



**American Association of Physicists in
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Electronically submitted VIA: <http://www.regulations.gov>

October 20, 2009

Michael T. Lesar,
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

8/7/09

74 FR 39716

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RULES AND DIRECTIVES
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RE: Docket ID NRC-2009-0346 (74FR38716)

Dear Mr. Lesar:

The American Association of Physicists in Medicine (AAPM)¹ is pleased to have the opportunity to provide input 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 (74FR38716). AAPM commends the NRC for providing this forum to address this important issue.

Research and medical institutions are currently safely and securely storing material that cannot be transferred to existing waste disposal sites. In part, the need to store waste is the only option for 36 states that do not have disposal access for Class B and C waste since the closure of Barnwell, SC to out-of-compact waste in June 2008. Medical institutions continue to provide care to patients even if the procedure produces waste. For instance, the yttrium-90 microspheres used in the treatment of liver cancer can produce long-lived contaminants or waste that must be stored at the facility. Because the waste

¹ The American Association of Physicists in Medicine's (AAPM) mission is to advance the practice of physics in medicine and biology by encouraging innovative research and development, disseminating scientific and technical information, fostering the education and professional development of medical physicists, and promoting the highest quality medical services for patients. Medical physicists contribute to the effectiveness of radiological imaging procedures by assuring radiation safety and helping to develop improved imaging techniques (e.g., mammography CT, MR, ultrasound). They contribute to development of therapeutic techniques (e.g., prostate implants, stereotactic radiosurgery), collaborate with radiation oncologists to design treatment plans, and monitor equipment and procedures to insure that cancer patients receive the prescribed dose of radiation to the correct location. Medical physicists are responsible for ensuring that imaging and treatment facilities meet the rules and regulations of the U.S. Nuclear Regulatory Commission (NRC) and various State regulatory agencies. AAPM represents over 6,700 medical physicists.

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includes body fluids and lead, it is identified as mixed waste and must be separated 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.

Research use with radioactive materials has dropped significantly in the past two decades. Many researchers used to purchase "bulk" isotope and tag molecules themselves. Now most researchers buy what they need directly. Also, radioimmunoassay (RIA) used to be a cornerstone in research and is now essentially gone, replaced by nonradioactive methods.

In fact the Council on Radionuclides and Radiopharmaceuticals (CORAR) stated at the October 7, 2009 NRC meeting that prior to 1994 the standard catalog of radiochemicals included approximately 1,500 radiochemicals. However, CORAR noted that over 100 of the 1,500 radiochemicals were deleted from the catalog directly due to radwaste issues and another 220 were deleted due to multiple reasons including issues related to radwaste. CORAR stated that other deletions from the standard catalog could be determined in the future. At the October 7th meeting, it was indicated that due to lack of access to waste disposal facilities, manufacturers are no longer producing bulk isotope that generate waste as a "by product" in the production and that the isotope when purchased by a researcher is significantly more expensive, because of long term storage of manufacturers waste.

With the decreasing money available for research, increased cost to procure radioisotopes to conduct research, increased cost for disposal of Class A waste at the Clive, UT site, and lack of disposal for Class B and C waste, the amount of grant money available to perform the actual research is decreased. Although we do not have hard statistics, anecdotally we are hearing of research requests being denied due to increased cost or lack of availability of the radioisotope and lack of disposal.

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. Increased amounts of waste in storage may cause unnecessary radiation exposure, result in increased possession limits and costly enhanced security requirements, thus decreasing the dollars available for research.

Through the Source Collection and Threat Reduction (SCATR) Program, many unwanted sealed sources have been registered 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. AAPM recommends that any decision impacting LLW include continuation of the SCATR and Orphan Source programs. Although the focus of this request for comment focused on waste due to research activities, NRC indicated that other concerns could be raised. If NRC is serious about addressing the broader issue of waste concerns, NRC should encourage licensees in non-agreement states to register unwanted sealed sources.

Although access to the existing disposal capacity is restricted to those fortunate licensees located in a compact state, there is no "true" shortfall in disposal capacity. However until the current compact system is revisited, uncertainties about future access to disposal facilities will remain. 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

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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.

AAPM 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. AAPM is concerned that limited access to disposal options and the escalating costs of available options will negatively impact medical and research institutions' abilities 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 Molybdenum-99 (Mo-99) for Technetium-99m (Tc-99m) generators. It is also critical to recognize that all of the solutions currently being proposed to deal with lack of a U.S. production facility for Mo-99 will require access to disposal facilities, and the proposed facilities are located in non-compact states and therefore, they do not have a disposal pathway under the current regulatory system.

In conclusion, it is AAPM's opinion that waste storage has diminishing returns and it will become more difficult for research review committees to continue to support medical research proposal with a cost that cannot be easily measured. It is hard to put storage in perpetuity into grant expenses. Because of this, research review committees may be discouraging any research that does not have a disposal option and we as a society may be suffering from future beneficial medical treatment because research cannot be conducted. Medical and research institutions need reliable and affordable access to disposal, as well as cost predictability for future disposal.

If the AAPM can supply any additional information to the Commission or the NRC staff in support of this issue, please do not hesitate to contact Lynne Fairbent, AAPM Manager of Legislative and Regulatory Affairs at 301-209-3364.

Thank you in advance for your consideration.

Sincerely,



Maryellen L. Giger, Ph.D., FAAPM, FAIMBE