ASTRO
TARGETING CANCER CARE

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Chief, Rulemaking and Directives Branch (RDB)
Division of Administrative Services
Office of Administration
Mail Stop: TWB–05–B01M
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Re: Comments on Docket ID NRC–2009–0346 (74FR38716)

Dear Mr. Lesar:

The American Society for Radiation Oncology (ASTRO) appreciates the opportunity to participate in this information-gathering process by offering the following comments to the U.S. Nuclear Regulatory Commission (NRC) regarding the effect of a lack of access to low-level waste (LLW) disposal facilities on those who use radioactive sources or materials in conducting research such as universities and hospitals. ASTRO commends the NRC's efforts to raise awareness of the growing disposal problem, and to bring stakeholders together in developing viable, cost-effective disposal pathways.

ASTRO is the largest radiation oncology society in the world, with 10,000 members who specialize in treating patients with radiation therapies. As a leading organization in radiation oncology, biology, and physics, the Society is dedicated to the advancement of the practice of radiation oncology by promoting excellence in patient care, providing opportunities for educational and professional development, promoting research and disseminating research results and representing radiation oncology in a rapidly evolving healthcare environment.

MEDICAL AND RESEARCH USES OF RADIOACTIVE SOURCES

Low-level radioactive waste is a byproduct of the beneficial uses of radioactive materials, including medical diagnosis and treatment, as well as biomedical and pharmaceutical research. Radioactive materials contribute to diagnosis of primary tumors, early detection of metastasis, and studies of metabolic functions, such as thyroid function. Moreover, new technologies such as monoclonal-antibody therapies are evolving that combine radioactive materials with molecules to target specific diseases within the patient's body.

Radioactive waste from biomedical research includes laboratory solutions containing radionuclides, counting vials for assessing radioactivity, biological materials such as tissue-culture cells and animal carcasses and materials that come into contact with radioactive substances, such as glass or plastic containers, gloves, paper and other absorbent materials for containing spills, and filters.

Diagnostic and therapeutic patient-care procedures also generate radioactive waste. For instance, the yttrium-90 microspheres used in the treatment of liver cancer, produce long-lived contaminates or

waste that are typically stored at the medical facility. That waste, which includes lead and body fluids, is identified as "mixed waste" requiring separation prior to disposal. Many institutions do not wish to open the containers for fear of possible contamination of their storage location or do not wish to expose radiation workers to unnecessary radiation and have chosen to store the mixed waste on site.

CURRENT ISSUES: COST AND ACCESS

ASTRO is concerned that high costs of available disposal options and limited access to existing disposal sites will negatively impact institutions that conduct biomedical research and hospitals where radionuclides are crucial for the diagnosis and treatment of disease. Because of the increasing costs associated with LLW disposal, more medical and research facilities are storing LLW on site—a practice that consumes valuable facility space, and requires ongoing surveillance and maintenance.

Research and medical institutions are currently safely and securely storing material that cannot be transferred to existing waste disposal sites. In part, storing waste is the only option for facilities in 36 states that do not have disposal access for Class B and C waste since the Barnwell, SC, disposal site closed to out-of-compact waste in June 2008. Medical institutions, however, continue to provide care to patients, even if the procedure produces waste, and research continues, to be conducted, with some evolution in radioactive material usage.

Research use with radioactive materials has dropped significantly in the past 15 years. In the past, many researchers purchased "bulk" isotope and tag molecules. Now most researchers buy the specific radioactive material they need directly. Also radioimmunoassay (RIA), which used to be a cornerstone in research, has been largely replaced by nonradioactive methods. The Council on Radionuclides and Radiopharmaceuticals (CORAR) stated at the October 7, 2009 NRC meeting that:

- Industry used to provide 1,500 radiochemicals prior to 1994;
- Over 100 radiochemical were deleted due to radwaste issues;
- Another 220 deleted due to multiple reasons including radwaste issues;
- Other deletions may be determined in the future; and
- The research community has reported similar reasons for restricting the use of radiochemicals.

With decreasing funds available for research, increased cost to procure radioisotopes to do the research, and increased cost for disposal of Class A waste at the Clive, UT, site as well as lack of disposal for Class B and C waste, the amount of grant money available to perform the actual research is decreased. Most academic institutions pass some or all of the direct costs for LLW disposal to investigators, and these costs compete directly with other research activities of the investigator. Moreover, anecdotal data, cited at the October 7 meeting, indicates research requests are being denied due to increased cost or lack of availability of the radioisotope and lack of disposal options. As costs mount, additional research funds will be diverted to LLW management and disposal. While medical and research facilities produce only a relatively small amount of the total LLW generated in the U.S., the escalating costs of management and disposal are impacting research.

Although, onsite storage is safe, it poses challenges to licensees and institutions. Storage space may be unavailable or costly to maintain. In some institutions, space that could be used for research laboratories may have to be converted to storage areas for waste. Further, increased amounts of waste in storage may cause unnecessary radiation exposure, result in increased possession limits and costly enhanced security requirements, thus decreasing the funds available for research. Moreover, even with on-site storage, the institution must put aside money for unknown future disposal cost.

SCATR AND ORPHAN SOURCE PROGRAMS

The Source Collection and Threat Reduction Program (SCATR) has registered many unwanted sealed sources for collection. Unfortunately, this program has come to a halt in part due to funding and the lack of disposal options. Other challenges include having a centralized collection location for consolidating the material prior to long-term storage or disposal. ASTRO recommends that any decision impacting LLW include continuation of the SCATR and Orphan Source programs.

UNIFORM INTEGRATED POLICY NEEDED

While no shortfall in disposal availability appears imminent, uncertainties about future access to disposal facilities remain under the current compact system. That system, implemented under the Low-Level Radioactive Waste Policy Act of 1980 and its 1985 amendments, obligated states to dispose of their own LLW and encouraged development of interstate compacts to share responsibility. Unfortunately, it has fallen short of its goals, inhibiting resolution of disposal issues, and forcing those states without access to a disposal facility to store their waste on-site until a permanent disposal facility becomes available. Moreover, issues remain about the disposition of wastes in the hands of brokers, handlers, incinerator and treatment facilities. One example, cited at the October 7 meeting, was a requirement that wastes/ash be segregated at the incineration facility and returned to the licensee and state of origin rather than allowing for disposal within the state or compact in which the incineration took place.

ASTRO urges development of a uniform, integrated LLW disposal policy to address the high costs of available disposal options and limited access to existing disposal sites for medical and research facilities. ASTRO is concerned that limited access to disposal options and the escalating costs of available options will negatively impact medical and research institutions' ability to further treatment and research goals, and urges the NRC to resolve LLW disposal issues before a crisis develops like the one we are currently working through with the severe shortage of Mo-99 for Tc-99m generators. Medical and research institutions need reliable and affordable access to disposal, as well as cost predictability for future disposal.

CONCLUSION

ASTRO advocates a pragmatic, measured approach to this issue that acknowledges the importance of medical procedures and research using radioactive sources in advancing patient care and the treatment of cancer and other diseases and avoids impairment to or dismantling of medical or research capabilities. To that end, ASTRO recommends development of viable, cost-effective LLW disposal pathways. Thank you for affording ASTRO this opportunity to provide comments on the effect of a lack of access to LLW facilities on those who use radioactive sources or materials in conducting research such as universities and hospitals. Please contact Richard Martin at 703-839-7366 or richardm@astro.org if you have any questions.

Sincerely,

Laura Thevenot

Laura I. Thevenot
Chief Executive Officer