Proposed Rules

Federal Register
Vol. 72, No. 205
Wednesday, October 24, 2007

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–35–19]

William Stein, III, M.D.; Denial of Petition for Rulemaking

AGENCY: Nuclear Regulatory Commission.

ACTION: Petition for rulemaking; denial.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is denying a petition for rulemaking (PRM–35–19) submitted by William Stein, III, M.D. (petitioner). The petitioner requested that the NRC amend the regulations that govern medical use of byproduct material concerning training for parenteral administration of certain radioactive drugs—samarium-153 lexidronam (Quadramet), iodine-131 tositumomab (Bexxar), and yttrium-90 ibritumomab tiuxetan (Zevalin)—used to treat cancer. The petitioner believes that these regulations are unduly burdensome for the use of these drugs. The petitioner requested that the regulations be amended to codify an 80-hour Laboratory and classroom, training and appropriate work experience, and written attestation as appropriate and sufficient for physicians desiring to attain authorized user status for therapeutic administrations of these unsealed byproduct materials.

ADDRESSES: Copies of the petition for rulemaking, the public comments received, and NRC's letter to the petitioner may be examined at the NRC Public Document Room, Public File Area Room O1F21, 11555 Rockville Pike, Rockville, MD. These documents also may be viewed and downloaded electronically via the rulemaking Web site.

The NRC maintains an Agencywide Document Access and Management System (ADAMS), which provides text and image files of NRC's public documents. These documents may be accessed through the NRC's Public Electronic Reading Room on the Internet at *http://www.nrc.gov/reading-rm/adams.html*. If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the NRC Public Document Room (PDR) Reference staff at 1–800–397–4209, 301–415–4737, or by e-mail to *pdr@nrc.gov*.

FOR FURTHER INFORMATION CONTACT: James R. Firth, Office of Federal and State Materials and Environmental Management Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone (301) 415–6628; e-mail: *jrf2@nrc.gov*.

SUPPLEMENTARY INFORMATION:

The Petition

On June 14, 2006 (71 FR 34285), the NRC published a notice of receipt of a petition for rulemaking filed by William Stein, III, M.D. The petitioner requested that the NRC amend the regulations that govern medical use of byproduct material concerning training for parenteral administration of certain radioactive drugs—samarium-153 lexidronam (Quadramet), iodine-131 tositumomab (Bexxar), and yttrium-90 ibritumomab tiuxetan (Zevalin)—used to treat cancer. The petitioner believes that these regulations are unduly burdensome for the use of these drugs. The petitioner requested that the regulations be amended to codify an 80-hour training and experience requirement as appropriate and sufficient for physicians desiring to attain authorized user status for these unsealed byproduct materials.

The petitioner requested that the NRC amend Title 10 of the Code of Federal Regulation (CFR) part 35, ''Medical Use of Byproduct Material'' to recognize that 80 hours of classroom and laboratory training, supervised work experience, and a written attestation for physicians are adequate and sufficient to attain authorized user status for parenteral administrations of Quadramet, Bexxar, and Zevalin. The petitioner provided three options for addressing this issue.

(1) Add a specific requirement to 10 CFR part 35 that is essentially equivalent to the language in § 35.394, ''Training for the oral administration of sodium iodide I–131 requiring a written directive in quantities greater than 1.22 Gigabecquerels (33 millicuries),'' which governs oral administration of sodium iodide I–131 particularly with regard to the alternate pathway, but requires experience with at least three parenteral administrations of dosages to patients or human research subjects for each of these drugs.

(2) Add a separate requirement for Quadramet, Bexxar, and Zevalin similar to the training and experience codification for administration of sodium iodide I–131 to allow the NRC to evaluate each substance individually so all radioactive drugs can be handled appropriately from a radiation safety perspective.

(3) Revise 10 CFR 35.396, ''Training for the parenteral administration of unsealed byproduct material requiring a written directive,'' to specify an 80-hour classroom and laboratory training period, appropriate work experience, and a written attestation to apply to the alternate pathway for any physician, not limited to board-certified radiation oncologists. Specifically, remove the current § 35.396(c) and redesignate §§ 35.396(d)(1), (d)(2), and (d)(3) as §§ 35.396(c)(1), (c)(2), and (c)(3). The petitioner recognizes that the Commission may not agree with this change if other more hazardous parenterally-administered radiopharmaceuticals become available, necessitating the increased training currently specified in this requirement.

The petitioner stated that the training and experience requirements for physicians who seek authorized user status for parenteral administration of Quadramet, Bexxar, and Zevalin to treat certain cancers should reflect the current requirements in 10 CFR 35.394 and not those currently in 10 CFR 35.396. The petitioner noted that all administrations of Quadramet, Bexxar, and Zevalin require written directives and believes that these drugs are generally less hazardous than oral dosages of sodium iodide I–131. The petitioner therefore believes that the training and experience requirements should not exceed the 80 hours specified for an endocrinologist who treats thyroid disorders with oral dosages of sodium iodide I–131.

The petitioner stated that § 35.396 was published in the **Federal Register** on March 30, 2005 (70 FR 16336), as part of the final rule that amended training and experience requirements for administration of radiopharmaceuticals. The petitioner believes that the NRC's rationale for the

training and experience requirements in § 35.396 is not known and that an opportunity for public comment period was not provided for this provision before it appeared in the final rule. The petitioner also stated that the NRC has not considered codification of new drugs that require written directives as they become available for medical use and that there is an unmet regulatory need to address the ability of physicians to qualify for medical use authorization for certain unsealed byproduct materials that are currently commercially available and for which written directives are required.

The petitioner believes that users of radiopharmaceuticals should be subjected to training requirements according to potential radiation risk as is the case for oral administrations of I–131, rather than being lumped into a collective group, which the petitioner characterized as being the NRC's current practice. The petitioner believes that the current requirements are burdensome and deficient in this regard and that, without regulatory relief, physicians would be discouraged from providing these U.S. Food and Drug Administration (FDA)-approved and commercially available treatments resulting in an adverse impact on their ability to practice medicine. Under the current requirements, the petitioner believes that physicians would be required to become board-certified radiation oncologists under § 35.396 or complete 700 hours of training (including 200 hours of classroom and laboratory training) under § 35.390 to attain authorized user status to parenterally administer Quadramet, Bexxar, or Zevalin.

Public Comments on the Petition

The notice of receipt of the petition for rulemaking invited interested persons to submit comments. The comment period closed on August 28, 2006. As of July 27, 2007, the NRC had received 25 comment letters from individuals, State government agencies, and non-governmental organizations. In addition, the Advisory Committee on the Medical Uses of Isotopes (ACMUI) took a position on the arguments made in the petition.

The NRC received 18 comment letters that supported granting the petition or agreed with the conclusions of the petitioner. Fourteen of these letters were submitted by 29 physicians. Two letters were submitted by State government agencies, the Arkansas Department of Health and Human Services and the Alabama Department of Public Health. Two letters were submitted by three individuals. Most of the commenters supporting the petition submitted form letters, or comments that were otherwise similar to one another. In general, these commenters stated that not granting the petition would intrude into the practice of medicine, discourage physicians from treating patients, and establish barriers to the use of potentially effective therapies, thus adversely impacting patient access to these therapies and increasing health care costs. These commenters also believed that the activity administrations of Quadramet, Bexxar, and Zevalin are from a radiation safety perspective less hazardous than oral administration of sodium iodide I–131 for which the NRC requires only 80 hours of classroom and laboratory training.

The NRC received seven comment letters that opposed granting the petition. Two of these were submitted by physicians, one was submitted by a State government agency (i.e., the Iowa Department of Public Health), and four were submitted by non-governmental organizations (i.e., the American Association of Physicists in Medicine (AAPM), American College of Radiation Oncology (ACRO), American College of Radiology (ACR), and American Society for Therapeutic Radiology and Oncology (ASTRO)). In addition, at its October 24, 2006, meeting, the ACMUI passed a unanimous motion rejecting the arguments made by the petitioner.

In general, many of these commenters disagreed that there was a shortage of individuals capable of performing these treatments or that patients were unable to access these treatments. Many of these commenters also raised concerns that there would be radiation safety issues and patients would be exposed to additional risk if the petition was granted; e.g., that medical oncology/hematology training does not include the extensive background necessary for administering these radiopharmaceuticals and that significant knowledge regarding handling of these radiopharmaceuticals cannot be imparted with limited training. These commenters also asserted that the amount of training required was debated many times during the revisions to 10 CFR part 35 and the NRC made a deliberate decision that the level of training required to administer these and similar treatments must include 700 hours of training and experience to ensure public health and safety. These commenters also stated that the intent of the regulations was not to regulate ''radionuclide by radionuclide,'' but to have generally applicable rules to accommodate new agents.

Reasons for Denial

After reviewing the information provided in the petition, the comment letters, and the views of the ACMUI, the NRC is denying the petition. The NRC believes that the current NRC regulations at 10 CFR 35.390 and 35.396 establish the appropriate amount of training and experience for a physician to become an authorized user for the parenteral administration of unsealed byproduct material requiring a written directive, including Quadramet, Bexxar, and Zevalin.

The decision to deny this petition is consistent with the NRC policy statement, ''Medical Use of Byproduct Material'' (65 FR 47654; August 3, 2000). The NRC indicated in its general statement of policy that ''NRC will, when justified by the risk to patients, regulate the radiation safety of patients, primarily to assure the use of radionuclides is in accordance with the physician's directions.'' In the discussion of public comments on the medical use policy statement, the NRC indicated that the regulations for the medical use of byproduct material are predicated on the assumption that properly trained and adequately informed physicians will make decisions that are in the best interests of their patients. The training and experience requirements for the medical use of unsealed byproduct material requiring a written directive help to ensure that authorized users are properly trained and adequately informed.

The elements of the current training and experience requirements for the use of unsealed byproduct materials were established through two separate rulemakings. The first rulemaking, a major revision to 10 CFR part 35 (67 FR 20250; April 24, 2002), was intended to focus NRC's regulations on those medical procedures that pose the highest risk to workers, patients, and the public, and structure the regulations to be more risk-informed and performance-based. The second rulemaking (70 FR 16336; March 30, 2005) revised the 10 CFR part 35 requirements for the recognition of specialty boards whose certifications may be used to demonstrate the adequacy of the training and experience of individuals for the purpose of serving as authorized persons and certain training and experience requirements for pathways for authorized status other than by the board certification pathways. Both rulemakings involved extensive input from the medical community, Agreement States, and the public, and

afforded substantial opportunity for public comment.

During the 2002 revision to 10 CFR part 35, the NRC increased the required amount of training and experience from 80 hours to 700 hours for most medical uses of unsealed byproduct material requiring a written directive. The 700 hours spent in training provides assurance that physicians spend an adequate amount of time in an environment in which radioactive drugs are routinely being prepared and/or administered for medical use. In 2005, the NRC clarified that to properly cover the topics important for the safety for these uses, for the alternate pathway to authorized status, the minimum amount of classroom and laboratory training was 200 hours (see 70 FR 16336). In this connection, to achieve authorization via the board certification pathway, the individual must successfully complete multiple year residency training in a radiation therapy or nuclear medicine training program or a program in a related medical specialty, each of which also includes 700 hours of training and experience as described in §§ 35.390(b)(1)(i) through (b)(1)(ii)(E) of the alternate pathway requirements. The required training is that considered appropriate for the purposes of radiation safety of workers, members of the public, and patients. The adequacy of the training of authorized users is an important contributor to radiation safety.

An important aspect of the NRC requirements for the medical use of byproduct material is the flexibility provided to medical practitioners. Medical use licensees have the flexibility to use radioactive drugs requiring a written directive for indications and methods of administration that are not listed in the FDA-approved package insert. These licensees are able to depart from the manufacturer's instructions for preparing radioactive drugs. Because of the flexibility offered to physicians, they are expected to have certain training, even if, for example, they choose not to exercise their flexibility, such as using only unit dosages.

The petitioner asserted, with regard to the requirements at 10 CFR 35.396, that the NRC's reasoning is not known and that no comment period was offered before this requirement appeared in the final rule. Concerning these assertions, the requirements at § 35.396 were established during the 2005 rulemaking and fully explained in the **SUPPLEMENTARY INFORMATION** accompanying the final rule. As explained in the final rule notice, the NRC established these requirements in the final rule in response to public comments on the proposed rule, published in the **Federal Register** on December 9, 2003 (68 FR 68549). The public comments expressed a concern that the training requirements in § 35.390 should consider the totality of all work experience for individuals trained in radiation oncology. As discussed in the **SUPPLEMENTARY INFORMATION** accompanying the final rule, the NRC agreed that certain physicians, such as those who meet the requirements for training and experience for uses under §§ 35.490 or 35.690, have a good understanding of radiation that includes topics common to the use of sealed sources and unsealed byproduct material. Therefore, the NRC included § 35.396 to provide a pathway to authorized status that allows individuals to take credit for training and experience associated with other medical uses of byproduct material that may be applicable to the use of unsealed byproduct material. To ensure that these individuals would have adequate training and experience to use unsealed byproduct material safely, the NRC requires that these individuals have training and experience applicable to the parenteral administration of unsealed byproduct material for which a written directive is required.

The petitioner also asserts that the administrations of Quadramet, Bexxar, and Zevalin are no more hazardous from a radiation safety perspective than the oral administration of sodium iodide I–131, and therefore the training and experience requirements for physicians treating their patients with these drugs should not exceed those for an endocrinologist treating thyroid disorders with oral sodium iodide I–131. The NRC has addressed the difference in the required number of hours of training and experience for the oral administration of sodium iodide I–131 requiring a written directive and other medical uses of unsealed byproduct material requiring a written directive in both the 2002 rulemaking and the 2005 rulemaking. When the proposed rule amending Part 35 was published in 1998 (63 FR 43516; August 13, 1998), the training and experience requirements then in existence pertaining to treatment of hyperthyroidism and thyroid carcinoma were deleted and were to be subsumed within the training requirements that applied to the use of unsealed material for which a written directive is required proposed in § 35.390. Under the proposed revision, individuals wishing to become authorized users of unsealed byproduct material for which a written directive is required (including the use of sodium iodide I–131 to treat hyperthyroidism and thyroid carcinoma) would have been required to obtain 40 hours of supervised practical experience at a medical institution, in addition to the 80 hours of didactic training which had been required by the prior regulations. This would have increased the amount of training and experience required for the use of sodium iodide I–131 to treat hyperthyroidism and thyroid carcinoma. However, as explained in the **SUPPLEMENTARY INFORMATION** accompanying the final rule, commenters were strongly opposed to the proposed changes to the requirements for the administration of sodium iodide I–131 for treatment of hyperthyroidism and thyroid cancer. These commenters indicated that the increased training was not warranted for these purposes in light of endocrinologists' impeccable safety record with the use of sodium iodide I–131 and the fact that there had been no records of therapeutic misadministrations of any byproduct material by endocrinologists, and that in reality most of the practical aspects of handling sodium iodide I–131 that would be covered in the proposed 40 hours of additional training were already covered in the 80 hours of didactic training and supervised clinical training.

The NRC considered these comments in making a determination that §§ 35.392 and 35.394 should be added in the final rule to specifically address oral administrations of sodium iodide I–131. These sections did not increase the duration of training for the oral administration of sodium iodide I–131 over the previous requirements for such use in §§ 35.932 and 35.934. However, with regard to all other uses of unsealed byproduct material for which a written directive is required, a specific determination was made to increase the training and experience requirements from 80 hours to 700 hours. The NRC made this determination after considering the potential for greater associated radiation risks of the use of these unsealed byproduct materials and the public comments received on the proposed rule (67 FR 20250; April 24, 2002).

Subsequently, during the revision made to the training and experience requirements in 2005, the NRC specifically determined not to change the existing requirements in §§ 35.390, 35.392, or 35.394. The **SUPPLEMENTARY INFORMATION** accompanying the final rule in 2005 notes that although the NRC continued to believe that the

increase in training and experience hours was generally necessary for physicians authorized under § 35.390, to qualify as an authorized user under the limited authorization of performing oral administration of sodium iodide I–131, a physician must have 80 hours of classroom and laboratory training and the specified supervised work experience. As noted in the **SUPPLEMENTARY INFORMATION** (70 FR 16336; March 30, 2005), the NRC based its determination on licensee use, NRC inspections, and experience with medical events reported after the effective date of the 2002 rule. The petitioner has not provided sufficient specific information that would warrant the NRC to reconsider this determination.

The petitioner has asserted that the training and experience requirements for the parenteral administration of unsealed byproduct material are unduly burdensome and that an entire class of physicians is unfairly discouraged from providing FDA-approved and commercially available treatments. The petitioner believes this results in an adverse impact on their ability to practice medicine and discourages medical oncologists/hematologists from providing these FDA-approved and commercially available treatments. The NRC is unaware of problems in Agreement States or non-Agreement States with patient access to these treatments that would indicate that the training and experience requirements represent an unnecessary burden. Neither the petitioner nor the commenters supporting the petition provided specific information or data supporting the assertion that there is a problem with patient access to these treatments resulting from unnecessarily burdensome requirements for training and experience. The training and experience requirements are intended to ensure that authorized users of byproduct material are properly trained and adequately informed. The NRC believes that the currently required amount of training and experience for the parenteral administration of unsealed byproduct material requiring a written directive is appropriate and does not represent an unnecessary burden.

The NRC notes that its requirements are not written to favor or penalize any class of physician (e.g., any physician can qualify as an authorized user for the oral administration of sodium iodide I–131), but are written to reflect the training necessary to ensure that authorized user physicians have adequate training. The alternate pathways for acquiring the training and experience necessary to become an authorized user were developed to provide physicians with a way to qualify for authorized user status, without having to acquire board certification or to have any particular specialty. Consequently, the NRC does not believe that medical oncologists/hematologists or any other class of physician are unfairly discouraged from becoming an authorized user or treating their patients.

The NRC's regulatory approach is intended to provide a flexible, risk-informed approach to the regulation of medical uses of byproduct material. In addition, the existing approach reduces the need to revise requirements for individual radiopharmaceuticals. The training and experience requirements for the medical use of byproduct material are a matter of strict compatibility between the NRC and the Agreement States and have been assigned Compatibility Category B. This means that Agreement States should adopt program elements essentially identical to those established by the NRC. In addition, training programs for candidates of the medical specialty boards may have to adapt their training programs to remain current with changes to NRC and Agreement State training and experience requirements. The current approach to training and experience for the medical use of unsealed byproduct material accommodates the introduction of new radiopharmaceuticals without requiring additional rulemaking, with its associated costs to the Agreement States. Attempting to tailor the training and experience requirements to specific uses of unsealed byproduct material and to the amount of flexibility that a user may wish to have would significantly increase the complexity of the regulatory oversight. The NRC does not believe that such added complexity would be of benefit to patients, the Agreement States, licensees, current and prospective authorized users, or the medical specialty boards.

The decision to deny the petition is consistent with the NRC strategic goals and strategies as described in the NRC Strategic Plan for fiscal years 2004 through 2009 (NUREG–1614). The training and experience requirements for the parenteral administration of unsealed byproduct material, including Quadramet, Bexxar, and Zevalin, do not present a significant regulatory impediment to the safe and beneficial use of these radioactive materials. In addition, the amount of classroom and laboratory training required to become an authorized user for the administration of these radiopharmaceuticals is necessary to protect public health and safety and the NRC regulations would not be improved by changing the requirements.

In conclusion, the NRC is denying the petition because the NRC has determined that the current requirements establish the appropriate amount of training and experience for a physician to become an authorized user for the parenteral administration of Quadramet, Bexxar, and Zevalin and that the NRC requirements do not impose an unnecessary regulatory burden for the use of Quadramet, Bexxar, Zevalin, and similar radiopharmaceuticals. The existing NRC regulations provide the basis for NRC to have reasonable assurance that public health and safety is adequately protected. Neither the petitioner nor the commenters supporting the petition have provided sufficient information such as would warrant the regulatory relief sought by the petitioner.

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

Dated at Rockville, Maryland, this 5th day of October, 2007.

For the Nuclear Regulatory Commission.

William F. Kane,

Acting Executive Director for Operations.

[FR Doc. E7–20918 Filed 10–23–07; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

10 CFR Part 63

[Docket No. PRM–63–2]

State of Nevada; Denial of a Petition for Rulemaking

AGENCY: Nuclear Regulatory Commission.

ACTION: Petition for rulemaking: Denial.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC or Commission) is denying a petition for rulemaking submitted by the State of Nevada (PRM–63–2). The petition requests that NRC amend its regulations for the proposed geologic repository at Yucca Mountain, Nevada (YM) to specify the limits of permissible spent fuel storage at the YM site. Petitioner believes that the U.S. Department of Energy (DOE) is planning to construct an Aging Facility at the YM site designed to store 21,000 metric tons of heavy metal in what petitioner believes is a manifest violation of the Nuclear Waste Policy Act of 1982, as amended, and the Commission's regulations. NRC is denying the petition because NRC's current regulations are