POLICY ISSUE INFORMATION

<u>January 22, 2010</u> <u>SECY-10-0008</u>

FOR: The Commissioners

FROM: Charles L. Miller, Director

Office of Federal and State Materials

and Environmental Management Programs

SUBJECT: STATUS REPORT REGARDING STAFF EFFORTS TO WORK WITH

STAKEHOLDERS TO CATALOGUE IMPORTANT RESEARCH THAT HAS BEEN AFFECTED BY THE LACK OF DISPOSAL OPTIONS FOR

RADIOACTIVE SOURCES

PURPOSE:

The purpose of this status report is to inform the Commission of the staff's outreach activities to obtain information about the effect of the lack of low-level radioactive waste (LLRW) disposal options on academic and medical research. The report is also intended to summarize the results of these activities and to further identify related challenges regarding impacts on other beneficial uses of radioactive material, including radioactive sealed sources. This paper does not address any new commitments.

SUMMARY:

The lack of disposal options for sources has resulted in a negative impact on important research for a large number of members of the medical and academic communities. Although the staff did not identify many specific cases where research had to be stopped as a result of reduced disposal options, disposal limitations have created significant challenges for many members of the medical and academic research communities. The primary impacts on research appear to be a gradual decrease in the ability to conduct some research using long-lived radiochemical compounds and sources.

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Faced with challenges related to disposal of LLRW over the past several decades, members of the medical and academic research communities have successfully reduced LLRW volumes and, in some cases, found non-radioactive or short-half-life substitutes for long-lived radioactive material. Despite this progress, stakeholders representing the perspective of the medical and academic research communities have recently provided a few examples of academic and medical research involving the use of radioactive sources and radioactive material that have been eliminated due to lack of LLRW disposal access. These include, but are not limited to, metabolic research using relatively long-lived isotopes.

According to respondents, LLRW management costs and lack of disposal access have contributed to the elimination or curtailment of certain research projects. Research has also been negatively affected by the lack of availability of some radiochemical compounds used in such research. In many cases these compounds have been discontinued because of LLRW disposal challenges associated with their manufacture and use. Further, some stakeholders cited the cost and inconvenience of storage of LLRW when they are not fully equipped to store such waste.

The staff heard stakeholders concerns that the impacts extend beyond research to other beneficial uses of radioactive material in medicine, academia, and industry. These concerns include the continued availability of certain radioactive material and devices with diagnostic and therapeutic significance.

While the staff gathered much useful and relevant information during this process, the staff believes that because the lack of disposal access for Class B and C LLRW for most generators is relatively recent, the nature and degree of impacts are still evolving. For this reason, the staff sees value in continuing to gather information on this topic. To accomplish this task, the staff plans to provide a topic specific link on the LLRW public website, "Impacts of Lack of Disposal Access to Beneficial Uses of Radioactive Materials" (http://www.nrc.gov/waste/llw-disposal.html), to allow for the continued collection and sharing of information related to the impacts of the lack of LLRW disposal access on research and other beneficial uses of radioactive material. In addition, the staff will attempt to identify an entity to take a leadership role with respect to this issue.

BACKGROUND:

Concerns regarding access to commercial LLRW disposal facilities by various generators of LLRW were heightened on July 1, 2008, when access to the Barnwell LLRW disposal facility was limited to the three States (New Jersey, Connecticut and South Carolina) that comprise the Atlantic LLRW Compact. The loss of access to Barnwell effectively eliminated disposal access for generators in 36 states that generate waste classified as Class B and C LLRW under 10 CFR Part 61. In order to obtain a broad perspective on the impacts of the Barnwell closure and other aspects of LLRW management in the United States, the Commission convened a day long briefing on LLRW on April 17, 2009. The Commission invited testimony from U.S. Nuclear Regulatory Commission (NRC) staff, other State and Federal partners, and a range of perspectives from industry, medicine, and academia. During the testimony, several stakeholders spoke of the negative impacts of the high cost or lack of access to LLRW disposal facilities on medical and academic research. In a May 1, 2009, Staff Requirements Memorandum (SRM-M090417; Agencywide Documents Access and Management System (ADAMS) Accession No. ML091210423), the Commission directed the staff to develop a list or

catalogue of medical and academic research that has been affected or stopped because of lack of disposal options.

Staff was aware of earlier concerns regarding the negative impacts of both the high cost of LLRW disposal and the lack of disposal access on the beneficial uses of radioactive material and radioactive sealed sources in medical, research, academic, and industrial applications associated with both the high cost of LLRW disposal and in some cases lack of disposal access altogether. For instance, a number of concerns were raised in a background paper supporting the Health Physics Society position on LLRW, BI009-0, "Background Information on Low-Level Radioactive Waste Management Needs a Complete and Coordinated Overhaul," Position Statement of the Health Physics Society, Adopted: October 1995, Revised September 2005 (http://hps.org/documents/lowlevelwaste_background_bi009-0.pdf). These concerns included, but were not limited to, the curtailment of metabolic studies involving the use of long-lived isotopes and curtailment of studies involving the need to dispose of radioactively contaminated animal carcasses. Such concerns were also addressed by the National Academy of Sciences in a report entitled, "The Impact of low-Level Radioactive Waste Management Policy on Biomedical Research in the United States," National Research Council, 2001 (available at http://www.nap.edu/catalog.php?record_id=10064). Therein, the Academy acknowledges the challenges to biomedical investigators presented by LLRW access limitations and cost. The report also highlights some of the adaptations that are necessitated by LLRW disposal challenges, such as the use of non radioactive surrogates.

DISCUSSION:

Staff Outreach Efforts to Acquire Information

In order to solicit information in response to the Commission's direction, the staff first made a request in a *Federal Register* Notice (FRN) (74 FR 39716; August 7, 2009). The FRN contained a series of questions related to the impacts on academic and medical research related to limitations in LLRW disposal for respondents to consider. The FRN also announced that the subject would be the topic of discussion at a public meeting to be held at NRC headquarters on October 7, 2009. Staff also expanded the information request to include the use of radioactive material as well as radioactive sources. Stakeholders were requested to provide information by October 20, 2009.

Because so many of the potential respondents were Agreement State licensees, an All Agreement States Letter, FSME-09-074 (ADAMS Accession No. ML092290586) was distributed on August 28, 2009, as a meeting reminder along with a copy of the original FRN.

The staff also announced the request for information and the October 7, 2009, meeting at the Radioactive Waste Summit in Las Vegas, Nevada on September 8-11, 2009, the semi-annual meeting of the Low-Level Waste Forum in Park City, Utah on September 21-22, 2009, and the annual meeting of the Organization of Agreement States in Baton Rouge, Louisiana on September 21-24, 2009.

Further, specific stakeholders who were likely to represent aspects of the community most affected by the lack of LLRW disposal options were identified and personally contacted by staff to solicit input and participation in the public meeting. These included: the American Association of Physicists in Medicine; the American College of Radiology; the American Nuclear Society; the American Society of Nuclear Cardiology; the American Society of Radiation Oncology; the Campus Radiation Safety Officers; the Conference of Radiation Control Program Directors; the Council on Radionuclides and Radiopharmaceuticals; the Health Physics Society; the Nuclear Energy Institute; the Organization of Agreement States; the SNM (formerly Society of Nuclear Medicine); and all of the Low-Level Radioactive Waste Compact Commissions.

In order to provide for extended stakeholder participation in the October 7, 2009, meeting, access was provided by webinar and teleconference as well as participation in person. In all, there were approximately 70 participants, 43 of whom, including a number of Campus Radiation Safety Officers, participated by webinar.

Formal stakeholder presentations were provided by representatives from the American Association of Physicists in Medicine, the Council on Radionuclides and Radiopharmaceuticals, the Nuclear Information and Resource Service, the University of Missouri Research Reactor, and the Physicians for Social Responsibility. A meeting summary, attendance list, slide presentations and other relevant information can be found at ADAMS Accession No. ML092880748.

Staff has included detailed stakeholder comments related to impacts of lack of LLRW disposal access on academic and medical research in Enclosure 1.

Following the meeting staff received several topical letters and emails from stakeholders. These can be found at Docket ID NRC-2009-0346 or in ADAMS as noted in Enclosure 2.

Associated Issues Identified by the Information Collection Process

While the emphasis of this information collection exercise is the impact on research due to the lack of disposal access, outreach efforts yielded insights related to impacts on other beneficial uses of radioactive material. These include:

- Impacts on medical diagnostic and therapeutic applications. During the information collection activity, NRC staff was reminded of specific examples of diagnostic and therapeutic applications of radioactive material that are affected by waste disposal challenges. For instance, yttrium-90 microspheres used in the treatment of liver cancer produce long-lived contaminates that often do not have a disposal pathway. Other medical applications have been affected by limitations in Class B and C LLRW disposal access. For instance, a campus Radiation Safety Officer Representative noted the inability of two retired ophthalmologists in California to dispose of several Sr-90 eye applicators. A Harvard University representative noted the inability to dispose of long-lived radioactive sources used in liquid scintillation counters.
- Impact on research that involves the use of biological tissue such as large animals.

 There is a significant cost associated with the processing and storage associated with the use of large animals in research where the carcasses become LLRW.

• Impacts on other beneficial uses of radioactive sealed sources. There are numerous other beneficial uses of radioactive sealed sources in medicine, industry, government and academia that are beyond the scope of this paper. For many of these sources, when they reach the end of useful life, there is no available disposal pathway. Programs such as the Off-Site Source Recovery Program administered by the National Nuclear Security Agency and the Source Control and Threat Reduction Program administered by the Conference of Radiation Control Program Directors have provided some relief for this situation. However, these programs do not have limitless resources and some of the relief they provide is temporary.

Challenges to Information Collection

The staff's efforts yielded some information related to the specific Commission inquiry cited in Enclosure 1. However, staff believes that to some extent the impacts of the lack of LLRW disposal access on the research communities and other beneficial users of radioactive material will continue to evolve with time.

While research impacts are significant for those experiencing them, in some cases they are subtle and the direct cause/effect linkage between research impacts and disposal access is difficult to discern. Researchers themselves may be shielded from waste disposal challenges within their own organizations. They may be aware of the need to change protocols and unavailability or expense of certain materials and devices to facilitate research, but they do not necessarily link these issues with LLRW waste disposal.

Also, the staff's solicitation of information was voluntary and directed in large measure toward stakeholders who are not NRC licensees. It was noted by some participants that there is some reluctance on the part of some licensees to identify specific problems or concerns, citing public relations concerns and reluctance to reveal information that may be useful to competitors.

Further, the lack of disposal access is a relatively recent circumstance. In many cases radioactive source and radioactive material disposition challenges may not be readily apparent to all who may eventually face these challenges as lack of LLRW disposal access becomes more acute with the passage of time.

Challenges and Opportunities within the Community of Users

The information gathering and dialogue with stakeholders led to several observations regarding challenges and possible opportunities accruing to the community of affected stakeholders.

The interests of stakeholders in the academic and medical communities who use radioactive material and radioactive sealed sources are broad and diverse. Further, not all of these stakeholders are uniformly represented by trade associations or users groups that can represent their interests and concerns. As noted above, staff specifically contacted a number of organizations thought to represent a wide cross-section of stakeholder interests in the academic and medical research communities. However, there are likely many more organizations that staff did not contact that could have added value.

Because the volume of LLRW generated by the communities of users represented here is considered to be small in comparison to the volume of LLRW generated by the nuclear power industry, there may be little financial incentive to develop market based solutions for some or all of the LLRW management challenges faced by the medical and academic communities.

The volume and activity of LLRW generated by academic and medical users of radioactive material is small in comparison to that generated by utilities. However, the volumes and activities are likely to be somewhat larger than reported by the U. S. Department of Energy (DOE) in its Manifest Information Management System (MIMS). The MIMS system reports volume and activity of waste that is disposed of at commercial LLRW disposal facilities. There is no specific requirement for reporting radioactive waste that licensees have chosen to or are compelled to store.

FOLLOW UP:

The staff believes that it is important to allow for the continued collection of information that reinforces the linkage between necessary medical and academic research using radioactive material and the challenges that users of this material face regarding the management of the LLRW generate as a result of its use. Therefore, the NRC staff believes that there is value in continuing information collection begun in August 2009. For the near term, the staff plans to continue to accept relevant information at a public website staff has provided, "Impact of Lack of Disposal Access to Beneficial Uses of Radioactive Waste." http://www.nrc.gov/waste/llw-disposal.html. This site will also provide a mechanism for dissemination of such information to other stakeholders, and will also provide links to other relevant websites such as those of some of the users groups cited above, the California Radioactive Materials Management Forum, and DOE's MIMS.

The staff will continue to encourage an ongoing dialogue on this topic not only between stakeholders and NRC but also among stakeholders themselves. The staff believes that such dialogue may lend itself to identification of solutions to some of the challenges created by limitations in LLRW disposal access faced by medical and academic users of radioactive material.

The staff will continue to exchange information related to the adverse impacts of the lack of LLRW disposal access with federal and state partners and private sector stakeholders. Further, the staff will attempt to identify an entity who would be willing to assume a leadership role in addressing solutions to the challenges identified above related to the adverse impacts of the lack of LLRW disposal access on the beneficial use of radioactive material.

RESOURCES:

Baseline LLRW staff resources for Fiscal Year 2010 are budgeted at 5.0 full-time equivalents (FTE). Staff estimates that approximately 0.2 FTE will be required to maintain stakeholder interaction on this topic as well as maintain the website described herein.

COORDINATION:

The Office of General Counsel has reviewed this paper and has no legal objection. The Office of the Chief Financial Officer review was unnecessary because of low resource implications.

/RA/

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Enclosures:

- Detailed Stakeholder Comments related to Academic and Medical Impacts
- 2. Summary of All Stakeholder Comments

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