FINAL ENVIRONMENTAL ASSESSMENT AND FINDING OF NO SIGNIFICANT IMPACT FOR THE FINAL RULE AMENDING 10 CFR PARTS 30, 32, and 35 MEDICAL USE OF BYPRODUCT MATERIAL: MEDICAL EVENT DEFINITIONS, TRAINING AND EXPERIENCE, AND CLARIFYING AMENDMENTS

Office of Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission
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INTRODUCTION AND BACKGROUND

In 2002, the U.S. Nuclear Regulatory Commission (NRC) revised the medical use regulations in Part 35 of Title 10 of the *Code of Federal Regulations* (10 CFR) in their entirety (67 FR 20250). The training and experience requirements in Part 35 were further revised through an additional rulemaking in 2005 (70 FR 16336). In implementing the current regulations in Part 35, the NRC staff, stakeholders, and the Advisory Committee on the Medical Uses of Isotopes (ACMUI) have identified numerous issues that need to be addressed through the rulemaking process.

The NRC proposed action is to amend its regulations related to the medical use of byproduct material. In this action, the NRC addresses three ongoing rulemaking projects and several other related topics. First, this rule amends the reporting and notification requirements for a medical event (ME) for permanent implant brachytherapy. Second, the rule makes changes: (1) to the requirements in multiple sections to remove the requirement to obtain a written attestation for an individual who is certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State; (2) to the requirements for measuring molybdenum-99 (Mo-99) contamination and reporting of failed technetium and rubidium generators; and (3) to allow Associate Radiation Safety Officers (ARSOs) to be named on a medical license. Third, the rule makes changes to address a request filed in a petition for rulemaking (PRM), PRM-35-20, to exempt certain board-certified individuals from certain T&E requirements (i.e., “grandfather” these individuals) so that they may be identified on a license or permit for materials and uses that they performed on or before October 24, 2005, the expiration date of the former Subpart J of Part 35 which contained the prior T&E requirements.

The categorical exclusions described in 10 CFR 51.22(c)(2) and (c)(3)(i-v) apply to all but two of the amendments in this rulemaking. The two amendments that do not meet the criterion for categorical exclusions are: (1) increasing the frequency of measuring Mo-99 concentration required in § 35.204 and (2) increasing the time interval from 5 years to 7 years for a gamma stereotactic radiosurgery unit full-inspection servicing to assure proper functioning of the source exposure mechanism as required in § 35.655. This environmental assessment analyzes these two actions.

On July 21, 2014, the NRC published a proposed rule in the Federal Register for public comment (79 FR 42410). The NRC also requested comments on the environmental assessment.

THE PROPOSED ACTION

1. **Increase the frequency of measuring the Mo-99 concentration required in § 35.204**

The current requirement to measure the Mo-99 concentration of the first eluate will be changed to require that the Mo-99 concentration be measured for each eluate. A Mo-99/technetium-99m (Tc-99m) generator can be eluted several times to obtain Tc-99m for formulating radiopharmaceuticals for human use.

Although generator manufacturers have always recommended testing each elution prior to use in humans, the medical and pharmaceutical community considered frequency of Mo-99 breakthrough to be a rare event. Based on this information, in a 2002 rulemaking, the NRC relaxed the then-existing regulatory requirement to measure all elutes to instead require only measuring the Mo-99 concentration of the first elution to ensure that the permissible concentrations listed in § 35.204(a) were not exceeded.

This change to return to the original requirement is in response to several incidents reported to the NRC in 2006, 2007, and 2008 of Mo-99 measurements exceeding the permissible concentration listed in § 35.204(a) in subsequent elutions beyond the initial elution. Concentrations of Mo-99 that exceed the permissible concentration listed in § 35.204(a) may cause unnecessary radiation exposure to patients.

2. **Increase the full-inspection servicing interval for a gamma stereotactic radiosurgery unit from 5 years to 7 years**

Currently, licensees are required to perform a full inspection and service of a teletherapy unit or a gamma stereotactic radiosurgery unit at intervals not to exceed 5 years to assure proper functioning of the source exposure mechanism. Generally, these inspections are done at the time of the source exchange when the decayed source is taken out of the unit and before the new radioactive source is installed. The final rule will allow a time interval of 7 years to perform this full service and inspection of a gamma stereotactic radiosurgery unit. Extending the inspection and service interval will provide licensees greater flexibility in arranging the radioactive source replacement.

THE NEED FOR THE PROPOSED ACTION

The purpose of the increased frequency of measurement of Mo-99 concentration will ensure that the patients are administered radiopharmaceuticals that meet the regulatory limits defined in § 35.204(a). The purpose of the increase inspection interval for a gamma stereotactic radiosurgery unit is to provide greater flexibility to licensees in arranging for source replacement and the full inspection and servicing of a gamma stereotactic radiosurgery unit.

ENVIRONMENTAL IMPACTS OF PROPOSED ACTION

The amendments to increase the frequency of Mo-99 tests required in § 35.204 and to increase the inspection interval required in § 35.655 for a gamma stereotactic radiosurgery unit from 5

years to 7 years are the types of actions that will have no significant impact on public health and safety, occupational health and safety, and the environment. By following standard radiological precautions (e.g., using tongs to handle radioactive material), the operator will receive minimum radiation exposure performing the Mo-99 tests. Extending the inspection frequency for a gamma stereotactic radiosurgery unit from 5 years to 7 years will not result in any additional radiation exposure to the public, workers, or the environment because the radiation sources in these units are sealed sources, securely located and adequately shielded, and the access to the units is limited to authorized personnel only.

ALTERNATIVES TO THE PROPOSED ACTION

The alternative to this proposed action is to take no action. This would leave in place the current regulations. With respect to the increase in the frequency of measurements of concentration of Mo-99 in eluates from Mo-99/Tc-99m generators, this alternative would not provide assurance that patients are administered only the permissible amounts of Mo-99 in the radiopharmaceutical that contains Tc-99m. With respect to the increase in the full-inspection servicing interval for gamma stereotactic radiosurgery unit licensees, this alternative would deprive licensees of having the necessary flexibility to extend the full inspection to more than 5 years to coincide with radioactive source replacement.

AGENCIES AND PERSONS CONTACTED

The NRC requested the views of the States and State Liaison Officers on the environmental assessment for the proposed rule. The NRC did not receive any comments.

FINDING OF NO SIGNIFICANT IMPACT

Under the National Environmental Policy Act of 1969, as amended, and the NRC regulations in Subpart A of 10 CFR Part 51, the NRC has determined that this rule is not a major Federal action significantly affecting the quality of the human environment and, therefore, an environmental impact statement is not required for this rulemaking. The amendments establish more frequent measuring of Mo-99 and increase the inspection interval for a gamma stereotactic radiosurgery unit from 5 years to 7 years. The amendments are procedural in nature and would have no significant impact on the environment.

The determination of this environmental assessment is that this proposed action will have no significant impact to the quality of the human environment.