

For further details with respect to this license amendment application, see the application for amendment dated February 19, 2008, which is available for public inspection at the Commission's PDR, located at One White Flint North, File Public Area O1 F21, 11555 Rockville Pike (first floor), Rockville, Maryland. Publicly available records will be accessible electronically from the Agencywide Documents Access and Management System's (ADAMS) Public Electronic Reading Room on the Internet at the NRC Web site, <http://www.nrc.gov/reading-rm/adams.html>. Persons who do not have access to ADAMS or who encounter problems in accessing the documents located in ADAMS, should contact the NRC PDR Reference staff by telephone at 1-800-397-4209, 301-415-4737, or by e-mail to [PDR.Resource@nrc.gov](mailto:PDR.Resource@nrc.gov).

Dated at Rockville, Maryland, this 9th day of June, 2008.

For the Nuclear Regulatory Commission.

**Justin C. Poole,**

*Project Manager, Plant Licensing Branch III-1, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.*

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## 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, IN

**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 e-mail at [Mike.McCann@nrc.gov](mailto: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 e-mail 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 e-mail to *pdr@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 5th day of June 2008.

For the Nuclear Regulatory Commission.

**Christine A. Lipa,**

*Chief, Decommissioning Branch, Division of Nuclear Materials Safety, Region III.*

[FR Doc. E8-13327 Filed 6-12-08; 8:45 am]

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## NUCLEAR REGULATORY COMMISSION

[Docket No. 50-293]

### Entergy Nuclear Operations, Inc.; Pilgrim Nuclear Power Station Exemption

#### 1.0 Background

Entergy Nuclear Operations, Inc. (Entergy or the licensee) is the holder of Facility Operating License No. DPR-35, which authorizes operation of the Pilgrim Nuclear Power Station (Pilgrim). The license provides, among other things, that the facility is subject to all rules, regulations, and orders of the Nuclear Regulatory Commission (NRC or the Commission) now or hereafter in effect.

The facility consists of a boiling-water reactor located in Plymouth County, Massachusetts.

#### 2.0 Request/Action

Title 10 of the Code of Federal Regulations (10 CFR), Part 50, § 50.75(f)(3), requires that "Each power reactor licensee shall at or about 5 years prior to the projected end of operations submit a preliminary decommissioning cost estimate which includes an up-to-date assessment of the major factors that could affect the cost to decommission." Section 50.75(f)(5) requires a licensee at the same time to include, if necessary, plans to adjust funding levels to demonstrate a reasonable level of financial assurance, that funds will be available when needed for decommissioning. The current operating licensee expires on June 8, 2012.

In summary, by letter dated February 28, 2008, Agencywide Documents Access and Management System (ADAMS) accession number ML081000176, Entergy requested an exemption to the schedule requirement of 10 CFR 50.75(f)(3) to allow Entergy to submit the Pilgrim site-specific preliminary cost estimate by August 1, 2008, which is less than 4 years from the date of the expiration of the operating license. The exemption request applies to the timing of the submission of the preliminary cost estimate and did not request an exemption from any of the information requirements of the regulation.

#### 3.0 Discussion

Pursuant to 10 CFR 50.12, the Commission may, upon application by any interested person or upon its own initiative, grant exemptions from the requirements of 10 CFR Part 50 when (1) the exemptions are authorized by law, will not present an undue risk to public

health or safety, and are consistent with the common defense and security; and (2) when special circumstances are present. One of these special circumstances, described in 10 CFR 50.12(a)(2)(ii), is that the application of the regulation is not necessary to achieve the underlying purpose of the rule.

As documented in the Decommissioning Considerations for 1991 Rules and Regulations, the underlying purpose of 10 CFR 50.75(f)(3) is to provide a preliminary decommissioning plan, a cost estimate for implementing the plan, and any changes in funding necessary to ensure that there will be sufficient funds for decommissioning.

The NRC staff reviewed the licensee's evaluation in support of the subject exemption request. Entergy submitted the decommissioning funding status report for Pilgrim on March 26, 2008. The NRC staff calculated Pilgrim's required minimum funding assurance based on the formula under 10 CFR 50.75. The trust fund balances to the midpoint of decommissioning (December 2015), as effectively allowed under NRC regulations, was also calculated by applying a 2 percent real rate of return. Based on the formula amount, the Pilgrim decommissioning trust fund has an excess of \$125 million as of December 31, 2007, and will have an excess of more than \$200 million by the time of expiration of the license.

Entergy submitted a license renewal application (LRA) for Pilgrim on January 25, 2006, which was approximately 6.5 years prior to the expiration date of the operating license for Pilgrim Station. In connection with the LRA, the final supplemental environmental impact statement was issued on July 27, 2007, and the safety evaluation report for the LRA was issued on June 28, 2007. Subsequently, the safety evaluation report was issued as NUREG-1891 on November 30, 2007. Although the licensee stated that the review of the LRA and milestones achieved constitute "a clear indication" that the LRA will be granted, the NRC does not agree.

Entergy's exemption request essentially relies on the fact that its LRA is pending before the NRC, certain milestones have been met, and that Entergy anticipates the NRC will render a final decision on the LRA on or about August 1, 2008. Entergy cites selected language from the statement of considerations for the proposed rule for license renewal, as well as language from the statement of considerations for the final license renewal rule, to support its exemption request. Entergy argues that the level of review, thus far, on the