

## Radiologic Safety: The Use of Radioactive Materials in Interventional Radiology

Doctor X is an Interventional Radiologist who uses fluoroscopy and angiography to perform Y-90 embolization. What are the NRC and state of Michigan radiation safety requirements of performing such a case? What fines can be levied against the institution for not being compliant?

The increasing use of radioactive materials in Interventional Radiology has renewed the focus on compliance with regulations governing the use of ionizing radiation. Performing or participating in these procedures involves the use of fluoroscopy and the administration of radioactive materials to patients; examples include liver embolization using yttrium-90 (Y-90) microspheres, lung shunt evaluation using technetium-99m (Tc-99m) microaggregated albumin (MAA), and [procedure] using indium-111 (In-111) [agent]. With this trend, the question arises: **what are the regulatory (radiation safety) requirements of performing these cases, and what are the ramifications of non-compliance?**

In Michigan, the use of fluoroscopy (and other radiation-producing machines) is regulated by the Michigan Occupational Safety & Health Administration (MIOSHA). The applicable regulations are found in the [\*Ionizing Radiation Rules Governing the Use of Radiation Machines\*](#) (last revised 2016).

However, the use of radioactive material in Michigan (other than naturally-occurring) is regulated by the U.S. Nuclear Regulatory Commission (NRC). NRC regulations governing the medical use of radioactive material are found in Title 10, Code of Federal Regulations, Part 19 (Notices, Instructions and Reports to Workers), Part 20 (Standards for Protection Against Radiation), and Part 35 (Medical Use of Byproduct Material).

While MIOSHA and NRC regulate different types and uses of ionizing radiation, their protection goals and methods are similar. For example, both require appropriate radiation safety instruction (training) for anyone likely to receive an occupational dose exceeding 100 mrem in a calendar year; this means training is required annually for most interventional radiologists. Both also have similar occupational (and public) dose limits, most notably the annual effective dose limit of 5,000 mrem. However, while MIOSHA regulates only radiation-producing machines, 10 CFR 20.1502(a) contains a subtle but important caveat that allows NRC to bring other activities into its regulatory purview:

“Each licensee shall monitor exposures to radiation and radioactive material at levels sufficient to demonstrate compliance with the occupational dose limits of this part. As a minimum, each licensee shall monitor occupational exposure to radiation from licensed **and unlicensed** radiation sources under the control of the licensee and shall supply **and require the use of** individual monitoring devices by adults likely to receive, in 1 year from sources external to the body, a dose in excess of 10 percent of the limits...”

This means NRC expects licensees to prove that occupational radiation doses are less than the applicable limits, including doses from sources not regulated by NRC (most notably, fluoroscopy). This presents a challenge, since the occupational dose contribution from State-regulated interventional fluoroscopy is always higher (and often significantly higher) than the dose contribution from NRC-licensed radioactive materials. For this reason, interventional radiologists performing or participating in these procedures must be diligent about wearing their assigned radiation dosimetry, wearing it properly, returning it promptly for processing, and completing radiation safety training annually.

In addition to the consistent and proper wear of dosimetry, NRC licensees and MIOSHA registrants are responsible for implementing an As Low As Reasonably Achievable (ALARA) program, and employees are responsible for complying with the ALARA program to keep their occupational doses as far below dose limits as

possible. For interventional radiologists, this includes consistent use of properly-fitted radiation protective apparel (protective aprons, thyroid shields, and protective eyewear), consistent and proper use of available supplemental (overhead) shielding, proper selection of machine geometry and settings, and being mindful of the ALARA principles of time, distance, and shielding. As a general rule, reducing dose to patient also reduces dose to personnel in the room.

The ramifications of non-compliance can be significant. While rarely exercised, MIOSHA has the authority to bring criminal misdemeanor charges against individuals and institutions for violations of State regulations, with penalties up to \$10,000 per day. But more importantly, NRC routinely exercises its enforcement policy, fining institutions to non-compliance. NRC has taken enforcement action and levied significant fines against several medical institutions in the last two years for violations relating to the administration of Y-90 in interventional radiology; these violations included failure to monitor exposure from licensed and unlicensed sources, failure to implement effective radiation protection programs, and failure to provide training for individuals receiving occupational dose >100 mrem per year. While some of the violations were attributable to ineffective radiation safety programs and inadequate management oversight, many of them were attributable to non-compliance by interventional radiologists (e.g., not wearing assigned dosimetry, not wearing dosimetry properly, sharing dosimetry with other wearers, not returning dosimetry on time, and not completing training). In an effort to alert licensees to these issues, NRC published [Information Notice 2021-02](#) in August 2021.

Regulatory violations are not just financial in nature; they reflect on the institution, the radiation safety professionals striving to promote a safe work environment, and the employee(s) responsible. Violations are published online, broadly circulated, and extensively discussed. In some cases, employees are relieved of their jobs. At the end of the day, each employee is responsible for compliance with the safety regulations and policies applicable to their work.

Karl Fischer, MEng, CHP  
Radiation Safety Officer  
Radiation Safety Service / EHS  
Michigan Medicine

Joseph J Gemmete, MD FACR FSIR FCIRSE FAHA  
Professor of Radiology  
Department of Radiology  
Sections of Interventional Neuroradiology and Vascular  
/ Interventional Radiology  
Michigan Medicine