



For Immediate Release

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NRC Advisory Committee to Reevaluate 1980 Nuclear Medicine Policy

Policy Exempted Reporting of Flawed Injections of Radiopharmaceuticals

Lucerno Dynamics CEO: Update Policy to Protect Patients, Improve Care, and Prevent Waste

ROCKVILLE, MD – A medical advisory committee to the Nuclear Regulatory Commission (NRC) this week began reevaluating an outdated policy from 1980 that exempts from reporting requirements flawed injections of radiopharmaceuticals. Such “infiltrations” can cause misdiagnosis, unnecessary invasive procedures and radiation exposure, and higher costs for patients and payers.

“I am pleased that NRC’s Advisory Committee on Medical Use of Isotopes (ACMUI) took this step to reevaluate an outdated, 39 year-old policy regarding injections of radiopharmaceuticals,” said Ron Lattanze, CEO of Lucerno Dynamics. **“Infiltrations are a pernicious issue that not only expose the patient to unintended radiation that may be reportable to NRC but can also compromise the effectiveness of diagnostic nuclear medicine scans, and the ensuing patient care. Once NRC and the ACMUI learned that the 1980 policy was based on an assumption that is no longer true in 2019, they acted very swiftly. The NRC and ACMUI are very focused on patient safety and I am excited that they are moving quickly on this issue.”**

Among NRC’s many responsibilities are ensuring safe and secure use of radioactive materials in medical applications. NRC’s Advisory Committee on the Medical Use of Isotopes (ACMUI) advises the agency on policy and technical issues that arise in the regulation of medical uses of radioactive material in diagnosis and therapy. Members include health care professionals from various disciplines and a patient advocate who comment on changes to NRC regulations and guidance and provide other independent advisory input.

On Wednesday, Mr. Lattanze presented research findings from a multi-center quality improvement project to the ACMUI regarding infiltrations in nuclear medicine procedures. He confirmed that nuclear medicine infiltrations occur much more frequently than commonly

understood. He also shared evidence that similar injection processes in chemotherapy and contrast CT procedures have significantly lower infiltration rates as a result of quality improvement efforts. He shared that new detection technology and similar quality improvement methods can also significantly improve nuclear medicine injection infiltration rates. Infiltrations negatively affect the sensitivity and quantification of nuclear medicine scans, which can result in inaccurate disease staging and treatment assessment, unnecessary invasive procedures and radiation exposure, and higher costs for patients and payers.

Mr. Lattanze called on NRC to reevaluate an outdated 1980 decision which held that an infiltration of a radiopharmaceutical should not be considered a misadministration or a medical event. In 1980, NRC stated that infiltrations frequently occur in otherwise normal intravenous and intraarterial injections and are virtually impossible to avoid. Mr. Lattanze demonstrated that infiltrations are not virtually impossible to avoid and suggested that by changing the policy infiltrations will be reportable and lead to greater protection for patients.

Following Mr. Lattanze's presentation and a period for questions and answers, the ACMUI elected to create a subcommittee of members to reevaluate the 1980 decision and report back to the ACMUI at its next meeting.

Lucerno Dynamics is a medical technology company based in Research Triangle Park, North Carolina.

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