



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

September 29, 2016

EA-16-097

Mr. Kevin Ho
Jenbo USA, LLC
Radiation Safety Officer
35117 King Ct
Fremont, CA 94536

SUBJECT: NOTICE OF VIOLATION – JENBO USA LLC, U.S. NUCLEAR REGULATORY
COMMISSION RECORDS INSPECTION

Dear Mr. Ho:

This letter refers to the records inspection conducted by U.S. Nuclear Regulatory Commission (NRC) staff from August 2014 to May 2016. The purpose of the inspection was to determine whether Jenbo USA, LLC (Jenbo) was in compliance with regulatory requirements related to Jenbo's importation and distribution of lamps containing radioactive material (Krypton-85) to persons exempt from licensing pursuant to Title 10 of the *Code of Federal Regulations* (10 CFR) 30.15.

In a telephone conversation on August 29, 2016, Mr. Hipolito Gonzalez of the NRC informed you, as Jenbo's Radiation Safety Officer, that the NRC was considering escalated enforcement for three apparent violations, and discussed with you the significance of the issue, and the need for lasting and effective corrective actions. The three apparent violations were described in NRC letter to you, dated August 29, 2016.

In the August 29, 2016 letter, we provided you with the opportunity to address the apparent violations identified in the letter by attending a predecisional enforcement conference, or by providing a written response before we made our final enforcement decision, or to request Alternative Dispute Resolution with the NRC in an attempt to resolve these issues. In a letter dated September 6, 2016, you provided a written response to the apparent violations.

Based on the information developed during the records inspection and the information that you provided in your response dated, September 6, 2016, the NRC has determined that three violations of NRC requirements occurred. The violations are cited in the enclosed Notice of Violation (Notice). Specifically, the violations involve: (1) failure to submit annual reports detailing all transfers of byproduct material, in accordance with 10 CFR 32.16, (2) failure to obtain a license amendment to change location authorized in the license No. 04-23986-01E under Condition No. 11, and (3) distribution of byproduct material from an unauthorized location. The failure to submit complete and timely required annual reports, the failure to obtain an

amendment to the license on the change of distribution location to NRC, and distribution from an unauthorized location are significant because they inhibit the process of regulatory oversight. Therefore, these violations have been categorized, in accordance with the NRC Enforcement Policy, at Severity Level III (SL III). Also, given the cause and effect relationship between the issues, the last two violations are categorized together as a single, SL III problem.

In accordance with the NRC Enforcement Policy, a base civil penalty in the amount of \$14,000 is considered for a SLIII violation, or SLIII problem.

Because your facility has not been the subject of escalated enforcement actions within the last two years or the last two inspections, 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. The NRC determined that credit was warranted for *Corrective Action*. Jenbo submitted annual reports for calendar years 2010 – 2015, provided documentation of a letter that Jenbo sent to NRC in October 2014 requesting a change in address, and in February 2016 submitted a request for termination of the license. On September 29, 2016, the NRC issued license termination for License Number: 04-23986-01E (Docket Number: 030-38397).

Therefore, to encourage prompt and comprehensive correction of violations, and in recognition of the absence of previous escalated enforcement action, I have decided not propose a civil penalty in this case. However, significant violations in the future could result in a civil penalty. In addition, issuance of these Severity Level III violations constitute escalated enforcement action that may subject you to increased inspection effort.

The NRC has concluded that information regarding: (1) the reason for the violation(s); (2) the corrective actions that have been taken and the results achieved; and (3) the date when full compliance will be achieved is already adequately addressed on the docket in letters from you dated February 1, 2016, and August 29, 2016. Therefore, you are not required to respond to this letter unless the description therein does not accurately reflect your 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.

If Jenbo applies in the future for a NRC license, the NRC may require Jenbo to address the underlying reasons for the violations and what measures Jenbo will have in place to ensure future compliance. In addition, pursuant to 10 CFR 15.29, the Commission may not consider an application for a license from an individual or entity unless all previous delinquent debts of the individual or entity to the NRC have been paid in full.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosure(s), and your response will be made available electronically for public inspection in the NRC Public Document Room and in the NRC's Agencywide Documents Access and Management System (ADAMS), 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 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

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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 Web site at (<http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions/>).

Sincerely,

/RA/

Patricia K. Holahan, Director
Office of Enforcement

Docket No.: 030-38397
License No.: 04-23986-01E

Enclosure: Notice of Violation

cc: State of California

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Docket No.: 030-38397
License No.: 04-23986-01E

Enclosure: Notice of Violation

cc: State of California

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Letter to K. Ho from Patricia Holahan dated September 29, 2016

SUBJECT: NOTICE OF VIOLATION – JENBO USA LLC, U.S. NUCLEAR REGULATORY
COMMISSION RECORDS INSPECTION

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NOTICE OF VIOLATION

Jenbo USA, LLC
Santa Ana, California

Docket No. 030-38397
License No. 04-23986-01E
EA-16-097

During a U.S. Nuclear Regulatory Commission (NRC) records inspection conducted from August 2014 to May 2016, three violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

- A. Title 10 of the *Code of Federal Regulations* (10 CFR) 32.16 requires, in part, that each person licensed under 10 CFR 32.14 shall file an annual report detailing all transfers of byproduct material.

10 CFR 32.16(c)(1) requires, in part, that the annual reports covering the preceding calendar year must be filed on or before January 31 of each year.

For annual reports filed in accordance with 10 CFR 32.16, the following requirements apply:

10 CFR 32.16(a)(1) requires, in part, inclusion of the license number.

10 CFR 32.16(a)(2) requires, in part, that the report must indicate that products were transferred for use under 10 CFR 30.15, giving the specific paragraph designation.

10 CFR 32.16(b)(2) requires, for each radionuclide in each type of product and each model number, if applicable, the total quantity of the radionuclide.

Contrary to the above, between 2012 and 2016, Jenbo USA, LLC (Jenbo) failed to file annual reports by January 31 of the following year detailing all transfers of byproduct material, and containing all required information. Specifically, Jenbo failed to file annual reports for transfers of byproduct material made in 2011, 2012, 2013, 2014, and 2015, on or before January 31 of the following year. In addition, when Jenbo submitted the annual reports at NRC staff's request, Jenbo failed to include all required information, such as the license number in accordance with 10 CFR 32.16(a)(1); an indication that the products were transferred for use under 10 CFR 30.15, with the specific paragraph designation in accordance with 10 CFR 32.16(a)(2); and, for each radionuclide in each type of product and each model number, if applicable, the total quantity of the radionuclide in accordance with 10 CFR 32.16(b)(2).

This is a Severity Level III violation (Section 6.9).

- B. 10 CFR 30.3(a), "Activities requiring license" provides, in part, that " ... no person shall manufacture, produce, transfer, receive, acquire, own, possess, or use byproduct material except as authorized in a specific or general license issued in accordance with the regulations in this chapter."

10 CFR 32.14 requires that an applicant for a specific license to apply byproduct material to, or to incorporate byproduct material into, the products specified in 10 CFR 30.15 or to initially transfer for sale or distribution such products containing byproduct

ENCLOSURE

material for use pursuant to 30.15 will be approved if the applicant satisfies the general requirements specified in 10 CFR 30.33 for possession and use of licensed material on Federal property, in an Agreement State, or in any State subject to NRC jurisdiction.

Contrary to the above, Jenbo USA, LLC (Jenbo) failed to conduct activities as authorized in their exempt distribution license. Specifically, in 2014, Jenbo distributed byproduct materials at 3672 Edison Way, Fremont, CA, which was not an authorized location in the specific license issued by NRC.

- C. License No.04-23986-01E Condition No. 11 on the license states: "The licensee is authorized to distribute only from its facilities located at 3672 Edison Way, Fremont, CA."

Contrary to the above, Jenbo USA, LLC (Jenbo, or the Licensee) distributed from a location other than the location listed in license No.04-23986-01E Condition No. 11. Specifically, in 2014, Jenbo moved from the location in Fremont and to Hayward, California. Licensee annual reports indicate that Jenbo distributed lamps containing Kr-85 in 2014.

These are a Severity Level III problem (Section 6.3).

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken to correct the violation and prevent recurrence, and the date when full compliance will be achieved, is already adequately addressed on the docket in letter from you dated February 1, 2016, and September 6, 2016. 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-16-097)" and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001 with a copy mailed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555-0001, and a copy mailed to Pamela Henderson, Deputy Director, Division of Material Safety, State, Tribal and Rulemaking Programs, Office of Nuclear Material Safety and Safeguards, 11555 Rockville Pike, Rockville, MD 20852, within 30 days of the date of the letter transmitting this Notice of Violation (Notice).

If you contest this enforcement action, you should 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, and a copy mailed to Pamela Henderson, Deputy Director, Division of Material Safety, State, Tribal and Rulemaking Programs, Office of Nuclear Material Safety and Safeguards, 11555 Rockville Pike, Rockville, MD 20852.

If you choose to respond, your response will be made available electronically for public inspection in the NRC Public Document Room or in the NRC's Agencywide Documents Access and Management 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. If personal privacy or proprietary information is necessary to provide an acceptable response, then 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 material, 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). If safeguards information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21. If Classified Information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR Part 95.

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

Dated this 29th day of September, 2016