

PUBLIC HEARING SCRIPT – AUGUST 16, 2023

Good morning. I would like to call the Hearing to Order. My name is Daniela Pelachyk, Rules Analyst with the MIOSHA Standards and FOIA Section, I will be facilitating the hearing today. This meeting is being recorded. At this time, please make sure your cell phones are silenced. Thank you.

This hearing is being called to order at 10:01 a.m., on August 16, 2023, at the Michigan Library & Historical Center, 1st Floor Forum, 702 West Kalamazoo, Lansing MI 48915.

This is a public hearing for proposed administrative rules for MIOSHA Part 5. Operator Qualifications.

This hearing is being conducted pursuant to provisions of the

- Administrative Procedures Act 306 of 1969, MCL 24.242;
- Public Health Code, Public Act 368 of 1978, MCL 408.1014r, MCL 333.13515, MCL 333.13521, MCL 333.13522, and MCL 333.13527;
- Executive Reorganization Order Nos. 1996-1, 1996-2, 2003-1, 2011-4, and 2019-3, MCL 330.3101, 445.2001, 445.2011, 445.2030, and 125.1998.
- and on behalf of the Michigan Department of Labor and Economic Opportunity.

The public hearing notice was published in three newspapers of general circulation, as well as the August 1, 2023, edition of the *Michigan Register*.

We are here today to receive your comments only on the proposed rules. If you wish to speak, please make sure you have signed in and indicated your willingness to speak. We will call on speakers in the order in which names are listed on the sign in sheets. When you come forward, please identify yourself by giving your name, as well as who you represent so that this information can be included in the hearing report. If you have additional comments to submit in writing, you may leave them at the registration desk or submit them to our department no later than 5 p.m. today, August 16, 2023.

Rex Miller:

Good morning, Mr. Ray and Ms. Kugler. My name is Rex Miller. I am a two time Past President and Board Chairman of the Michigan Society of Radiographic Technologists. I have worked in the radiologic sciences for nearly 40 years and have recently retired as the radiology service manager for the College of Veterinary Medicine in the Veterinary Teaching Hospital at Michigan State University. Prior to that I worked for the Department of Radiology at the Michigan State University Clinical Center where I spent 24 years in the Magnetic Resonance Imaging department. I have also taught Magnetic Resonance Imaging at Michigan States MRI Program as well as at Lansing Community College. As Ms. Richmond testified, she was one of my students, and I am pleased she has risen to leadership in my professional organization.

The Department, MiOSHA, and the Radiation Safety Unit are to be commended for taking this significant step forward toward enhancing public safety by

establishing education and training standards for those who operate sophisticated imaging machinery. By taking this step, the Department will put Michigan in line with over 40 other states, placing minimum education and training standards for operators.

I do recommend, however, the Department reconsider its position regarding its authority to regulate nuclear medicine, or in the alternative, explicitly exclude nuclear medicine and nuclear medicine technologists from the ambit of the regulations so as so avoid confusion.

I also recommend that consideration be given to the following amendments involving replacement of the word "therapeutic" with "research" as the term "therapeutic" is covered by the term "radiation therapy."

On page 3, Rule 5206(1), delete the word "therapeutic" and insert the word "research," so that the last clause reads:

"... involving the application of x-radiation to human beings for diagnostic and research purposes."

Moreover, I recommend that changing "therapeutic" to "research" be used for Rule 5206(2) so that the operative language would read:

"... application of x-radiation to human beings for diagnostic and research purposes."

And, to be consistent, I recommend replacement of the word "therapeutic" with the word "research" for Rule 5206(4), so the operative language would read:

"... applying x-radiation to human beings for diagnostic and research purposes."

I also suggest favorable consideration be given to amendments to Rule 5210(2)(d) by removing the long list of body parts allowed for imaging for limited scope procedures. In its stead, I recommend a list of areas of the body - namely, chest, extremities, spine, skull/sinuses and

podiatric. By so doing, the Department avoids any misunderstandings and lessens the chance for any errors by omission.

Finally, I recommend amending Rule 5212(1), again dealing with limited scope, by requiring a minimum of 40 hours of clinical and didactic training to the radiologic science within the limited scope of practice.

Thank you once again for hearing my testimony and thank you for your efforts toward enhancing public safety.

If you have any questions, I will do my best to answer them or, if I cannot answer them today, find those answers for you.

Ralph Lieto:

My name is Ralph Lieto and I am a board-certified medical physicist and radiation safety officer, retired, with over 35 years of experience in large health care systems in Michigan. I am speaking on behalf of the Michigan Radiological Society (MRS), and I am a past-president of the MRS.

The MRS is a professional and educational organization of board-certified diagnostic radiologists, radiation oncologists, nuclear medicine physicians, medical physicists, and interventional radiologists. MRS members work with and supervise technologists who perform diagnostic and therapeutic procedures with ionizing radiation. Many of our members are involved in the education of student technologists both for their classroom and clinical training.

The MRS strongly supports the Michigan Department of Labor and Economic Opportunity (OLEO) proposing rules to establish credentialing regulations for technologists who use ionizing radiation for diagnostic and therapeutic medical purposes. MRS is disappointed that efforts for nearly 30 years have been unsuccessful. The patient in the state of Michigan deserves government's commitment that those directly administering ionizing radiation have demonstrated adequate training. Michigan is one of the minority of states that has not done this. Establishing proper credentials for technologists will be a tremendously positive step to assure the use of medical ionizing radiation is done in a manner that optimizes the patient dose and clinical objectives of the study.

MRS supports the proposed rules with following clarifications and changes:

General - Use the term "ionizing radiation" to replace "x-radiation". It is the proper term and is inclusive of electron and gamma radiation used in medical applications, especially therapy.

Purpose and Scope, Rule 5210- This needs to clearly indicate that medical research subjects, and not just patients, are included. The proposed rules may be interpreted to exempt them by their exclusion. Such exemption would be improper and inconsistent with federal rules.

Definitions, Rules 5206-5208 - There are outdated and missing definitions which need to be addressed. The MRS is suggesting language but strongly recommend OLEO obtain definitive language from the American Society of Radiologic Technologists (ASRT) and the American Registry of Radiologic Technologists (ARRT).

"Medical x-radiation technologist" is obsolete and should be deleted.

Revise: "Medical radiographer means an individual, other than licensed practioners, who is a registered technologist under that general supervision of licensed practioner and performs procedures using machine produced medical ionizing radiation for diagnostic and interventional purposes."

Add: "Medical radiation therapist means an individual, other than licensed practioners, who is a registered technologist under that direct supervision of radiation oncologist and performs procedures using machine produced medical ionizing radiation for therapeutic purposes."

Add: "Nuclear medicine technologist means an individual, other than licensed practioners, who is a registered technologist under that general supervision of an authorized user of the U.S. Nuclear Regulatory Commission and performs procedures using medical ionizing radiation for diagnostic and therapeutic purposes."

Delete: "technology" from "Radiation therapy technology" and revise definition to be consistent with language for "Radiology", such as "branch of medicine that uses ionizing radiation machines for therapeutic purposes."

Categories and Qualifications, Rule 5210 - Subpart Rule 5210 (c) needs clarification in the description of the three categories of conditional status after the three years following effective date of the final rules. As written, it appears that an individual who has not met active status can obtain conditional status every 3 years with a simple "statement of assurance". This should be clarified to assure it is NOT a means to circumvent requiring completion of active status criteria.

Credentials Requirements, Rule 5211 -Add the category of "nuclear medicine technology" with the appropriate credentials from the (i) ARRT and the (ii) NMTCB (Nuclear Medicine Technology Certification Board).

Limited Scope, Rule 5212 - This addresses limited scope operator requirements. MRS is pleased that minimum training requirements are being established for this category. However, 40 hours, or one week, of unspecified training is inadequate to work independently. As proposed, the training also does not require actual patients be imaged. The MRS supports the limited scope training recommendations of the ASRT which specifies classroom hours plus a minimum number of patient studies. This will provide prudent assurance of adequate clinical training for this category.

The MRS strongly support the inclusion of nuclear medicine technologists (NMT) in the credentialing requirements of these proposed rules. No current Nuclear Regulatory Commission (NRC) regulations or guidance specifies the credentials of persons performing duties under an Authorized User (i.e., physician named on an NRC licensee with authorized uses). This absence of specifications for supervised personnel is a well-known void, very analogous to the current situation in Michigan which can allow a clerical person or nurse to perform radiography under the supervision of a licensed

practioner. A misinformed assertion is that Michigan cannot establish NMT credentials because it is not an Agreement State. This is false! Indiana, an NRC regulated state, has had NMT licensure since 2008! It is MRS's understanding from the NRC that an NRC regulated state can establish credentials for personnel under an Authorized User as long as it does not impose on NRC's supervision rule (10 CFR 35.27).

Accordingly, inclusion of NMT in these proposed rules is permissible, justified, and assures that all areas using ionizing radiation for medical use are employing properly credentialed technologists. This change also necessitates replacing "x-radiation" with "ionizing radiation".

MRS applauds the MLEO initiative to establish technologist credentials for performing medical procedures which is decades overdue. Because of the type and significance of the recommendations and comments being made today, we request that a proposed final rule be published with a 30-45 day comment period. This request is a reasonable considering these rules are an initial proposal to the regulated medical users, and it is unclear what if any medical radiation resources provided input into these proposed rules. The MRS is willing to assist the MLEO in achieving a needed final draft satisfactory to both the state and the regulated medical community.

The MRS appreciates the opportunity to comment on these proposed credentialing rules.

Melissa Snody:

Director Pickelman

I am here to testify today on behalf on the SNMMI regarding the Administrative Rules for Ionizing Radiation Governing the Use of Radiation Machines.

SNMMI is a non-profit, scientific, and professional organization representing the interests of more than 15,000 nuclear medicine and molecular imaging professionals globally, including physicians, scientists, pharmacists, and technologists. The SNMMI-Technologists Section (SNMMI-TS) advocates for best practices in evidence-based science that promotes the highest quality in patient care and safety. In addition, SNMMI is committed to the advancement of policy, regulation, and legislation that promotes the science, technology, and practical application of nuclear medicine and molecular imaging and strives to be a leader in the unifying, advancing, and optimizing molecular imaging. Our mission is to empower nuclear medicine and molecular imaging professionals to transform the science and practice of precision nuclear medicine for diagnosis and therapy to advance patient care.

Earlier this year, the SNMMI recommended language to be included in this rule that would define the requirements and standards of technologists administering nuclear materials for diagnostic and therapeutic procedures specifically, recommending registration and certification standards to be included as set forth under the

American Registry of Radiologic Technologists (ARRT), Nuclear Medicine Technology Certification Board (NMTCB) and/or equivalent standards. Unfortunately, despite this request, the proposed rule makes no mention of nuclear medicine and fails to include certification and/or licensing standards for nuclear medicine technologists.

Therefore, SNMMI would recommend strict exemption language be included in this rule to make it abundantly clear that the proposed rule does, in fact, exclude nuclear medicine.

Rule 333.5209 Exemptions

We recommend inserting the following language:

A nuclear medicine technologist who, under the supervision of an authorized user, utilizes sealed and unsealed radioactive materials for diagnostic, treatment, and research purposes.

We believe that explicitly excluding nuclear medicine technologists from the Ionizing Radiation Rules Governing the Use of Radiation Machines will allow for the continued use of radioactive materials by nuclear medicine technologists for diagnostic, treatment and research purposes.

*In Michigan, no department or agency regulates the profession of nuclear medicine technology--nor does the practice of nuclear medicine technology **fall** under the purview of any federal agency. This explicit exemption will avoid any misinterpretation of the rule and ensure that nuclear medicine technologists are able to continue to practice within their scope.*

On behalf of the SNMMI, I thank you for your time and careful consideration on this matter.

If there are no further comments at this time, I will close the hearing, at 10:24 a.m. The record will remain open until 5 p.m. today, August 16, 2023, for any additional comments you may wish to share regarding the proposed rules.

Thank you all for coming today.