

June 28, 2006

MEMORANDUM TO: Luis A. Reyes
Executive Director for Operations

FROM: Annette L. Vietti-Cook, Secretary **/RA/**

SUBJECT: STAFF REQUIREMENTS - SECY-06-0069 - PROPOSED RULE:
REQUIREMENTS FOR EXPANDED DEFINITION OF
BYPRODUCT MATERIAL (RIN: 3150-AH84)

The Commission has approved the staff's recommendations to publish a proposed rule in the *Federal Register* that would amend Title 10 of the *Code of Federal Regulations* (10 CFR) Parts 20, 30, 31, 32, 33, 35, 50, 61, 62, 72, 110, 150, 170, and 171, subject to the comments and changes noted below.

The Commission has approved the staff's proposed implementation strategy that would allow NARM users to possess and use material without a license for a limited period of time, i.e., authorization by rule rather than the use of enforcement discretion. It is unnecessary for the staff to solicit comments on using enforcement discretion.

The key issue associated with the Health and Safety (H&S) designation of the definition of byproduct material is its implementation within the context of IMPEP reviews. The staff should be flexible when working with States, the Organization of Agreement States, and the Conference of Radiation Control Program Directors to develop IMPEP evaluation guidelines that meet the NRC's needs for making health and safety judgments, while accommodating existing State programs and needs, consistent with the intent of Section 651(e) of the Energy Policy Act of 2005. The staff should continue to work with the States during the development of the transition plan in order to accomplish a smooth transition as well as to provide adequate implementation time for Agreement States. The staff should continue to communicate with the States to resolve any residual misunderstanding that might have occurred regarding the compatibility category of the definition of byproduct material.

Changes to the Federal Register notice

1. Page 6, under the heading "*Current Regulatory Structure for NARM*", the first paragraph should be revised to reflect the new Agreement with the State of Minnesota.
2. Page 17, under the heading "*B. The New Expanded Definition of Byproduct Material*", the last sentence reads "A different definition for the term Byproduct material is used in 10 CFR Part 40, and it remains unchanged by this proposed rule." It may not be obvious to the general public why the Part 40 definition of byproduct material is not also being revised by this regulatory action. A short justification (1 to 3 sentences at most) should be provided in this paragraph.

3. Page 17, last paragraph, revise line 2 to read ' ... Ra. Radium-226, the most abundant and most stable isotope of radium, is formed by the' Revise line 3 to read ' ... uranium-238. Radium-226 can be found' Delete the sentence beginning in line 4 and continuing on the next page (Of the isotopes of radium, the most abundant and most stable is the isotope with a mass number of 226.)
4. Page 21, 1st full paragraph, revise lines 1 and 2 to read ' ... give the NRC any authority to regulate the possession or use of particle accelerators, themselves.'
5. Page 23, 2nd full paragraph, revise lines 3 through 5 to read ' ... particle accelerators. In recent years, radiopharmaceuticals using The use of fluorine-18, carbon-11, nitrogen-13, and even oxygen-15 in radiopharmaceuticals, also known as the PET drugs, have become popular has increased in recent years. PET radionuclides'
6. Page 31, 2nd full paragraph, revise lines 1 through 3 to read 'The NRC is proposing to define the term In defining radium-226 and other naturally occurring radioactive material as byproduct material, Discrete source means , in defining radium-226 and other naturally occurring radioactive material, other than source material, as byproduct material, as " a radioactive source with physical boundaries, which is separate and distinct from the radioactivity radiation present' Conforming changes should be made to other instances of this definition, such as on pages 111, 117, 156, and 159.
7. Page 35, 1st full paragraph, revise lines 1 and 2 to read ' ... timepieces that were previously manufactured prior to'
8. Page 48, last paragraph, revise lines 6 and 7 to read ' ... of values based on dose factors published in National Council on Radiation Protection and Measurements (NCRP) Report No. 123I on Screening Models for Releases of Radionuclides to Atmosphere, Surface Water, and Ground. Certain dose conversion factors were not readily available. This necessitated using an alternative approach to calculate these values for nitrogen-13 and oxygen-15. Results from' Revise lines 12 and 13 to read ' ... calculated values are larger than relatively close to the default values for DAC and effluent concentration and different only by a factor of 40'
9. Page 49, revise lines 3 through 6 from the top to read ' ... Appendix B, and because the NRC's preliminary calculated DAC and effluent concentration values for both nitrogen-13 and oxygen-15 are relatively close to the default values in 10 CFR Part 20, Appendix B, the NRC is not proposing to add specific values for these radionuclides in this rulemaking at this time. Since certain medical communities have expressed the desire of having specific DACs for these two radionuclides, the Commission specifically requests public comment on the default values, and whether it should include larger specific values for oxygen-15 and nitrogen-13 in the final rule.
10. Page 65, under section G. *Summary of Issues for Public Comment*, insert a new item (4) as follows, and renumber the subsequent items.
 - (4) The adequacy of the applicable default ALIs and DACs in Appendix B to 10 CFR 20 for oxygen-15 and nitrogen-13, and whether should staff develop larger specific values for these radionuclides.

The proposed rule language should be modified to grant an exemption to antique collector facilities and repair shops which repair less than a specified number of dials and watch faces containing Ra-226 in a given year. The Statement of Consideration should state that this exemption is being granted in recognition of historical practices while staff gathers data to determine if more specific requirements should be placed on the possession and repair of antiques containing Ra-226. The *Federal Register* Notice should contain appropriate specific questions requesting data on provisions which should be considered concerning antiques with Ra-226, the safety significance of these provisions, alternatives to potential regulations, or justification for continuing exemptions in this area. When the final rule is proposed to the Commission, there should be a stronger justification for whatever the staff proposes in this area.

Separate from this rulemaking concerning byproduct regulations, questions have been raised concerning the implementation of grandfather provisions in the training and experience regulations in 10 CFR Part 35, particularly as they relate to the medical physicists. To determine the extent of the problem, the staff will conduct an outreach program with the Agreement States and appropriate Medical Boards. This outreach program will outline and explain the grandfather provisions and potential methods by which the provisions may be implemented. The staff should also conduct an appropriate survey of the Agreement States to determine if there are specific problems to be resolved. The staff will document the results of the interactions with the Agreement States, interactions with the Medical Boards seeking certification under the new training and experience regulations, and, if necessary, recommendations for Commission action in a paper submitted to the Commission.

(EDO)

(SECY Suspense:

9/29/06)

cc: Chairman Diaz
Commissioner McGaffigan
Commissioner Merrifield
Commissioner Jaczko
Commissioner Lyons
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