

NUCLEAR REGULATORY COMMISSION

DOCKET NO. 030-04336

**NOTICE OF ENVIRONMENTAL ASSESSMENT RELATED TO THE ISSUANCE OF A
LICENSE AMENDMENT TO TERMINATE BYPRODUCT MATERIAL LICENSE**

NO. 13-02249-01, FOR BAYER HEALTHCARE, LLC.,

ELKHART, INDIANA

AGENCY: Nuclear Regulatory Commission

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

FOR FURTHER INFORMATION CONTACT: George M. McCann, Senior Health Physicist, Decommissioning Branch, Division of Nuclear Materials Safety, Region III, U.S. Nuclear Regulatory Commission, 2443 Warrenville Road, Lisle, Illinois 60532; telephone: (630) 829-9856; fax number: (630) 515-1259; or by email at Mike.McCann@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Introduction

The U.S. Nuclear Regulatory Commission (NRC) is considering the issuance of an amendment to terminate NRC Byproduct Materials License No. 13-02249-01, which is held by Bayer Healthcare, LLC (licensee). The issuance of the amendment would authorize the unrestricted release of the licensee's facilities located at 1884 Miles Avenue, Elkhart, Indiana, and 1000 Randolph Street, Elkhart, Indiana (the facilities). The addresses specified in the licensee's license, 1884 Miles Avenue, Elkhart, Indiana and 1000 Randolph Street, Elkhart, Indiana all refer to the same licensed site.

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. 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 Bayer Healthcare's request to terminate its license and release the licensee's former facilities for unrestricted use in accordance with 10 CFR Part 20, Subpart E. The licensee requested termination of the Bayer Healthcare, LLC. license in a letter dated October 23, 2006 (ADAMS Accession Number ML062970437), and the NRC's "Certificate of Disposition of Materials," dated October 31, 2007 (ML073050274), with a "Historical Site Assessment for the Elkhart, Indiana Facility" (ML081400331), and a "Final Status Survey Report for Selected Laboratories in Building 18," Report No. 2007006/G-4349, October 29, 2007 (ML081400331) attached. The Bayer Healthcare License No. 13-02249-01 was originally issued March 21, 1957, to Miles Laboratory, Inc. (later known as Miles-Ames Research Laboratory) pursuant to 10 CFR Part 30, and has been amended periodically since that time. This license authorized the Licensee to use unsealed byproduct materials for conducting research and development activities involving animals, production of reagent test kits, and on laboratory bench tops and in hoods.

Since that time, research facilities were built on the Miles-Ames campus, consisting of approximately seven acres and as many as 41 buildings. The campus was operated by Miles, Inc. until 1978 when the property was purchased by Bayer Corporation. The company name, Bayer HealthCare, LLC, was changed in 1995. The licensee's research campus is bounded by Bristol Street (State Route 19) to the north, North Michigan Street to the east, Mishawaka Street to the south, and Oak Street to the west. Building 9, the C.S. Beardsley Building, was the principal building in which radioactive materials were used. This

C.S. Beardsley Building was demolished in 1999, and research involving radioactive materials was moved to Building 18. The licensee's license was amended by the NRC on November 18, 1999 (Amendment No. 47), authorizing the release of the C.S. Beardsley Building.

Radioactive materials were used in Building 18 until 2006. The licensee had also used materials in other buildings and at remote locations approved by the NRC, which were subsequently removed from the license by previous amendments. A complete list of these locations of use, both at the Elkhart, Indiana research campus and at remote sites are discussed in the licensee's "Historical Site Assessment for the Elkhart, Indiana Facility."

Building 18 is located on the Elkhart, Indiana research campus, and is a multi-story brick building that was constructed to house various chemical research and development activities. Radioactive materials were used in Building 18 from 1975 to 2006. The Building 18 laboratories were equipped with cabinets, ventilation hoods, and sinks. The concrete floors in each of the laboratories were covered with an industrial-grade tile to restrict the absorption of liquids. The building is currently maintained by Bayer.

A wide range of research was conducted in Building 18, wherein both short- and long-lived radioisotopes were used. Several areas in Building 18 used hydrogen-3 and carbon-14 during the late 1970s and into the early 1990s. These isotopes were used in quantities ranging from microcuries to millcuries in different chemical forms. From 1995 until the present day, the use of radioactivity was limited primarily to microcurie quantities of iodine-125.

Miles Laboratories and Bayer did not dispose of radioactive waste via on-site burial. All waste containing long-lived radioisotopes was shipped offsite to a licensed landfill approved to receive and dispose of radioactive materials. There were no related environmental concerns identified during the record search or interviews of the radiation safety staff. There were no recorded spills or loss of control that required additional investigation.

The licensee ceased licensed activities and completed decontamination of the licensee's facilities in 2006. The licensee also completed "in-house surveys," which were submitted to the NRC on October 23, 2006 (ML0629704371). The licensee completed a "Historical Site Assessment for the Elkhart, Indiana Facility, Bayer Healthcare, LLC," and a "Final Status Survey Report for Selected Laboratories in Building 18," which was completed between August 13 and 15, 2007. Based on the licensee's survey results, it was determined that only routine decontamination activities, in accordance with the licensee's NRC-approved operating radiation safety procedures, were required. The licensee was not required to submit a decommissioning plan to the NRC because worker cleanup activities and procedures are consistent with those approved for routine operations. The licensee conducted surveys of the facilities 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 at its facilities and it seeks the unrestricted use of its facilities.

Environmental Impacts of the Proposed Action

The historical review of licensed activities conducted at the facility shows that such activities involved use of the following radionuclides with half-lives greater than 120 days: hydrogen-3 and carbon-14. Prior to performing the final status survey, the licensee conducted radiation surveys and decontamination activities, as necessary, in the areas of the facility affected by these radionuclides.

The licensee conducted a final status survey between August 13 and 15, 2007, in Building 18. Based on previous surveys by the licensee and the historical site assessment, surveys were only required in two rooms of Building 18, the previous Room C.05 (the former

“Rad Lab”) and the former Waste Storage Room. The licensee’s surveys included the liquid drain and ventilation exhaust systems.

The licensee elected to demonstrate compliance with the radiological criteria for unrestricted release as specified in 10 CFR 20.1402 by using the screening approach described in NUREG-1757, “Consolidated NMSS Decommissioning Guidance,” Volume 2. The licensee used the radionuclide-specific derived concentration guideline levels (DCGLs), developed there by the NRC, which comply with the dose criterion in 10 CFR 20.1402. These DCGLs define the maximum amount of residual radioactivity on building surfaces, equipment, materials, and in soils, that will satisfy the NRC requirements in Subpart E of 10 CFR Part 20 for unrestricted release. The licensee's final status survey results were below these DCGLs and are in compliance with the As Low As Reasonably Achievable requirement of 10 CFR 20.1402. The NRC thus finds that the licensee’s final status survey results are 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). The staff finds there were no significant environmental impacts from the use of radioactive material at the facility. The NRC staff reviewed the docket file records and the final status survey report to identify any non-radiological hazards that may have impacted the environment surrounding the facility. No such hazards or impacts to the environment were identified. The NRC has identified no other radiological or non-radiological activities in the area that could result in cumulative environmental impacts.

The NRC staff finds that the proposed release of the facility for unrestricted use is in compliance with 10 CFR 20.1402. Based on its review, the staff considered the impact of the

residual radioactivity at 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 leave things as they are by simply denying 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. The NRC's analysis of the licensee's final status survey data confirmed that the facility meets the requirements of 10 CFR 20.1402 for unrestricted release. Additionally, denying the amendment request would result in no change in current environmental impacts. The environmental impacts of the proposed action and the no-action alternative are, therefore, 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

The NRC provided a draft of this Environmental Assessment to the Emergency Response Program, Entomology and Epidemiology Labs, Radiation Control, Indiana State Department of Health, for review on May 18, 2008. On May 19, 2008, the Program Director of the Emergency Response Program, responded by email indicating, "We concur with the NRC decision that a Finding of No Significant Impact (FONSI) is appropriate with respect to the

proposed action, meaning that the licensee's facilities can be utilized for unrestricted use and NRC Byproduct Materials License No. 13-02249-01 will subsequently be terminated.”

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 further 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 further 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:

1. Shannon L. Gleason, Ph.D., Bayer HealthCare, letter to U.S. Nuclear Regulatory Commission, Region III, dated October 23, 2006 (ML062970437);
2. Certificate of Disposition of Materials, dated November 31, 2007, signed by Shannon L. Gleason, Ph.D. (ML073050274);

3. Bayer HealthCare, LLC, Report No. 2007006/G4349, "Final Status Report for Selected Laboratories in Building 18" (ML081400331);
4. Bayer HealthCare, LLC, Report No. 2007006/G-4351, "Historical Site Assessment for the Elkhart, Indiana Facility" (ML081400331);
5. Title 10 Code of Federal Regulations, Part 20, Subpart E, "Radiological Criteria for License Termination;"
6. Title 10 Code of Federal Regulations, Part 51, "Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions;"
7. NUREG-1496, "Generic Environmental Impact Statement in Support of Rulemaking on Radiological Criteria for License Termination of NRC-Licensed Nuclear Facilities;"
8. NUREG-1757 Consolidated NMSS Decommissioning Guidance.

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 Lisle, Illinois, this day of June 2008

For the Nuclear Regulatory Commission,

Christine A. Lipa, Chief
Decommissioning Branch
Division of Nuclear Materials Safety
Region III

- *3. Bayer HealthCare, LLC, Report No. 2007006/G4349, "Final Status Report for Selected Laboratories in Building 18" (ML081400331);
4. Bayer HealthCare, LLC, Report No. 2007006/G-4351, "Historical Site Assessment for the Elkhart, Indiana Facility" (ML081400331);
5. Title 10 Code of Federal Regulations, Part 20, Subpart E, "Radiological Criteria for License Termination;"
6. Title 10 Code of Federal Regulations, Part 51, "Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions;"
7. NUREG-1496, "Generic Environmental Impact Statement in Support of Rulemaking on Radiological Criteria for License Termination of NRC-Licensed Nuclear Facilities;"
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Dated at Lisle, Illinois, this 5th day of June 2008

For the Nuclear Regulatory Commission,

/RA/

Christine A. Lipa, Chief
 Decommissioning Branch
 Division of Nuclear Materials Safety
 Region III

DOCUMENT NAME: G:\SEC\Work in progress\May 19 2008 EA for Bayer Healthcare.doc

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