ENVIRONMENTAL ASSESSMENT
RELATED TO THE ISSUANCE OF LICENSE AMENDMENT FOR THE COVANCE CLINICAL RESEARCH UNIT, INC., HONOLULU, HAWAII IN SUPPORT OF LICENSE TERMINATION

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DOCKET NUMBER 030-36585
BYPRODUCT MATERIALS LICENSE NUMBER 53-27775-01

PREPARED BY

U.S. NUCLEAR REGULATORY COMMISSION
REGION IV
NUCLEAR MATERIALS LICENSING BRANCH

NUCLEAR REGULATORY COMMISSION
[Docket No. 030-36585]

ISSUANCE OF ENVIRONMENTAL ASSESSMENT AND FINDING OF NO SIGNIFICANT IMPACT FOR AMENDMENT TO BYPRODUCT MATERIALS LICENSE 53-27775-01 FOR COVANCE CLINICAL RESEARCH UNIT, INC., HONOLULU, HAWAII

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. This license is held by Covance Clinical Research Unit, Inc., (Licensee) located at 401 Kamakee Street, Honolulu, Hawaii, a commercial area of Honolulu. By letter dated October 10, 2006, the Licensee stated they had discontinued the use of radioactive materials at their facility and decommissioned the laboratory called the *Hood Room* and requested the release of their facility for unrestricted use. The issuance of the license amendment would authorize release of the Licensee's facility for unrestricted use with termination of the license. The NRC prepared this 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 the 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. NRC Byproduct Materials License No. 53-27775-01 was issued on July 13, 2004, pursuant to 10 CFR Part 30. The license was amended on August 29, 2006, to authorize a change of control from Radiant Research, to Covance Clinical Research Unit, Inc., as a result of a total acquisition of the clinical site. There were no changes in authorization on the license and Covance Clinical Research Unit, Inc., continued to be authorized for any uptake, dilution and excretion studies permitted by 10 CFR 35.100; any imaging or localization studies permitted by 10 CFR 35.200; and Phase one *in-vivo* research studies in humans to explore the pharmokinetics of uptake, excretion and distribution of pharmaceuticals in the body. Phase one is considered early phase clinical testing of potential drugs which provides a preliminary evaluation of drug safety, tolerance and pharmacokinetics in accordance with applicable U.S. Food and Drug Administration requirements.

Phase one research trials conducted by the Licensee consisted of providing a pre-packaged, pharmaceutical capsule with approximately 100 microcuries (μCi) of tagged carbon-14, as authorized by the NRC byproduct materials license, to each trial subject. The Licensee conducted three separate Phase one research trials under the license, with the final trial being conducted in February 2006. Each trial consisted of approximately eight to nine subjects. The facility areas where the subjects remained during each trial were surveyed and documented to be less than background, upon completion of each trial.

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.

The laboratory where the radioactive materials were confined to and used was approximately 7' x 12.5' with a ceiling height of 8.5'. The laboratory contained standard laboratory counters against three walls, with a sink and ventilation hood located within the laboratory. Since, the pharmaceutical was tagged with the carbon-14 in a pre-packaged capsule, there was no compounding or mixing of loose radioactive material at the facility.

The Licensee conducted applicable surveys of the laboratory during August 2006. 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 Licensee submitted a final status survey report to the NRC to demonstrate that the laboratory met the criteria in Subpart E of 10 CFR Part 20 for unrestricted use.

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. Additionally, the owner of the facility is intending to lease the facility to another company, such as a graphics design company or physical therapy office.

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 Licensee's facility is located in a commercial area of Honolulu and the owner of the facility is intending to lease the area to a graphics design company or physical therapy facility. The building will be re-designed and a build-out performed within the internal structure of the facility. Therefore, there will not be any destruction or demolition of the external structure of the facility. 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 laboratory during August 2006. The final status survey report was submitted on October 10, 2006, in support 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

licensee's 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 performed a confirmatory survey of the Licensee's laboratory on February 2, 2007. The survey consisted of loose surface contamination analyses for low energy beta. The collected samples were sent to Oak Ridge Institute for Science and Education (ORISE) for liquid scintillation analysis. ORISE is an independent laboratory under contract to the NRC. The contamination analysis for low energy beta was below the minimum detectable concentration (MDC) for carbon-14 analyses, which was 14 picocuries (pCi) per smear. Therefore, the results of the confirmatory survey did not reveal any radiation distinguishable from accepted background radiation levels and the NRC 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 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, 2007. 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/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. 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).

SUNSI Review Completed: RSB ADAMS: ■ Yes □ No Initials: RSB
■ Publicly Available □ Non-Publicly Available □ Sensitive ■ Non-Sensitive

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