

ACTION: Notice of Issuance and Availability of Draft Regulatory Guide, DG-6007.

FOR FURTHER INFORMATION CONTACT: Jack Foster, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone: (301) 415-6250 or e-mail to Jack.Foster@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Introduction

The U.S. Nuclear Regulatory Commission (NRC) is issuing for public comment a draft guide in the agency's "Regulatory Guide" series. This series was developed to describe and make available to the public such information as methods that are acceptable to the NRC staff for implementing specific parts of the NRC's regulations, techniques that the staff uses in evaluating specific problems or postulated accidents, and data that the staff needs in its review of applications for permits and licenses.

The draft regulatory guide (DG), entitled, "Establishing Quality Assurance Programs for the Manufacture and Distribution of Sealed Sources and Devices Containing Byproduct Material," is temporarily identified by its task number, DG-6007, which should be mentioned in all related correspondence. DG-6007 is a proposed Revision 1 of Regulatory Guide 6.9, dated February 1995.

This regulatory guide directs the reader to the type of quality assurance (QA) and quality control (QC) program acceptable to the staff of the NRC during the review of an application to manufacture or distribute sealed sources and devices containing byproduct materials.

Title 10 of the *Code of Federal Regulations* (10 CFR) Part 32, "Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material," regulates the manufacture and distribution of sealed sources or devices containing byproduct material. Regulations in 10 CFR 32.210(c) require the applicant or registrant to submit information about the QC program in sufficient detail to allow the NRC reviewers to ensure that the product is manufactured and distributed in a manner that is adequate to protect health and minimize danger to life and property.

This regulatory guide endorses the methods and procedures for a QA/QC program described in Section 10.7, "Quality Assurance and Quality Control" of NUREG-1556, Volume 3, "Consolidated Guidance About Materials Licenses: Applications for Sealed Source and Device Evaluation

and Registration," issued April 2004, as a process that the NRC finds acceptable. As described in Volume 3 of NUREG-1556, the applicant must provide details of the QA program that ensure that the product is manufactured and distributed in accordance with the representations made in the application and the statements contained in the registration certificate for the product.

II. Further Information

The NRC staff is soliciting comments on DG-6007. Comments may be accompanied by relevant information or supporting data and should mention DG-6007 in the subject line. Comments submitted in writing or in electronic form will be made available to the public in their entirety through the NRC's Agencywide Documents Access and Management System (ADAMS).

Personal information will not be removed from your comments. You may submit comments by any of the following methods:

1. *Mail comments to:* Rulemaking and Directives Branch, Mail Stop: TWB-05-B01M, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

2. *Federal e-Rulemaking Portal:* Go to <http://www.regulations.gov> and search for documents filed under Docket ID [NRC-2009-0418]. Address questions about NRC dockets to Carol Gallagher, 301-492-3668; e-mail Carol.Gallagher@nrc.gov.

3. *Fax comments to:* Rulemaking and Directives Branch, Office of Administration, U.S. Nuclear Regulatory Commission at (301) 492-3446. Requests for technical information about DG-6007 may be directed to the NRC contact, Jack Foster at (301) 415-6250 or e-mail to Jack.Foster@nrc.gov.

Comments would be most helpful if received by November 21, 2009. Comments received after that date will be considered if it is practical to do so, but the NRC is able to ensure consideration only for comments received on or before this date. Although a time limit is given, comments and suggestions in connection with items for inclusion in guides currently being developed or improvements in all published guides are encouraged at any time.

Electronic copies of DG-6007 are available through the NRC's public Web site under Draft Regulatory Guides in the "Regulatory Guides" collection of the NRC's Electronic Reading Room at <http://www.nrc.gov/reading-rm/doc-collections/>. Electronic copies are also available in ADAMS (<http://www.nrc.gov/reading-rm/adams.html>), under Accession No. ML091670485.

In addition, regulatory guides are available for inspection at the NRC's Public Document Room (PDR) located at 11555 Rockville Pike, Rockville, Maryland. The PDR's mailing address is USNRC PDR, Washington, DC 20555-0001. The PDR can also be reached by telephone at (301) 415-4737 or (800) 397-4205, by fax at (301) 415-3548, and by e-mail to pdr.resource@nrc.gov.

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Dated at Rockville, Maryland, this 17th day of September 2009.

For the Nuclear Regulatory Commission.

Andrea D. Valentin,

Chief, Regulatory Guide Development Branch, Division of Engineering, Office of Nuclear Regulatory Research.

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NUCLEAR REGULATORY COMMISSION

[NRC-2009-0410; Docket No. 030-35904]

Notice of Availability of Environmental Assessment and Finding of No Significant Impact for License Amendment to Byproduct Materials License No. 29-30707-01, for Termination of the License and Unrestricted Release of the Memory Pharmaceuticals Corporation Facility Located in Montvale, NJ

AGENCY: Nuclear Regulatory Commission.

ACTION: Issuance of Environmental Assessment and Finding of No Significant Impact for License Amendment.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Introduction

The U.S. Nuclear Regulatory Commission (NRC) is considering the issuance of a license amendment to Byproduct Materials License No. 29-30707-01. This license is held by Memory Pharmaceuticals Corporation (the Licensee) for its facility located at 100 Philips Parkway in Montvale, New Jersey (the Facility). Issuance of the amendment would authorize release of the Facility for unrestricted use and termination of the NRC license. The

Licensee requested this action in a letter dated June 25, 2009. The NRC has prepared an Environmental Assessment (EA) in support of this proposed action in accordance with the requirements of Title 10, *Code of Federal Regulations* (CFR), part 51 (10 CFR part 51). Based on the EA, the NRC has concluded that a Finding of No Significant Impact (FONSI) is appropriate with respect to the proposed action. The amendment will be issued to the Licensee following the publication of this FONSI and EA in the **Federal Register**.

II. Environmental Assessment

Identification of Proposed Action

The proposed action would approve the Licensee's June 25, 2009 license amendment request, resulting in release of the Facility for unrestricted use and the termination of its NRC materials license. The license for this facility was originally issued, pursuant to 10 CFR part 30, to Memory Pharmaceuticals Corporation on May 15, 2000. At that time, the corporate mailing address for Memory Pharmaceuticals Corporation was located in the State of New York so License No. 31-30570-01 was assigned. On January 7, 2002, License No. 31-30570-01 was terminated and replaced with License No. 29-30707-01 following the licensee's change of mailing address to a location in the State of New Jersey. License No. 29-30707-01 has been amended periodically since that time. The License authorized the licensee to use byproduct material for purposes of conducting research and development activities on laboratory bench tops and in hoods.

The Facility occupies 53,362 square feet of space within a 74,000 square foot complex and consists of office, storage, and laboratory space. The Facility is located in a commercial area. Within the Facility, use of licensed materials was confined to 4,605 square feet of space.

During April 2008, the Licensee ceased licensed activities and initiated a survey and decontamination of the Facility. Based on the Licensee's historical knowledge of the site and the conditions of the Facility, the Licensee determined that only routine decontamination activities, in accordance with their NRC-approved, operating radiation safety procedures, were required. The Licensee was not required to submit a decommissioning plan to the NRC because worker cleanup activities and procedures are consistent with those approved for routine operations. The Licensee conducted surveys of the Facility and provided information to the NRC to demonstrate

that it meets the criteria in Subpart E of 10 CFR part 20 for unrestricted release and for license termination.

Need for the Proposed Action

The Licensee has ceased conducting licensed activities at the Facility, and seeks the unrestricted use of its Facility and the termination of its NRC materials license. Termination of its license would end the Licensee's obligation to pay annual license fees to the NRC.

Environmental Impacts of the Proposed Action

The historical review of licensed activities conducted at the Facility shows that such activities involved use of the following radionuclides with half-lives greater than 120 days: Hydrogen-3 and carbon-14. Prior to performing the final status survey, the Licensee conducted decontamination activities, as necessary, in the areas of the Facility affected by these radionuclides.

The Licensee conducted final status surveys during April-July 2009. The final status survey report was attached to the Licensee's amendment request dated June 25, 2009, as supplemented by additional information letters dated July 10 and 14, 2009. The Licensee elected to demonstrate compliance with the radiological criteria for unrestricted release as specified in 10 CFR 20.1402 by using the screening approach described in NUREG-1757, "Consolidated NMSS Decommissioning Guidance," Volume 2. The Licensee used the radionuclide-specific derived concentration guideline levels (DCGLs), developed there by the NRC, which comply with the dose criterion in 10 CFR 20.1402. These DCGLs define the maximum amount of residual radioactivity on building surfaces, equipment, and materials, and in soils, that will satisfy the NRC requirements in subpart E of 10 CFR part 20 for unrestricted release. The Licensee's final status survey results were below these DCGLs and are in compliance with the As Low As Reasonably Achievable (ALARA) requirement of 10 CFR 20.1402. The NRC thus finds that the Licensee's final status survey results are acceptable.

Based on its review, the staff has determined that the affected environment and any environmental impacts associated with the proposed action are bounded by the impacts evaluated by the "Generic Environmental Impact Statement in Support of Rulemaking on Radiological Criteria for License Termination of NRC-Licensed Nuclear Facilities" (NUREG-1496) Volumes 1-3 (ML042310492, ML042320379, and ML042330385. The

staff finds there were no significant environmental impacts from the use of radioactive material at the Facility. The NRC staff reviewed the docket file records and the final status survey report to identify any non-radiological hazards that may have impacted the environment surrounding the Facility. No such hazards or impacts to the environment were identified. The NRC has identified no other radiological or non-radiological activities in the area that could result in cumulative environmental impacts.

The NRC staff finds that the proposed release of the Facility for unrestricted use and the termination of the NRC materials license is in compliance with 10 CFR 20.1402. Based on its review, the staff considered the impact of the residual radioactivity at the Facility and concluded that the proposed action will not have a significant effect on the quality of the human environment.

Environmental Impacts of the Alternatives to the Proposed Action

Due to the largely administrative nature of the proposed action, its environmental impacts are small. Therefore, the only alternative the staff considered is the no-action alternative, under which the staff would leave things as they are by simply denying the amendment request. This no-action alternative is not feasible because it conflicts with 10 CFR 30.36(d), requiring that decommissioning of byproduct material facilities be completed and approved by the NRC after licensed activities cease. The NRC's analysis of the Licensee's final status survey data confirmed that the Facility meets the requirements of 10 CFR 20.1402 for unrestricted release and for license termination. Additionally, denying the amendment request would result in no change in current environmental impacts. The environmental impacts of the proposed action and the no-action alternative are therefore similar, and the no-action alternative is accordingly not further considered.

Conclusion

The NRC staff has concluded that the proposed action is consistent with the NRC's unrestricted release criteria specified in 10 CFR 20.1402. Because the proposed action will not significantly impact the quality of the human environment, the NRC staff concludes that the proposed action is the preferred alternative.

Agencies and Persons Consulted

NRC provided a draft of this Environmental Assessment to the New

Jersey Department of Environmental Protection for review on June 25, 2009. On August 11, 2009, the New Jersey Department of Environmental Protection responded by letter. The State agreed with the conclusions of the EA, and otherwise had no comments.

The NRC staff has determined that the proposed action is of a procedural nature, and will not affect listed species or critical habitat. Therefore, no further consultation is required under section 7 of the Endangered Species Act. The NRC staff has also determined that the proposed action is not the type of activity that has the potential to cause effects on historic properties. Therefore, no further consultation is required under Section 106 of the National Historic Preservation Act.

III. Finding of No Significant Impact

The NRC staff has prepared this EA in support of the proposed action. On the basis of this EA, the NRC finds that there are no significant environmental impacts from the proposed action, and that preparation of an environmental impact statement is not warranted. Accordingly, the NRC has determined that a Finding of No Significant Impact is appropriate.

IV. Further Information

Documents related to this action, including the application for license amendment and supporting documentation, are available electronically at the NRC's Electronic Reading Room at <http://www.nrc.gov/reading-rm/adams.html>. From this site, you can access the NRC's Agencywide Documents Access and Management System (ADAMS), which provides text and image files of NRC's public documents. The documents related to this action are listed below, along with their ADAMS accession numbers.

1. NUREG-1757, "Consolidated NMSS Decommissioning Guidance";
2. Title 10, *Code of Federal Regulations*, part 20, subpart E, "Radiological Criteria for License Termination";
3. Title 10, *Code of Federal Regulations*, part 51, "Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions";
4. NUREG-1496, "Generic Environmental Impact Statement in Support of Rulemaking on Radiological Criteria for License Termination of NRC-Licensed Nuclear Facilities";
5. Memory Pharmaceuticals Corporation Termination Request Letter dated June 25, 2009 [ML091950247];
6. Memory Pharmaceuticals Corporation Additional Information

Letter dated July 10, 2009 [ML091950568]; and

7. Memory Pharmaceuticals Corporation Additional Information Letter dated July 14, 2009 [ML091970047].

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.Resource@nrc.gov. These documents may also be viewed electronically on the public computers located at the NRC's PDR, O 1 F21, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852. The PDR reproduction contractor will copy documents for a fee.

Dated at Region I, 475 Allendale Road, King of Prussia, PA this 17th day of September 2009.

For the Nuclear Regulatory Commission.

James P. Dwyer,

Chief, Commercial and R&D Branch, Division of Nuclear Materials Safety, Region I.

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NUCLEAR REGULATORY COMMISSION

[Docket No. 030-04192; NRC-2009-0420]

Notice of Environmental Assessment Related to the Issuance of a License Amendment to Byproduct Material License No. 12-10243-01, for Unrestricted Use of Environmental Protection Agency Facilities in Chicago, IL

AGENCY: Nuclear Regulatory Commission.

ACTION: Issuance of Environmental Assessment and Finding of No Significant Impact for License Termination.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Introduction

The U.S. Nuclear Regulatory Commission (NRC) is considering the issuance of an amendment to terminate NRC Byproduct materials License No. 12-10243-01, which is held by the U.S.

Environmental Protection Agency (licensee). The issuance of the amendment would authorize the unrestricted use of the licensee's laboratory facilities located at 536 South Clark Street, Chicago, Illinois, and similar facilities onboard the Research Vessel (R.V.) Lake Guardian (collectively, the Facilities).

The NRC has prepared an Environmental Assessment (EA) in support of this proposed action in accordance with the requirements of Title 10, Code of Federal Regulations (CFR), Part 51 (10 CFR Part 51). Based on the EA, the NRC has concluded that a Finding of No Significant Impact (FONSI) is appropriate with respect to the proposed action. The amendment will be issued to the Licensee following the publication of this FONSI and EA in the **Federal Register**.

II. Environmental Assessment

Identification of Proposed Action

The proposed action would approve the licensee's amendment request dated October 9, 2008 (ML082890377), and approve release of the Facilities for unrestricted use in accordance with 10 CFR Part 20, Subpart E. License No. 12-10243-01 was issued on August 20, 1964, pursuant to 10 CFR Part 30, and has been amended periodically since that time. The licensee used unsealed Carbon-14 for primary productivity analyses in laboratories located on the seventh and tenth floor of 536 South Clark Street, Chicago, Illinois from November 1977. Unsealed Carbon-14 was also used onboard the R.V. Lake Guardian from August 1992. Nickel-63 sealed sources were used for gas chromatography at the 536 South Clark Street laboratories. Other authorized locations for use of licensed materials under License No. 12-10243-01 were released for unrestricted use pursuant to previous license amendments. The licensee ceased licensed activities in the mid-1990s and disposed of all material licensed under License No. 12.10243-01 by 2005, and has thus requested that its license be terminated.

Based on the licensee's historical knowledge of the site and the conditions of the Facilities, the licensee determined that only routine decontamination activities, in accordance with its NRC approved, operating radiation safety procedures, were required. The licensee was not required to submit a decommissioning plan to NRC because worker cleanup activities and surveys are consistent with those approved for routine operations. The licensee submitted a Historical Site Assessment and Final Status survey report to the