Proposed Rules

Federal Register
Vol. 67, No. 2
Thursday, January 3, 2002

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

NUCLEAR REGULATORY COMMISSION

10 CFR Part 35

[Docket No. PRM–35–15]

Jeffery C. Angel; Denial of Petition for Rulemaking

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Petition for rulemaking: denial.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is denying a petition for rulemaking submitted by Jeffery C. Angel (PRM–35–15). The petitioner requested that the NRC amend its regulations concerning the medical use of byproduct material to prohibit the hand-held administration of radiopharmaceuticals by injection. In addition, the petitioner requests amendments to require the use of the ''Angel Shield'' instead of the currently used syringe radiation shields. The NRC is denying the petition because it would be inconsistent with the Commission's overall program for revising its regulatory framework for the medical use of byproduct material, to make requirements more risk-informed, more performance based, and less prescriptive.

ADDRESSES: Copies of the petition for rulemaking, the public comments received, and the NRC's letter to the petitioner are available for public inspection or copying in the NRC Public Document Room, One White Flint North, 11555 Rockville Pike, Room 0–1F23, Rockville, Maryland 20852. These documents are also available on NRC's rulemaking website at *http://ruleforum.llnl.gov.* For information about the interactive rulemaking website, contact Carol Gallagher, (301) 415–5905, email: *CAG@nrc.gov.*

FOR FURTHER INFORMATION CONTACT: Gary Comfort, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, (301) 415–8106, e-mail: *GCC1@nrc.gov.*

SUPPLEMENTARY INFORMATION:

The Petition

On August 23, 1999 (64 FR 45907), the Commission published in the **Federal Register** a notice of receipt of a petition for rulemaking filed by Jeffery C. Angel. The petitioner requested that the NRC amend its regulations concerning the medical use of byproduct material (10 CFR part 35) to prohibit the hand-held administration of radiopharmaceuticals by injection. The petitioner also requested the amendment of 10 CFR 35.60(c), ''Syringe shields and labels,'' to require the use of the ''Angel Shield,'' designed by the petitioner, instead of the syringe radiation shields currently in use. The petitioner believes that recent improvements in technology, specifically the invention of the Angel Shield, support the need to require its use by all NRC licensees when preparing or injecting radiopharmaceuticals in patients or human research subjects.

In his supporting information, the petitioner contends that the use of the Angel Shield instead of the currently required syringe radiation shield would reduce radiation exposures by:

1. Eliminating hand-held injections of radiopharmaceuticals.
2. Completely encapsulating the syringe within the administrator, providing 360 degrees of protection.
3. Shielding 100 percent of low energy (140 Kev) and 88 percent of high energy photons (511 Kev).
4. Allowing for the remote administration of the radiopharmaceutical.
5. Reducing the number of missed injections and subsequent multiple exposures.

The petitioner supports his contention by stating that he has been a nuclear medicine technologist for over 20 years and has been exposed to radiation daily, using the traditional syringe radiation shield. The petitioner invented the Angel Shield to protect himself and others administering radiopharmaceuticals by injection. He states that other syringe radiation shields are neither designed nor engineered according to sound radiation protection principles.

Public Comments on the Petition

The NRC received five comment letters. Three comment letters opposed the petition. Two of these were from certified health physicists and consultants in the area of radiation protection, and one was from an industry trade association. Two comment letters supported the petition. One of the letters is from a certified nuclear medicine technologist and the other is signed by five radiology physicians.

One commenter stated that the petition cannot be justified in terms of cost-benefit, and that the petitioner failed to demonstrate that current exposures were excessive, thus presenting a significant risk to workers. Two commenters stated that the petition is self-serving in that it would provide a monopoly for the petitioner, as he is the only manufacturer of the Angel Shield. Another commenter said that licensees should be able to decide what procedures and equipment are necessary for the practice of their ''as low as reasonably achievable'' (ALARA) programs. One commenter said that prohibiting hand-held injections would adversely affect the practice of medicine, while another commenter stated that existing radiation syringe shields have been in use for many years without compromising worker or patient safety.

A commenter supporting the petition stated that the majority of her occupational exposure as a nuclear medicine technologist came from the injection of radiopharmaceuticals and their preparation. The commenter contends that lowering radiation dose rates is more than enough justification for granting the petition, stating that this device will make her profession safer. The commenter also stated that unless the device is mandated, employers would not spend the money to provide adequate protection to achieve ALARA objectives.

The other commenters in favor of the petition cite NRC Regulatory Guides 8.10 and 8.29 in support of their conclusion that the petitioner's device clearly furthers the objective of reducing occupational exposures as far below the specified limits as is reasonably achievable. According to these commenters, the Angel Shield should simply be viewed as a new, better, and safer syringe radiation shield than the ones currently employed and required pursuant to 10 CFR 35.60(c). These commenters also assert that the new

technology would permit the rejection of the antiquated practice and the unnecessary exposure associated with hand-held injections.

Reasons for Denial

Based on consideration of the petition and public comments, the NRC is denying the petition because it would be inconsistent with the Commission's overall program for revising its regulatory framework for the medical use of byproduct material. This framework focuses Commission regulation on those medical procedures that pose the highest risk, structures its regulations to be more risk-informed and more performance-based and significantly reduces regulatory burden in many areas, consistent with NRC's ''Strategic Plan for Fiscal Year 1997—Fiscal Year 2002,'' cited in ''Medical Use of Byproduct Material; Policy Statement; revision,'' 65 FR 47654 (August 2, 2000).

The amendment the petitioner seeks would be contrary to this regulatory approach by prohibiting the hand-held administration of radiopharmaceuticals by injection and/or requiring the use of a specific shield (the Angel Shield). Licensees should have the flexibility to determine what kind of syringe or vial shields to use in order to meet the requirements contained in 10 CFR 20.1101, ''Radiation protection programs.'' This regulation requires licensees to use practical procedures and engineering controls designed to achieve doses that are ALARA (as low as reasonably achievable). In its inspection program, the NRC assesses whether licensees have complied with these requirements. Denial of this petition does not prohibit the licensee from using the ''Angel Shield'' or other shields, as practicable to meet these requirements. However, if this petition were granted, it would limit the flexibility of licensees to use other, including more effective, strategies to meet ALARA without additional rulemaking.

The decision to deny the petition is consistent with our performance goals. There is no impact on public health and safety, the environment, or common defense and security. Use of the requested device is not essential to limit or minimize doses to the public, workers, or patients. Public confidence should not be affected because the existing regulations require licensees to minimize doses and this decision continues to allow licensees the flexibility to use the ''Angel Shield'' or other strategies, as best fits their individual practices, in achieving this outcome. The decision maintains the effectiveness, efficiency, and realism of the current regulations. Lastly, the denial decision does not impose unnecessary regulatory burden on licensees or the NRC staff, whereas granting the petition would cause undue burden by imposing prescriptive criteria on licensees.

For reasons cited in this document, the NRC denies the petition.

Dated at Rockville, Maryland, this 18th day of December, 2001.

For the Nuclear Regulatory Commission.

William D. Travers,

Executive Director for Operations.

[FR Doc. 02–72 Filed 1–2–02; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF THE INTERIOR

Minerals Management Service

30 CFR Part 250

RIN 1010–AC83

Oil and Gas and Sulphur Operations in the Outer Continental Shelf—Procedures for Dealing With Sustained Casing Pressure

AGENCY: Minerals Management Service (MMS), Interior.

ACTION: Extension of comment period for proposed rule.

SUMMARY: This document extends to March 9, 2002, the deadline for submitting comments on the proposed rule that describes procedures for dealing with sustained casing pressure (SCP) in oil and gas wells on the Outer Continental Shelf. The rule will codify these procedures and ensure uniform regulatory practices among MMS regional offices, and will also help ensure that lessees will continue to conduct operations in a safe manner.

DATES: We will consider all comments received by March 9, 2002, and we may not fully consider comments received after March 9, 2002.

ADDRESSES: Mail or hand-carry written comments (three copies) to the Department of the Interior; Minerals Management Service; 381 Elden Street; Mail Stop 4024; Herndon, Virginia 20170–4817; Attention: Rules Processing Team. If you wish to e-mail comments, the e-mail address is: rules.comments@MMS.gov. Reference ''AC83 SCP Comments'' in your e-mail subject line. Include your name and return address in your e-mail message and mark your message for return receipt.

FOR FURTHER INFORMATION CONTACT: Larry Ake, Engineering and Operations Division, at (703) 787–1559.

SUPPLEMENTARY INFORMATION: MMS was asked to extend the deadline for submitting comments on the proposed regulations revising 30 CFR 250, subpart E to describe procedures for dealing with SCP in oil and gas wells. The request stated that the complexity of the issue and the high cost to the domestic petroleum industry require careful consideration for comprehensive comments.

Public Comments Procedures: Our practice is to make comments, including names and home addresses of respondents, available for public review during regular business hours. Individual respondents may request that we withhold their home address from the rulemaking record, which we will honor to the extent allowable by law. There may be circumstances in which we would withhold from the rulemaking record a respondent's identity, as allowable by law. If you wish us to withhold your name and/or address, you must state this prominently at the beginning of your comment. However, we will not consider anonymous comments. We will make all submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, available for public inspection in their entirety.

Dated: December 5, 2001.

John V. Mirabella,

Acting Chief, Engineering and Operations Division.

[FR Doc. 02–42 Filed 1–2–02; 8:45 am]

BILLING CODE 4310–MR–W

POSTAL SERVICE

39 CFR Part 111

Eligibility Standards for Free Matter for the Blind and Other Physically Handicapped Persons

AGENCY: Postal Service.

ACTION: Proposed rule.

SUMMARY: The Postal Service proposes to amend the Domestic Mail Manual (DMM) to clarify and simplify the eligibility standards for free matter for the blind and other physically handicapped persons in conformance, to the extent practicable, with similar standards adopted by the Library of Congress for its National Library Service for the Blind and Physically Handicapped. This proposed rule also would require free matter mailers that