

**NUCLEAR REGULATORY COMMISSION**

**DOCKET NO. 030-36603**

**NOTICE OF AVAILABILITY OF ENVIRONMENTAL ASSESSMENT AND FINDING OF NO  
SIGNIFICANT IMPACT FOR LICENSE AMENDMENT TO BYPRODUCT MATERIALS  
LICENSE NO. 37-30924-01, FOR THE UNRESTRICTED RELEASE OF THE TETRALOGIC  
PHARMACEUTICAL FACILITY IN MALVERN, PENNSYLVANIA**

**AGENCY:** Nuclear Regulatory Commission.

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

**FOR FURTHER INFORMATION CONTACT:** Farrah Gaskins, Health Physicist, Commercial and R&D Branch, Division of Nuclear Materials Safety, Region I, 475 Allendale Road, King of Prussia, Pennsylvania 19406; telephone (610) 337-5143; fax number (610) 337-5269; or by email: fcg@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. 37-30924-01. This license is held by TetraLogic Pharmaceuticals (the Licensee), for its facility located at 365 Phoenixville Pike in Malvern, Pennsylvania (the Facility). Issuance of the amendment would authorize release of the Facility for unrestricted use. The Licensee requested this action in a letter dated March 27, 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 March 27, 2007, license amendment request, resulting in release of the Facility for unrestricted use. License No. 37-30924-01 was issued on September 8, 2004, pursuant to 10 CFR Part 30, and has been amended periodically since that time. This license authorized the Licensee to use byproduct material in any form for purposes of conducting research and development activities as defined in 10 CFR 30.4.

The Facility contains 4,000 square feet of office space and laboratories. Within the Facility, use of licensed materials was confined to the Biology lab and adjacent lab corridor.

In July 2004, the Licensee ceased licensed activities, initiated a survey and began decontamination of the Facility. Based on the Licensee's historical knowledge of the site and the conditions of the Facility, the Licensee determined that only routine decontamination activities, in accordance with their 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 Facility 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 the Facility, and seeks the unrestricted use of its Facility.

**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. Prior to performing the final status survey, the Licensee conducted decontamination activities, as necessary, in the areas of the Facility affected by these radionuclides.

The Licensee conducted a final status survey on January 31, 2007. This survey covered the Biology lab, the adjacent lab corridor, and adjacent areas. The final status survey report was attached to the Licensee's amendment request dated March 27, 2007. 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, and 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 (ALARA) 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**

NRC provided a draft of this Environmental Assessment to the Commonwealth of Pennsylvania's Department of Environmental Protection, Bureau of Radiation Protection for review on September 10, 2007. On December 27, 2007, the Commonwealth of Pennsylvania responded by email. The Commonwealth agreed with the conclusions of the EA and otherwise had no comments.

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. NUREG-1757, "Consolidated NMSS Decommissioning Guidance;"
2. Title 10 Code of Federal Regulations, Part 20, Subpart E, "Radiological Criteria for License Termination;"
3. Title 10, Code of Federal Regulations, Part 51, "Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions;"
4. NUREG-1496, "Generic Environmental Impact Statement in Support of Rulemaking on Radiological Criteria for License Termination of NRC-Licensed Nuclear Facilities;"
5. Letter dated March 27, 2007; Final Site Survey and NRC Form 314 (ML071550135).

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 [pdr@nrc.gov](mailto: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 King of Prussia, Pennsylvania this 12<sup>th</sup> day of February, 2008.

FOR THE NUCLEAR REGULATORY COMMISSION

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