



**UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TEXAS 76011-4005**

August 25, 2006

GlaxoSmithKline Biologicals - Hamilton
ATTN: Brian Poletti
Radiation Safety Officer
553 Old Corvallis Road
Hamilton, Montana 59840-3131

SUBJECT: NRC INSPECTION REPORT 030-19324/06-001

Dear Mr. Poletti:

This refers to the inspection conducted on August 3, 2006, at the GlaxoSmithKline Biologicals - Hamilton (GSK) facility located in Hamilton, Montana. The inspection consisted of a confirmatory survey of Building 7, which had been used for storage and decay of radioactive materials since 2004. The facility no longer stored radioactive materials and GSK had requested a license amendment to approve the release of Building 7 for unrestricted use, based on the supporting final status survey report (FSSR). The confirmatory survey included ambient gamma exposure rates and fixed and loose surface measurements for low-energy beta contamination. Results of the confirmatory survey did not reveal any radiation distinguishable from accepted background radiation levels. Details of the confirmatory survey are provided in the enclosed report. The NRC's conclusion of the final status survey report will be provided to you at a later date under separate correspondence.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS). ADAMS is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

Should you have any questions regarding this inspection or the associated licensing action, please contact the undersigned at (817) 860-8191 or Ms. Rachel S. Browder at (817) 276-6552.

Sincerely,

/RA/

D. Blair Spitzberg, Ph.D., Chief
Fuel Cycle & Decommissioning Branch

Docket No.: 030-19324
License No.: 25-19852-01
Control No.: 471003

Enclosure: NRC Inspection Report 030-19324/06-001

cc: Montana Radiation Control Program Director

bcc w/enclosure (via ADAMS e-mail distribution):

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RIV Nuclear Materials File - 5th Floor

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ENCLOSURE

U.S. NUCLEAR REGULATORY COMMISSION
REGION IV

Docket No: 030-19324

License No: 25-19852-01

Report No: 030-19324/06-001

Licensee: GlaxoSmithKline Biologicals - Hamilton

Facility: Building 7

Location: Hamilton, Montana

Date: August 3, 2006

Inspector: Rachel S. Browder, Health Physicist
Nuclear Materials Licensing Branch

Approved By: D. Blair Spitzberg, Ph.D., Chief
Fuel Cycle & Decommissioning Branch

Attachment: Supplemental Inspection Information

EXECUTIVE SUMMARY

GlaxoSmithKline Biologicals - Hamilton
NRC Inspection Report 030-19324/06-001

By letter dated June 8, 2006, GlaxoSmithKline Biologicals - Hamilton requested an amendment to its NRC materials license to release Building 7 for unrestricted use. The amendment request was supported by a final status survey report (FSSR). The release of Building 7 for unrestricted use was necessary due to the facility expansion project, in which the building was going to be demolished to allow room for the utilities infrastructure. The radioactive materials stored in Building 7 had already been removed to another storage location within the licensee's facility.

Decommissioning Inspection Procedure for Materials Licenses

- An NRC confirmatory survey was conducted in the radiological storage area of Building 7. The confirmatory survey included ambient gamma exposure rate measurements, fixed surface contamination measurements and loose surface contamination analyses for low-energy betas. Results of the confirmatory survey did not reveal any radiation distinguishable from accepted background radiation levels and the results were within the performance characteristics of the instrumentation. The contamination analysis for low-energy beta was below the minimum detectable concentration (MDC) for the tritium and carbon-14 analyses. The NRC confirmatory survey data results are documented in this inspection report. However, the staff's review and approval of the submitted license amendment request and supporting FSSR is still under review and has not been approved. There will be a separate report and environmental assessment documenting the staff's review of the FSSR and respective licensing action.

Report Details

Summary of Building Status

NRC byproduct materials License No.25-19852-01 authorizes GlaxoSmithKline Biologicals - Hamilton (GSK) to possess small quantities of radioactive material, in both sealed and unsealed form, for laboratory research in immunological and biochemical studies, as well as instrument calibration. Additionally, the license authorizes an irradiator; however, the irradiator is not currently being used by the researchers at the facility.

By letter dated June 8, 2006, GSK requested an amendment to its NRC byproduct materials license to release Building 7 for unrestricted use. The release of Building 7 for unrestricted use was necessary due to the facility expansion project, in which the building was going to be demolished to allow room for the utilities infrastructure. The radioactive materials stored in Building 7 had already been removed to another storage location within the licensee's facility.

The amendment request was supported by a final status survey report (FSSR). The licensee based their release criteria on the surface contamination limits for beta-gamma emitters provided in Regulatory Guide 1.86, Table 1, *Acceptable Surface Contamination Levels*, as the derived concentration guideline levels (DCGLs) for release of Building 7 for unrestricted use. The surface contamination limits submitted by the licensee are significantly lower than the NRC acceptable screening values for the respective radionuclides, as documented in NUREG-1757.

1 Decommissioning Inspection Procedure for Material Licenses (87104)

1.1 Inspection Scope

The objective of the inspection was to perform a confirmatory survey of Building 7 to determine if the licensee's FSSR supported the release of Building 7 for unrestricted use.

1.2 Observations and Findings

Building 7 at the GSK facility in Hamilton, Montana, was used for storage and decay of radioactive materials. The building was constructed of filled concrete block walls set on a concrete floor, with no drains or other fixtures, such as sinks or plumbing. The building had a filled concrete block wall down the center which separated the building into two east/west rooms. Each room had a separate entry door on the south side of the building. The west room of Building 7 was used to store hazardous materials, while the east room was licensed for storage and decay of low level radioactive materials. The east room was approximately 15 x 15 square-foot (ft²) area and was the location where the confirmatory surveys were performed.

The licensee stated that Building 7 had been used since 2004, as a storage location for small quantities of radioactive wastes. The radioactive wastes stored in the building were contained in lined UN rated 55 gallon steel drums. The licensee's historical assessment documented that the wastes were either dry-solid, liquid scintillation vials, or bulk liquid in sealed heavy plastic carboys. The primary constituents of concern and the respective quantity stored in the

building were carbon-14 (29 microcuries) and tritium (13.06 millicuries). The drums and radioactive waste packages were never opened while stored in Building 7.

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 to an average member of the critical group. The licensee referenced Regulatory Guide 1.86, Table 1, *Acceptable Surface Contamination Levels*, and NUREG-1556, Volume 11, Table S.5, *Acceptable Surface Contamination Levels*. Both tables provide an average (5,000 dpm/100 cm²) and maximum (15,000 dpm/100 cm²) limit for release of the facility. Although these values are not dose-based calculations as required by the license termination rule in 10 CFR Part 20, as stated above, they may be compared to the screening values documented in NUREG-1757, Volume 1, Revision 1, *Consolidated NMSS Decommissioning Guidance*, Table B.1. NUREG-1757 provides screening values for building surface contamination which are equivalent to 25 millirem per year. The NRC approved screening value for carbon-14 is 3.7E+6 dpm/100 cm². Assuming a loose/removable contamination fraction of 10 percent, the removable surface contamination screening value is 3.7E+5 dpm/100 cm². Therefore, the surface contamination level as submitted by the licensee is significantly lower than the acceptable screening value for carbon-14 which is equivalent to 25 millirem per year, as documented in NUREG-1757. The carbon-14 screening value is bounding, since the tritium screening value is a factor of 32 greater, as documented in NUREG-1757.

The licensee performed a thorough survey of the 15 x15 ft² area. The survey was performed in accordance with the methodology provided in NUREG-1575, *Multi-Agency Radiation Survey and Site Investigation Manual* (MARSSIM.) The licensee used a Ludlum Model 3 with a GM pancake Model 44-9 detector (serial numbers 161222 / PR158497) for the scanning surveys and a William B. Johnson Model GSM-110 with a GM probe (serial numbers 6302/RN014986) for the exposure rate surveys. The instruments used were in current calibration as documented in the submitted calibration certificates. The licensee performed scanning surveys over 100% of the floor, door, and lower walls of the building. The results did not locate any radioactive contamination above background readings, which were recorded to be 100 counts per minute (cpm). The exposure rate surveys were taken at each one square meter grid marking on the floor and lower walls of the building. The licensee stated that the survey results were taken at one meter above the working surfaces. The exposure results did not identify any radiation readings above background, which was documented as 0.02 milliRoentgen per hour (mR/hr). Additionally, the licensee took 45 swipe samples for tritium and carbon-14 liquid scintillation analysis. The results did not identify any radioactive contamination above the instrument minimum detectable activity (MDA) of 25 disintegrations per minute (dpm). Therefore, the licensee concluded that the building may be released for unrestricted use.

The NRC performed an independent historical review of the license docket folder which confirmed the radiological materials used at the facility. The primary radionuclides of concern and the respective quantity stored in the Building 7 were tritium (13.06 millicuries) and carbon-14 (29 microcuries). The latest, documented NRC inspection of the facility was performed on September 9, 2004, with no findings or violations identified.

An NRC confirmatory survey was conducted on August 3, to independently assess the radiological conditions of Building 7. The survey included measurements of ambient gamma exposure rates, residual contamination surveys, and swipe samples for loose low-energy beta contamination, that were sent to Oak Ridge Institute for Science and Education (ORISE) for liquid scintillation analysis. ORISE is an independent laboratory under contract to the NRC. The ambient gamma exposure rate measurements were collected with a Ludlum Model 2401-P survey meter (NRC No. 21448G, calibration due date: February 15, 2007). The residual contamination survey was conducted with an Eberline E600 survey meter (NRC No. 079977, calibration due date: June 26, 2007) with Eberline SHP380AB alpha-beta probe (NRC No. 079976). Prior to the survey, the instruments were response-checked for operability. Background exposure rates and count rates of non-impacted concrete were determined in areas adjacent to Building 7 which were not expected to have been affected by the storage of radioactive materials.

The background ambient gamma exposure rates were measured and ranged from 14 to 25 microRoentgens per hour ($\mu\text{R/hr}$), which is consistent with the licensee's measurement of 0.02 mR/hr. Background surface measurements were collected on concrete areas outside of Building 7. The three background concrete surface beta particle measurements ranged from 369 counts per minute (cpm) to 399 cpm, with an average of 383 cpm. Based on the average background of 383 cpm for beta particles, the lower limit of detection (LLD) for the Eberline E600 survey meter was calculated using Equation 3-8 from NUREG-1507, *Minimum Detectable Concentrations with Typical Radiation Survey Instruments for Various Contaminants and Field Conditions*. Field measurements greater than the calculated LLD of 477 cpm may be indicative of the presence of radioactive material.

$$\text{LLD}_{(\text{concrete})} = 3 + 4.65(383)^{\frac{1}{2}} + 383 \text{ cpm} = 477 \text{ cpm}$$

Following is a table of the concrete surface gross beta particle measurements (which include background) as measured in Building 7. The reference point is the grid location as submitted in the licensee's amendment request and which was still visibly marked on the floor and walls of Building 7. The measurement was taken for one minute, with the results documented in cpm. All measurements were below the LLD calculated for concrete.

Grid Location	Gross Beta Measurement (cpm)
27	423
23	417
25	410
32	425
34	378
30	425

Grid Location	Gross Beta Measurement (cpm)
40	407
42	390
43	454
44	375
45	416

The gross beta measurements as documented in the confirmatory survey above, is numerically greater than the measurements submitted by the licensee, which were 100 cpm, which was also the same as the background measured by the licensee. The difference between the values is based on different types of detectors and corresponding efficiency and measurement sensitivity capability, as well as the difference in the physical size of the probe area. Nevertheless, both measurements indicate that the measured value is within the background value for concrete.

Five swipe samples were taken in Building 7 for loose contamination. The five samples collected were approximately 10% of the 45 swipe samples collected by the licensee. The swipe samples were sent to ORISE for analysis by liquid scintillation for tritium and carbon-14. The tritium and carbon-14 measured activities were below the minimum detectable concentrations (MDC) for each analysis. The tritium MDC was 16.7 pCi/smear and the carbon-14 concentration was 5.8 pCi/smear.

1.3 Conclusion

An NRC confirmatory survey was conducted in the radiological storage area of Building 7. The confirmatory survey included ambient gamma exposure rate measurements, fixed surface contamination measurements and loose surface contamination analyses for low-energy betas. Results of the confirmatory survey did not reveal any radiation distinguishable from accepted background radiation levels and the results were within the performance characteristics of the instrumentation. The contamination analysis for low-energy beta was below the minimum detectable concentration (MDC) for the tritium and carbon-14 analyses. The NRC confirmatory survey data results are documented in this inspection report. However, the staff's review and approval of the submitted license amendment request and supporting FSSR is still under review and has not been approved. There will be a separate report and environmental assessment documenting the staff's review of the FSSR and respective licensing action.

2 Exit Meeting Summary

The inspector presented preliminary inspection results to members of the licensee at the conclusion of the confirmatory survey on August 3, 2006. Once the confirmatory survey results from ORISE were received, then a telephonic exit meeting was conducted with the licensee on August 11, 2006. The licensee did not identify as proprietary any information provided to, or reviewed by, the inspector.

ATTACHMENT

PARTIAL LIST OF PERSONS CONTACTED

GlaxoSmithKline Biologicals - Hamilton

Brian Poletti, Radiation Safety Officer
Jeff Albano, Environmental Health & Safety Supervisor

INSPECTION PROCEDURES USED

87104 Decommissioning Inspection Procedure for Materials Licenses

ITEMS OPENED AND CLOSED

Opened

None

Closed

None

Discussed

None

LIST OF ACRONYMS USED

cpm	counts per minute
DCGL	derived concentration guideline level
dpm/100 cm ²	disintegrations per minute per 100 square centimeters
FSSR	Final Status Survey Report
μR/hr	microRoentgens per hour
mR/hr	milliRoentgen per hour
LLD	lower limit of detection
MDA	minimum detectable activity
MDC	minimum detectable concentration
MARSSIM	Multi-Agency Radiation Survey and Site Investigation Manual