

September 12, 2002

Mr. Edgar D. Bailey, Chief
Radiologic Health Branch
Division of Food, Drug, & Radiation Safety
California Department of Health Services
P. O. Box 942732
Sacramento, CA 94234-7320

Dear Mr. Bailey:

This is in response to your August 30, 2001 letter in which you asked a series of questions on the regulation of source material. The focus of your questions was on the application of the exemptions and other regulatory requirements in 10 CFR Part 40.

The Nuclear Regulatory Commission (NRC) has initiated several activities to address, in part, the exemptions that you referred to in your letter. These activities are still ongoing but the staff believes that the enclosed responses to your questions reflect the current regulatory policy.

If you have any questions on our responses, please contact me at 301-415-3340 or Osiris Siurano-Perez at 301-415-2307.

Sincerely,

/RA/

Paul H. Lohaus, Director
Office of State and Tribal Programs

Enclosure:
As stated

RESPONSES TO CALIFORNIA STATE'S QUESTIONS ON THE NRC's REGULATION OF SOURCE MATERIAL

In response to your questions, the NRC recognizes that over the course of years since the Atomic Energy Act of 1954, as amended (AEA), was enacted, the AEC/NRC has not consistently approached the regulation of the material in question. However, based on our review of that history as well as our more recent research on this topic, the answers provided below reflect the current position of the NRC.

1. Does NRC exert authority (and if so, what is the regulatory basis for such authority) at facilities such as rare-earth licensed sites (licensed for the possession of source material) over source material that is being processed but that is less than 0.05% by weight uranium and thorium, or does the regulatory control only begin once the material has been processed to the point that the concentration of the uranium or thorium is above 0.05% by weight?

Response: The AEA, provides the NRC with broad authority, including the authority to determine, under Section 62 of the AEA the quantities of source material that are “unimportant,” and the authority to determine the concentration of uranium and thorium in an ore that subjects the ore, *en masse*, to licensing, i.e., ores containing less than 0.05% uranium or thorium by weight do not fall within the definition of “Source Material” in 10 CFR 40.4(2). Therefore, when a rare-earth facility processes an ore that contains less than 0.05% uranium or thorium by weight, that ore, even though it may contain uranium or thorium, is not licensable source material. If during processing, however, uranium or thorium contained in an ore becomes concentrated so that the process material, products, or wastes contain by weight 0.05% or more uranium or thorium, or these materials become concentrated by evaporation so that the concentration of uranium or thorium exceeds the 0.05% threshold, these materials would then contain licensable source material over which the NRC can, and does, exert regulatory authority.

2. Does NRC exert regulatory authority (and if so, what is the regulatory basis for such authority) at facilities such as rare-earth licensed sites over tailings and other wastes if the source material content of the tailings or other wastes is less than 0.05% by weight? What if those tailings or other wastes reconcentrate (e.g., by evaporation) to greater than 0.05%? In your response, please consider tailings that emanate from the process both before and after the process reaches the 0.05% by weight source material concentrations, and situations where the tailings or other wastes are maintained separate, and situations where the tailings or other wastes are commingled.

Response: As explained in the response to question #1, the NRC can, and does, exert regulatory authority at rare-earth facilities when the processing at such facilities results in material, products and/or wastes that contain by weight 0.05% or more uranium or thorium; or, where evaporation creates a waste with a concentration exceeding that 0.05% threshold. In cases where a facility recognizes that it will generate wastes exceeding the 0.05% threshold, the facility will often segregate the wastes subject to NRC licensing from other wastes. However, a facility may have combined what has become licensable source material with some other material, either inadvertently or as a legitimate step in the processing of an ore, reducing the overall concentration of the combined material to less than the 0.05% threshold. Because the facility created a licensable source material, it must apply for an NRC license authorizing

the activity generating the licensable source material. The license, when issued, would cover the activity involving the licensed source material, the material itself, and the resulting waste material even though the material or the resulting waste may be less than the 0.05% weight threshold. Material associated with a licensed activity regardless of its concentration of source material is part of the licensee's inventory of licensed material. In addition, a licensed facility must take into consideration doses from both its licensed and unlicensed material for purposes of 10 CFR Part 20 and its required decommissioning plan.

Note: When a facility requires an NRC license either because its ore, product or wastes contain uranium or thorium in concentrations that make such material licensable source material, the facility must take into consideration doses from both its licensed and unlicensed material (including material below the 0.05% weight threshold) for purposes of 10 CFR Part 20 and its required decommissioning plan. While the NRC does not regulate unlicensed material, it does require a licensee to consider the dose associated with the unlicensed material.

3. Under what circumstances, and regulatory authority, does NRC exert jurisdiction over radium, particularly at facilities such as rare earth processing facilities?

Response: The NRC does not have statutory authority to regulate the radium associated with source material; however, because radium exists naturally with uranium and/or thorium, the NRC may regulate this material indirectly when regulating the uranium and/or thorium content of a material. As stated above, NRC must consider both licensed and unlicensed material in implementing 10 CFR Part 20 and in its National Environmental Policy Act (NEPA) analysis.

4. How does the NRC interpret the phrase "finished commercial products?" Does it include, for example, bulk quantities (2,000 lbs. or more) of rare-earth compounds, irrespective of the future use of the material, or does it only refer to the finished commercial products that incorporate the rare-earth compounds? For example, if Molycorp distributes a bulk quantity of rare-earth compounds to a facility that will then further process the material for the extraction of a particular rare-earth for a different customer, was Molycorp's initial product a "finished commercial product" for the purposes of the exemption contained in 10 CFR 40.13(c)(1)(vi)? Are there circumstances under which Molycorp's products would be considered "finished commercial products" given they are incorporated into other products before reaching consumers?

Response: The phrase "finished commercial product" is not defined in the regulations, nor does it appear in the exemption in 10 CFR 40.13(c)(1)(vi). This exemption clearly applies to the transfer and use of "rare-earth metals and compounds, mixtures, and products" (even bulk quantities of such material) provided that the metals and compounds, mixtures and products' source material content does not exceed 0.25% by weight uranium or thorium. In our view, the bulk quantities of rare-earths under 0.25% qualify for the exemption. The term "finished commercial product" was used in HPPOS-029 in discussing whether a rare-earth refiner could be exempt from licensing. It was used to distinguish the "product" of the refiner (extractor of the rare-earth from an ore) from the incoming ore and the wastes from the extraction. The health physics position was clarifying that, for extraction, the incoming ore or concentrates which are further extracted and the wastes from the extraction do not fall under the exemption in 10 CFR 40.13(c)(1)(vi).

5. If a site has residual contamination located from two to four meters below grade, and the existing cover is necessary to reduce doses to below the 25-mrem/year criterion, would an unrestricted site release be appropriate? Similarly, if the residual contamination were under two to four meters of placed (i.e., not naturally-existing) cover, under the same dose circumstances, would an unrestricted site release be appropriate?

Response: Regardless of whether the cover is natural or constructed, if a site has contamination, at depth, and the licensee intends to request license termination for unrestricted site release, then the licensee must demonstrate, using reasonable future site use scenarios, that doses from residual radioactive material at the site will not exceed 25 mrem/year from all pathways and that these doses are ALARA. The issue here is whether it is reasonably foreseeable that the scenario being modeled to demonstrate compliance with the 25 mrem/year criterion will be preserved. Thus, the licensee's demonstration should include an evaluation of reasonable disruptive scenarios. If the licensee's demonstration relies on institutional controls (e.g., maintenance of the cover) to prevent disturbance of the site in order to maintain the 25 mrem/year criterion in 10 CFR 20.1402, then a site would not be considered acceptable for license termination for unrestricted release.

6. Which of the specific parameters contained in the RESRAD code, if changed from their default values to less conservative site-specific parameters, would imply a restricted as opposed to an unrestricted site release?

Response: Revisions of default parameters in the RESRAD code to reflect site-specific values do not imply a restricted or unrestricted use release. If a licensee decides to request license termination for unrestricted release, the licensee should develop a reasonable site-specific future use scenario and revise the default parameters to appropriately model this scenario. If a licensee can demonstrate that a particular dose pathway does not contribute to potential doses, given natural site characteristics (e.g., ground water flow is and has been insufficient to support a drinking water well at the site) the parameter may be "turned off" in the dose model or may be revised to better model actual site conditions. However, all parameters, revised, used, or not used, to estimate potential future doses, must be adequately justified. (Additional guidance can be found in NUREG-1727, NMSS Decommissioning Standard Review Plan, Appendix C.)

7. How is the release of a site, using site-specific parameters that are less conservative than the default parameters, justified in light of the fact that once the site is released, the residually-contaminated soil may be physically removed from the site and transferred to another site with wholly different site-specific conditions? (This question is not hypothetical, but is based on actual transfers of residually-contaminated soil in California.)

Response: There is always a possibility that once a site has been released without restrictions, residually-contaminated soil may be physically removed from the site and transferred to another site with wholly different site-specific conditions, making such transfers inappropriate. To minimize the possibility of such occurrences, licensees should evaluate the reasonableness of their modeling to ensure that their proposed scenario could reasonably be expected to be effective into the foreseeable future. If it appears to be reasonably foreseeable that transfers will occur, a licensee's modeling may want to include, as appropriate, an analysis discussing

the likelihood and impact of contaminated soil at a site being excavated and transferred to another site to be used in scenarios with wholly different site-specific parameters. Consideration might be given to the assumption that a certain amount of dilution occurs when soil is removed from a site, and that a certain amount of dilution occurs when soil is placed at another site. However, in some cases, licensees may conclude that a restricted release employing institutional controls which prevent excavation at a site, is necessary. In any case, modeling should be done with the objective of demonstrating that the dose criterion will be met for 1,000 years. The NRC appreciates the difficulty of providing absolute proof that a proposed scenario would endure over such a long period of time, however, and does not intend to require this proof of licensees. It does require the licensee to expect the scenario to be in place for the foreseeable future.

8. What are the appropriate decommissioning criteria for the following types of source materials at the facility:
- a. processed product at greater than 0.05% by weight concentrations,
 - b. processed product at less than 0.05% by weight concentrations,
 - c. tailings or other wastes at greater than 0.05% by weight concentrations, and
 - d. tailings or other wastes at less than 0.05% by weight concentrations?

Response: Assuming that the processed product and/or waste is generated by a licensed facility in each of the above cases, the criteria in the License Termination Rule (LTR), 10 CFR Part 20, Subpart E, should be applied.

9. How is this policy, based on a 100-mrem/year criterion, consistent with the decommissioning rule? (For instance, what would prevent transfer of large quantities of soil or water contaminated with source material with a 100 mrem/year dose criterion instead of release in place under the decommissioning rule with a 25 mrem/year criterion?)

Response: The documents you cited in your footnote (1), i.e., SECY-98-284, and SECY-99-259, address the control and/or transfer of material containing less than 0.05% by weight uranium or thorium. The documents acknowledge the NRC's approval on a case-by-case basis, the disposal of such material produced by an NRC-licensed activity, in hazardous waste disposal facilities. While this policy appears to be in conflict with the dose criteria for unrestricted release in the LTR because it indicates that the NRC may approve transfers of such material containing doses of up to 100 mrem/year, to date, the cases that the NRC has reviewed demonstrate that the 25 mrem/year criteria (found in the LTR) has not been exceeded for the disposal of such material at non-NRC-licensed facilities.

Edgar D. Bailey

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