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Subject: CORAR Comments on 10 CFR Part 61. Docket ID NRC-2011-0012.

Reference: Federal Register Vol. 77, No 89, May 8, 2012, Pages 26991-26993. 10 CFR 61, Low-Level Radioactive Waste Management Issues.

These comments are submitted on behalf of the Council on Radionuclides and Radiopharmaceuticals (CORAR)¹. CORAR members and their customers are material licensees that generate a broad range of Hold for Decay, Very Low Level, Low Level and Greater than Class C radioactive waste. These waste forms are generated during the production and uses of radionuclides, radiopharmaceuticals and sealed sources that are immensely beneficial to society. Most of this waste involves short lived radionuclides that are already decayed. Disused material and sources containing long lived radionuclides are reprocessed and recycled by manufacturers. However, prompt disposal is the best practice for radwaste forms that cannot be effectively treated this way. CORAR is consequently highly supportive of uniform regulations that promote the safe, secure, prompt, reliable and cost-effective disposal of these wastes.

1. CORAR members include major manufacturers and distributors of radioactive chemicals, radioactive sources, radiopharmaceuticals and research radionuclides used in the U. S. for therapeutic and diagnostic medical applications and for industrial, environmental and biomedical research and quality control.

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Add = M. Lee (MPL)
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CORAR agrees with the NRC perception that the 10 CFR 61 regulations have been successfully protective of the public environment. However, during the past 30 years we have gained much experience with waste disposal practices and recognize that the waste forms and disposal engineering and radiation protection technology has changed significantly. CORAR favors a comprehensive revision of 10 CFR 61 to align with international practice, including the IAEA radwaste classification system, based on up-to-date ICRP dose conversion recommendations and take full advantage of recent advances in disposal technology and practices.

Certain unique radwaste forms, such as long-lived radionuclides currently designated as Class C, require more accurate quantification that should be addressed in revised waste acceptance criteria. The concentration and bulk quantity limits on these radionuclides should be reconsidered to ensure that they are appropriately disposed in a LLW or Intermediate Level Waste site. C-14 radwaste should be reevaluated to establish disposal practices that take full advantage of isolation and benign dilution and dispersion techniques that are appropriate for the radiochemical waste forms that are offered for disposal.

CORAR fully appreciates the NRC primary focus on safe and secure disposal. There is also a critical need to ensure that the disposal of radwaste from the biomedical community and their suppliers is cost-effective. In particular there should be a careful evaluation of the cost of extending institutional control versus limiting bulk quantities or concentrations in a LLW site. This is necessary to promote two important benefits, to encourage biomedical licensees to promptly dispose LLW and not store it and ensure that more biomedical researchers can continue important research that can only be done using radioactive materials.

CORAR appreciates the opportunity to provide these comments on this important regulation and shall be glad to provide clarification and additional information.

Yours sincerely, 

Leonard R. Smith, CHP

Co-chair CORAR Committee on Manufacturing, Health and Safety.

Enclosure: CORAR Comments on 10 CFR 61.

CORAR COMMENTS ON 10 CFR 61

LLW Program Timeline

1. The NRC timeline presented at the March 2, 2012 meeting in Phoenix appears realistic to CORAR. We favor a one-time comprehensive revision of 10 CFR 61 that more closely aligns with international practice to foster increasing trans-boundary employment and associated training. This development is similar to the NRC revision of 10 CFR 20. In both developments we perceive a need to use new ICRP dose conversion coefficients that are expected to be available in 2015. Changes to 10 CFR 20 and 10 CFR 61 should be implemented at the same time. There are a number of technical and financial issues to be resolved that will need significant NRC staff and contractor input.

Intruder Assessment

2. CORAR recognizes that there are multiple and alternative ways to protect intruders from unacceptable exposure. They include:

- a. Extending institutional controls from 100 to 200 or 300 years.
- b. Limiting LLW to ensure it has decayed below the level for unacceptable exposure after institutional controls have ended.
- c. Provide barriers and/or containment that survive beyond the institutional control period for long-lived radionuclides that an inadvertent intruder can recognize and avoid.

Either of these methods could be used individually or in combination to ensure adequate protection. The most cost-effective method(s) should be determined and selected.

3. Protection against intentional intrusion should consider that future generations may have much better prospecting technology. They may be able to remotely detect and identify materials in demand such as lead and uranium without knowing the presence of residual radioactivity. This implies the consideration of other protective measures such as prohibition of these materials in the facility or retrieval of these materials prior to closure of institutional controls. This situation only applies if there are radionuclides that have not adequately decayed when institutional controls have been terminated.

4. CORAR has often recommended that an effort be made to ensure that decommissioning and disposal impact assessments are accurate and risk-informed rather than highly conservative. Consequently we support the concept that inadvertent intruder protection should include reasonable assessment of the probability of intrusion. For example the scenario could be treated as a succession of potential intruders who form a critical group for whom the average exposure is determined.

Alignment with ICRP 103 Recommendations

5. CORAR recommends that 10 CFR 61 and 10 CFR 20 should both be updated to be based on ICRP 103 Recommendations. The ICRP has started publishing new dose conversion data which should be completed in 2015. The two regulations should be made effective at the same time to enable licensees to update their standard operating procedures and administrative action levels in one comprehensive effort. Major material licensees may need about a year to make these changes and some may need support from consultants to do this.

6. CORAR recommends that the NRC consider the DOE practice of promptly reviewing ICRP and NCRP recommendations to determine any significant changes in technical data that warrants updating a disposal site performance assessment. Minor updates could be scheduled on a 5-10 year cycle.

IAEA Waste Classification System and Unique Waste Forms

7. CORAR perceives that the IAEA Waste Classification System could be adopted in the U.S. to resolve several issues. The U.S. needs an Intermediate Level Radioactive Waste Site to dispose GTCC waste. Such a site could also be more suitable than a LLW site for the disposal of depleted uranium and longer lived radionuclides. One potential solution to consider is to establish a two-level facility in which intermediate level waste would be placed at the lower level at a greater than 30 meters depth and LLW would be subsequently placed above this. The NRC should also consider authorizing RCRA Class D Hazardous waste disposal sites for Very Low Level Radioactive Waste. These could be used to accept decommissioning rubble and unstable Class A dry active waste.

8. CORAR questions the practice of including greater than de minimis concentrations of long-lived radionuclides such as depleted uranium, Tc-99, I-129 and C-14 in a LLW site together with shorter lived radionuclides. It appears that higher concentrations and bulk quantities of these longer-lived radionuclides should be placed at a deeper level in an Intermediate Level Waste Disposal Site. Does the Texas, Andrews County, Federal Radwaste Disposal facility meet the requirements for disposing Intermediate Level Radwaste? Would this facility also be suitable for GTCC radwaste?

9. CORAR is concerned that existing LLW sites are receiving longer-lived radionuclides whose quantities are greatly overestimated such that the sites inventory limit is inadvertently threatened to be reached. This could be corrected by the NRC providing guidelines on the appropriate methods to estimate the quantities of these radionuclides in the waste and specify the MDAs that must be used to ensure that serious overestimate are avoided. This issue could be avoided if only de minimis concentrations (as a contaminant) were accepted in a LLW site and higher concentrations disposed in an Intermediate level waste site.

10. CORAR is concerned that LLW C-14 disposal practices are excessively conservative and consequently a barrier to the use of this radionuclide in biomedical research. The primary problem is that ICRP uses a conservative 4-compartment biokinetic model to characterize the retention of organic-C-14. In this model the dose conversion factor is dominated by the fraction of uptake retained in the compartment with a 40 day biological half-life. However, only a few commonly used research radiochemicals are metabolized this way. Most have much faster clearance with dose conversion factors that are 10-100 times lower than the ICRP model predicts. CORAR recommends that the NRC considers sponsoring research into this issue with a purpose to determine groups of radiochemicals in use that are less potent and provide less restrictive disposal requirements for them. Furthermore, most organic-C-14 radiochemicals in common use that are disposed in a LLW site will oxidize or anaerobically decompose, according to the disposal conditions, to carbon dioxide-C-14 or methane-C-14 which are 100 times less potent than assumed for organic-C-14. These gases will diffuse through the site and be gradually released to the atmosphere. This results in the residual C-14 in the site having an effective half life of only a few years. Since C-14 can be more safely managed by benign dilution and dispersion shouldn't it be disposed in a facility that promotes and controls this process?

LLW Sites Period of Performance

11. To ensure public credibility there should be more consistency in the period of performance decided for each LLW site. Since the majority of LLW sites are DOE sites that use a 1000 year period of performance, which seems reasonable, we recommend that the NRC adopts the same practice. However, if future LLW sites accept only de minimis concentrations of longer-lived radionuclides and all disposed radwaste is decayed to de minimis levels during the institutional control period there should not be a need for the 2-tiered system of a period of performance and a peak dose assessment.

12. CORAR was interested to learn of the practice in Finland to allow long term performance to reach estimated dose-rates that are close to the local natural background. This seems both logical and practical.

10 CFR 61.55 and 61.58

13. It appears to CORAR that the 10 CFR 61.55 waste classification system and tables would be more useful if they reflected actual disposal site conditions rather than the most conservative conditions. At the March 2, 2012 meeting in Phoenix NRC staff mentioned that it would be too costly to establish classifications and tables for each disposal site currently in use. However, if each site operator is required to establish a site performance assessment and radwaste acceptance criteria, is it comparatively easy for NRC to review this information and establish a site specific waste classification system and corresponding tables?

14. CORAR is aware that the NRC is considering developing one or more generic performance assessments. We perceive that at least two sets of performance requirements, one for a wet site and another for an arid site could be very useful in the absence of site specific assessments.

15. CORAR understands that certain longer-lived radionuclides are better addressed in a site specific performance assessment. Many material licensees are puzzled why waste classification is not currently based on site specific performance assessments. If the issue is just the high cost of the assessment we would recommend that the overall costs of assessment and disposal be evaluated for each option to help decide which is the best and most cost-effective option.

Agreement State Compatibility

16. It seems reasonable to CORAR that the NRC should maintain Category A and B Compatibility for States for the basic standards and direct trans-boundary activities. Material Licensees perceive the need for uniform regulations when radwaste is generated, processed and disposed in different States. However, if radwaste is generated, processed and disposed in one State it seems reasonable that the State be allowed to adopt requirements that are more in line with local conditions. For this practice to be permitted the different State requirements should be formally justified and subject to NRC approval.