



# LUCERNO DYNAMICS®

## MYTH vs. FACT

### *NRC's Rule Exempting Nuclear Medicine Infiltration Reporting*

**Background:** The U.S. Nuclear Regulatory Commission (NRC) is charged with ensuring safe medical use of radiopharmaceuticals, including for diagnostic and therapeutic nuclear medicine. NRC requires medical event reporting if a patient's skin or tissue is exposed unintentionally to radiation above a certain threshold (0.5 Sieverts). A 40 year-old loophole to this rule provides an exemption from reporting requirements if the exposure happens through an infiltration, in which an injected radiopharmaceutical partially or completely misses the vein, and ends up in the tissue surrounding the vein. NRC's outside advisory panel, the Advisory Committee on Medical Use of Isotopes (ACMUI) – made up of nuclear medicine industry representatives – recommended NRC retain this loophole and change rules to shift blame for infiltrations away from clinicians and onto patients themselves.

NRC is currently evaluating the issue and ACMUI's conflicted, biased, and unjustifiable recommendations. Eliminating the loophole that prevents infiltrations from being reported as medical events is critical for patients, who are being harmed directly and indirectly by misadministration of radiopharmaceuticals.

**MYTH:** **Infiltrations are not a widespread problem in nuclear medicine.**

**FACT:** 18.5 million nuclear medicine injections occur each year, and the number is growing rapidly with the advance of radio-therapeutics. Published studies indicate average infiltration rates of more than 15% percent, or 2.8 million injections per year. Of those, an estimated 800,000 injections entail significant unintended radiation exposure, above levels that would trigger NRC medical event reporting in any other context.

**MYTH:** **Infiltrations are virtually impossible to avoid.**

**FACT:** This key assumption underlying the 1980 NRC policy exempting infiltrations from medical event reporting requirements, is completely false. Infiltrations have declined to exceedingly low levels in other health care applications, including chemotherapy and contrast CT, which average infiltration rates 0.10% and 0.24% respectively, as a result of dedicated quality improvement efforts, hospital reporting requirements and root cause analysis for each incident, and accreditation review. A multi-center quality improvement project published in the Journal of Nuclear Medicine Technology (JMNT) demonstrates that similar results can be accomplished in nuclear medicine injections, as centers interested in improving extravasation rates achieved statistically significant improvement, and that improvement was sustained over time. An article published by the American Society of Clinical Oncology reports a center's nuclear medicine infiltration rates decreasing from 13.3% to 2.9% virtually overnight as a result of a dedicated quality improvement process.

**MYTH:** There is no evidence that infiltrations cause harm to patients.

**FACT:** NRC's own regulations state clearly that patient outcomes are irrelevant to the question of medical event reporting: *"The term "medical event" may sound alarming when used in nuclear medicine and radiation therapy. But it may not mean a patient has been harmed. It means there may have been a problem in a medical facility's use of radioactive materials."*

Notwithstanding this fact, infiltrations do harm patients in several ways. Peer-reviewed articles report patient tissue is harmed by infiltrations that exceed NRC reporting thresholds. In fact, NRC's website includes a "Guide for Diagnostic Nuclear Medicine", authored by 49 leading experts in nuclear medicine. This guide states that excess unintended radiation exposure to the skin or tissue can have "deterministic effects" – including skin damage, sterility, and radiation sickness. Below are photos of a patient's arm that had been damaged by an infiltration.



**Figure 4** Pre-operative view of the left elbow, necrosis identified by the black shape.



**Figure 6** Debridement of the erythematous and necrosis wound. Respect of the tendinous, vascular and nervous structures (median nerve is identified by siliconed silastic<sup>®</sup> and the black shape) in the bending area.



**Figure 7** Covering of the cutaneous defect.

*Images provided in a presentation by Royal Free London hospital.*

The "Guide for Diagnostic Nuclear Medicine" also states that the risk of stochastic effects like cancer increases as a function of radiation dose. Recently, Baylor University Medical Center published a case study of a patient developing skin cancer resulting from a nuclear medicine infiltration.



**Figure 2.** A 1.2 × 1 cm hyperkeratotic papule on the left dorsal hand at the site of the previous injection of radium-223, without background actinic keratosis.

Infiltrations and patient harm are also documented 38 times in the FDA FAERS database. Indirect patient harm can also result when physicians use images, compromised by infiltrations, to guide care. There are over 50 peer-reviewed articles that show how infiltrations can or have caused patient harm from inaccurate disease staging, missed disease results, improper treatments, or unnecessary invasive procedures. In the past six months, NRC has been provided 22 case studies of patients receiving radiation above the NRC reporting threshold.

**MYTH: Infiltrations should be considered a “patient intervention.”**

**FACT:** This is perhaps the most cynical of the recommendations ACMUI conveyed to NRC in 2019, and continues to push today. A patient intervention is defined in NRC regulations as “actions by the patient or human research subject, intentional or unintentional, such as dislodging or removing treatment devices or prematurely terminating the administration.”

Yet in 2019 and 2020, ACMUI has attempted to distort this legal definition to blame patients themselves for improper administration of a radiopharmaceutical. This is an attempt to find a new justification for not requiring reporting of infiltrations above NRC limits as a medical event, and directly conflicts with previous ACMUI transcripts confirming that infiltrations are caused by technologists and their injection technique. This 2019 recommendation would also require a rule change inconsistent with both NRC’s intent to ensure proper administration of radiopharmaceuticals and known causes of infiltrations.

**MYTH: Medical event reporting of infiltrations is a “practice of medicine” issue that NRC should not be involved with regulating.**

**FACT:** NRC has consistently considered improper administration of radiopharmaceuticals to be a regulatory concern, and by definition, an injection intended for the vein that infiltrates surrounding tissue is an improper administration. NRC’s regulation 10 CFR Part 35 exists “to provide for the radiation safety of workers, the general public, patients, and human research subjects,” in order to identify underlying causes, correct them, and prevent recurrence. If requiring medical event reporting of infiltrations exceeding NRC thresholds is outside the Commission’s role, then the entire rule must be jettisoned. Indeed, ever since 10 CFR Part 35 was created in 1980, the nuclear medicine community has objected to any reporting whatsoever – not just for infiltrations. NRC must act on behalf of patients, and resist pressure from the very entities that it is charged with regulating.

**MYTH: Nuclear medicine physicians will be overwhelmed by reporting requirements if forced to report radiation exposure above NRC limits caused by infiltrations.**

**FACT:** The NRC asked the ACMUI to reconsider the infiltration in 2008/2009. In the transcripts of these meetings, ACMUI members reached the conclusion to retain the exemption, because they stated they would be overwhelmed by the reporting. They also stated that they strongly urged the NRC to retain the exemption, so they would not have to report these unintentional high doses to the patient, their physician, and NRC. To argue that providers will be overwhelmed with medical event reporting, one must accept the premise that severe infiltrations exposing patients to high levels of radiation occur frequently. But not reporting because of the workload is not appropriate. The solution is to fix the problem – not to sweep it under the rug. One way to minimize burden on providers would be to phase in an elimination of the loophole over 12 or 18 months. This would allow providers who infiltrate time to create and execute a quality improvement plan to fix their infiltration issues before medical event reporting becomes a requirement. Providers who are not infiltrating would not be affected.