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DOCKETED  
USNRC

May 7, 2008 (4:45pm)

OFFICE OF SECRETARY  
RULEMAKINGS AND  
ADJUDICATIONS STAFF

May 7, 2008

Secretary,  
U.S. Nuclear Regulatory Commission  
Washington, DC 20555-0001

**Attn: Rulemaking and Adjudication Staff**

**Subject: CORAR comments on Decommissioning Planning. RIN 3150-AH45.**

**Reference: 1) Federal Register Vol. 73, No 14, January 22, 2008. Pages 3812-3846.**

**2) SECY-03-0069 Results of License Termination Rule Analysis. May 2, 2003.**

**3) SECY-07-0177 Proposed Rule: Decommissioning Planning. October 3, 2007.**

**4) Regulatory Analysis for Proposed Rulemaking Decommissioning Planning. September 2007.**

These comments are submitted on behalf of the Council on Radionuclides and Radiopharmaceuticals (CORAR)<sup>1</sup>. CORAR members and their customers regularly remodel and move operations to new facilities and have long experience with decommissioning activities. In these comments we have focused only on 10 CFR 20 and 30 provisions since other changes in the proposed rule affect few of our facilities and those of our customers in the medical, biotech and education communities.

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

Template = SECY-067

SECY-02

Current decommissioning funding mechanisms in 10 CFR 30.35 (f) have been effective for our industry. However, since the industry has major incentives for ensuring effective decommissioning we consider the current financial assurance requirements to be an unnecessary burden which could compromise the financial viability of a business if allowed to escalate. Furthermore, these unnecessary costs are mostly passed on to customers in the biomedical research and medical community which increases the cost of healthcare with obvious adverse effects to society.

The current decommissioning provisions in 10 CFR 20 and 10 CFR 30 are more than sufficient for manufacturing licensees and should be assigned Agreement State Compatibility Category B to eliminate inconsistencies in states that have not adopted NRC requirements. The decommissioning issues raised in this proposed rule could be better addressed on a case-by-case basis through the licensing, inspection and enforcement process for the unusual licensee that may have those concerns. This would be much more effective and efficient than attempting to adjust regulations that 23,000 licensees are obliged to read.

We appreciate the opportunity to provide these comments as well as the following specific comments on this proposed rule and support documents and shall be glad to provide clarification or additional information.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'Roy Brown', written in a cursive style.

Roy Brown  
Senior Director, Federal Affairs  
Council on Radionuclides and Radiopharmaceuticals

**SPECIFIC CORAR COMMENTS TO NRC ON SECY-03-0069, "RESULTS OF THE  
LICENSE TERMINATION RULE ANALYSIS." MAY 2, 2003.**

- 1. Attachment 7, page 2: "3.2 Operational Indicators of Increasing Costs...7) Actual remediation costs that exceed the initial cost estimate."**

Actual remediation costs can exceed decommissioning cost estimates due to a licensee deciding for business purposes to choose an expensive method to remediate. This might be to minimize a business interruption or to organize the remediation around ongoing operations. While we agree that licensees might consider increasing decommissioning costs when remediation cost exceed the initial decommissioning cost estimate the increase should not be a requirement.

- 2. Attachment 7, Page 3: "A parent company or self-guarantee does not require the guarantor to set aside any funds unless the licensee fails to carry out decommissioning. As a result, during operation there is no requirement to set aside funds because the licensee is not in decommissioning. The lack of actual funding makes the parent company and self-guarantee vulnerable in the event of bankruptcy."**

To qualify for the parent-company guarantee, the licensee's guarantor must pass a rigorous financial test with acceptance criteria that banks, which would engage with licensees to establish the standby trust fund, may not satisfy. There would be no need for such a company, particularly with a AAA rating, to establish a trust fund with a bank with a rating that is at the same level or lower. It makes no sense for NRC to prefer to accept this potentially greater vulnerability.

- 3. Attachment 7, page 4: "Balanced against the concern over vulnerability is NRC's experience that no licensee providing a parent company or self-guarantee has entered bankruptcy or has failed to proceed with decommissioning projects in an adequate manner."**

CORAR appreciates this statement and supports NRC's decision to continue to allow parent company and self-guarantees for decommissioning financial assurance purposes.

- 4. Attachment 7, page 4: "To provide the same amount of assurance [using parent company or self-guarantees] using letters of credit would cost about \$8 million per year in aggregate."**

CORAR considers this to be a very good reason for preserving the current financial assurance options in proposed 10 CFR 30.35 (f) (2).

**SPECIFIC COMMENTS TO NRC ON SECY-07-0177, "PROPOSED RULE:  
DECOMMISSIONING PLANNING" October 3, 2007**

1. **RIN: 3150-AH45, Page 35, "When ground water is being monitored, the surveys conducted by the licensee also would include hydro-geologic evaluations that lead to a determination of effective sampling and analysis, ..."**

Licensees typically do not have qualified staff to conduct hydro-geologic evaluations to determine effective subsurface sampling and analysis. It is inappropriate to expect licensees to contract for these services unless there is reasonable evidence that they are warranted.

2. **RIN: 3150-AH45, page 36. "There are no reporting requirements for licensees under proposed changes to 10 CFR 20.1406 (c) and 20.1501."**

Licensees are currently required to report significant environmental impacts to both NRC-Agreement State agencies and the EPA.

**SPECIFIC CORAR COMMENTS TO NRC ON “REGULATORY ANALYSIS FOR  
PROPOSED RULEMAKING- DECOMMISSIONING PLANNING.” SEPTEMBER  
2007.**

1. **Page 3, “... materials facilities who have a license to possess relatively small amounts of radioactive material are permitted to use a Certification Amount of funding as decommissioning financial assurance.”**

Decommissioning cost estimates should be based on the actual radionuclide inventory and not license limits. For example, broad scope licensees may be licensed to possess multi-Ci quantities of a broad range of radionuclides but in practice only possess mCi quantities of many of these and zero quantities of most radionuclides. The estimates should be based on the historic use as indicated in licensee inventory records.

2. **Page 3, “Current regulations do not require the licensee to increase its decommissioning funding assurance following a spill if the licensee decides to defer remediation to a later date.”**

CORAR disagrees that current regulations do not require the licensee to increase its decommissioning funding assurance following a spill if the licensee decides to defer remediation to a later date. This requirement is not specified in the regulation but is covered by broader requirements including ALARA provisions and the cradle-to-grave principle in managing licensed materials. These provisions can be written into the section of the decommissioning plan that specifies how the cost estimate and assurance funding is maintained up to date. Also the plan typically will have a 25% contingency for unexpected cost increases that would cover all but the most unusual spill.

3. **Page 3, “Amendments to 30.35 (e)... would require all material licensees to plan unrestricted use of the site...”**

Amendments to 30.35 (e) to require materials licensees to plan unrestricted use of the site is not necessary because it is already current practice in the radiochemical and radiopharmaceutical manufacturing industry. However, sites with short-lived materials should be allowed to include the costs of short-term site surveillance to allow decay-to-background in lieu of the more costly option of immediate remediation.

4. **Page 8, “... the GEIS presented an analysis of ground-water remediation with licensees divided into three classes based on their likelihood for significant soil and ground-water contamination:”**

Radiopharmaceutical and research radiochemical manufacturers should be included on this page as having little contamination and very low potential for soil and ground water contamination due to the following considerations:

- a. Radiopharmaceutical and medical radionuclide manufacturing facilities typically utilize radionuclides with short half-lives that are unable to accumulate in the environment to produce a significant hazard from residual radioactivity.

- b. Radionuclides used in radiopharmaceuticals and other medical purposes are typically gamma emitters that are easy to detect and control.
  - c. Also, the research radiochemical manufacturing facilities typically utilize radionuclides with short half-lives that are unlikely to create a significant residual radioactivity hazard.
  - d. <sup>3</sup>H- and <sup>14</sup>C- labeled radiochemicals manufacturers are also unlikely to create a significant residual radioactivity hazard due to the low potency of these radionuclides and their high mobility and rapid dispersion to insignificant concentrations in the environment from facilities that are typically located in non-desert climate zones.
  - e. Similarly, sealed source manufacturers utilizing fission products are unlikely to create a residual radioactivity hazard due to the non-dispersible form of the material and the relative ease in detecting and controlling the radionuclides.
  - f. Radiopharmaceuticals and research radiochemical manufacturers must maintain extreme controls on radionuclide inventory and processes to prevent cross contamination of products. These controls are typically more stringent than those necessary to ensure adequate occupational safety and environmental protection.
  - g. Radiopharmaceutical and biomedical research radiochemical manufacturing controls are subject to a multitude of regulatory and quality requirements and inspections from NRC, Agreement State Radiation Control Agencies, FDA, DOT and ISO auditors, etc..
  - h. Radionuclide manufacturers use continuous improvement programs to maintain competitiveness which typically require frequent renovation and upgrading of facilities, reducing opportunity for accumulation of residual radioactivity.
  - i. Manufacturing processes are typically carried out in custom designed closed facilities that are isolated from the public environment to ensure security of proprietary technical information and materials.
  - j. Airborne and liquid effluents from these facilities are typically of low concentration and in a readily dispersible form and do not have a history of accumulating in the adjacent environment, sanitary sewer or publicly owned sewage treatment works.
  - k. Continuous improvements (which are ongoing) in this industry have resulted in more effective control, lower emissions and lower occupational and public exposure.
  - l. Consequently current decommissioning requirements in 10 CFR 30.35 are not necessary for this industry.
5. **Page 17, “among the byproduct material facilities, subsurface and ground-water contamination was caused primarily from permissible onsite burials under the now-rescinded regulations in 10 CFR 20.304.”**

The radionuclide and radiopharmaceutical manufacturing licensees do not currently practice onsite radioactive waste burials.

**6. Page 17, “currently operating byproduct material sites were not expected to be legacy sites...”**

Radionuclide and radiopharmaceutical manufacturing licensees are within this scope of currently operating sites that NRC would not expect to become “legacy sites.” The regulations should therefore categorically exempt them from the additional residual radioactivity monitoring requirements.

**7. Page 17, “... 65 µCi of sulphur – 35 ... 3.3 mCi of H-3.”**

The two examples of material licensees loss of 13 µCi <sup>35</sup>S and 3.3 mCi of <sup>3</sup>H have no potential for a significant off-site impact or justification for remediation that would affect a decommissioning plan. A statement to that effect should be included in the analysis.

**CORAR COMMENTS TO NRC ON “DECOMMISSIONING PLANNING; PROPOSED RULE. RIN 3150-AH45. Federal Register, VOL. 73 No. 14, January 22, 2008. Pages 3812-3846.”**

- 1. Page 3815, col 2, paragraph 3: “The proposed rule would address the potential vulnerability of the parent company guarantee...”**

The requirement for a standby trust fund in support of a parent company guarantee in the proposed rule is counterproductive to NRC’s interest to address vulnerability. The current financial tests in Appendix A of Part 30 have demonstrated be an economical way for licensees in our industry to establish financial assurance sufficient to cover decommissioning liabilities. The criteria included in the current financial test are rigorous enough to eliminate the need for a third party standby trust fund, held by an entity whose financial rating may be lower than that maintained by the parent company guarantor, thereby increasing NRC’s “legacy site” liability.

- 2. Page 3817, col 2, paragraph 2: “NRC has decided not to propose amendments to require material licensees to obtain environmental cleanup insurance.”**

CORAR supports the NRC’s recommendation that materials licensees should not be required to obtain onsite property damage insurance or environmental clean up insurance to cover the cost of cleaning up an accidental release. We agree that the cost of such insurance, if available, is likely to be prohibitive for a very rare event.

- 3. Page 3819, col 3, paragraph 4: “All licensees with operating facilities must have performed an assessment of background radiation prior to operating their facility, to be compliant with the requirements in 10 CFR 20.1301 (a) (1).”**

This statement is very misleading. Material licensees have never been required to make comprehensive background measurements and certainly not those necessary to be able to distinguish residual licensed radioactive material from radioactivity in soil and groundwater due to natural background or prior or adjacent activities.

- 4. Page 3820, col 3, paragraph 2: “A continued trend of high disposal costs could increase the number of environmental contamination incidents at operating facilities, resulting in substantially higher decommissioning costs.”**

While the reduced availability of disposal sites and increased costs are an additional burden to materials licensees, these challenges have resulted in licensees taking actions to more effectively manage their wastes, by reducing volumes generated and improving storage methods. Based on our experience, this statement by NRC is unfounded.

- 5. Page 3820, col 3, paragraph 4: “The amended 20.1501(a) would retain previous survey requirements and would specify that such requirements include consideration of subsurface residual activity.”**

NRC has stated, “the vast majority of NRC materials licensees do not have processes that would cause subsurface processes that would cause subsurface contamination.” We agree with this

position. Rather than codify subsurface monitoring requirements, additional survey requirements should be added, along with other commitments to radiation surveys, to license requirements for the limited sites where subsurface contamination may be a concern.

**6. Page 3832, Compatibility Table for Decommissioning Planning Proposed Rule**

This table should be expanded to include existing 10 CFR 20.1401 and 20.1402 in order to assign Agreement State Compatibility Category B. While maintaining our position stated on specific sections of 10 CFR 30.35 and 30.36 elsewhere in these comments, these regulations as they currently exist should also be assigned Agreement State Compatibility Category B. This change is needed to eliminate inconsistency in approach taken by various agreement states. This is important to ensure that licensees, particularly that have a number of different facilities in different states under different jurisdiction, apply a satisfactory and consistent approach to protect the health and safety of the public. Some states, left with the current option to adopt NRC “essential objectives,” are regulating site termination and release under schemes that are unreasonable and impractical. This has resulted in excessive burdens on licensees without measurable benefit to the public or the environment.

**7. Page 3836, col 2, 10 CFR 20.1406 (c): “Licensees shall; ... residual radioactivity into the site, including the subsurface ...”**

- a. The recommendation for licensees to conduct operations to minimize subsurface and other residual radioactivity is already covered by the requirement in 10 CFR 20 to maintain contamination to as low as reasonably achievable.
- b. The need to consider subsurface contamination in a decommissioning cost estimate is already covered in current regulations. For sites with unusual subsurface contamination conditions or potential, the issue could be better addressed on a case-by-case basis by license conditions.
- c. Material licensees are already required to minimize contamination, survey contamination and keep records of this and appropriate records in decommissioning files.

**8. Page 3836, col 3, 10 CFR 20.1501 (a): “Each licensee shall make or cause to be made, surveys of areas, including the subsurface, that...”**

While 10 CFR 20 requires licensees to demonstrate compliance through surveys that evaluate the magnitude and extent of radiation and contamination there can be extremely rare occurrences where subsurface contamination may not be known by the licensee. It would be highly inappropriate to expect all licensees to carry out periodic complex groundwater and subsurface surveys to prove that there was no residual radioactivity. A practical approach would be to require those licensees, where residual contamination is known or suspected, to conduct appropriate surveys. This requirement could be established as a license condition. There is no need to codify this in NRC regulations.

**9. Page 3837, col 1: 10 CFR 30.35 (c) (6): If ... residual radioactivity... is detected... if left uncorrected, prevent the site from meeting... the criteria for unrestricted use, the licensee must submit a decommissioning funding plan within one year...**

The proposed rule statement, “residual radioactivity is found that if uncorrected would prevent the site from being released for unrestricted use, the licensee must submit a decommissioning funding plan within a year” is impractical and would almost always be unnecessary. When licensees find such residual radioactivity, such as in a dropped vial the common practice is to promptly remove it.

**10. Page 3837, col 1: 10 CFR 30.35 (e) (1) (i) (A): Each decommissioning funding plan must ... contain... the cost of an independent contractor to perform all decommissioning activities.**

CORAR is opposed to a regulatory requirement to use an independent decommissioning contractor to complete a decommissioning cost estimate and/or carry out decommissioning. Our industry has long experience of using licensee staff to frequently remodel facilities and who are qualified and experienced in decommissioning activities. Our industry has some unique custom designed equipment that only licensee staff has experience with and cannot be safely decommissioned by a contractor. In recent years, our industry has typically used contractors to carry out decommissioning activities when licensee staff could not be made available or to ensure the decommissioning was completed quickly to minimize business interruptions. However, in the case of a shut down of a facility, decommissioning activities can proceed on an optimal cost effective schedule which might include using licensee staff for this purpose.

**11. Page 3837, col 1: 10 CFR 30.35 (e) (1) (C): “Each decommissioning funding plan must ... contain ... the volume of onsite subsurface material containing residual radioactivity...”**

The vast majority of material licensees are unlikely to have a reason for or means of determining the volume of onsite subsurface material containing residual radioactivity that will require remediation.

**12. Page 3837, col 1: 10 CFR 30.35 (e) (2): “At the time of licensee renewal add at interval, not to exceed 3 years”**

- a. The proposed rule requires resubmission of the decommissioning funding plan at least every three years and at the time of license renewal. However, the license renewal interval is typically five years. This will cause an excessive frequency of submissions. This can be avoided by requiring submission to be at time of renewal only or when a substantive change is necessary or as otherwise specified as a license condition.
- b. CORAR recommends that it is impractical to define a renewal period for decommissioning funding plans that is appropriate for all licensees. In our industry, renewal every 5-6 years is more appropriate because even though radiopharmaceutical sales are increasing, operations are subject to continuous improvement using automation and consolidations which cancel out the inflation of costs of decommissioning and waste disposal activities. The actual renewal period should be established as a license condition.

**13. Page 3837, Col 2: 10 CFR 30.35 (f) (2).**

The use of escrow accounts and line of credit for financial assurance should be retained.

**14. Pages 3838, Col 1, Appendix A and C to Part 30 II “exclude all intangible assets and the net book value of the .... site.”**

- a. Financial tests for parent company and self-guarantees should allow consideration of intangible assets.
- b. Decommissioning cost estimates should consider offsetting the cost from the resale value of product and other viable assets. This can be determined on a case-by-case basis. One condition might be to limit these assets to less than the contingency for unexpected cost increases.

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Subject: RIN 3150-AH45 NRC Proposed Rule - Decommissioning Planning  
Date: Wed, 7 May 2008 16:23:18 -0400  
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To: <SECY@NRC.gov>  
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## Secy

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**From:** Doruff, Mark (GE Healthcare) [Mark.Doruff@ge.com]  
**Sent:** Wednesday, May 07, 2008 4:23 PM  
**To:** Secy  
**Subject:** RIN 3150-AH45 NRC Proposed Rule - Decommissioning Planning  
**Attachments:** CORAR Comments RIN 3150-AH45\_May 7,2008.pdf

Please accept the attached comments from the Council on Radionuclides and Radiopharmaceuticals, Inc (CORAR) on NRC Proposed Rule - Decommissioning Planning. RIN 3150-AH45.