



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

October 31, 2012

EA-12-177

Dr. William W. Wood
Research Products Manager and Director of Chemistry
Cambridge Isotopes Laboratories, Inc
50 Frontage Road
Andover, MA 01810

SUBJECT: NOTICE OF VIOLATION - FAILURE TO OBTAIN NUCLEAR REGULATORY
COMMISSION SPECIFIC EXPORT LICENSES FOR DEUTERIUM SHIPMENTS

Dear Dr. Wood:

This refers to a U.S. Nuclear Regulatory Commission (NRC) evaluation of Cambridge Isotope Laboratories, Inc (CIL) voluntary self disclosure dated March 12, 2012 and supplemental written information dated May 14, 2012. The disclosure identified that deuterium was exported in excess of authorized quantities under the General License for the Export of Deuterium in 10 CFR §110.24 to China and Japan in the years 2010 and 2011 and to India and Israel (both are restricted destinations per 10 CFR §110.29) in the years 2007 – 2011 without first obtaining an NRC specific export license, stated the apparent cause of the violations, and identified CIL's corrective actions to preclude recurrence.

In a telephone conversation on August 24, 2012, Mrs. Jill Shepherd-Vladimir, Office of International Programs, NRC, informed your attorney that the NRC was considering escalated enforcement for an apparent violation involving failure to obtain specific licenses for export of deuterated compounds and heavy water as required by 10 CFR 110.20. Mrs. Shepherd-Vladimir also informed you that we had sufficient information regarding the apparent violations and your corrective actions to make an enforcement decision without the need for a predecisional enforcement conference or a written response from you. Your attorney indicated that neither he nor CIL believed that a predecisional enforcement conference or written response was needed.

Based on the information developed during the evaluation of CIL's voluntary disclosure and subsequent discussions, the NRC has determined that multiple failures to follow NRC requirements occurred, based on similar misunderstandings of the regulations. These instances are cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding it are described in detail in your voluntary self disclosure letter. Specifically, CIL exported deuterium in excess of the 200 kilogram (kg)/year limit to China and Japan in the years 2010 and 2011 and in excess of the 5 kg/year limit to India and Israel in the years 2007-2011 without applying for and obtaining NRC specific export licenses, in violation of 10 CFR 110.20. CIL identified the cause of the violation as resulting from: (1) insufficient communication between International Sales Staff (ISS) and the Export Compliance Officer (ECO) with regard to the volume of deuterium being exported; (2) there was no automated procedure to allow the

ready calculation of deuterium equivalences; (3) there were no procedures to allow the tracking of cumulative volumes of deuterium containing substances throughout the year; (4) the ISS, although aware of the regulatory restrictions on exports of deuterium, was improperly interpreting the regulations as allowing the separate tracking of deuterium oxide as compared to other deuterium containing materials; and (5) the ISS improperly believed that exports made through CIL's European subsidiary, ET did not count as exports to a customer located in a different final destination country. CIL initiated corrective actions that addressed these and other process deficiencies upon identifying the potential violations described in the voluntary self disclosure.

The NRC has determined that the apparent violations have regulatory significance because they impacted the NRC's ability to perform its regulatory function. The instances resulted in exports to China, Japan, India and Israel without NRC approved specific licenses as required by 10 CFR 110.20(a), which ensures appropriate checks and verifications, as well as obtaining government-to-government assurances of peaceful use, are completed for quantities not approved for general license export, which ensures exports are not inimical to the common defense and security.

The exports at issue primarily were exported in a physical form conducive to the intended non-nuclear end-use in medical, pharmaceutical, chemical and industrial markets. The foreign customers are all authorized to use these deuterated compounds under their country's respective regulatory structures. All of the shipments arrived at their destinations intact and fully accounted for.

In accordance with the NRC Enforcement Policy, since CIL has not been the subject of escalated enforcement actions within the last two years, the NRC did not need to consider credit for *identification*. The NRC considered whether credit was warranted for *Corrective Action* in accordance with the civil penalty assessment process in Section 2.3.4 of the Enforcement Policy. CIL corrective actions included: (1) conducting a full internal investigation of deuterium containing exports; (2) ceasing all exports of such products, pending approval of a license application to support any exports in excess of the regulatory limits; (3) retaining legal counsel to provide counsel regarding the application of export control laws to your operations; (4) implementing new tracking procedures to provide real-time monitoring of exports as compared to the regulatory limits for deuterium; (5) preparing a voluntary self disclosure; (6) preparing new compliance procedures intended to prevent future inadvertent exports in excess of the regulatory limits; (7) developing plans to conduct training on U.S. export control requirements, including with regard to nuclear export controls; and (8) developing plans to implement real-time monitoring procedures to track all exports of deuterium to automatically provide reports regarding these exports on a regular basis to senior and compliance managers. Based on CIL's prompt and comprehensive corrective actions, the NRC determined that *Corrective Action* credit was warranted.

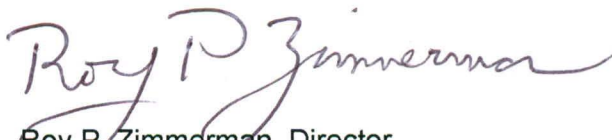
Therefore, to encourage prompt identification and comprehensive correction of violations, and in recognition of the absence of previous escalated enforcement action, the NRC has decided not to propose a civil penalty in this case. However, significant violations in the future could result in a civil penalty.

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to correct the violation and prevent recurrence, and the date when

full compliance was achieved is already adequately addressed on the docket in CIL's VSD dated March 12, 2012. Therefore, you are not required to respond to this letter unless the description herein does not accurately reflect corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosures, and your response, if you choose to respond, will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system Agencywide Documents Access and Management System, accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction. If personal privacy, proprietary information or safeguards information is necessary to provide an acceptable response, please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such information, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). The NRC also includes significant enforcement actions on its website at <http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions>.

Sincerely,



Roy P. Zimmerman, Director
Office of Enforcement

Enclosure:
Notice of Violation

NOTICE OF VIOLATION

Cambridge Isotopes Laboratories, Inc
Andover, MA 01810

EA-12-177

During the review of information you provided to the U.S. Nuclear Regulatory Commission (NRC) on March 12, 2012, a violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

10 CFR 110.20(a) states, in part, that "if an export or import is not covered by the NRC general licenses described in §§ 110.21 through 110.27, a person must file an application with the Commission for a specific license in accordance with §§ 110.31 through 110.32."

10 CFR 110.24(a) states, "A general license is issued to any person to export to any country not listed in §110.28 or §110.29 deuterium in individual shipments of 10 kilograms or less (50 kilograms of heavy water). No person may export more than 200 kilograms (1000 kilograms of heavy water) per calendar year to any one country."

10 CFR 110.24(b) states, "A general license is issued to any person to export to any country listed in §110.29 deuterium in individual shipments of 1 kilogram or less (5 kilograms of heavy water). No person may export more than 5 kilograms (25 kilograms of heavy water) per calendar year to any one country listed in §110.29."

Contrary to the above, in the years 2007-2011, Cambridge Isotope Laboratories, Inc (CIL) failed to file an application with the Commission for specific export licenses. Specifically, CIL exported deuterium, a material subject to NRC licensing jurisdiction per 10 CFR 110.9 in excess of the quantities covered by 10 CFR 110.24 general license:

1. CIL exported deuterium in excess of the 200 kilogram (kg)/year limit set by 10 CFR 110.24(a) to China and Japan in the years 2010 and 2011 without applying for and obtaining NRC specific licenses.
2. CIL exported deuterium in excess of the 5 kg/year limit set by 10 CFR 110.24(b) to restricted destinations per 10 CFR 110.29, India and Israel, in the years 2007-2011 without applying for and obtaining NRC specific licenses.

This is a Severity Level III violation.

The NRC has concluded that information regarding the reason for the violation, the corrective action taken to correct the violation and prevent recurrence, and the date when full compliance was achieved, is already adequately addressed on the docket in CIL's voluntary self disclosure dated March 12, 2012. However, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation (EA-12-177)" and send it to the U.S. Nuclear Regulatory

ENCLOSURE

Commission, ATTN: Document Control Desk, Washington, DC 20555-0001, with a copy to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

If you choose to respond, your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. Therefore, to the extent possible, the response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction.

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days.

Dated this 31st day of October 2012