**Lucerno questions regarding NRC’s March 17, 2020 Report to Congress**

1. NRC suggests extravasations also occur in many different types of medical procedures, with rates ranging 0.1 – 16%. The report’s references demonstrate vast disparity between the extravasation rate in nuclear medicine (15.2%) and chemotherapy (0.18%), both of which rely on peripheral IV injections. **Why does NRC believe nuclear medicine extravasation rates are 70x higher than extravasation rates in other similar IV injections?**
2. The basis of NRC’s 1980 policy decision regarding the extravasations exemption was that extravasations are “virtually impossible to avoid.” Yet literature demonstrates centers in Australia and the United States drastically reducing extravasation rates. **Does NRC have evidence today that extravasations are “virtually impossible to avoid?”**
3. In 2018 a medical event (53434) was reported of a radiopharmaceutical spilled on a patient resulting in a dose exceeding the reporting limit. Currently, an extravasation of the same dose (spilling the radiopharmaceutical into the patient’s tissue), which is more dangerous, is exempted from reporting. **How does NRC justify this discrepancy?**
4. 85% of radioactive material users fall under an agreement state’s authority. As such, the recent letter by the Organization of Agreement States (OAS) to Chairman Svinicki affirming support for eliminating the medical event reporting exemption for extravasations and opposition to the recommendations of ACMUI (and support for the dissenting opinion) seems critical. **Has NRC included OAS as a full partner in its evaluation of a potential change to this policy?**
5. Literature shows Australian nuclear medicine centers have drastically reduced extravasation rates, even without using technology cited by ACMUI. **How have Australian centers achieved such low extravasation rates while literature shows high rates in American centers? Does it matter to NRC what injection quality assurance methods a facility uses to lower rates?**
6. Questions about of relying on ACMUI, given composition of Committee and conflict of interest inherent in an industry dictating how a regulatory authority should act:
   1. In 2008 and 2009, ACMUI recommended retaining the extravasation reporting exemption, and transcripts from those meetings show members only discussed paperwork burden rather than patient safety. **What peer-reviewed clinical evidence did ACMUI consider while reaching their recommendations in 2008 and 2009?**
   2. In 2019, ACMUI claimed extravasations are a practice of medicine issue that should not be regulated by NRC. **But isn’t the NRC position that “The Commission has a role in assuring accurate delivery of radiation doses and dosages to patients and has rejected the notion that NRC should not regulate patient radiation safety?”**
   3. ACMUI was unaware of cases where patients were harmed by extravasations. **However, isn’t it true that patient harm is not a requisite for medical event reporting?** Even if it was requisite, NRC cited examples of patient harm in its report to the Committee. FDA and EU databases on adverse events identify patient harm and a FDA representative sits on ACMUI. **Should ACMUI have been aware of these clear examples of patient harm?**
   4. ACMUI did not reference relevant literature and evidence on whether extravasation rates can be reduced (the basis of the 1980 policy), and case studies demonstrating extravasations exceeding medical event reporting limits. **Does NRC commit to considering these relevant publications and case studies?**
   5. ACMUI recommended classifying extravasations as a patient intervention. **Is NRC considering evidence in Wong et al indicating contributing factors are not patient-related?**
   6. ACMUI stated it was difficult to assign a radiation dose to extravasated tissue. **Is the process that providers use to assign radiation doses to currently reported medical events different or more difficult than estimating extravasation doses?**
7. In referencing the comprehensive study by Van der Pol et al., is NRC suggesting that there are minimal cases of extravasation dosimetry and patient follow-up because there are few cases of patient harm or is NRC suggesting that because of lack of reporting requirements (that lead to dosimetry and patient follow-up) and the 2-3 year delays in the onset of side-effects that there are minimal cases of documented patient harm in the literature?
8. Can NRC provide more information on why the Boston VA initiated the retraction of their extravasation report?
9. NRC indicates that as part of **Next Steps** several other organizations will be consulted. Will the NRC review existing nuclear medicine protocols written by medical professional societies that specify actions needed in case of extravasations and will NRC consider the recent literature from global radiation experts on the role extravasations play in producing unintended radiation exposure to patients?
10. NRC refers to the risk-informed approach to medical event reporting. Does the 0.5 Sv limit reflect the emphasis on reporting more significant exposures and did the ACMUI support this limit when it was introduced?