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EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

[FR Doc. E7-20485 Filed 10-16-07; 8:45 am]

BILLING CODE 7555-01-P

NUCLEAR REGULATORY COMMISSION

[Docket No. 030-33266]

Notice of Environmental Assessment Related to the Issuance of a License Amendment to Byproduct Material License No. 21-26519-01, for Unrestricted Release of Former Facilities for Aastrom Biosciences, Ann Arbor, MI

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 an amendment to NRC Byproduct Materials License No. 21-26519-01. This license is held by Aastrom Biosciences (licensee) for its Gene Therapy Laboratory (the facility) located at 24 Frank Lloyd Wright Drive, Lobby L, Domino's Farm, Ann Arbor, Michigan. Issuance of the amendment would authorize the unrestricted release of the licensee's Gene Therapy Laboratory and associated offices for unrestricted use. The licensee requested this action in a letter dated July 16, 2007. 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 July 16, 2007, license amendment request, resulting in the release of the facility located at 24 Frank Lloyd Wright Drive, Lobby L, Domino's Farm, Ann Arbor, Michigan for

unrestricted use. License No. 21-26519-01 was issued on September 10, 1993, pursuant to 10 CFR Part 30, and has been amended periodically since that time. This license authorized the licensee to use unsealed byproduct materials for conducting research and development activities on laboratory bench tops and in hoods.

The licensee's facility is situated in a four-story commercial office building, which is located at 24 Frank Lloyd Wright Drive, Lobby L, Domino's Farm, Ann Arbor, Michigan, and consists of office space and a "Gene Therapy Laboratory." The site is located in a mixed residential, agricultural and commercial area. Within the facility, use of licensed materials was confined to the Gene Therapy Laboratory, which was approximately 414 square feet.

On May 16, 2007, the licensee ceased licensed activities in the Gene Therapy Laboratory and initiated a survey and decontamination of the licensee's 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. The licensee will continue licensed operations at another approved location.

Need for the Proposed Action

The licensee has ceased conducting licensed activities at the facility, and seeks the unrestricted use of the facility.

Environmental Impacts of the Proposed Action

The historical review of licensed research activities conducted at the facility shows that the activities involved only the use of hydrogen-3, which has a half-life greater than 120 days. Prior to performing the final status survey, the licensee conducted decontamination activities, as necessary, in the areas of the facility affected by the hydrogen-3.

The licensee conducted a final status survey on May 29, 2007. This survey covered the facility located at 24 Frank Lloyd Wright Drive, Lobby L, Domino's Farm, Ann Arbor, Michigan (ADAMS Accession No. ML072010257). The final status survey report was attached to the

Licensee's amendment request dated July 16, 2007. 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 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. 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 Radioactive Material and Medical Waste Materials Unit, Waste and Hazardous Materials Division, Michigan Department of Environmental Quality for review on September 10, 2007. On September 14, 2007, Mr. Robert Skowronek, Chief, Radioactive Material and Medical Waste Materials Unit, Waste and Hazardous Materials Division, Michigan Department of Environmental Quality, responded by e-mail. 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 Document 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 NRC Public Document Room (PDR) Reference staff at 1-800-397-4209, 301-415-4737, or by e-mail to pdr@nrc.gov. The documents related to this action are listed below, along with their ADAMS accession numbers.

1. Report on the Final Radiological Status of Areas Being Vacated by Aastrom Biosciences, Inc., dated May 29, 2007 (ADAMS Accession No. ML072010257).

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;" NUREG-1757, Consolidated NMSS Decommissioning Guidance.

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 Lisle, Illinois, this 5th day of October 2007.

For the Nuclear Regulatory Commission,
Patrick Loudon,

Chief, Decommissioning Branch, Division of Nuclear Materials Safety Region III.

[FR Doc. E7-20453 Filed 10-16-07; 8:45 am]

BILLING CODE 7590-01-P