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

consistent with law and do not permit storage of spent nuclear fuel at the YM site unless such storage is integral to waste handling, necessary treatment, and disposal at the proposed repository, including storage which is integral to the thermal-loading strategy for disposal that DOE may include in its design of the entire repository system. DOE must make the case, in its anticipated license application, that any contemplated storage of spent nuclear fuel is permissible because it is integral to waste handling, necessary treatment, and disposal activities. NRC believes that, without an application currently before the agency, the issues raised by the petition are best addressed during the agency's review of the application when a final design will be available and an opportunity to request a hearing will be offered.

ADDRESSES: Publicly available documents related to this petition, including the petition for rulemaking and NRC's letter of denial to the petitioner may be viewed electronically on public computers in NRC's Public Document Room (PDR), 01F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland. The PDR reproduction contractor will copy documents for a fee. Publicly available documents created or received at NRC after November 1, 1999, are also available electronically at the NRC's Electronic Reading Room at *http://www.nrc.gov/reading-rm/adams.html*. From this site, the public can gain entry into the NRC's Agencywide Documents Access and Management System (ADAMS), which provides text and image files of NRC's public documents. If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the PDR reference staff at (800) 387–4209, (301) 415–4737 or by e-mail to *pdr@nrc.gov*.

FOR FURTHER INFORMATION CONTACT: E. Neil Jensen, Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone (301) 415–1637 or Toll Free: 1–800–368–5642, e-mail: *enj@nrc.gov*.

SUPPLEMENTARY INFORMATION:

The Petition

On December 22, 2006, the State of Nevada (petitioner or the State) submitted a ''Petition for Rulemaking to Amend Part 63 to Clarify the Limits on Spent Fuel Storage at the Yucca Mountain Site'' (petition) which was docketed as a petition for rulemaking under 10 CFR 2.802 of the Commission's regulations (PRM–63–2) (available in the Agencywide Document Access and Management System (ADAMS) No. ML070030020). The State supplemented its petition by letter of January 23, 2007 (ML070330245). The petition requests amendments to 10 CFR part 63, NRC's regulations governing the disposal of high-level radioactive waste (HLW) in a proposed geologic repository at YM. The petitioner believes that 10 CFR part 63 must be amended to specify the limits of permissible spent fuel storage at YM, together with related changes to 10 CFR part 71.

Petitioner asserts that, at an August 29, 2006 technical exchange and management meeting between NRC and DOE, DOE indicated that its design for the geologic repository included both a ''Receipt Facility'' and an ''Aging Facility'' or ''Aging Pad''. (Meeting summary, ML062710597). The Receipt Facility would be designed to receive commercial spent nuclear fuel (SNF) from off-site and prepare it for the Aging Facility. The Aging Facility would be designed to store 21,000 metric tons of heavy metal (MTHM) on the YM site. See DOE, Office of Civilian Radioactive Waste Management, *Surface Facilities Overview and Canister Receipt and Closure Facility,* slides presented to NRC/DOE Technical Exchange and Management Meeting on Design Changes Approved Through DOE's Critical Decision (CD–1) Process, August 29, 2006, Las Vegas, Nevada (DOE slides) (ML062510423). Petitioner further asserts that, in an NRC Staff response to the State's letter asking about what surface storage of SNF might be allowed at YM under the Nuclear Waste Policy Act of 1982, as amended (NWPA), 42 U.S.C 10101 *et seq.*, and 10 CFR Part 63, NRC stated that surface storage is permissible ''to the extent such storage is integral to waste handling and disposal at the proposed repository,'' and that ''storage may also be integral to the thermal-loading strategy the applicant may adopt in its design of the entire repository system.'' See Letter to Robert R. Loux from Jack R. Strosnider, December 4, 2006 (ML062900384).

Petitioner believes that it is unclear why a thermal loading strategy must necessarily require the storage of significant quantities of SNF on the YM site and holds that ''it is absurd to suppose that storage in capacities approaching anywhere near 21,000 MTHM on the Site could be justified as part of a 'thermal loading' strategy that 'is integral to waste handling and disposal.'' Petition at 1. Further, petitioner supplemented its petition to state that DOE's preliminary specifications for a transportation, aging and disposal (TAD) canister system suggest that DOE is planning on long-term storage of SNF at YM. See DOE, Office of Civilian Radioactive Waste Management, *Civilian Radioactive Waste Management System: Preliminary Transportation, Aging and Disposal Canister System Performance Specification, Revision A,* DOE/RW–0585, November 2006 (DOE Performance Specification) (Licensing Support Network No. DN20023585505).

Petitioner believes that DOE's plans for an Aging Facility that could contain 21,000 MTHM are ''manifestly unlawful'' and requests that NRC amend 10 CFR part 63 to specify by rule the limits of permissible spent fuel storage at YM, together with related changes to 10 CFR part 71. As support for its petition, the State provides an analysis of provisions of the NWPA which demonstrate, in petitioner's view, that storage of SNF at YM is unlawful. In brief, petitioner argues that the structure and text of the NWPA show that Congress intended the repository to be for disposal only. This is because Congress provided for a repository for disposal of SNF in Subtitle A of the statute, but separately provided for a limited interim storage program in Subtitle B and for potentially longer term storage in a monitored retrievable storage facility (MRS) in Subtitle C. Both Subtitle B and Subtitle C contain provisions which would effectively prevent storage in a state being considered for a repository. Petitioner points out that ''if Congress had intended a repository site to be used for storage, neither Subtitle B nor Subtitle C would have been necessary, and the statutory prohibition on co-location of a repository and an interim storage facility or MRS would have been nonsensical.'' Petition at 3. Thus, petitioner concludes, the structure of NWPA demonstrates that a repository is for disposal only.

Petitioner requests three changes to NRC's rules. First, 10 CFR 63.21(c)(22) (regarding the contents of the license application) would be amended to add a new paragraph viii at the end:

> viii. Plans for the emplacement of spent nuclear fuel in the underground facility within a reasonably short time after it is received (in no event longer than one year), and information to explain why any facilities for the storage of spent nuclear fuel in the repository operations area or on the Site are integral to safe waste handling and disposal in the underground facility.

Second, 10 CFR 63.41(b) (regarding required license conditions) would be amended to add a new subsection (c):

> (c). The license shall include additional conditions as follows: (1) No spent nuclear

fuel may be received in the geologic repository operations area, or on the Site, unless there is reasonable assurance that it can be moved into the underground facility within a reasonably short time (in no event later than one year after receipt); (2) no spent nuclear fuel may be stored in the geologic repository operations area, or on the Site, unless such storage is necessary for the safe and efficient emplacement of spent fuel in the underground facility; and (3) no spent nuclear fuel may be stored in the geologic repository operations area, or on the Site, for the purpose primarily of aging (cooling or radioactive decay) prior to emplacement in the underground facility. The foregoing conditions do not preclude the construction of storage space to allow retrieval of spent fuel after its emplacement in the underground facility or for the amelioration of emergency conditions associated with the repository's operation.

Third, to ensure proper coordination between DOE and reactor licensees desirous of sending spent fuel to the repository, 10 CFR 71.5 would be amended by adding a new subsection (c):

(c). No licensee possessing spent reactor fuel may deliver the fuel to the Department of Energy or to a carrier for transport to Yucca Mountain, or transport the fuel to Yucca Mountain, unless the fuel either complies with waste disposal criteria (including thermal loading criteria) approved by the Commission, or the fuel is expected to do so within one year after receipt at the Yucca Mountain site. In complying with this subsection, a licensee may rely on compliance certifications provided by the Department of Energy.

Reasons for Denial

Petitioner recognizes that NRC's regulations are currently in harmony with its view of what storage is permissible:

In the preamble to the original Part 63, NRC stated that no license to receive waste or spent fuel would be issued until NRC is able to find that DOE has completed construction of sufficient underground storage space for initial operations, and it concluded that Part 63 does not allow early use of surface facilities for storage of spent fuel. 66 FR 55738 (November 2, 2001). This is consistent with the text of 10 CFR 63.41(a)(1), which provides that no license may be issued until NRC finds that construction of ''[a]ny underground storage space required for initial operation [is] substantially complete.'' Thus, NRC's regulations appear consistent with NWPA in eliminating the possibility of spent fuel storage that is decoupled from actual repository operations and logistics.

Petition at 4, n.3. Indeed, NRC recently reaffirmed this interpretation of its regulations when it informed petitioner that surface storage of spent fuel is only permissible, under 10 CFR part 63, to the extent such storage is integral to waste handling and disposal at the proposed repository (including storage which is integral to the thermal-loading strategy the applicant may adopt in its design of the entire repository system). See NRC Staff Letter of December 4, 2006. In the preamble to NRC's final rule incorporating 10 CFR part 63 into its regulations, the Commission stated:

The DOE has not indicated to the Commission any intention to seek an authorization for early use of the surface facilities for storage of spent nuclear fuel. Such an authorization likely would necessitate a change to (or an exemption from) the regulations. Before NRC would make changes of this type to its regulations, NRC would need to publish the proposed changes and seek public comment (66 FR 55738; November 2, 2001).

These statements make it clear that the Commission does not regard its regulations as sanctioning the type of spent fuel storage imagined by petitioner; i.e., storage of large amounts of spent nuclear fuel on an Aging Pad divorced from waste handling, necessary treatment, and disposal operations.

Petitioner's concern about DOE's supposed intent to construct a ''gigantic'' Aging Facility in violation of law apparently stems from information exchanged between DOE and NRC at the August 29, 2006 NRC/DOE Technical Exchange and Management Meeting. The DOE slides presented design changes that DOE had approved for the repository, including the preliminary hazards analysis (PHA) performed as part of DOE's process for approving design changes. The radiological consequence analysis of the PHA was based on key assumptions with respect to source terms, site weather and the location of workers and members of the public. One of these assumptions was an assumption of aging pads at full capacity which was identified as being 21,000 MTHM. However, assumptions used in a hazards analysis are not the equivalent of an actual plan for SNF storage. Petitioner also cites DOE's draft Performance Specification for a TAD canister system in support of its claim that DOE is planning for ''an illegal Yucca aging pad.'' This document explains, *inter alia,* that a TAD canister may be aged in an aging overpack which is used to safely contain a loaded TAD canister on the aging pad until repository emplacement thermal limits are met and that it could take a long period of time (years) for sufficient radioactive decay to take place. Clearly, this document suggests that DOE plans to age some amount of spent nuclear fuel for some period of time on an aging pad at the repository but it provides no information on the actual amount or length of time nor explanation as to how whatever DOE is planning complies with 10 CFR 63.41(a). This information should be part of DOE's license application and will be subject to review by the NRC staff.

As stated in NRC Staff's December 4, 2006 letter, ''NRC fully expects that DOE would seek authorization for a facility that complies with Federal law. If the application includes an aging facility, the NRC staff would review that facility in the context of the overall repository design to determine if it is integral to waste handling and disposal at the proposed repository * * *.'' Precisely what amount of spent nuclear fuel would meet that test, and precisely what amount of time can be justified, is an issue best resolved in the licensing proceeding. DOE's technical rationale supporting its intended use of the Aging Pad is dependent upon the actual repository design DOE intends to implement and will not be fully known until DOE submits its license application. DOE's design will be subject to scrutiny by the NRC staff in the licensing proceeding. Potential parties to the adjudicatory proceeding may seek to raise contentions on this issue if, in their view, DOE's case does not meet NRC's regulations.

Conclusion

In sum, NRC's rules already bar storage of SNF at the repository which is not integral to waste handling, necessary treatment, and disposal operations. The Commission believes that, without an application currently before the agency, the issues raised by the petition are best addressed during the agency's review of the application when a final design will be available and an opportunity to request a hearing will be offered.

For these reasons, the Commission denies PRM–63–2.

Dated at Rockville, Maryland, this 18th day of October 2007.

For the Nuclear Regulatory Commission.

Annette L. Vietti-Cook,

Secretary of the Commission.

[FR Doc. E7–20919 Filed 10–23–07; 8:45 am]

BILLING CODE 7590–01–P