

company's background and history. Therefore, pursuant to 21 U.S.C. 952(a) and 958(a), and in accordance with 21 CFR 1301.34, the above named company is granted registration as an importer of the basic class of controlled substance listed.

Dated: December 21, 2004.

William J. Walker,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

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NUCLEAR REGULATORY COMMISSION

[Docket No. 50-312]

Sacramento Municipal Utility District; Rancho Seco Nuclear Generating Station; Partial Exemption from Requirements of 10 CFR 50.719(c); 10 CFR Part 50, Appendix A; 10 CFR Part 50, Appendix B

1.0 Background

Sacramento Municipal Utility District (SMUD) is the licensee and holder of Facility Operating License No. DPR-54 for the Rancho Seco Nuclear Generating Station (Rancho Seco), a permanently shutdown decommissioning nuclear plant. Although permanently shutdown, this facility is still subject to all rules, regulations, and orders of the U.S. Nuclear Regulatory Commission (NRC).

The Sacramento Municipal Utility District (SMUD) shut down Rancho Seco Nuclear Generating Station permanently on June 7, 1989, after approximately 15 years of operation. On August 29, 1989, SMUD formally informed the NRC that the plant was shut down permanently. On May 20, 1991, SMUD submitted the Rancho Seco decommissioning plan and on March 20, 1995, the NRC issued an Order approving the decommissioning plan and authorizing the decommissioning of Rancho Seco.

SMUD began actively decommissioning Rancho Seco in February 1997, and completed the transfer of all of the spent nuclear fuel to the 10 CFR Part 72 licensed Independent Spent Fuel Storage Installation (ISFSI) on August 21, 2002. Accordingly, the only quality-related structures, systems, or components (SSCs) at the Rancho Seco 10 CFR Part 50 licensed site are the radioactive sources used to calibrate the instrumentation used to measure radioactivity in gaseous and liquid effluents.

Plant dismantlement is substantially (approximately 80%) complete and most of the SSCs that were safety-related or important-to-safety have been removed from the plant and shipped for disposal. The pressurizer was shipped to Envirocare for disposal in April 2004, removal of the steam generators is in progress with both steam generators scheduled to be shipped to Envirocare by spring 2005 (one by the end of 2004 and the second in spring 2005), and activities in preparation for the reactor vessel internals segmentation are underway and mobilization of the segmentation contractor is scheduled to begin in early 2005.

On September 2, 2004, SMUD filed a request for NRC approval of a partial exemption from the recordkeeping requirements of 10 CFR 50.71(c); 10 CFR 50, Appendix A; and 10 CFR 50, Appendix B.

2.0 Request/Action

Pursuant to the requirements of 10 CFR 50.71(d)(2) and 10 CFR 50.12, SMUD requested partial exemption to the recordkeeping requirements of 10 CFR 50.71(c); 10 CFR Part 50, Appendix A; CFR Part 50, Appendix B. This exemption request was characterized as "partial" because the exemption would apply only to the disposal of hardcopies of records, prior to termination of the Rancho Seco license, that: (1) Are associated with the operation, design, fabrication, erection, and testing of structures, systems, and components (SSCs) that are no longer quality-related or important to safety or have been removed from the plant for disposal; and (2) require storage in their original hard copy format due to practical and feasibility limitations associated with transferring them to microfilm or microfiche.

Most of these records are for SSCs that have been removed from Rancho Seco and disposed of off-site. Disposal of these records will not adversely impact the ability to meet other NRC regulatory requirements for the retention of records [e.g., 10 CFR 50.54(a), (p), (q), and (bb); 10 CFR 50.59(d); 10 CFR 50.75(g); *etc.*]. These regulatory requirements ensure that records from operation and decommissioning activities are maintained for safe decommissioning, spent nuclear fuel storage, completion and verification of final site survey, and license termination.

3.0 Discussion

NRC licensees are required to maintain their records according to the NRC regulatory recordkeeping requirements. Pursuant to the requirements of 10 CFR 50.12, "Specific

Exemptions," and 10 CFR 50.71(d)(2), SMUD filed a request for a partial exemption from the NRC regulatory recordkeeping requirements contained in 10 CFR 50.71(c), 10 CFR 50, Appendix A, and 10 CFR 50, Appendix B. The NRC recordkeeping requirements at issue in SMUD's request for exemption are as follows.

10 CFR 50.71, "Maintenance of records, making of reports," subpart (c) states: Records that are required by the regulations in this part, by license condition, or by technical specifications, must be retained for the period specified by the appropriate regulation, license condition, or technical specification. If a retention period is not otherwise specified, these records must be retained until the Commission terminates the facility license.

10 CFR 50, Appendix A, "General Design Criteria for Nuclear Power Plants," establishes the necessary design, fabrication, construction, testing, and performance requirements for structures, systems, and components important to safety; that is, structures, systems, and components that provide reasonable assurance that the facility can be operated without undue risk to the health and safety of the public. Specifically, SMUD requests an exemption from Criterion 1, "Quality standards and records," which states in part:

Appropriate records of the design, fabrication, erection, and testing of structures, systems, and components important to safety shall be maintained by or under the control of the nuclear power unit licensee throughout the life of the unit."

10 CFR 50, Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," establishes quality assurance requirements for the design, construction, and operation of structures, systems, and components that prevent or mitigate the consequences of postulated accidents that could cause undue risk to the health and safety of the public. Specifically, SMUD requests an exemption from Criterion XVII, "Quality Assurance Records," which states:

Sufficient records shall be maintained to furnish evidence of activities affecting quality. The records shall include at least the following: Operating logs and the results of reviews, inspections, tests, audits, monitoring of work performance, and materials analyses. The records shall also include closely-related data such as qualifications of personnel, procedures, and equipment. Inspection and test records shall, as a minimum, identify the inspector or data recorder, the type of observation, the results, the acceptability, and the action taken in connection with any deficiencies noted. Records shall be identifiable and retrievable.

Consistent with applicable regulatory requirements, the applicant shall establish requirements concerning record retention, such as duration, location, and assigned responsibility.

Exemption Requirements

As stated in 10 CFR 50.12, “[t]he Commission may, upon application by any interested person or upon its own initiative, grant exemptions from the requirements of the regulations of this part.” In order to permit specific exemptions from the requirements of this part the criteria of 10 CFR 50.12(a)(1) and the requirements of 10 CFR 50.12(a)(2) must be met.

10 CFR 50(a)(1) requires three criteria to be met before an exemption can be granted: first, the exemptions must be authorized by law; second, the exemption must not present an undue risk to the public health and safety; and third, it must be consistent with the common defense and security. In addition, for the Commission to consider granting an exemption from the requirements of Part 50, special circumstances as required by 10 CFR 50.12(a)(2) must be present. The special circumstance at issue in the present request for exemption is 50.12(a)(2)(ii) which states, “[a]pplication of the regulation in the particular circumstances would not serve the underlying purpose of the rule or is not necessary to achieve the underlying purpose of the rule.” The application of the three criteria in 50.12(a)(1) and the requirement of special circumstances in 50.12(a)(2) are addressed below.

Specific Exemption Is Authorized by Law

The partial exemption from the recordkeeping requirements of 10 CFR 50.71(c); 10 CFR Part 50, Appendix A; and 10 CFR Part 50, Appendix B, as requested for the hard copy records described above is authorized by law. Specifically, 10 CFR 50.71(d)(2) allows for the granting of specific exemptions to the record retention requirements specified in the regulations.

NRC regulation 10 CFR 50.71(d)(2) states, in part:

the retention period specified in the regulations in this part for such records shall apply unless the Commission, pursuant to § 50.12 of this part, has granted a specific exemption from the record retention requirements specified in the regulations in this part.

Based on 10 CFR 50.71(d)(2), since the specific exemption requirements of 10 CFR 50.12 are satisfied as described below, the exemption from the recordkeeping requirements of 10 CFR 50.71(c); 10 CFR Part 50, Appendix A;

and 10 CFR Part 50, Appendix B is authorized by law.

Specific Exemption Will Not Present an Undue Risk to the Public Health and Safety

With all of the spent nuclear fuel transferred to the Rancho Seco ISFSI, there is insufficient radioactive material remaining on the Rancho Seco 10 CFR Part 50 licensed site to pose any significant potential risk to the public health and safety under any credible event scenario. This provides additional assurance that the partial exemption for the specified hard copy records will not present any reasonable possibility of undue risk to the public health and safety.

In two letters dated February 5, 2002, the NRC granted Amendment Nos. 129 and 130 to the Rancho Seco Operating License (Possession Only). These amendments deleted definitions, LCOs, surveillance requirements, and administrative requirements from the 10 CFR Part 50 Technical Specifications on the basis that all of the spent nuclear fuel was transferred to the Rancho Seco ISFSI. In a letter dated October 10, 2002, the NRC issued an exemption from 10 CFR Part 50 security requirements and Amendment No. 131 to the Rancho Seco Operating License to reflect this security exemption. Hence, the NRC has already concurred with the conclusion that granting regulatory exemptions will have no reasonable possibility of presenting any undue risk to the public health and safety.

The partial exemption from the recordkeeping requirements of 10 CFR 50.71(c); 10 CFR Part 50, Appendix A; and 10 CFR Part 50, Appendix B, for the hard copy records described above is administrative in nature and will have no impact on any remaining decommissioning activities or on radiological effluents. The exemption will merely advance the schedule for destruction of the specified hard copy records. Considering the content of these records, the elimination of these records on an advanced timetable will have no reasonable possibility of presenting any undue risk to the public health and safety.

Specific Exemption Consistent With the Common Defense and Security

The partial exemption from the recordkeeping requirements of 10 CFR 50.71(c); 10 CFR Part 50, Appendix A; and 10 CFR Part 50, Appendix B, for the types of hard copy records described above is consistent with the common defense and security as defined in the Atomic Energy Act (42 U.S.C. 2014, Definitions) and in 10 CFR 50.2

“Definitions.” The partial exemption requested does not impact remaining decommissioning activities and does not involve information or activities that could potentially impact the common defense and security of the United States.

Rather, the exemption requested is administrative in nature and would merely advance the current schedule for destruction of the specified hard copy records. Considering the content of these records, the elimination of these records on an advanced timetable has no reasonable possibility of having any impact on national defense or security. Therefore, the partial exemption from the recordkeeping requirements of 10 CFR 50.71(c); 10 CFR Part 50, Appendix A; and 10 CFR Part 50, Appendix B, for the types of hard copy records described above is consistent with the common defense and security.

Special Circumstances

The current status of Rancho Seco facility, 80% dismantled and all irradiated fuel transferred to the ISFSI, constitutes special circumstances which will allow the NRC to consider granting the partial exemption requested. Consistent with 10 CFR 50.12(a)(2)(ii), applying the recordkeeping requirements of 10 CFR 50.71(c), 10 CFR Part 50, Appendix A, and 10 CFR Part 50, Appendix B to the continued storage of the hard copy records described previously is not necessary to achieve the underlying purpose of the rules.

The underlying purpose of the subject recordkeeping regulations is to ensure that the NRC staff has access to information that, in the event of an accident, incident, or condition that could impact public health and safety, would assist in the recovery from such an event and could also help prevent future events or conditions that could adversely impact public health and safety. Additionally, the NRC staff would access the records as part of the normal inspection process related to the subject SSCs.

Given the current status of Rancho Seco decommissioning, the records that would be subject to early destruction would not provide the NRC with information that would be pertinent or useful. The types of records that would fall under the exemption would include hard copy radiographs, vendor equipment technical manuals, and recorder charts associated with operating nuclear power plant SSCs that had been classified as important to safety during power operations, but that are no longer classified as important to safety, are no longer operational, or have

removed from the Rancho Seco site for disposal.

With the majority of the primary and secondary systems removed for disposal, the Rancho Seco site no longer houses "a nuclear power reactor and associated equipment necessary for electric power generation." Thus, with respect to the underlying intent of the recordkeeping rules cited above, Rancho Seco is not able to generate electricity and is no longer a nuclear power unit as defined in 10 CFR Part 50, Appendix A.

In addition, with all the spent nuclear fuel having been transferred to the ISFSI, there is not sufficient radioactive material inventory remaining on the 10 CFR Part 50 licensed site to pose any significant potential risk to the public health and safety. Thus, there are no longer any "structures, systems, and components required to provide reasonable assurance the facility can be operated without undue risk to the health and safety of the public." This provides additional assurance that, with respect to the underlying intent of the recordkeeping rules, Rancho Seco is no longer a nuclear power unit as defined in 10 CFR Part 50, Appendix A.

Based on the above, application of the subject recordkeeping requirements to the Rancho Seco hard copy records specified above is not required to achieve the underlying purpose of the rule. Thus, special circumstances are present which the NRC may consider, pursuant to 10 CFR 50.12(a)(2)(ii), to grant the requested exemption.

4.0 Conclusion

The staff agrees that 10 CFR 50.71(d)(2) allows the Commission to grant specific exemptions to the record retention requirements specified in regulations provided the requirements of 10 CFR 50.12 are satisfied.

The staff agrees that the requested partial exemption from the recordkeeping requirements of 10 CFR 50.71(c); 10 CFR Part 50, Appendix A; 10 CFR Part 50, Appendix B, will not present an undue risk to the public health and safety. The destruction of the identified hard copy records will not impact remaining decommissioning activities; plant operations, configuration, and/or radiological effluents; operational and/or installed SSCs that are quality-related or important to safety; or nuclear security.

The staff agrees that the destruction of the identified hard copy records is administrative in nature and does not involve information or activities that could potentially impact the common defense and security of the United States.

The staff agrees that the purpose for the recordkeeping regulations is to ensure that the NRC Staff has access to information that, in the event of any accident, incident, or condition that could impact public health and safety, would assist in the protection of public health and safety during recovery from the given accident, incident, or condition, and also could help prevent future events or conditions adversely impacting public health and safety. Further, since most of the Rancho Seco SSCs that were safety-related or important-to-safety have been removed from the plant and shipped for disposal, the staff agrees that the records identified in the partial exemption would not provide the NRC with useful information during an investigation of an accident or incident.

Therefore, the Commission grants SMUD the requested partial exemption to the recordkeeping requirements of 10 CFR 50.71(c); 10 CFR Part 50, Appendix A; 10 CFR Part 50, Appendix B, as described in the September 2, 2004, letter.

Pursuant to 10 CFR Part 51, the Commission has determined that the granting of this exemption will not have a significant effect on the quality of the human environment as documented in **Federal Register** (69 FR 67371, Nov. 17, 2004).

This exemption is effective upon issuance.

Dated at Rockville, Maryland this 23rd day of December, 2004.

For the Nuclear Regulatory Commission.

Daniel M. Gillen,

Deputy Director, Decommissioning Directorate, Division of Waste Management and Environmental Protection, Office of Nuclear Material Safety and Safeguards.

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NUCLEAR REGULATORY COMMISSION

[Docket No. 72-30]

Maine Yankee Atomic Power Company, Maine Yankee Independent Spent Fuel Storage Installation, Issuance of Environmental Assessment and Finding of No Significant Impact

I. Introduction

The U.S. Nuclear Regulatory Commission (NRC) is considering issuance of exemptions to Maine Yankee Atomic Power Company (the licensee), pursuant to title 10 of the Code of Federal Regulations (10 CFR) 72.7, from specific provisions of 10 CFR 72.212(a)(2), 72.212(b)(2)(i),

72.212(b)(7), and 72.214. The licensee is storing spent nuclear fuel under the general licensing provisions of 10 CFR part 72 in the NAC-UMS® Universal Storage System at an independent spent fuel storage installation (ISFSI) located at the Maine Yankee Atomic Power Station in Wiscasset, Maine. The requested exemptions would allow the licensee to deviate from requirements of the NAC-UMS® Certificate of Compliance (CoC) No. 1015, Amendment 2, Appendix A, Technical Specifications for the NAC-UMS® System, Section A 5.1, Training Program, and Section A 5.5, Radioactive Effluent Control Program. Specifically, the exemptions would relieve the licensee from the requirements to: (1) Develop training modules under its systematic approach to training (SAT) that include comprehensive instructions for the operation and maintenance of the ISFSI, except for the NAC-UMS® Universal Storage System; and (2) submit an annual report pursuant to 10 CFR 72.44(d)(3).

II. Environmental Assessment (EA)

Identification of Proposed Action: The proposed action is to exempt the licensee from regulatory requirements to develop certain training and submit an annual report. By letter dated February 25, 2004, as supplemented June 8, 2004, the licensee requested exemptions from certain regulatory requirements of 10 CFR 72.212(a)(2), 72.212(b)(2)(i), 72.212(b)(7), and 72.214 which require a general licensee to store spent fuel in an NRC-certified spent fuel storage cask under the terms and conditions set forth in the CoC. The proposed exemptions would allow the licensee to deviate from the requirements in CoC No. 1015, Amendment 2, Appendix A, Technical Specifications for the NAC-UMS® System, Section A 5.1, Training Program, and Section A 5.5, Radioactive Effluent Control Program.

CoC No. 1015, Amendment 2, Appendix A, Technical Specifications for the NAC-UMS System, Section A 5.1, Training Program, requires that a training program for the NAC-UMS® Universal Storage System be developed under the general licensee's SAT. Further, the training modules must include comprehensive instructions for the operation and maintenance of both the NAC-UMS® Universal Storage System and the ISFSI. In addition, CoC No. 1015, Amendment 2, Appendix A, Technical Specifications for the NAC-UMS System, Section A 5.5, Radioactive Effluent Control Program, Item c. requires an annual report to be submitted pursuant to 10 CFR 72.44(d)(3). By exempting the licensee