NUCLEAR REGULATORY COMMISSION
DOCKET NO. 030-04544
December 14, 2005

Environmental Assessment Related to Issuance of a License Amendment
of U.S. Nuclear Regulatory Commission Materials License No. 19-07538-01,
Department of Health and Human Services, Food and Drug Administration, Center for Devices
and Radiological Health (FDA/CDRH) in Rockville, Maryland

Introduction

The U.S. Nuclear Regulatory Commission (NRC) has prepared this environmental assessment (EA) of the amendment of the Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health (FDA/CDRH) Materials License Number 19-07538-01, and the release of its 12709 Twinbrook Parkway, Rockville, Maryland site for unrestricted use. The facility is operated by FDA/CDRH in Rockville, Maryland. FDA/CDRH was authorized by NRC from August 1965 to use radioactive materials for research and development purposes at the site. In 2005, FDA/CDRH ceased operations with licensed materials at the 12709 Twinbrook Parkway, Rockville, Maryland site, and requested that NRC release the facility for unrestricted use. FDA/CDRH has conducted surveys of the facility and determined that the facility meets the license termination criteria in Subpart E of 10 CFR Part 20. The NRC staff has evaluated FDA/CDRH's request and the results of the surveys, and has developed an EA in accordance with the requirements of 10 CFR Part 51. Based on the staff evaluation, the conclusion of the EA is a Finding of No Significant Impact (FONSI) on human health and the environment for the proposed licensing action.

FDA/CDRH requested release for unrestricted use of the building at 12709 Twinbrook Parkway, Rockville, Maryland, as authorized by the NRC License No. 19-07538-01. The building is approximately 23,200 square feet of general office and laboratory space located in a commercial area. Approximately 14,000 square feet of space was used for licensed activities.

License No. 19-07538-01 was issued in 1961 and amended periodically since that time. NRC-licensed activities performed at the 12709 Twinbrook Parkway, Rockville, Maryland site were limited to laboratory procedures typically performed on bench tops and in hoods, typically using tritium, carbon-14, sulfur-35, phosphorus-32 or iodine-125. No outdoor areas were affected by the use of licensed materials.

The Proposed Action

The proposed action is to amend Materials License No. 19-07538-01 and release the facility at 12709 Twinbrook Parkway, Rockville, Maryland for unrestricted use. By letter dated August 23, 2005, FDA/CDRH stated that no further actions are required to remediate the facility, and requested release of the facility for unrestricted use. FDA/CDRH stated that licensed activities ceased completely at this location in August 2004. Based on the FDA/CDRH's historical knowledge of the site and the conditions of the facility, the licensee determined that only routine

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decontamination activities, in accordance with licensee radiation safety procedures, were required. A decommissioning plan was not required to be submitted to the NRC. The licensee surveyed the facility, decontaminated or remediated areas as needed, and provided documentation that the facility meets the license termination criteria specified in Subpart E of 10 CFR Part 20, and does not require additional decommissioning activities to be performed. The licensee demonstrated this using the screening criteria described in 65 FR 37186.

Need for the Proposed Action

The purpose of the proposed action is to amend NRC Materials License No. 19-07538-01, to allow for the release of 12709 Twinbrook Parkway for unrestricted use. The licensee needs this license change because it no longer plans to conduct licensed activities at this facility. NRC is fulfilling its responsibilities under the Atomic Energy Act to make a timely decision on a proposed license amendment for release of facilities for unrestricted use that ensures protection of public health and safety and the environment. The licensee has requested the action to reduce their regulatory burden since they no longer intend to conduct licensed activities at this location.

Environmental Impacts of the Proposed Action

The affected environment was described in the Introduction. The licensee has completed all remediation at the site. The NRC staff has reviewed the surveys performed by FDA/CDRH to demonstrate compliance with the 10 CFR 20.1402 license termination criteria. Based on its review, the staff has determined that the affected environment and environmental impacts associated with the release for unrestricted use of the FDA/CDRH facilities 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). The staff also finds that the proposed release for unrestricted use of the FDA/CDRH facilities is in compliance with Title 10, Code of Federal Regulations, Part 20.1402, “Radiological Criteria for Unrestricted Use.” The NRC has found no other activities in the area that could result in cumulative impacts.

Environmental Impacts of the Alternatives to the Proposed Action

Since the facility at the 12709 Twinbrook Parkway, Rockville, Maryland site has already been surveyed and found acceptable for release for unrestricted use, the only alternative to the proposed action of amendment of the license and release of the 12709 Twinbrook Parkway, Rockville, Maryland site for unrestricted use is denial of the proposed action (i.e. no action). Denial of the application would result in no change in current environmental impacts. The environmental impacts of the proposed action and the alternative action are similar.

Agencies and Persons Consulted

The NRC staff has determined that the proposed action will not affect listed species or critical habitat. Therefore, no further consultation is required under Section 7 of the Endangered Species Act. Likewise, the NRC staff have 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.

NRC provided a draft of its Environmental Assessment to the State of Maryland Department of the Environment for review. The State of Maryland Department of the Environment provided no comments.

Conclusions

Based on its review, the NRC staff has concluded that the completed action complies with 10 CFR Part 20. The NRC staff have prepared this EA in support of the proposed action to amend License No. 19-07538-01. On the basis of the EA, NRC has concluded that there are no significant environmental impacts and the license amendment does not warrant the preparation of an Environmental Impact Statement. Accordingly, it has been determined that a Finding of No Significant Impact is appropriate.

List of Preparers

Betsy Ullrich, Senior Health Physicist, Division of Nuclear Materials Safety, Region I

List of References

1. NRC License No. 19-07538-01 inspection and licensing records.

2. Final Status Survey Report, Food and Drug Administration, Center for Devices and Radiological Health, 12709 Twinbrook Parkway, Rockville, Maryland, August 22, 2005, Final Report [ADAMS Accession No. ML052380179].

3. Federal Register Notice, Volume 65, No. 114, page 37186, dated Tuesday, June 13, 2000, “Use of Screening Values to Demonstrate Compliance With The Federal Rule on Radiological Criteria for License Termination.”

4. Title 10 Code of Federal Regulations, Part 20, Subpart E, “Radiological Criteria for License Termination.”

5. Title 10, Code of Federal Regulations, Part 51, “Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions.”

6. NUREG-1496, “Generic Environmental Impact Statement in Support of Rulemaking on Radiological Criteria for License Termination of NRC-Licensed Nuclear Facilities.”

The application for the license amendment and supporting documentation are available for inspection at NRC’s Public Electronic Reading Room at http://www.nrc.gov/reading-rm/adams.html. Any questions with respect to this action should be referred to Betsy Ullrich, Commercial and R&D Branch, Division of Nuclear Materials Safety,

FDA/CDRH
Environmental Assessment

Region I, 475 Allendale Road, King of Prussia, Pennsylvania 19406, telephone (610) 337-5040, fax (610) 337-5269.

Dated at King of Prussia, Pennsylvania this 14th day of December 2005

FOR THE NUCLEAR REGULATORY COMMISSION

/RA/

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

SISP Review Complete: JDK

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