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Chief,
Rules and Directives Branch,
Mail Stop T6-D59
U.S. Nuclear Regulatory Commission,
Washington, DC 20555-0001

Reference: **Requests for Comments on the Nuclear Regulatory Commission's Low Level Radioactive Waste Program.**
Federal Register Vol 71, No 130, July 7, 2006.

These comments concerning the NRC's LLRW program are submitted on behalf of the Council on Radionuclides and Radiopharmaceuticals (CORAR) [1]. CORAR members and their customers generate LLRW incidental to manufacturing and using radioactive materials. We consequently have considerable experience in managing LLRW and appreciate the opportunity to share our perspective with the NRC.

CORAR would be glad to provide clarification of the attached comments or further information.

Yours sincerely,

Leonard R. Smith, CHP
Co Chairman CORAR Manufacturing Quality and Safety Committee.

1. CORAR members include manufacturers and distributors of diagnostic and therapeutic radiopharmaceuticals, life science research radiochemicals and sealed sources used in therapy, diagnostic imaging and calibration of instruments used in medical applications.

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CORAR COMMENTS ON NRC LLRW PROGRAM

1. **What are your key safety and cost drivers and/or concerns relative to LLW disposal?**

   1) The Barnwell, S.C. LLRW disposal site is scheduled to close to operators in 36 states in July 2008. Many generators in these States will then not have access for disposing Class B and C and some Class A waste.

   2) When Barnwell, S.C. LLRW disposal site closed for one year in 1994-1995 many licensees restricted the use of or eliminated using long-lived radioactive materials. The loss to the research community was roughly 20% with many licensees not resuming their research activities when the Barnwell site reopened.

   3) The cost of managing LLRW for the biomedical research community is a significant concern. The cost is particularly high for certain forms of mixed waste and for LLRW that can only be disposed at the Barnwell Site. This unnecessary high cost varies from one institution to another but affects virtually all institutions and erodes the available funds for critical biomedical research and contributes to the high cost of healthcare.

   4) A significant concern is the political resistance in Utah against allowing the Clive LLRW disposal site to accept Class B and C radwaste. Acceptance of Class B and C waste at Clive is considered a possible resolution of the problem of Barnwell restricting access.

2. **What vulnerabilities or impediments, if any, are there in the current regulatory approach toward LLW disposal in the U.S., in terms of their effects on:**

   a. **Regulatory system reliability, predictability, and adaptability.**

   5) CORAR is concerned that the radwaste and compact community does not recognize the urgency in providing for alternative disposal access by July 2008. We therefore agree with NRC's comment to GAO (June 2004) that it is in the national interest to explore alternatives that would potentially provide a better legal and policy framework for new disposal options for commercial generators of LLRW.

6) The main impediment to the safe disposal of LLW in the U.S. is the limited access of cost-effective disposal due to the majority of States failure to participate in a few regional compacts as intended by the Low-Level Radioactive Waste Policy Amendments Act of 1985. In the current situation generators in 36 states do not have long-term access for disposal of Class B and C and certain forms of Class A radioactive waste. Current access is scheduled to be closed in July 2008.

7) Nuclear Regulatory Commission (NRC), 10 CFR 61 regulations provide appropriate requirements for the safety and security of radioactive waste containing byproduct material. The NRC should consider determining any possible regulatory issues that might arise if non-DOE radwaste were to be disposed of at DOE disposal facilities after July 1, 2008, and resolution of those issues if identified.

8) Some States are in process of adopting the EPA's Conditional Exemption Rule. The EPA should require States to implement the Rule.

b. Regulatory burden (including cost); and

9) The NRC's current regulatory developments to accommodate the expanded definition of byproduct material to include accelerator produced material should ensure more equitable treatment of materials with similar risks and different origins while maintaining the current cost effective access for disposal of accelerator produced materials for all generators.

10) The current excessive cost for generators in 36 states for disposing Class B and C waste and sealed sources and biological materials in Class A waste is due to only one site being currently available to these generators.

11) The current excessive cost for treatment and disposal of certain mixed wastes is partially due to States not yet implementing the EPA's Conditional Exemption Rule.

12) CORAR has previously commented on the inability to offset the estimated cost of decommissioning a licensed facility by the resale value of viable assets. CORAR is concerned that sealed sources with considerable resale value are generally included in the cost of decommissioning as a potential radwaste disposal cost. The NRC could consider, on a case by case basis, allowing the potential cost of disposal to be part of the contingency for unexpected cost increases.

c. **Safety, Security, and protection of the environment?**

13) NRC and Agreement State LLR regulations have robust and well tested provisions to ensure safety, security and protection of the environment. The regulations require optimization of controls using the ALARA principle and require that generator's expedite the disposal of LLW and only store LLW on the generator's site to accumulate a practical shipment or to allow short lived radionuclides to decay. These objectives cannot be met if generators do not have reliable cost effective access for LLW disposal.

3. **Assuming the existing legislative and regulatory framework remains unchanged, what would you expect the future to look like with regard to the types and volumes of LLW streams and the availability of disposal options for Class A,B,C and greater-than-class-C (GTCC) LLW. Five years from now? Twenty years from now? What would more optimistic and pessimistic disposal scenarios look like, compared to your expected future?**

Expectation:

14) CORAR expects that the use of radiopharmaceuticals, radiochemicals and sealed sources will continue to increase in the U.S. The nuclear medical community expects to be using increasing quantities of high energy beta emitters and alpha emitters for therapy. These expected increases in use might be off set by greater efficiencies in minimizing radwaste. Hence we would expect that LLW generation would not change significantly during the foreseeable future.

5 years Expectation:

15) Five years from now we expect that disposal options for LLW will be similar to today with the major exception that generators in 36 states will not have access to the Barnwell, S.C. disposal site and will be storing Class B and C and some Class A LLW on the generator's site.

5 years Optimistic Scenario:

16) A more optimistic disposal scenario in five years time would be if the Clive, Utah Site accepted all Class A,B and C waste and if the Texas-Vermont, SE , NW and Mountain Compacts voluntarily accepted Class A,B and C waste from out-of-compact States. Also there could potentially be emergency access to a DOE site for "non-DOE" generators in the event that the commercial disposal sites close access.

5 years Pessimistic Scenario:

17) A more pessimistic disposal scenario in five years would be if the Barnwell, S.C. disposal site had to close due to not being economically viable and the Clive, Utah site significantly increased the cost of disposal.

20 years Expectation:

18) In 20 years time the Clive, Utah site might be reaching capacity and planning to close. The Texas-Vermont Compact should be viable and CORAR would expect that after a period of storing waste on generator sites and public concern that there would be a DOE site accessible for non-DOE waste disposal when other commercial sites are not available.

20 years Optimistic Scenario:

19) A more optimistic disposal scenario in 20 years time would be that the compact system is not needed and that the public would be educated to appreciate the need for a few disposal sites and that these would be available and would not be allowed to discriminate against out-of-state generators also the DOE would still maintain a part of a site for non-DOE waste needing emergency access.

20 years Pessimistic Scenario:

20) A more pessimistic disposal scenario in 20 years time would be no viable sites available and licensees forced to store on the generator's sites or cease using radioactive materials.

4. How might potential future disposal scenarios affect LLW storage and disposal in the U.S., in terms of :

a. Regulatory system reliability, predictability , and adoptability;

21) The loss of access to the Barnwell LLW disposal site might necessitate the federal government securing waste orphaned due to bankruptcy. Currently it appears that federal facilities are only suitable for storing orphaned sealed sources at the DOE Los Alamos National Laboratory. Some Licensees will need to apply for increased possession limits to store LLW on site. This may cause the need for costly enhanced security provisions.

b. **Regulatory burden (including cost); and**

22) The loss of access to the Barnwell LLRW disposal site will cause licensees to store LLRW on the generator's site for an indefinite period. Many licensees do not have space for long-term storage. For those that do have the space storage will be expected to incur facility and management costs with no benefit. If the loss of access is prolonged, further costs may be needed to repackage waste. When access to a disposal site is regained, disposal conditions may be different, requiring further changes in processing and packaging and additional costs. We would expect a sharp decline in the use of radioactive materials and cut back in research in the biomedical community. The majority of licensees do not have the ability to store waste for a number of years.

c. **Safety, security and protection of environment?**

23) If the loss of access to the Barnwell LLW disposal site causes licensees to store radwaste on the generator's sites, local residents and other members of the public are likely to perceive this as unsafe and could be genuinely concerned that stored waste could become an attractive terrorist target with a purpose to cause panic. Radwaste stored on a generator's site will need to be periodically inspected and may incur unnecessary radiation exposure.

5. **What actions could be taken by NRC and other federal and state authorities, as well as by private industry and national scientific and technical organizations, to optimize management of LLW and improve the future outlook? Which of the following investments are most likely to yield benefits:**

a. **Changes in regulations;**

24) 10 CFR 110.2 exempts used sealed sources from radwaste export and import requirements provided that the source is being returned to a manufacturer that is qualified to receive and possess the sealed source. This is a necessary and useful exemption because radwaste export and import regulations are particularly burdensome and could be a significant barrier to expediting the proper disposition of used sources. As similar regulatory provision is needed within the U.S. to facilitate the recovery, reworking and reuse of sealed sources, particularly large sources containing long-lived radionuclides such as ^{60}Co. This provision should recognize the value of the recovered material, the need to expedite recovery to optimize security and the need to avoid sources being unnecessarily or prematurely classified as radwaste. In this context, there is a need for a better definition of radwaste to ensure that used sealed sources with recovery value are distinguished from materials that have no useful value.

25) Mixed wastes could be better and more cost effectively managed under a materials license in accordance with the EPA's Conditional Exemption Rule. The EPA should revisit their rule and require States to adopt it and provide the necessary training and funding to promote this development. States should be required to implement this rule because it promotes the safe and expeditious treatment and disposal of mixed waste.

26) The EPA has approved the treatment of mixed wastes in two Project XL Site Specific Rules. The EPA should establish a rapid procedure to approve all qualified NRC and Agreement licensees to use this process for similar mixed wastes to enable these wastes to be safely and expeditiously disposed.

27) The NRC should continue to implement the regulation of NARM and ensure uninterupted access for disposal of NARM waste.

28) The NRC should reevaluate 10 CFR 61.55 waste classifications and provide more realistic concentration limits for disposal sites in arid regions where brackish groundwater is unsuitable for sustaining agriculture.

29) The NRC should continue finalizing rulemaking on the clearance of solid materials and then work with the EPA on disposal alternatives for slightly contaminated materials that are not accommodated by the clearance rule.

30) The EPA should continue to work with the NRC on proposing access to RCRA-subtitle C hazardous waste disposal sites for low activity radioactive waste.

31) The EPA should amend the Condition Exemption Rule to require its implementation by the States and provide the necessary funding and training to expedite this.

32) The EPA should permit qualified licensees to use catalytic chemical conversion treatment of specified mixed wastes and delist these wastes.

b. Changes in regulatory guidance;

33) The EPA should provide a list of hazardous organic chemicals in mixed wastes that may be treated using the catalytic chemical conversion method.

c. Changes in industry practice

34) Sealed source manufacturers are concerned that some used sources, possessed by licensees that have the means to pay for reasonable cost of recycle or disposal, are instead being sent as orphaned sources to the DOE. Another concern is that licensees offering a discount recovery service for used sealed sources are placing the sources in long-term storage without accumulating the financial means to properly dispose of them in the future. In both cases CORAR does not think that a regulatory change is warranted but instead recommends that these issues be addressed by establishing appropriate license conditions and assured by routine regulatory oversight.

d. Other (name).

35) Congress should ensure that the DOE Offsite Source Recovery Program is adequately staffed and funded to continue their capable and responsible handling and storage of orphaned sources including GTTC waste. Congress should consider expanding the program for disposing GTTC waste to include non-DOE Class B and C LLW.

36) The Government Accountability Office should investigate the differences in cost for disposing accelerator and reactor produced radionuclides and the reasons for these differences.

37) Regulations should continue to focus on safety, security and protection of the environment. Access for disposal should be subject to the market economy with emergency disposal provisions maintained by the DOE in the event of a lapse in access for non-DOE waste generators..

38) The DOE should characterize waste generators according to the use of radioactive materials to ensure that legislators and the public are properly educated to be aware of the social benefits that are jeopardized by loss of access for waste disposal.

6. Are there actions (regulatory and/or industry initiated) that can/should be taken in regard to specific issues such as;

a. Storage, disposal, tracking and security of GTTC waste (particularly sealed sources);

39) The DOE should continue funding the Los Alamos National Laboratory source recovery program for sealed sources and develop a GTTC disposal site.

b. Availability and cost of disposal of Class B and C LLW;

40) Legislative action is needed to ensure ongoing availability of cost-effective disposal of class B and C LLW when the Barnwell, S.C. disposal site restricts access in 2008. The DOE should establish and maintain emergency disposal capacity for non-DOE waste generators in accordance with NRC 10 CFR 61 requirements. This provision should be accessible to any generator that cannot obtain more cost-effective disposal in a commercial LLW disposal site.

d. Extended storage of LLW;

41) The need to store LLW on generator sites should be avoided by ensuring continuity of access to disposal sites. However, in the event of a lapse in access, the NRC and Agreement States should be prepared to allow short-term storage and provide for increasing license possession limits to accommodate this.

e. Disposal options for low-activity waste (LAW)/very low level waste (VLLW);

42) The NRC should promulgate a clearance rule for solid materials and then work with the EPA to evaluate using RCRA-subtitle C hazardous waste sites for disposing LLW not accommodated by the clearance rule. The use of RCRA-subtitle D disposal sites for mixed waste should also be evaluated.

f. On-site disposal of LLW;

43) This is not a viable option for most material licensees who are located on urban and suburban sites.

g. Other (name).

7. What unintended consequences might result from the postulated changes identified in response to questions 5 and 6?

44) States that adopt the EPA's conditional exemption rule might add further conditions that provide no useful benefit and cause regulations to vary. This can be avoided by the EPA requiring that the States must be strictly compatible with the EPA rule.

45) The NRC might receive significant adverse reactions from members of the public concerning the clearance rule.

46) The EPA has not yet established concentration limits or other parameters to characterize low-activity waste. If these limits are set too low, there will be little practical value in qualifying RCRA-subtitle C sites for LLW disposal. The concern that disposing LLW in EPA RCRA-subtitle C sites might reduce the economic viability of established LLW sites should be fully evaluated. Also the need to provide segregated cells on a RCRA-C site for disposing LLW should be considered, particularly with respect to minimizing generator liability.

8. **Based on your observations of what works well and not-so-well domestically an/or internationally, with regard to the management of radioactive and/or hazardous waste, what actions can the NRC and other Federal regulatory agencies take to improve their communications with affected and invested stakeholders?**

47) DOE should continue to disseminate information on LLRW but should update their Manifest Information Management System to more clearly characterize the generators of LLRW to ensure that the public and legislators and other stakeholders understand the benefit of practices to society that generate waste. For example, the DOE projected waste volumes at the Barnwell, S.C. disposal site were characterized as 1470 cu. ft. non-utility and 50 cu. ft. medical when much of the "non-utility" radwaste is from government, academic and industry biomedical research laboratories and from the manufacturers that supply radiochemcial's for these users and for drug discovery and hospital uses. Hence most of the "non-utility" radwaste should be characterized as medical waste.

48) The clearance rule should be published with comprehensive explanation on its value and the protection provided in terms that can be readily understood by the public. It would be helpful if the EPA and other federal agencies worked with the NRC to harmonize the rule and avoid the impression that regulatory agencies have different standards.