

I. Introduction

The U.S. Nuclear Regulatory Commission (NRC) is issuing for public comment a draft regulatory 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 "Physical Models for Design and Operation of Hydraulic Structures and Systems for Nuclear Power Plants," is temporarily identified by its task number, DG-1198, which should be mentioned in all related correspondence.

This guide describes the desired coordination of an applicant with the staff of the NRC and the detail and documentation of data and studies that an applicant should include in the preliminary safety analysis report (PSAR) or final safety analysis report (FSAR) to support the use of physical hydraulic model testing for predicting the performance of hydraulic structures and systems for nuclear power plants. The regulatory position of this guide is applicable only to physical models used to predict the action or interaction of surface waters with features located outside of containment. The recommendations of this guide do not apply to internal plant systems or structures.

Title 10, Section 50.34(a)(3)(ii) of the Code of Federal Regulations (10 CFR 50.34(a)(3)(ii)) requires that the PSAR include information on the design bases of the facility and the relation of the design bases to the principal design criteria. In part, 10 CFR 50.34(a)(4) requires a preliminary analysis of the adequacy of structures, systems, and components provided for the prevention of accidents and the mitigation of the consequences of accidents.

II. Further Information

The NRC staff is soliciting comments on DG-1198. Comments may be accompanied by relevant information or supporting data, and should mention DG-1198 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 the comments. Comments

may be submitted by any of the following methods:

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

2. *E-mail to:* NRCREP@nrc.gov.

3. *Hand-deliver to:* Rulemaking, Directives, and Editing Branch, Office of Administration, U.S. Nuclear Regulatory Commission, 11555 Rockville Pike, Rockville, Maryland 20852, between 7:30 a.m. and 4:15 p.m. on Federal workdays.

4. *Fax to:* Rulemaking, Directives, and Editing Branch, Office of Administration, U.S. Nuclear Regulatory Commission at (301) 415-5144.

Requests for technical information about DG-1198 may be directed to John Burke at (301) 415-1529 or e-mail to John.Burke@nrc.gov.

Comments would be most helpful if received by September 5, 2008. 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-1198 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. ML081080301.

In addition, regulatory guides are available for inspection at the NRC's Public Document Room (PDR), which is 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@nrc.gov.

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Dated at Rockville, Maryland, this 2nd day of July, 2008.

For the Nuclear Regulatory Commission.

Stephen C. O'Connor,

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

[FR Doc. E8-15674 Filed 7-9-08; 8:45 am]

BILLING CODE 7590-01-P

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, MT

AGENCY: Nuclear Regulatory Commission.

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

FOR FURTHER INFORMATION CONTACT:

Rachel S. Browder, Health Physicist, Nuclear Materials Safety Branch B, Division of Nuclear Materials Safety, Region IV, U.S. Nuclear Regulatory Commission, 612 Lamar Drive, Suite 400, Arlington, Texas 76011; telephone: (817) 276-6552; fax number: (817) 860-8188; or by e-mail: rachel.browder@nrc.gov.

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 milliSieverts 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 e-mail to pdr.rosource@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,
Jack E. Whitten,
Chief, Nuclear Materials Safety Branch B,
Division of Nuclear Materials Safety, Region IV.

[FR Doc. E8-15675 Filed 7-9-08; 8:45 am]

BILLING CODE 7590-01-P

NUCLEAR REGULATORY COMMISSION

[Docket No. 030-33658]

Notice of Availability of Environmental Assessment and Finding of No Significant Impact for License Amendment Request to Byproduct Materials License 01-25316-01 for the Department of Defense, Defense Intelligence Agency, Redstone Arsenal, AL

AGENCY: Nuclear Regulatory Commission.

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

FOR FURTHER INFORMATION CONTACT:

Thomas Thompson, Senior Health Physicist, Commercial and R&D Branch, Division of Nuclear Materials Safety, Region I, 475 Allendale Road, King of Prussia, PA 19406. Telephone: (610) 337-5303; fax number: (610) 337-5269; e-mail: TKT@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Introduction

The U.S. Nuclear Regulatory Commission (NRC) is considering the issuance of a license renewal to Byproduct Materials License No. 01-25316-01. This license is held by the Department of Defense, Defense Intelligence Agency (the Licensee), for activities conducted at the Redstone Arsenal facility, located in Redstone Arsenal, Alabama. As part of its license renewal, the Licensee has requested an exemption from the requirement in 10 CFR 30.32(g) to list sealed sources by their manufacturer and model number as registered under the provisions of 10 CFR 32.210. The Licensee requested this exemption in a letter received on November 1, 2005. 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 license renewal, including the approval of the exemption request, 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 renew License No. 01-25316-01, including approval of the Licensee's request for exemption received on November 1, 2005. License No. 01-25316-01 was issued on January 26, 1995, pursuant to 10 CFR Parts 30 and 70, and has been amended periodically since that time. This license authorized the Licensee to receive, store, use and/or transfer specified radioactive materials incident to research and development as defined in 10 CFR 30.4.

On December 29, 2004, the Licensee submitted its renewal application for License No. 01-25316-01. In a letter received on November 1, 2005, submitted in response to an inquiry from the NRC, the Licensee requested an exemption from the requirement in 10 CFR 30.32(g) to list sealed sources by their manufacturer and model number as registered under the provisions of 10 CFR 32.210. In requesting this exemption, the Licensee states that the sole purpose of possessing the sealed sources on this license "is to be able to remove and store for disposal devices of foreign manufacture which may be contained on, or in, foreign military vehicles or conveyances." Furthermore, the Licensee states that it will not know in advance what sources or devices may be received at its facility and that, in the interest of national security and Department of Defense policy, the sources or origination of foreign equipment cannot be revealed. The Licensee states that it immediately surveys all such foreign vehicles for radioactive material and places them in storage for future disposal if radioactive contamination is found.

Need for the Proposed Action

The Licensee receives and takes possession of sealed sources and devices which have not been registered with the NRC under 10 CFR 32.210 or with an Agreement State. As these sources and devices are of foreign manufacture, the Licensee would not be able to continue this activity without this exemption.