



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
612 EAST LAMAR BLVD, SUITE 400
ARLINGTON, TEXAS 76011-4125

July 16, 2008

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

SUBJECT: LICENSE AMENDMENT

Please find enclosed Amendment No. 22 to NRC License No. 25-19852-01. This license amendment authorizes the release of the outdoor facility listed as Building 11 for unrestricted use in accordance with 10 CFR 20.1402, "Radiological criteria for unrestricted use." An Environmental Assessment (EA) was performed in accordance with 10 CFR Part 51 and published in the Federal Register on Thursday, July 10, 2008 (**73 FR 39732**). On the basis of the EA, the NRC concluded there were no significant environmental impacts from the proposal to decommission and demolish Building 11. Based on these conclusions, no further remediation or actions with respect to NRC regulated material at Building 11 is required. A copy of the EA is enclosed for your records.

In addition, this license amendment authorizes the removal of the self-shielded irradiator from your license. Based on the documentation submitted and a review of the historical file, the staff concluded there was no evidence of leakage of radioactive material from the sealed source. In addition, the records submitted were sufficient to document the transfer of the sealed source to MDS Nordion on April 22, 2008. No further documentation is necessary. An EA for this action is not required, since this action is categorically excluded under 10 CFR 51.22(c)(20)(ii), for decommissioning of sealed sources. You should review the enclosed license carefully and be sure that you understand all conditions. If there are any questions regarding your license or these two licensing actions, please contact me at (817) 276-6552.

Please note that License Condition 21 was removed from your license. I have sent an electronic mail message to our Headquarter's office, informing them that the radionuclide of concern has been transferred from your license and that you are no longer required to implement the Increased Controls and fingerprinting Orders. If you obtain quantities of concern in the future, then you will have to notify in writing, the Director, Office of Federal and State Materials and Environmental Management Programs, U.S. NRC, Washington, DC, 20555, when you have completed the requirements of the Orders and prior to possession of the materials of concern.

NRC's Regulatory Issue Summary (RIS) 2005-31, provides criteria to identify security-related sensitive information and guidance for handling and marking of such documents. This ensures that potentially sensitive information is not made publicly available through ADAMS. The RIS may be located on the NRC Web site at: <http://www.nrc.gov/reading-rm/doc-collections/gen-comm/reg-issues/2005/>. In addition, the NRC website for frequently asked questions (FAQ) is available at: <http://www.nrc.gov/reading-rm/sensitive-info/materials.html>; then select "Withholding of Sensitive Information." Pursuant to NRC's RIS 2005-31, the enclosed radioactive materials license will be made publicly available.

NRC expects licensees to conduct their programs with meticulous attention to detail and a high standard of compliance. Because of the serious consequences to employees and the public that can result from failure to comply with NRC requirements, you must conduct your radiation safety program according to the conditions of your NRC license, representations made in your license application, and NRC regulations. In particular, note that you must:

1. Operate by NRC regulations 10 CFR Part 19, "Notices, Instructions and Reports to Workers: Inspection and Investigations," 10 CFR Part 20, "Standards for Protection Against Radiation," and other applicable regulations.
2. Notify NRC in writing of any change in mailing address.
3. By 10 CFR 30.36(d) and/or license condition, notify NRC, promptly, in writing, and request termination of the license:
 - a. When you decide to terminate all activities involving materials authorized under the license whether at the entire site or any separate building or outdoor area;
 - b. If you decide not to acquire or possess and use authorized material; or
 - c. When no principal activities under the license have been conducted for a period of 24 months.
4. Request and obtain a license amendment before you:
 - a. Change Radiation Safety Officers;
 - b. Order byproduct material in excess of the amount, radionuclide or form authorized on the license;
 - c. Add or change the areas or address(es) of use identified in the license application or on the license; or
 - d. Change the name or ownership of your organization.

In addition, please note that NRC Form 313 requires the applicant, by signature, to verify that the applicant understands that all statements contained in the application are true and correct to the best of the applicant's knowledge. The signatory for the application should be the licensee or certifying official rather than a consultant. Since the NRC also accepts a letter requesting amendment of an NRC license, the signatory for such a request should also be the licensee or certifying official rather than a consultant.

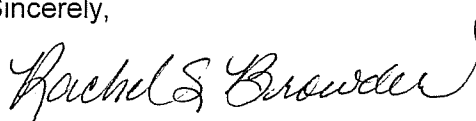
NRC will periodically inspect your radiation safety program. Failure to conduct your program according to NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC may result in enforcement action against you. This could include issuance of a notice of violation; imposition of a civil penalty; or an order suspending, modifying, or revoking your license as specified in the NRC Enforcement Policy. The NRC Enforcement Policy is available at: <http://www.nrc.gov/reading-rm/doc-collections/enforcement>.

NRC no longer publishes the NRC Rules and Regulations loose leaf supplements. However, an electronic version of the NRC's regulations is available on the NRC Web site at www.nrc.gov. Additional information regarding use of radioactive materials may be obtained on the NRC Web site at <http://www.nrc.gov/materials/miau/mat-toolkits.html>. This site also provides the link to the toolbox for updated information on the revised regulations for naturally-occurring and accelerator-produced radioactive materials (NARM).

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>.

Thank you for your cooperation.

Sincerely,

A handwritten signature in black ink, reading "Rachel S. Browder". The signature is fluid and cursive, with a large, sweeping flourish at the end of the last name.

Rachel S. Browder, Health Physicist
Nuclear Materials Safety Branch B

Docket: 030-19324
License: 25-19852-01
Control: 471620; 471815

Enclosures: As stated

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

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| Licensee | | In accordance with letters dated December 21, 2007, May 12, 2008 |
| 1. GlaxoSmithKline Biologicals - Hamilton | | 3. License number 25-19852-01 is amended in its entirety to read as follows: |
| 2. 553 Old Corvallis Road Hamilton, Montana 59840-3131 | | 4. Expiration date June 30, 2015 |
| | | 5. Docket No. 030-19324 Reference No. |
| 6. Byproduct, source, and/or special nuclear material | 7. Chemical and/or physical form | 8. Maximum amount that licensee may possess at any one time under this license |
| A. Hydrogen-3 | A. Any, except sealed sources | A. 100 millicuries |
| B. Chromium-51 | B. Any, except sealed sources | B. 60 millicuries |
| C. Phosphorus-32 | C. Any, except sealed sources | C. 25 millicuries |
| D. Sulfur-35 | D. Any, except sealed sources | D. 10 millicuries |
| E. Carbon-14 | E. Any, except sealed sources | E. 19 millicuries |
| F. Calcium-45 | F. Any, except sealed sources | F. 5 millicuries |
| G. Iodine-125 | G. Any, except sealed sources | G. 100 millicuries |
| H. Iodine-131 | H. Any, except sealed sources | H. 25 millicuries |
| I. Iodine-131 | I. Radiolabeled antibody drug product | I. 325 millicuries |
| J. Barium-133 | J. Sealed sources (Isotope Products Laboratories RV-133) | J. 1 millicurie |
| K. Cesium-137 | K. Sealed sources (Isotope Products Laboratories RV-137) | K. 1 millicurie |
| L. Cesium-137 | L. Sealed source (NES 356) | L. 218 microcuries |
| M. Cobalt-60 | M. Sealed source (NES 354) | M. 53 microcuries |
| N. Barium-133 | N. Sealed source (NES 358) | N. 285 microcuries |

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**License Number
25-19852-01Docket or Reference Number
030-19324

Amendment No. 22

9. Authorized Use:

- A. through I. For use in laboratory research in immunological and biochemical studies, excluding animal studies.
- J. through N. For use in instrument calibration.

CONDITIONS

10. Licensed material shall be used only at the licensee's facilities located at 553 Old Corvallis Road, Hamilton, Montana
11. A. Licensed material described in Items 7.A. through 7.N. shall be used by or under the supervision of Jory Baldrich, Ph.D., Kent Myers, Ph.D., or David Moore.
- B. The Radiation Safety Officer for this license is Brian Poletti.
12. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee.
13. A. Sealed sources shall be tested for leakage and/or contamination at intervals not to exceed the intervals specified by the certificate of registration issued by the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or under equivalent regulations of an Agreement State.
- B. In the absence of a certificate from a transferor indicating that a leak test has been made within the intervals specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or under equivalent regulations of an Agreement State, prior to the transfer, a sealed source received from another person shall not be put into use until tested and the test results received.
- C. Sealed sources need not be tested if they contain only hydrogen-3; or they contain only a radioactive gas; or the half-life of the isotope is 30 days or less; or they contain not more than 100 microcuries of beta and/or gamma emitting material or not more than 10 microcuries of alpha emitting material.
- D. Sealed sources need not be tested if they are in storage and are not being used; however, when they are removed from storage for use or transferred to another person and have not been tested within the required leak test interval, they shall be tested before use or transfer. No sealed source shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.
- E. The leak test shall be capable of detecting the presence of 0.005 microcurie (185 becquerels) of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie (185 becquerels) or more of removable contamination, a report shall be filed with the U.S. Nuclear Regulatory Commission in accordance with 10 CFR 30.50(c)(2), and the source shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. The report shall be filed within 5 days of the date the leak test result is known with the U.S. Nuclear Regulatory Commission, Region IV, 612 E. Lamar Blvd., Suite 400, Arlington, Texas 76011, ATTN: Director, Division of Nuclear Materials Safety. The report shall specify the source involved, the test results, and corrective action taken.

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- F. Tests for leakage and/or contamination, limited to leak test sample collection, shall be performed by the licensee or by other persons specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services. The licensee is not authorized to perform the analysis; analysis of leak test samples must be performed by persons specifically licensed by NRC or an Agreement State to perform such services.
14. Licensed material shall not be used in or on human beings.
15. The licensee shall conduct a physical inventory every 6 months, or at other intervals approved by the U.S. Nuclear Regulatory Commission, to account for all sources and/or devices received and possessed under the license. Records of inventories shall be maintained for 5 years from the date of each inventory, and shall include the radionuclides, quantities, manufacturer's name and model numbers, and the date of the inventory.
16. The licensee is authorized to hold byproduct material with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal without regard to its radioactivity if the licensee:
- A. Monitors byproduct material at the surface before disposal and determines that its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey meter set on its most sensitive scale and with no interposed shielding; and
 - B. Removes or obliterates all radiation labels, except for radiation labels on materials that are within containers and that will be managed as biomedical waste after they have been released from the licensee; and
 - C. Maintains records of the disposal of licensed materials for 3 years. The record must include the date of the disposal, the survey instrument used, the background radiation level, the radiation level measured at the surface of each waste container, and the name of the individual who performed the disposal.
17. The licensee shall not use licensed material in field applications where activity is released except as provided otherwise by specific condition of this license.
18. The licensee is authorized to transport licensed material only in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

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19. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

- A. Application dated February 28, 2005 (ML050810183)
- B. E-mail dated July 5, 2006 (ML061940119)
- C. Letter dated February 28, 2007 (ML070710048)
- D. Letter dated June 8, 2006 (ML062920087)



FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date: July 16, 2008

By: _____

Rachel S. Browder, Health Physicist
Nuclear Materials Safety Branch B
Region IV
Arlington, Texas 76011-4125