July 31, 2006

MEMORANDUM TO: Brian W. Sheron, Director
Office of Nuclear Regulatory Research

FROM: Jack R. Strosnider, Director **/MFederline for RA/**
Office of Nuclear Material Safety
and Safeguards

SUBJECT: USER-NEED REQUEST FOR INFORMATION NEEDED FOR IMPLEMENTING ENERGY POLICY ACT OF 2005 RULEMAKING REQUIREMENTS

This memorandum describes an Office of Nuclear Material Safety and Safeguards (NMSS) user-need request for assistance in obtaining information necessary to implement the rulemaking requirements of the Energy Policy Act (EPAct) of 2005. In a Staff Requirements Memorandum dated June 28, 2006, for SECY-06-0069 ("Proposed Rule: Requirements for Expanded Definition of Byproduct Material"), the Commission directed the staff to exempt antique-collector facilities and repair shops that repair less than a specified number of watch faces and dials containing radium-226 in a given year. The Commission noted that, "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 antiquities containing Ra-226." The Commission also noted that when the final rule is proposed to the Commission [in late calendar year 2006], "... there should be a stronger justification for whatever the staff proposes in this area." It is essential to develop a strong technical basis in support of the final rule, in a very short time period, given the Commission's recent direction. We request that the Office of Nuclear Regulatory Research (RES) complete some of the efforts described below (i.e., Task 3, for timepieces containing radium-226) within this fiscal year (FY), to support a statutory deadline to publish the final rule in February 2007. NMSS staff has coordinated this need with the Health Effects Branch in RES.

In August of 2005, the President signed the EPAct into law. The EPAct amended, *inter alia*, section 11e. of the Atomic Energy Act, to place certain accelerator-produced radioactive material and discrete sources of radium-226 as byproduct material under U.S. Nuclear Regulatory Commission (NRC) regulatory authority. In the case of accelerator-produced radioactive material, two radionuclides (nitrogen-13 and oxygen-15), used frequently in medicine, are not currently listed in Appendix B to Part 20, and licensees would use default activities and concentrations in complying with current regulations. We request RES' assistance in determining the quantity and/or concentration values for these two radionuclides, in lieu of the default value, for potential inclusion of specific values into Appendix B to Part 20,

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because of these radionuclides frequent use. Also, in conjunction with the accelerator-produced radioactive material, the EPAct expanded the Commission's regulatory authority to include discrete sources of radium-226. In the past, NRC had limited jurisdiction over radium-226, and seldom dealt with discrete sources. Therefore, information on discrete radium-226 sources in the public domain is limited. To formulate regulations with solid technical bases, we request RES' assistance in obtaining background data for existing radium-226 sources and their distribution, and in estimating the potential risk to the public.

BACKGROUND INFORMATION

1. Nitrogen-13 and Oxygen-15

There are a number of U.S. commercial manufacturers that produce radiopharmaceuticals, using radionuclides (e.g., thallium-201, iodine-123, indium-111, and gallium-67) that are produced in particle accelerators. Radiopharmaceuticals using fluorine-18, carbon-11, nitrogen-13, and even oxygen-15, also known as the Positron Emission Tomography (PET) drugs, have increased dramatically in recent years. PET radionuclides are produced primarily in cyclotron facilities (often referred to as PET centers). PET drugs use radionuclides that decay by positron emission, which provides dual photons traveling in opposite directions, which give a better spacial resolution of images for the area of diagnostic interest. Because of the relatively short half-life (minutes to hours), PET radionuclides and drugs are produced at locations in close proximity to the patients (e.g., in hospitals or academic institutions) or at nearby locations.

Nitrogen-13 and oxygen-15 have almost identical decay schemes, both decaying by electron capture and positron emission. The photon emissions are also nearly identical, consisting of sub-kilovolt x-rays and two 0.511 MeV photons per transformation. Both emit very low-energy (sub-kilovolt) Auger electrons of very low intensity that will not have any dosimetric significance. Thus the hazard from both radionuclides is therefore primarily caused by high-energy annihilation photons.

2. Radium-226

Because of its properties, after radium's discovery in the early 1900s, industries started manufacturing hundreds of consumer products containing radium. Radium was added to products such as hair tonic, toothpaste, ointments, and elixirs. Radium paint was used in the mid-1900s to paint the hands and numbers of some clocks, watches, doorknobs, and other objects, to make them glow in the dark. Most of these uses were discontinued for health and safety reasons, but radium's wide use in luminescent paints continued through World War II, because radium's luminescent glow made aircraft dials, gauges and other instruments visible at night. Many of these early products still remain, within museums and individual collections. Large inventories of radium luminescent military and aircraft devices remain. These devices periodically turn up in gauge repair shops and have resulted in contamination incidents.

Radium-226, the most abundant and most stable isotope of radium, is formed by the radioactive disintegration of thorium-230, in the decay series starting with uranium-238. Radium can be found in all uranium ores. The half-life of radium-226 is 1599 years. Radium-226 emits alpha particles, gamma radiation, and decays to radon gas.

USER-NEED REQUEST

1. Nitrogen-13 and Oxygen-15

Nitrogen-13 and oxygen-15 are not listed in Appendix B of Part 20, nor are they listed in the Suggested State Regulations (SSRs), which NRC is to use as much as possible in formulating new regulations as required by the EPAct. For any single radionuclide not listed in Appendix B to Part 20, with decay mode other than alpha emission or spontaneous fission and with radioactive half-life less than 2 hours, one must use the default values provided in: a) Table 1, Column 2 inhalation Annual Limit on Intake (ALI) of 7.4E+3 kilobecquerels (kBq) (2E+2 microcurie (FCi)); b) Table 1, Column 3 Derived Air Concentration (DAC) of 3.7E-6 kBq (1E-7 FCi/milliliter (ml)) for occupational values; and c) Table 2 air effluent concentrations of 3.7 E-8 kBq/ml (1E-9 FCi/ml). These default values may be too low for nitrogen-13 and oxygen-15, given the dose conversion factors for these nuclides.

The limit for quantity of gases in Appendix B to Part 20, ALI, or the limit for concentration of gas, DAC, may be based on one of three criteria, namely inhalation dose to the lungs, limited to 0.5 sievert/year (Sv/yr) (50 rem/yr): inhalation effective dose equivalent, limited to 0.05 Sv/yr (5 rem/yr); or submersion in a semi-infinite cloud of the gas. Each criterion should be considered separately to determine the ALI and/or DAC, and the lowest (most restrictive) quantity or concentration will be considered the appropriate ALI or DAC to be listed in Appendix B to Part 20.

It should also be noted that, aside from using of the DAC-hour to show compliance with NRC's dose limit, the DAC is also used for certain other purposes in Part 20. For example, an area in a licensee's facility is classified as an airborne radioactivity area on the basis of the concentration of airborne radioactive material, relative to the DAC for that material, and these areas must be posted as such. In addition, licensees are expected to increase monitoring and to consider the use of respiratory protection equipment, consistent with the As Low As Is Reasonably Achievable requirement, in areas classified as airborne radioactivity areas. Both of these functions are therefore triggered by the value of the DAC for the airborne radioactive material.

2. Radium-226

The EPAct mandated that NRC use model State regulations to the extent practicable in promulgating regulations for the expanded definition of byproduct material. The Conference of Radiation Control Program Directors, Inc. (CRCPD) published the SSRs as the model regulations. Since SSRs are the model regulations that most CRCPD Member States have adopted, they provide NRC with the basic regulatory framework for regulating the additional byproduct materials as defined by the EPAct. The SSRs provide an exemption for previously acquired timepieces with no more than 37 kBq (1 µCi) of radium-226. NRC is proposing to include this exemption, but to clarify that it only applies to intact timepieces. However, the proposed exemption would also allow repairs on a limited (no more than 10) number of radium-containing timepieces per year.

Both the NRC staff and the State representatives indicated that there may be a need to establish some type of additional exemptions for certain products and items containing radium-226. However, because of lack of health and safety information associated with many

of the old radium-226 sources, NRC is proposing a graded approach by using the general license to regulate different groups of radium-226 sources. To determine if additional exemptions may be appropriate, the staff needs further evaluation of certain products and items, particularly antiquities, containing radium-226, and the extent of repair activities on these products and items.

SCOPE OF REQUESTED TASKS

Task 1: Nitrogen-13 and Oxygen-15

A. The scope should include determination of the internal (inhalation) dose-conversion factors, for oxygen-15 and nitrogen-13, for the organ dose equivalent, and the effective dose equivalent, based upon the weighting factors set forth in International Commission on Radiological Protection (ICRP) Publication 26, and the lung-clearance classes D, W, and Y[1] and fractional uptake concept from the small intestine to blood (f_1) as delineated in ICRP Publication 30.

B. The scope should include determination of the external dose-conversion factors, for oxygen-15 and nitrogen-13, for submersion of an individual worker. For oxygen-15, the submersion-conversion factor should be calculated for the molecular form and for the water-vapor form.

Using ICRP 26 and 30 methodologies will produce conversion factors similar to what was used for the U.S. Environmental Protection Agency (EPA) publication EPA-520/1-88-020, September 1998, entitled, "Limiting Values of Radionuclide Intake and Air Concentration and Dose Conversion Factors for Inhalation, Submersion, and Ingestion." This document formed the foundation of the 1991 revision to Appendix B to Part 20.

C. The scope should include the determination of the internal (inhalation) and external dose-conversion factors, based on the latest ICRP biokinetic and organ-weighing factors, to be analogous to the ICRP 26 and 30 methodologies. For the dose-conversion factors, calculate the ALI and DAC in a way similar to the methodologies EPA used in EPA-520/1-88-020.

Task 2: Items Containing Radium-226

A. The scope should provide information to identify the different types of antiquities and estimate the numbers of items that are in the public domain, and by whom/how possessed (individual members of the public, vs. dealers, vs. museums); estimate radium content for the various antiquities; and estimate public/individual doses for different scenarios; identify antiquities that used naturally occurring material vs. concentrated radium (names seem to imply radium, but may have only used natural uranium ore); and provide radium activity levels and doses for watches and clocks that appear available through antique stores, e-bay, etc., including products that may qualify under the proposed exemption.

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[1]Clearance classes of D, W, and Y indicates day, week, or year of retention in a specified anatomical region.

B. Provide dose estimates for possessors/users of small radium sources and products containing no more than 37 kBq (1 μCi).

C. Provide radium activity levels and doses for luminous devices used in aircraft, and other surplus military vehicles available to the public; estimate doses to workers who might be conducting repairs on the devices.

D. Identify other products or devices containing radium (activity levels, doses) that may not currently be subject to licensing (for example lightning rods, wires used for static elimination, etc.), or that may not comply (or there is insufficient information to determine compliance) with the proposed rule criteria for generally licensed devices or exempt products such as smoke detectors.

Task 3: Timepieces Containing Radium-226

A. Provide radium activity levels and dose estimates for possessors/users of intact timepieces (both watches and clocks).

B. Provide radium activity levels and dose estimates for timepieces (both watches and clocks) available as individual components (including dials, watch faces, and hands).

C. Provide dose estimates for workers conducting repairs on radium timepieces.

SCHEDULE OF REQUESTED TASKS

We request that RES complete the requested Task 1 and Task 3 within this FY to support publication of the final rule in February 2007. Task 1 should not be initiated if it cannot be completed within this FY. Preliminary data from Task 2 would be used to inform the general license approach included in the proposed rule. Once Task 2 is completed, it may be used to justify further exemptions for additional items containing radium-226 in a future rulemaking. Task 3 has the highest priority within NMSS, and it must be completed by this FY to form the necessary technical basis to exempt repair shops so as to comply with the Commission's direction for the final rule.

PRIORITY

The priority for this research effort was ranked, using RES' prioritization process, against the four performance goals with a simple scale of One (lowest priority) to Three (highest priority). This effort was ranked with a high priority, based on an overall score of 9 out of a possible 12 (3 for safety, 1 for security, 2 for openness, and 3 for efficiency, effectiveness, realism, and timeliness).

cc: Stephanie Bush-Goddard, RES

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