NUCLEAR REGULATORY COMMISSION
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Environmental Assessment Related to an Amendment
of U.S. Nuclear Regulatory Commission Materials License No. 29-30698-01,
Issued to Purdue Pharma, L. P.

The U.S. Nuclear Regulatory Commission (NRC) is considering amending Materials License Number 29-30698-01 and authorizing the release of the licensee's facilities in Cranbury, New Jersey for unrestricted use and has prepared an Environmental Assessment (EA) in support of this action.

SUMMARY: The NRC reviewed the results of the decommissioning of the Purdue Pharma, L. P. facility in Cranbury, New Jersey. Purdue Pharma, L. P. was authorized by NRC from January 3, 2002 to use radioactive materials for research and development purposes in three sections of the building at the site. In February 2005, Purdue Pharma, L. P. ceased operations with licensed materials in two sections of the building at the Cranbury site, and requested that NRC release those sections of the facility for unrestricted use. Purdue Pharma, L. P. 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 the Purdue Pharma, L. P. request and the results of the surveys, and has developed an EA in accordance with the requirements of 10 CFR Part 51. The NRC has determined that a Finding of No Significant Impact (FONSI) is appropriate for the proposed action.

Introduction

Purdue Pharma, L. P. requested release for unrestricted use of two sections of the building at 6 Cedarbrook Drive, Cranbury, New Jersey, as authorized by the NRC License No. 29-30698-01. A third section of the building will continue to be used for licensed operations. The building is 110,000 square feet of general office and laboratory space located in a mixed industrial/commercial area. The licensee reported that only 2,327 square feet of laboratory space was ever used for licensed activities.

License No. 29-30698-01 was issued in 2002 and amended periodically since that time. NRC-licensed activities performed at the Cranbury, New Jersey, site were limited to laboratory procedures typically performed on bench tops and in hoods using hydrogen-3 (tritium), carbon-14, sulfur-35, chromium-51, yttrium-90 and iodine-125. No outdoor areas were affected by the use of licensed materials.

Licensed activities with unsealed licensed materials ceased completely in the two sections of the facility in February 2005 and the licensee requested release of these sections for unrestricted use, except for a laboratory in which a self-shielded irradiator is possessed. 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 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,

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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. The licensee subsequently requested that the facility be released for unrestricted use.

The Proposed Action

The proposed action is to amend Materials License No. 29-30698-01 and release two sections of the facility at 6 Cedarbrook Drive, Cranbury, New Jersey, for unrestricted use. By letters dated April 21 and June 30, 2005, Purdue Pharma, L. P. stated that no further actions are required to remediate the facility and provided survey results which demonstrate that the Cranbury facility is in compliance with the radiological criteria for license termination in Subpart E, 10 CFR Part 20, "Radiological Criteria for License Termination."

Purpose and Need for the Proposed Action

The purpose of the proposed action is to amend NRC Materials License No. 29-30698-01, to allow for the release of two sections of the facility at 6 Cedarbrook Drive for unrestricted use. The licensee needs this license change because it no longer plans to conduct licensed activities in these sections of 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 in these sections of the facility.

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 Purdue Pharma, L. P. 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 Purdue Pharma, L. P. 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 Purdue Pharma, L. P. 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 Purdue Pharma, L. P. 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 two sections of the facilities at 6 Cedarbrook Drive, Cranbury, New Jersey, site for unrestricted use is no action. The no-action alternative is not acceptable because the licensee does not plan to perform any activities with licensed materials

in these facilities and does not plan to maintain staff to perform licensed activities. Maintaining the areas under a license would impose an unnecessary regulatory burden. The effect of the no-action alternative would be to restrict potential benefits from future uses of the site.

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 New Jersey, Department of Environmental Protection for review. On September 13, 2005, the State of New Jersey, Department of Environmental Protection responded by letter and agreed with the conclusions of the EA.

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. 29-30698-01. 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. 29-30698-01 inspection and licensing records.

2. Decommissioning Survey Report for Purdue Pharma, L. P., NRC License No. 29-30698-01, dated April 21, 2005 [ADAMS Accession No. ML052590192].

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, 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 5th day of October

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: JPD1

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