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Secretary, U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

ATTN: Rulemaking and Adjudications Staff, Docket ID NRC-2022-2018

Dear Sir:

The preliminary proposed rule is clearly a medical practice issue. NRC has no statutory authority over medical practice. NRC's medical activities are quite limited in the Atomic Energy Act. Section 104, Medical Therapy and Research and Development. Section 104(a) states:

"The Commission is authorized to issue licenses to persons applying therefor for utilization facilities for use in medical therapy. In issuing such licenses the Commission is directed to permit the widest amount of effective medical therapy possible with the amount of special nuclear material available for such purposes and to impose the minimum amount of regulation consistent with its obligations under this Act to promote the common defense and security and to protect the health and safety of the public."

While physicians no longer have "utilization facilities" (reactors) on their premises and purchase radiopharmaceuticals from companies that do have them, and accelerator-produced radionuclides have been added to the Atomic Energy Act, nowhere is the NRC given the authority to regulate the practice of medicine. Part 20 takes care of protecting the health and safety of the public. States regulate the practice of medicine, and every state has a Board of Medicine. Between the Medical Boards and the courts medical errors are adequately addressed. The NRC is superfluous. In addition, NRC's "Medical Program" is run by bureaucrats with no competence in medical practice, and the management and the Commissioners are likewise incompetent, naïve dilettantes in this area.

I therefore ask for a review of this Proposed Regulation by the Administrative Law Judges to decide if NRC even has jurisdiction here.

Extravasation vs. Clot Dislodgement

When a hypodermic needle enters a vein it makes a hole. When the needle is withdrawn pressure is put on the site. A small amount of blood may nevertheless leak out before a clot is formed over the hole. In addition, the clot may be dislodged because of motion of the patient's arm (the usual site of injection). For example, a patient may be injected for a bone scan and then told to drink water and wait for two hours to promote urination of radiopharmaceutical that has not gone to bone. Then he is imaged. Radioactive material is seen at the injection site. Is this extravasation from the needle being pushed out of the vein, or clot dislodgement and subsequent blood leakage along with radiopharmaceutical that is carried in the blood? **I don't think that there is any way of knowing the difference, yet it is an important distinction.** While extravasation is usually (but not always) the fault of the person injecting the patient, clot dislodgement is a physiologic occurrence that is **not** the fault of the person injecting the patient. **The important thing to realize is that these blood leakages are medically inconsequential. Nevertheless, NRC is trying to make them into a crime.**

Nuclear medicine personnel have been injecting patients with therapy radiopharmaceuticals since 1936. The number of patients who have had severe damage from leaked radiopharmaceuticals could probably be counted on the fingers of one hand, or perhaps two hands. This hardly constitutes a public health and safety crisis demanding regulation. What we have is a feather-bedded bureaucracy of medical incompetents at NRC trying to give the illusion that they deserve their jobs. They don't.

Severe Radiation Burns from Radiation Oncology Treatment

Occasionally during radiation oncology treatment, the rate of tissue death is greater than the rate of tissue repair and moist desquamation occurs. Moist desquamation is a deep radiation burn, with raw, oozing flesh. It is exceedingly painful, requires medical attention, and takes weeks to close and months to heal. It is looked upon as an acceptable side effect of radiation therapy. It can sometimes be avoided by altering the frequency of radiation treatments, but my impression is that most radiation oncology practices do not bother to do so. There is no regulation against causing moist desquamation.

Burns from Extravasation of Chemotherapy Agents

Chemotherapy drugs are often exceedingly toxic, and extravasation can cause ulcers from dead tissue. These ulcers require medical attention. While medical oncologists and specialist nurses take great care to avoid extravasation, sometimes it occurs. It is looked upon as an acceptable side effect of medical oncology. There is no regulation against it.

Radiopharmaceutical Extravasation or Clot Dislodgement Dosimetry

It is virtually impossible to calculate accurate dosimetry of radiopharmaceutical extravasation or clot dislodgement. The rate of leakage, the rate of entering the lymphatic circulation, and the changing physical dimensions of the leaked fluid are unknown. Any attempt at dosimetry would be highly inaccurate. Given the fact that "acceptable" methods of dosimetry calculation published by the NRC "medical" section

for estimating doses from radioactive patients to others to comply with the 500 mrem patient discharge rule have been conservative by about 1000% for the last 26 years, there is no hope of any intelligent life coming out of that group.

The Language of the Preliminary Proposed Rule is Inconsistent

10 CFR 35.3045 states that a licensee shall report any event as a medical event, except for an event that results from patient intervention, in which (3) The administration of byproduct material results in an extravasation that requires medical attention for a suspected radiation injury. The skin dose at which one expects a 50% complication rate within 5 years is 2000 rads for a single dose[1], so this is approximately the radiation dose that will require medical attention. The skin dose at which one expects a 5% complication rate within 5 years is 1500 rads[1]. But in the preliminary rule language, 35.42 (a) states that for any administration in which an extravasation can occur, the licensee must develop, implement, and maintain written procedures to provide high confidence that an extravasation that requires medical attention for a suspected radiation injury will be detected and reported in a timely manner and in accordance with 35.3045. 35.3045 sets the reporting limit at only 50 rads above intended dose, which means that extravasations and clot dislodgements that will have no deleterious effects at all on the patient and will not require medical attention will have to be reported as well. That's ridiculous.

In addition, when a very high dose is delivered, it still may take weeks, months, or even years before a deleterious effect is seen, and medical intervention called for, and the patient may be long gone and the Authorized User may not even know about it. "Timely reporting" is impossible. It is obvious that the staff has no understanding of radiation biology.

Unintended Consequences of This Rule

The NRC requests information on unintended consequences of this rule. One possibility is that many licensees will stop offering diagnostic and therapeutic procedures that could result in them having to report an extravasation. Many technologists will refuse to perform intravenous administrations of radiopharmaceuticals, insisting that the Authorized User must administer the doses. Many practices could thus fall into great disarray, with many patients unable to receive the diagnostic and therapeutic procedures that they require. In addition, many would-be nuclear medicine technologists will change their training plans and become radiology technologists instead. We could have a great shortage of nuclear medicine technologists. Pediatric nuclear medicine could start to die out, as the chances of a small extravasation in infants and children is very likely.

Conclusion

This rulemaking is a disaster waiting to happen, and I strongly encourage the Commissioners to end this effort in its entirety.

Thank you for your attention and consideration.

Sincerely,

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1. Vaeth JM, Meyer JL, eds. Radiation Tolerance of Normal Tissues, Karger Inc., p.13 Table II, 1989.