

FOR FURTHER INFORMATION CONTACT:
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Secretary of the Board.

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NUCLEAR REGULATORY COMMISSION

[Docket No. 030-36585]

Issuance of Environmental Assessment and Finding of No Significant Impact to Byproduct Materials License 53-27775-01 for Covance Clinical Research Unit, Inc., Honolulu, HI

AGENCY: Nuclear Regulatory Commission.

ACTION: Issuance of environmental assessment and finding of no significant impact for license amendment.

FOR FURTHER INFORMATION CONTACT:
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SUPPLEMENTARY INFORMATION:

I. Introduction

The U.S. Nuclear Regulatory Commission (NRC) is considering the issuance of an amendment to NRC Byproduct Materials License No. 53-27775-01, which was originally issued on July 13, 2004, pursuant to 10 CFR part 30. This license is held by Covance Clinical Research Unit, Inc., (Licensee), and authorizes the possession and use of carbon-14 in pre-packaged capsules at the Licensee's laboratory located at 401 Kamakee Street, in Honolulu, Hawaii (the facility), a commercial area of Honolulu. The facility in which all licensed radioactive materials were kept and used is a room approximately 7' x 12.5' with a ceiling height of 8.5', and contains a sink and ventilation hood.

By letter dated October 10, 2006, the Licensee stated that use of carbon-14 had been discontinued at their facility, and accordingly requested that the facility be released for unrestricted use, and that the NRC license be terminated.

The NRC has prepared an Environmental Assessment (EA) in support of the 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 is to approve the Licensee's October 10, 2006, license amendment request to release the facility for unrestricted use and terminate the license. Licensed activities at the facility were limited to conducting research trials, in which a pre-packaged, pharmaceutical capsule with approximately 100 microcuries (μCi) of tagged carbon-14 was given to each trial subject. The licensee conducted three separate research trials under the license, with the final trial being conducted in February 2006. Each trial consisted of approximately eight to nine subjects. Upon completion of each trial, the facility (where the subjects remained during each trial) was surveyed and documented to contain less than background levels of radiation.

The subjects remained at the facility until approximately 80-90% of the excretion was collected. The uptake, excretion and distribution of the pharmaceutical in the respective subjects were observed and measured. The samples were collected by the licensee and analyzed by a liquid scintillation counter, and subsequently disposed of in the sanitary sewerage. The total activity of carbon-14 ordered by the licensee was 5,089 μCi , of which 2,494 μCi was used during the Phase one trials. The remainder of the radioactive material was either returned to the sponsor or transferred to a licensed recipient.

Based on the use of the radioactive materials in accordance with 10 CFR 30.36(g), the Licensee was not required to submit a decommissioning plan to the NRC since any decommissioning activities and procedures implemented were consistent with those approved for routine operations.

The Need for the Proposed Action: The Licensee has ceased licensed activities at the facility and seeks to release the facility for unrestricted use and subsequent license termination. *Environmental Impacts of the Proposed Action:* The historical review of licensed activities conducted at the facility documents that the activities involved the use of only carbon-14 as a tagged pharmaceutical in a pre-packaged capsule. The quantity amount in each capsule was approximately 100 μCi and

the last use of licensed material was conducted in February 2006. During the research trials, the Licensee disposed of the excretion samples into the sanitary sewerage in accordance with the regulatory requirements in 10 CFR 20.2003.

The licensee has requested termination of the license because all work with radioactive materials at the facility have been discontinued. The proposed release of the licensee's facility for unrestricted use does not effect any environmental resource, since there are no remediation requirements for the facility or potential release of radioactive materials to the environment.

The Licensee conducted a final status survey of the facility during August 2006. The final status survey report was submitted on October 10, 2006, as part of the license amendment request. The submitted results were not statistically significant from background and therefore, the net results did not contain any activity above background. The NRC allows licensees to demonstrate compliance with the radiological criteria for unrestricted use as specified in 10 CFR 20.1402 by using the screening approach described in NUREG-1757, "Consolidated NMSS Decommissioning Guidance," Volume 2. The Licensee's results did not contain any activity above background and therefore were below any NRC criteria and were 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 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 licensee's 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 and the termination of the NRC license are in compliance with 10 CFR 20.1402. Based on its review, the staff considered the impact of any residual radioactivity in the laboratory 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 deny 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 release of the facility meets the requirements of 10 CFR 20.1402 for unrestricted use. 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 use 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 Contacted: NRC provided a draft of this EA to the State of Hawaii for review on January 22, 2006. The State of Hawaii did not provide any comments to the draft EA.

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 amendment and supporting documentation, are available electronically at the NRC's Electronic Reading Room at <http://www.nrc.gov/reading-rm.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. NRC, "Generic Environmental Impact Statement in Support of Rulemaking on Radiological Criteria for License Termination of NRC-Licensed Nuclear Facilities," NUREG-1496, July 1997 (ML042310492, ML042320379, and ML042330385).

2. NRC, "Consolidated NMSS Decommissioning Guidance," NUREG-1757, Volume 1, Revision 1, September 2003 (ML053260027).

3. Title 10 Code of Federal Regulations, Part 20, Subpart E, "Radiological Criteria for License Termination."

4. Title 10, Code of Federal Regulations, Part 51, "Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions."

5. Jacobs, Mark, Covance Clinical Research Unit, Inc., Decommissioning Report, October 10, 2006 (ML062900229).

6. Browder, Rachel S., Acknowledgment of Receipt of Final Status Survey, October 31, 2006 (ML063040400).

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 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 Arlington, Texas, this 2nd day of March 2007.

For the Nuclear Regulatory Commission.

D. Blair Spitzberg,

Chief, Fuel Cycle Decommissioning Branch,
Division of Nuclear Materials Safety, Region IV.

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OFFICE OF MANAGEMENT AND BUDGET

Draft 2007 Report to Congress on the Costs and Benefits of Federal Regulations

AGENCY: Office of Management and Budget, Executive Office of the President.

ACTION: Notice of availability and request for comments.

SUMMARY: The Office of Management and Budget (OMB) requests comments on its 2007 Draft Report to Congress on the Costs and Benefits of Federal Regulations. The full Draft Report is available at http://www.whitehouse.gov/omb/inforeg/regpol-reports_congress.html, and is divided into four chapters. Chapter I examines the costs and benefits of major Federal regulations issued in fiscal year 2006 and summarizes the costs and benefits of major regulations issued between September 1996 and 2006. It also discusses regulatory impacts on State, local, and tribal governments, small business, wages, and economic growth. Chapter II examines trends in regulation since OMB began to compile benefit and cost estimates records in 1981. Chapter III provides an update on implementation of the Information Quality Act, and Chapter IV summarizes agency compliance with the Unfunded Mandates Reform Act.

DATES: To ensure consideration of comments as OMB prepares this Draft Report for submission to Congress, comments must be in writing and received by June 11, 2007.

ADDRESSES: We are still experiencing delays in the regular mail, including first class and express mail. To ensure that your comments are received, we recommend that comments on this draft report be electronically mailed to OIRA_BC_RPT@omb.eop.gov, or faxed to (202) 395-7245. You may also submit comments to Mabel Echols, Office of Information and Regulatory Affairs, Office of Management and Budget, NEOB, Room 10201, 725 17th Street, NW., Washington, DC 20503. All comments submitted in response to this notice will be made available to the public, including by posting them on OMB's Web site. For this reason, please