Status and Plans for Implementation of NRC Regulatory Authority for Certain Naturally Occurring and Accelerator-Produced Radioactive Material

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On August 8, 2005, the president signed into law the Energy Policy Act of 2005 (EPAct). Section 651(e) of the EPAct, "Treatment of Accelerator-Produced and other Radioactive Material as Byproduct Material," expanded the definition of byproduct material as defined in the Atomic Energy Act of 1954, as amended (AEA). The EPAct placed additional byproduct material under the jurisdiction of the U.S. Nuclear Regulatory Commission (NRC), as defined in section 11e.(3) and 11e.(4) of the AEA. The additional byproduct material includes certain naturally occurring and accelerator-produced radioactive material (NARM). Examples of radioactive materials that are produced by an accelerator include ^{18}Fluorine used in positron emission tomography (PET) scanning, ^{57}Cobalt used in flood sources, and ^{67}Gallium, ^{111}Indium, ^{123}Iodine, and ^{201}Thallium used for nuclear medicine diagnostic studies.

While many of the 34 "agreement states" regulate accelerator-produced radioactive materials used in nuclear medicine, some of the nonagreement states did not regulate the accelerator-produced material. As a result of NRC's new regulations, the accelerator-produced radioactive material (as defined in the new definition) will be regulated throughout the country and U.S. territories. The following discussion provides additional information on NRC's regulations and implementation activities and indicates when persons in certain states will be required to apply for an NRC license or an amendment for the newly defined byproduct materials. It is important that any potential licensee refer to NRC's regulations for further information to determine whether a license will be required for their materials.

Regulations

Section 651(e) of EPAct requires that NRC issue final regulations establishing requirements for licensing and regulating the new byproduct material, while cooperating with the states and using model state standards to the maximum extent practicable. NRC has made significant progress toward completion of the final regulations, which, as of this writing, are expected to be published before the end of June 2007. The final regulations will become effective 60 days after the date of publication and will be posted to NRC's public involvement rulemaking Web site, which is located at /www.nrc.gov/about-nrc/regulatory/rulemaking/public-involvement.html. Throughout the rulemaking process, the NRC has actively worked with both agreement states and nonagreement states, through the Organization of Agreement States and the Conference of Radiation Control Program Directors, as well as with NRC's Advisory Committee on the Medical Uses of Isotopes, other federal agencies, professional organizations, and the medical community.

Waiver

As provided by EPAct, NRC issued a waiver on August 31, 2005 (70 FR 51581):

(1) To allow states to continue with their regulatory programs for NARM;
(2) To allow persons engaged in activities involving NARM to continue with their operations in a safe manner; and
(3) To allow continued use of radiopharmaceuticals for medical purposes.

The waiver is in effect through August 7, 2009, unless the NRC terminates it earlier.

The NRC plans to terminate the waiver in phases after the final rule is issued, starting from the effective date of the rule and ending on August 7, 2009. During the initial phase of waiver terminations, which will occur in conjunction with the effective date of the final rule, the Commission intends to terminate the waiver for federal agencies, federally recognized Indian tribes, Delaware, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, Indiana, Wyoming, and Montana.

At this time, the timing and schedule for waiver terminations for the remainder of the nonagreement states and U.S. territories have not been established. A notice in the

Federal Register will be published approximately six months before the effective date of the waiver termination to notify users of their waiver terminations and the implementation dates of the rule. NRC staff will notify impacted state regulators individually prior to the publication of the *Federal Register* notice. The NRC also plans to provide additional notification to known entities impacted by the initial phase of waiver terminations following publication of the final rule in the *Federal Register.*

Upon waiver termination, all persons who possess the new byproduct materials in these states, U.S. territories, or areas of exclusive federal jurisdiction must be in compliance with NRC regulations, including, for example, meeting the reporting and record-keeping requirements for the new byproduct material. Such persons will also either be required to: 1) apply for license amendments for the new byproduct material within six months from the date the waiver is terminated, if they hold an NRC specific byproduct materials license; or 2) submit a license application for the new byproduct material within 12 months from the date the waiver is terminated.

In conjunction with the effective date of the final rule, the NRC also intends to terminate the waiver for any of the 34 agreement states that provide a certification from their governor to the NRC as described in the EPAct and the NRC's transition plan mandated by the EPAct (see below). Users of the new byproduct materials in agreement states should contact their respective agreement state regulatory agency with any questions related to plans for continuing to regulate these materials.

Transition Plan

The EPAct requires the NRC to prepare and publish a transition plan to facilitate an orderly transition of regulatory authority with respect to the newly added byproduct material. The transition plan addresses both agreement and nonagreement states, and has been coordinated extensively with the states. The NRC anticipates that the final transition plan will be published in conjunction with the final regulations in the *Federal Register,* as required by section 651(e) of the EPAct.

Additional Information and Supportive Activities

On March 20 the NRC issued a Regulatory Issue Summary (RIS) 2007–05, to inform recipients of the status of the NRC's efforts to implement the requirements of Section 651(e) of the EPAct and where to locate a copy of the draft transition plan. The RIS, along with a list of frequently asked questions is available for review at: www.nrc.gov/reading-rm/doc-collections/gen-comm/reg-issues/2007/ri200705.pdf. You may also access the ANARM Toolbox on NRC's Web site at: http://nrc-stp.ornl.gov/narmtoolbox.html for additional information on NARM-related activities.

The NRC staff is also working on several activities that will be needed to support NRC's new regulatory authority. Specifically, the NRC staff is working on finalizing revisions to guidance contained in NUREG-1556, Volumes 9 and 13, and developing a new NUREG (NUREG-1556, Volume 21), which is focused on the production of radioactive material using an accelerator. The NRC staff is also planning to make minor revisions to other guidance documents and procedures to reflect the regulation of the new byproduct material.

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