

January 14, 2016

EA-15-219

Mr. Jon Appel
Torrey Pines Institute for Molecular Studies
3550 General Atomics Court
San Diego, CA 92121

SUBJECT: FAILURE TO PROPERLY NOTIFY U.S. NUCLEAR REGULATORY
COMMISSION IN ADVANCE OF EXPORT SHIPMENT AND NOTICE OF
VIOLATION

Dear Mr. Appel:

This letter refers to a review of a Torrey Pines Institute for Molecular Studies (Torrey Pines) Advanced Notification associated with the export of a Category 2 quantity of cesium-137 to Canada. Title 10 of the *Code of Federal Regulations* (10 CFR) Section 110.50(c) requires, in part, that a licensee authorized to export or import radioactive material listed in Appendix P to 10 CFR Part 110 is responsible for notifying the NRC and, in cases of exports, the government of the importing country in advance of each shipment. In accordance with 10 CFR 110.50(c)(4), export notifications must be received by the NRC at least 7 days in advance of each shipment, to the extent practicable, but in no case less than 24 hours in advance of each shipment. Additionally, in accordance with 10 CFR 110.50(c)(3)(i)(H), these notifications must include a copy of the foreign recipient's authorization or confirmation of that authorization from the government of the importing country as required by 10 CFR 110.32(g) unless the authorization has already been provided to the NRC.

Based on the information developed during our review of this activity, the NRC has determined that a Severity Level IV violation of NRC requirements occurred. Specifically, on June 16, 2015, Torrey Pines notified the NRC of its intent to export a Category 2 quantity of cesium-137 to Canada. That export was shipped on June 17, 2015. The export notification provided by Torrey Pines was incomplete in that: (1) it did not include a copy of the foreign recipient's authorization or confirmation of that authorization from the government of the importing country as required by 10 CFR 110.32(g), and (2) a copy or confirmation of the authorization had not already been provided to the NRC. The NRC staff contacted Torrey Pines regarding the omission, and on June 18, 2015, Torrey Pines submitted the missing documentation. The export notification provided by Torrey Pines was incomplete and therefore not submitted at least 24 hours in advance of each shipment and is identified as an example of a violation of 10 CFR 110.50(c).

The violation was evaluated in accordance with the NRC Enforcement Policy. The current Enforcement Policy is available on the NRC's Web site at <http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>. The violation is cited in the enclosed Notice of Violation (Notice) because all of the criteria in Section 2.3.2 of the NRC Enforcement Policy were not met in that Torrey Pines did not identify the violation.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. If you have additional information that you believe the NRC should consider, you may provide it in your response. The NRC will use your response, in part, to determine whether or not further enforcement action is necessary to ensure compliance with regulatory requirements.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosures and your response will be made available electronically for public inspection in the Public Document Room or from the NRC's document system Agencywide Documents Access and Management System accessible from the NRC Website at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, your response should not include any personal privacy or proprietary information so that it can be made available to the public without redaction. If personal privacy or proprietary 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).

Please contact Andrea R. Jones at (301) 415-2309 if you have any questions regarding this matter.

Sincerely,

/RA/

Nick D. Hilton, Chief
Enforcement Branch
Office of Enforcement

Enclosure: Notice of Violation

cc: State of California

J. Appel

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Sincerely,

/RA/

Nick D. Hilton, Chief
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Office of Enforcement

Enclosure: Notice of Violation

cc: State of California

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NOTICE OF VIOLATION

Torrey Pines Institute for Molecular Studies
San Diego, CA

EA-15-219

During a U.S. Nuclear Regulatory Commission (NRC) review completed on October 8, 2015, a violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

Section 110.50(c)(1) of Title 10 of the *Code of Federal Regulations* (10 CFR) requires, in part, that a licensee authorized to export or import the radioactive material listed in Appendix P to 10 CFR Part 110 is responsible for notifying the NRC and, in cases of exports, the government of the importing country in advance of each shipment.

Section 110.50(c)(4) of 10 CFR requires, in part, that export notifications must be received by the NRC at least 7 days in advance of each shipment, to the extent practicable, but in no case less than 24 hours in advance of each shipment.

Section 110.50(c)(3)(i)(H) of 10 CFR requires that this notification must include a copy of the foreign recipient's authorization or confirmation of that authorization from the government of the importing country as required by 10 CFR 110.32(g) unless the authorization has already been provided to the NRC.

Contrary to the above, on June 16, 2015 Torrey Pines Institute for Molecular Studies (Torrey Pines) failed to submit a complete notification to the NRC in advance of an export shipment as required by NRC regulations. Specifically on June 16, 2015, Torrey Pines notified the NRC of its intent to export a Category 2 quantity of cesium-137 to Canada. The export was shipped on June 17, 2015. The notification provided by Torrey Pines was an incomplete notification because it did not include a copy of the foreign recipient's authorization or confirmation of that authorization from the government of the importing country as required by 10 CFR 110.32(g), and a copy or confirmation of the authorization had not already been provided to the NRC.

This is a Severity Level IV violation (NRC Enforcement Policy, Section 6.15)

Pursuant to the provisions of Title 10 of the *Code of Federal Regulations* (10 CFR) 2.201, Torrey Pines is hereby required to submit a written statement or explanation to the Director, Office of International Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, within 30 days of the date of this Notice of Violation. This reply should be clearly marked as a "Reply to a Notice of Violation (EA-15-219)" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation or severity level; (2) the corrective steps that have been taken and the results achieved; (3) any additional corrective steps that will be taken; and (4) the date when full compliance will be or was achieved. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, the NRC may issue an Order or a Demand for Information requiring you to explain why your license should not be modified, suspended, or revoked or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

Enclosure

If you contest this enforcement action, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555-0001.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," 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 Website 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.

In accordance with 10 CFR 19.11, you may be required to post this Notice within 2 working days of receipt.

Dated this 14th day of January, 2016

J. Appel

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cc:

Gonzalo Perez, Branch Chief
Radiologic Health Branch
Div. of Food, Drug, & Radiation Safety
CA Dept. of Health Services
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1500 Capitol Ave., MS 7610
Sacramento, CA 95899-7414