DRAFT ENVIRONMENTAL ASSESSMENT AND FINDING OF
NO SIGNIFICANT IMPACT
FOR THE
PROPOSED 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 Federal and State Materials and Environmental Management Programs
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 is proposing 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 proposes amendments to the reporting and notification requirements for a medical event (ME) for permanent implant brachytherapy. Second, the rule proposes changes: (1) to the training and experience (T&E) requirements for authorized users (AUs), medical physicists, Radiation Safety Officers (RSOs), and nuclear pharmacists; (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 proposes 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.

Although the majority of the amendments, including the revised ME definitions, being proposed are the types of actions described in categorical exclusions in 10 CFR 51.22(c)(2) and (c)(3)(i-v), there are two actions that need to be considered in the environmental assessment. The proposed actions that do not meet the criterion for categorical exclusions as described in § 51.22 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.

THE PROPOSED ACTIONS

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 would 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 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 proposed 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 one. Mo-99 concentrations exceeding 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 proposed rule would 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 would provide licensees greater flexibility in arranging the radioactive source replacement.

THE NEED FOR THE PROPOSED ACTIONS

The first proposed action (i.e., more frequent measurement of Mo-99 concentration) would assure that the patients are administered radiopharmaceuticals that meet the regulatory limits defined in § 35.204(a). The second proposed action (i.e., increasing the inspection interval for a gamma stereotactic radiosurgery unit) would 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 ACTIONS

The proposed 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 would have no significant impact on public health and safety, occupational health and safety, and the environment. By following standard radiological precautions (i.e., using tongs to handle radioactive material) the operator would 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. This alternative was rejected for the Mo-99/Tc-99m generators because the NRC must be assured that patients are administered only the permissible amounts of Mo-99 in the radiopharmaceutical that contains Tc-99m. For the gamma stereotactic radiosurgery unit licensees, the no action alternative was rejected because that 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.

ALTERNATIVE USE OF RESOURCES

There were no irreversible commitments of resources determined in this assessment.

AGENCIES AND PERSONS CONTACTED

No agencies or persons outside the NRC were contacted in connection with the preparation of this draft environmental assessment. The NRC has sent a copy of the draft environmental assessment and the proposed rule to every State Liaison Officer and requested their comments on the environmental assessment.

FINDING OF NO SIGNIFICANT IMPACT

The Commission has determined under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in Subpart A of 10 CFR Part 51, that the proposed amendments are not a major Federal action significantly affecting the quality of the human environment, and therefore, an environmental impact statement is not required. The proposed amendments would 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 proposed amendments are procedural in nature and of themselves would have no significant impact on the environment.

The determination of this environmental assessment is that there will be no significant impact to the public from this action. However, the general public should note that the NRC welcomes public participation. Comments on any aspect of the environmental assessment may be submitted to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, Attn: Rulemakings and Adjudications Staff.