

NUCLEAR REGULATORY COMMISSION

[Docket No. 030-19324]

NOTICE OF AVAILABILITY OF ENVIRONMENTAL ASSESSMENT AND
FINDING OF NO SIGNIFICANT IMPACT FOR LICENSE AMENDMENT TO
BYPRODUCT MATERIALS LICENSE NO. 25-19852-01 FOR UNRESTRICTED RELEASE OF
BUILDING 11 OF THE GLAXOSMITHKLINE BIOLOGICALS-HAMILTON FACILITY IN
HAMILTON, MONTANA

AGENCY: Nuclear Regulatory Commission.

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

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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. 25-19852-01. The license is held by GlaxoSmithKline Biologicals-Hamilton (the Licensee), for its Hamilton facility (the Facility), located at 553 Old Corvallis Road in Hamilton, Montana. Issuance of the amendment would authorize release of Building 11 of the Facility for unrestricted use. The Licensee requested this action in a letter dated December 21, 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 December 21, 2007 license amendment request, resulting in the release of the stand-alone Building 11 at the Facility for unrestricted use. NRC License No. 25-19852-01 was issued on June 24, 1988, pursuant to 10 CFR Part 30, and has been amended periodically since that time. This license authorizes the Licensee to possess and use small quantities of byproduct material, in both sealed and unsealed form, for laboratory research in immunological and biochemical studies. Additionally, the license authorizes the Licensee to possess and use a self-shielded irradiator device and to possess and use sealed sources for the purposes of performing instrument calibration.

The Facility is situated on 35 acres (14 hectares) and consists of a main building comprised of office space and laboratories as well as several smaller buildings used for various purposes. The Facility is located in a mixed residential/commercial area. The Licensee's December 21, 2007, license amendment request specifically addressed the release of Building 11 at the Facility for unrestricted use. Building 11 was used as a storage building to store equipment, wood shavings (animal bedding for a vivarium), biomedical waste materials and low level radioactive waste. The building was originally designed as an overhead shelter. In 2004 walls were added to divide a portion of the structure into four rooms. The building was constructed with a concrete slab floor, wood framing and walls, and a sheet metal roof. There are no floor drains or other fixtures such as sinks with plumbing inside Building 11. The center

east room within Building 11 is the only area licensed for storage and decay of low level radioactive materials. The floor dimensions of the center east room are approximately 8 feet (2.4 meters) by 20 feet (6.1 meters).

The Licensee removed the low-level radioactive materials from Building 11 and initiated a final status survey for the stand-alone building. The Licensee was not required to submit a decommissioning plan to the NRC. The Licensee conducted surveys of the center east room of Building 11 and provided information to the NRC to demonstrate that it meets the criteria in Subpart E of 10 CFR Part 20 for unrestricted release.

Need for the Proposed Action

The Licensee has ceased conducting licensed activities in the stand-alone Building 11 of the Facility and seeks the unrestricted use of Building 11.

Environmental Impacts of the Proposed Action

The low level wastes generated as a result of the licensed activities at the Facility consisted of the following radionuclides with half-lives greater than 120 days: hydrogen-3 (tritium), carbon-14, and calcium-45. The radioactive materials were in the form of dry-solids, sharps, scintillation vials, and bulk liquid in polypropylene carboys. The licensee stored the low level radioactive wastes in plastic lined UN 55 gallon steel drums and stored the drums in the center east room of Building 11. The drums were never opened while stored in Building 11. Prior to performing the final status survey, the Licensee removed the low level radioactive drums from Building 11.

The Licensee conducted a final status survey during November and December 2007. This survey covered the center east room of Building 11. The final status survey report was attached to the Licensee's amendment request dated December 21, 2007. NRC regulation 10 CFR 20.1402, *Radiological Criteria for Unrestricted Use*, states in part that a site will be considered acceptable for unrestricted use if the residual radioactivity that is distinguishable from

background radiation results in a total effective dose equivalent not to exceed 25 millirems per year (0.25 milliSeiverts per year) to an average member of the critical group (the group of individuals reasonably expected to receive the greatest exposure to residual radioactivity for any applicable set of circumstances). The Licensee elected to demonstrate compliance with the radiological criteria for unrestricted use as specified in 10 CFR 20.1402 by comparing the final status survey results to background radiation levels for the area. Since the Licensee's survey results did not identify any radioactive contamination in excess of background radiation levels for the area, then the results adequately met the criteria for unrestricted use. Accordingly, the Licensee's final status survey results were 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). Further, no incidents were recorded involving spills or releases of radioactive material in Building 11 of the Facility. Accordingly, there were no significant environmental impacts from the use of radioactive material at the Facility.

The NRC staff finds that the proposed release of the portion of the Facility described above for unrestricted use is in compliance with 10 CFR 20.1402. The NRC has found no other activities in the area that could result in cumulative environmental impacts. Based on its review, the staff considered the impact of the residual radioactivity at Building 11 of 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 simply deny 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. Additionally, this denial of the application would result in no change in current environmental impacts. The environmental impacts of the proposed action and the no-action alternative are 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 EA to the State of Montana Department of Public Health and Human Services for review on April 25, 2008. The State of Montana Department of Public Health and Human Services did not have any comments to the draft EA.

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 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 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. The documents related to this action are listed below, along with their ADAMS accession numbers, if applicable.

1. 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;"

2. NRC, "Generic Environmental Impact Statement in Support of Rulemaking on Radiological Criteria for License Termination of NRC-Licensed Nuclear Facilities," NUREG-1496, July 1997 (ML042310492, ML042320379, and ML042330385);

3. NRC, "Consolidated NMSS Decommissioning Guidance," NUREG-1757, Volume 1, Revision 1, September 2003 (ML053260027);

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;"

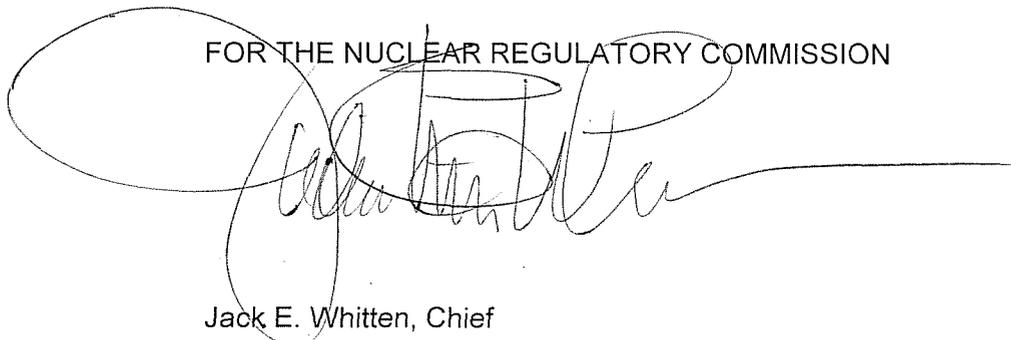
6. Poletti, Brian, GlaxoSmithKline Biologicals - Hamilton, License Amendment Request dated December 21, 2007 (ML080380101).

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 email to pdrc@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 Arlington, Texas this 27th day of June 2008.

FOR THE NUCLEAR REGULATORY COMMISSION

A large, stylized handwritten signature in black ink, appearing to read 'Jack E. Whitten', is written over the typed text. The signature is highly cursive and extends across the width of the typed name.

Jack E. Whitten, Chief

Nuclear Materials Safety Branch B

Division of Nuclear Materials Safety

Region IV