that since several of the screws were misplaced into the spine, a change of signal would have been observable. Lastly, one of the patient's experts indicated that some of the IONM documentation from the procedure may have been missing.

The outcome of this lawsuit is unknown since the information provided did not contain the final verdict. The surgeon in this case misplaced the screws in the patient's spine, which is the alleged cause of the paralysis. However, standard procedure in IONM is to maintain records, and if elements of the IONM reports were missing and could not be substantiated, this could potentially indicate a lack of performance of some of the essential functions required in the role of an IONM technologist. Further, if the signals had reflected a change and the surgeon was not notified, this could also indicate that the IONM technologist may not have performed an important duty to communicate signal changes when they occur.

Lack of Supervision

One specific case is offered in consideration of this type of harm, as well as additional anecdotal evidence.

[45] *Mitchell v. Swanson,* 2020 WL 6065986 (Tx.App.).

Example #4

In New Jersey (2013), a supervising physician and an IONM technologist were scheduled to monitor signals during a patient's surgery. The supervising physician did not reveal his remote location at the beginning of the surgery, or the time he initially logged on to the procedure, which was 50 minutes after the surgery began. The supervising physician who was supposed to be reviewing the IONM signals was completing a variety of other activities instead, including driving his car, reviewing medical records from other patients, and talking on his cell phone, rather than reviewing the IONM signals. During the procedure, the patient's signals weakened and the IONM technologist did not report this change to the surgeon. After the surgery, the patient was in a coma for several months and died of catastrophic hypoxic brain injury. A settlement was awarded to the plaintiff totaling approximately $4.1 million, with a $1.1-million judgement against the IONM technologist and the IONM company.[46]

Analysis

The supervising physician clearly violated a variety of ethical and procedural standards by claiming to be supervising a surgery while completing other tasks, although the regulatory status of IONM supervising physicians is not the subject of this sunrise review.

As was previously stated, it is the role of the supervising physician to *interpret* changes in signals, whereas the IONM technologist often alerts the supervising physician of a change in signal so that the change can be evaluated from a medical perspective.

Had the IONM technologist alerted the supervising physician or the surgeon regarding the changes in signals that occurred during the operation, the supervising physician may have stopped what he was doing to review the signal change, or the surgeon may have changed the course of the operation. However, no such alert was provided by the IONM technologist.

Although it is unknown if any other factors contributed to the death of the patient, this example outlines several types of harm committed by both the supervising physician and the IONM technologist. The supervising physician appears to have been derelict in his duties to interpret signals during the surgery, and the IONM technologist was also negligent by not alerting anyone that a change had been detected.

[46] Outpatient Surgery Magazine. *Negligence Suit: Reckless Intraoperative Neuromonitoring During Spinal Surgery Led to Deadly Catastrophic Hypoxic Brain Injury*. Retrieved May 15, 2023, from www.aorn.org/outpatient-surgery/article/2019-July-negligence-suit-reckless-intraoperative-neuromonitoring-during-spinal-surgery-led-to-deadly-catastro

Information regarding additional cases was also anecdotally relayed by stakeholders regarding a lack of supervision during surgeries where IONM was utilized, including:

- In North Dakota, a patient suffered paralysis due to the lack of communication from the IONM technologist regarding a change in monitored signals. Additionally, no supervising physician was viewing the procedure.
- In California, a patient underwent a lumbar fusion surgery in which IONM was utilized for the procedure. Monitoring was performed by the surgeon and the IONM technologist with no additional supervising physician. Electrodes were not placed in enough muscles, and the patient awoke from the surgery with continuing pain and drop foot (inability to lift the foot).
- In Illinois, IONM was utilized during a surgical procedure. No supervising physician was present, and the IONM technologist did not react to changes that occurred in the monitored signals. Paralysis of the patient resulted.

Improper Setup of Equipment

Two specific cases are offered in consideration of this type of harm.

Example #5

In Colorado, a surgical procedure was performed in which IONM was utilized. The IONM technologist placed the electrode needles in the patient prior to the procedure, and due to the location of the needles, the patient allegedly sustained a burn injury. Additionally, the electrode needle allegedly broke off inside of the patient, and a surgical procedure had to be performed to remove it. Litigation in this case is pending as of the writing of this report.

Analysis

This case was anecdotally relayed by a stakeholder. The alleged injuries to the patient regarding the placement of the electrode by the IONM technologist appear to be the primary focus of the ongoing litigation, and if true, could be a demonstration of a lack of competency on the part of the IONM technologist.

Example #6

A surgical procedure was performed that utilized IONM monitoring. The surgeon was interpreting the signals received while the IONM technologist was viewing the signals, and no supervising physician was present. No signal changes were viewed during the operation that were perceived as concerning. However, the patient woke up paralyzed. The case was published in a medical journal to share the outcome of the procedure. Upon further review of the case, it was determined that the lead wires that plug into the IONM equipment were plugged into incorrect inputs on the machine by the technologist. Therefore, the surgeon and the IONM technologist were viewing signals

that related to nerves and/or muscles that were switched in the readouts from the IONM equipment.

Analysis

This case was presented anecdotally by a stakeholder who had knowledge of the case and outcome.

The case indicates that the IONM technologist is alleged to have incorrectly set up the IONM equipment, and IONM signals were misread during the entire surgical procedure. The case also illustrates that no supervising physician was monitoring the operation, and interpretation of the IONM data was left to the surgeon.

Typically, when a supervising physician is present for a procedure, they are able to check the baseline signals with the IONM technologist before the procedure begins to ensure that a strong signal is being received from each nerve/muscle that needs to be monitored. Additionally, the supervising physician is trained to interpret each signal, as well as the potential impact on the surgical procedure if a signal were to weaken or be lost.

It is unknown how much additional training the surgeon may have had relating to the interpretation of IONM data. However, it is clear that the surgeon was unaware of any complications until other experts reviewed the case after the fact.

Additionally, since the IONM technologist is alleged to have set up the electrodes attached to the patient by plugging the wires into the incorrect inputs on the monitoring equipment, this may have been a case of lack of competency on the part of the technologist.

Billing Issues

Several examples relating to billing issues were provided by stakeholders throughout the course of the review. Namely, cases were relayed that dealt with IONM companies that may be incorrectly billing for services[47] or fraudulent reporting of services

[47] United States Department of Justice, United States Attorney's Office, Middle District of Tennessee. *Largest Independent Provider of Intraoperative Neuromonitoring Services to Hospitals Agrees to Pay $1.9 Million To Settle Fraud Allegations.* Retrieved May 16, 2023, from www.justice.gov/usao-mdtn/pr/largest-independant-provider-intraoperative-neuromonitoring-services-hospitals-agrees

provided, or both,[48, 49] and information was also received regarding cases that originated in Colorado.[50,51]

Analysis

These examples may have resulted in financial hardship for third party payors that receive a fraudulent or inflated bill for IONM services, or even patients themselves who may be overcharged and confused regarding the sum of money requested for these services.

However, the application submitted for this sunrise review relates specifically to IONM technologists, and whether regulation of this profession would be of benefit to the public welfare.

Billing for services is completed by IONM companies, and although IONM companies are employers of IONM technologists, IONM companies themselves are not the subject of this review, nor are any aspects of healthcare billing which may require the analysis of other types of state or federal regulatory mechanisms.

Discussion regarding Examples

Certification, such as that proposed by the sunrise applicant, would require training in a variety of core competencies, including intraoperative techniques, provider communication and documentation, as well as safety and ethics. However, it is unknown whether any of the IONM technologists mentioned in the examples above had obtained certification, and therefore, whether the training and examination received through the certification process would have changed the outcome.

In an attempt to identify additional examples of harm, COPRRR staff reached out to staff at the Colorado Medical Board and the Colorado Department of Public Health and Environment (CDPHE). Although IONM technologists are not regulated by the Colorado Medical Board, supervising physicians are. Similarly, many of the facilities in which IONM technologists work are regulated by CDPHE. However, neither staff with the Medical Board nor CDPHE was aware of any complaints involving IONM technologists in the state, certified or not, in recent years.

[48] United States Department of Justice, United States Attorney General's Office. *Intra-Operative Monitoring Company Agrees to Pay $550,000 To Settle False Claims Act Claims.* Retrieved May 16, 2023, from www.justice.gov/usao-edpa/pr/intra-operative-monitoring-company-agrees-pay-550000-settle-false-claims-act-claims

[49] LA Podcast. *Whistleblower Alleges Fraudulent Billing at USC Hospital Led to "Hundreds of Avoidable Patient Deaths and Injuries."* Retrieved March 16, 2023, from thelapod.com/posts/whistleblower-alleges-fraudulent-billing-at-usc-med-school-led-to-hundreds-of-avoidable-patient-deaths-and-injuries/

[50] Chris Vanderveen, "Why an 'outrageous' $169,600 medical bill actually got paid," *9news.com*, June 8, 2020. Retrieved March 18, 2023, from www.9news.com/article/news/investigations/medical-cost/why-an-outrageous-169600-medical-bill-actually-got-paid/73-488265310

[51] The United States Attorney's Office, Colorado Archive. *Dr. Steven Spillers settles allegations that he overbilled Medicare by paying over $740,000.* Retrieved May 17, 2023, from www.justice.gov/archive/usao/co/news/2012/june/6-21-12.html

Further, the American Board of Registration of Electroencephalographic and Evoked Potential Technologists (ABRET) has a disciplinary process in place, including for instances where it has been found that the IONM technologist violated one of the tenants of the Certification for Neurophysiologic Intraoperative Monitoring (CNIM).

ABRET provided information regarding violations that occurred recently relating specifically to IONM technologists. These violations include:

- Taking pictures in the operating room,
- Falsified documentation,
- Fraudulent use of the CNIM credential, and
- Intoxication.

According to ABRET, none of these recent disciplinary actions involved CNIMs with a Colorado address, nor were any complaints received in the past year related to CNIM-certified IONM technologists with Colorado addresses.

Further, none of these violation types seem to infer any reported instances of harm caused to a patient, yet examples of harm involving IONM technologists have been provided by other sources as discussed throughout this report.

Additionally, it is unknown if the examples provided in this report were potentially caused by IONM technologists who may be CNIM-certified but did not follow ABRET's requirement to report, or if any harm was caused by uncertified IONM technologists.

If the IONM technologists mentioned in the examples above had been CNIM-certified and the violation had been reported, these IONM technologists may have potentially faced a variety of sanctions, including suspension or revocation of their CNIM certification in severe circumstances.

Currently, if an IONM technologist has chosen not to obtain certification, the technologist may continue to practice even if substantial harm occurs, since there is no other regulatory mechanism in place. Consequently, if the regulation proposed by the sunrise applicant were in place, the regulator could ensure that disciplinary action could be imposed when necessary, including the option to suspend or revoke the IONM technologist's ability to practice.

In the final analysis, the examples discussed in this report seem to have occurred mostly outside of Colorado, and the timespan during which some examples occurred is unclear.

Independent Judgement

Sunrise criterion I.5 asks:

> Whether the practitioners of the profession or occupation exercise independent judgment, and whether the public can reasonably be expected to benefit from the direct regulation of the profession or occupation if a practitioner's judgment or practice is limited or subject to the judgment or supervision of others.

The current industry standard stipulates that the majority of functions performed by an IONM technologist during a surgical procedure are supervised, typically remotely, by a supervising physician. Stakeholders have indicated that best practice would be for the IONM technologist to maintain contact with the supervising physician throughout the surgical procedure, and any important information acquired should also be appropriately shared with the anesthesiology team, other members of the surgical team, and importantly, directly with the surgeon when necessary.

Although IONM technologists themselves are not regulated, many of professionals that they work with, as well as the facilities in which they work, are highly regulated.

However, there are some functions of the work engaged in by IONM technologists that are performed largely independent of direct supervision. These tasks include preoperative setup, including connecting or inserting electrodes into the patient's muscles, connecting lead wires to the electrodes, and inserting those wires into the appropriate inputs in the IONM equipment. Establishing a baseline reading prior to the beginning of a procedure may also be conducted independently by the IONM technologist.

Since the majority of supervising physicians are remotely observing one or more surgical procedures at a time, circumstances in which technology does not optimally perform can occur. One of the previously mentioned examples indicated that a supervising physician was not able to log into the system remotely. Since remote observation of a procedure often requires a stable, functioning internet connection, there is always a possibility that a supervising physician would not be able to visually observe signals for the full length of a surgery in the event of an internet issue. However, stakeholders have indicated that a supervising physician and IONM technologists can communicate with one another by phone and can even communicate by phone with the surgeon when needed.

In the event that a supervising physician is not utilized, or if utilized, is not able to log into a remote system, or is reviewing multiple surgeries simultaneously, the knowledge-base and minimal competency of the IONM technologist may be even more critical to ensure that changes in signal or loss of signal can be identified in a timely manner.

Since the supervising physician has the ability to *interpret* the signals received, they can look at the signal's wavelength and discern if a quality signal is being received, which helps to ensure that equipment was properly set up by the IONM technologist in the preoperative environment. However, since the majority of supervising physicians are remote, it is ultimately the IONM technologist who must carry out many of the recommendations made by the supervising physician.

The examples provided that relate to instances where a supervisor was not available all occurred in other states, and stakeholders have indicated that they are not aware of any instance in Colorado where a supervising physician has not been utilized.

In Colorado, some stakeholders have indicated that, although the majority of IONM technologists may be certified and appear to approach their work with competency, instances in which electrode wires were incorrectly connected to IONM machines have been observed, and preoperative conversations have occurred between IONM technologists and supervising physicians that appeared to demonstrate a lack of an IONM technologists' competency. However, in all of these instances expressed by stakeholders, a supervising physician has been remotely present and could inform the technologist of their mistake so that it could be remedied prior to the start of the surgical procedure. In such instances, supervision seems to have been effective.

In sum, although industry standard is to provide supervision for IONM technologists, there are tasks that are independently carried out by the technologists, some of which may be critical to the safety and success of the IONM being performed. Since supervising physicians are typically remote, minimal competency of IONM technologists is important to ensure that critical information is communicated accurately and efficiently to prevent harm to the patient.

Need for Regulation

Sunrise criterion II asks:

> Whether the public needs, and can be reasonably expected to benefit from, an assurance of initial and continuing professional or occupational competence.

Stakeholders have provided a variety of examples, some of which were provided anecdotally, with the intent to demonstrate circumstances in which harm may have occurred. An analysis of these examples is necessary to examine whether there is a need for regulation. Examples were separated into categories, including:

- Lack of communication during the procedure in which IONM was utilized,
- Lack of documentation regarding the IONM monitoring,
- Lack of supervision of IONM technologists during a surgical procedure,
- Improper set up of IONM equipment, and
- Billing issues related to IONM services.

Some of the examples provided pertain to ongoing litigation, in which the finding of harm is left to the determination of the legal system.

However, harm can be determined in situations where an IONM technologist demonstrated a lack of competency by taking specific actions that are not standard practice—or not completing required actions—that caused harm, or contributed to the harm, of a patient.

This report contains several such examples where a lack of competency of the IONM technologist has been demonstrated, with resulting harm to the patient in varying degrees of severity, including bite injuries (Example #2), paralysis (Example #1), and death (Example #4).

Although the examples were categorized into groups with similar themes, many of the examples relate to several circumstances which, when combined, may have led to a perfect storm of events that caused harm to a patient. Namely, a lack of supervision combined with a demonstrated lack of competency on the part of the IONM technologist, as was the case in Examples #1 and #4.

In general, the vast majority of examples provided occurred in other states. However, one anecdotal example was presented within the state of Colorado which is currently in ongoing litigation. Other examples from Colorado that were provided relate to billing issues, which do not directly relate to work performed by IONM technologists and do not involve competency.

Since the lack of competency is the focus of this sunrise criterion, and several examples have demonstrated harm relating to the lack of competency of IONM technologists, minimal competency requirements might serve to protect Coloradans from similar types of harm.

Alternatives to Regulation

Sunrise criterion III asks:

> Whether the public can be adequately protected by other means in a more cost-effective manner.

The sunrise applicant has indicated licensure to be the appropriate level of regulation for the profession of IONM technologists.

Licensure is typically considered the most restrictive form of regulation, and typically involves the completion of a specific educational program as well as the passage of an examination to ensure minimal competency.

Certification, on the other hand, is a form of regulation that may offer similar aspects of consumer protection to that of licensure, with typically reduced regulatory requirements. Certification may still require an educational program and/or examination to demonstrate minimal competency. Additionally, certification programs may also involve a non-governmental organization to establish training requirements and/or administer any required examinations.

Additionally, since licensure is considered a more restrictive form of regulation, it may be prudent to consider the alternative of certification.

Stakeholders have indicated that the CNIM is widely considered the standard for evaluating technical competency and is also considered the baseline certification for IONM technologists.

In the case of the CNIM certification, ABRET has already established processes related to application, examination, discipline, and continuing education. Therefore, once an IONM technologist is CNIM-certified, they are already under the guidance and review of a regulatory structure which is meant to ensure competency in the field.

Additionally, the American Clinical Neurophysiology Society recently published consensus guidelines that were developed by four national societies related to IONM monitoring, including the American Clinical Neurophysiology Society, the American Association of Neuromuscular and Electrodiagnostic Medicine, the American Society of Neurophysiological Monitoring and ASET – The Neurodiagnostic Society. Within these consensus guidelines, job titles for several categories of IONM technologists with various job duties and experience levels have been developed, several of which recommend certification be required before some tasks are performed independently.[52]

Therefore, certification may represent a viable alternative to licensure.

Collateral Consequences

Sunrise criterion IV asks:

> Whether the imposition of any disqualifications on applicants for licensure, certification, relicensure, or recertification based on criminal history serves public safety or commercial or consumer protection interests.

Since IONM technologists are not currently regulated, ABRET is the only known entity to impose disqualifications based upon criminal history for the profession. Further, the sunrise applicant did not propose any additional sanctions for criminal activity, since

[52] Jaime R. Lopez, et al., (2023), "Guidelines for Qualifications of Neurodiagnostic Personnel: A Joint Position Statement of the American Clinical Neurophysiology Society, the American Association of Neuromuscular and Electrodiagnostic Medicine, the American Society of Neurophysiological Monitoring and ASET—The Neurodiagnostic Society," *Journal of Clinical Neurophysiology*, 40 (4), pp. 271-285.

the CNIM certification administered by ABRET already has a disciplinary process in place and that certification represents the basis for the sunrise applicant's proposal.

ABRET may suspend, deny, revoke, or take additional disciplinary actions relating to the grounds for discipline of a conviction of, or a plea of guilty or *nolo contendere* to a felony or misdemeanor related to public health and safety, or to the profession.

The examples discussed in this sunrise report did not indicate any instances in which criminal conduct occurred, and therefore do not support a regulatory requirement that an IONM technologist's criminal history should serve as a barrier to entry into the profession.

Conclusion

Coloradans often have choices as consumers regarding the goods and services they utilize and can choose to conduct additional research to ensure that they are being provided services by a competent professional.

However, surgical procedures where IONM is utilized almost never involve the patient in the selection process of the IONM technologist. Such decisions are typically made by the hospital or the surgeon participating in the surgical procedure.

The patient often meets the IONM technologist for the first time prior to the procedure when the IONM process is explained, and consent forms are signed. Additionally, patients typically do not have knowledge regarding the training or competency level of the IONM technologist performing the monitoring in their surgical procedure, since these decisions are largely made by the hospital or the surgeon.

Given the incredible amount of trust that a patient places in a surgical team, the number of complex tasks that an IONM technologist must perform, sometimes independently, and given the types of harm that have been demonstrated, some with catastrophic consequences, as well as the widely varying training and education available, one could conclude that regulation of IONM technologists could serve to protect the public health and welfare.

However, the sunrise review process requires that the sunrise criteria established by the General Assembly be applied as the primary basis for the determination regarding whether regulation in this state is warranted, and evidence of harm to Coloradans, as well as the competency of IONM technologists performing their duties in Colorado, is the primary focus in order to protect the public safety and welfare in this state.

Several of the examples provided by the sunrise applicant and others were found through analysis to have demonstrated a lack of competency of the IONM technologist in which harm resulted to the patient—more specifically, Examples #1, #2, and #4. Of these examples where harm resulted, they either did not occur in Colorado (Examples #1 and #4) or the location in which the harm occurred could not be determined (Example #2).

Of those examples provided relating directly to Colorado, several were related to billing issues, which do not directly impact the question regarding whether to regulate IONM technologists. Additionally, one anecdotal example related to Colorado was provided in which harm to a patient was alleged. This case is currently in the process of litigation, and the outcome of whether a competency issue occurred on the part of the IONM technologist has not yet been determined by the legal system. Therefore, no conclusion regarding this case can be inferred at this time.

Additionally, no evidence of complaints related to IONM technologists working within the state of Colorado have been received throughout the writing of this sunrise report. For example, no complaints related to CNIM-certified IONM technologists with Colorado addresses have been presented, and the staff of the Colorado Medical Board and CDPHE are also not aware of any complaints involving IONM technologists in recent years.

In sum, although evidence of harm has been demonstrated which indicates a lack of competency on the part of IONM technologists in other states, the examples presented do not confirm that harm has occurred within Colorado, and therefore, do not at this time meet the threshold of burden required to recommend the imposition of regulation in this state.

Recommendation— Do not regulate IONM technologists.