



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

August 29, 2016

EA-16-097

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

SUBJECT: U.S. NUCLEAR REGULATORY COMMISSION RECORDS INSPECTION,
JENBO USA, LLC

Dear Mr. Kevin 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.

Based on the results of the record inspection, three apparent violations were identified and are being considered for escalated enforcement action in accordance with the NRC Enforcement Policy. The Enforcement Policy is included on the NRC's Web site at <http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>. The apparent violations involve (1) failure to submit annual reports detailing all transfers of byproduct material, in accordance with 10 CFR 32.16 (2) failure to submit a license amendment request to change the location authorized on 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 submit an amendment request to the NRC on the change of distribution location on the license, and distribution from an unauthorized location are significant because they inhibit the process of regulatory oversight. The apparent violations are listed in Enclosure 1.

During an August 29, 2016, telephonic exit meeting conducted with you, as Jenbo's Radiation Safety Officer, Mr. Hipolito Gonzalez, of the NRC, discussed these apparent violations, the significance of the issues, and the need for lasting and effective corrective actions.

As discussed with you, the NRC has not made a final determination that the violations occurred, or that enforcement action will be taken against Jenbo. Since the NRC has not made a final determination in this matter, a Notice of Violation is not being issued at this time. In addition, please be advised that the characterization of the apparent violations may change as a result of further NRC review.

Before the NRC makes its enforcement decision, we are providing you an opportunity to: (1) within 30 calendar days of the date of this letter, respond to the apparent violations addressed in this letter; (2) within 10 calendar days of the date of this letter, request a Pre-decisional Enforcement Conference (PEC); or (3) within 10 calendar days of the date of this letter, request Alternative Dispute Resolution (ADR). If you decide to participate in a PEC or pursue ADR, please contact Mr. Hipolito Gonzalez at (301) 415-5637 within 10 calendar days of the date of this letter. A PEC should be held within 30 calendar days and an ADR session within 45 calendar days of the date of this letter.

If you choose to provide a written response, it should be clearly marked as a "Response to Apparent Violations in NRC Records Inspection; EA-16-097" and should include for each apparent violation: (1) the reason for the apparent violation or, if contested, the basis for disputing the apparent violation; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken; and (4) the date when full compliance will be achieved. Your response may reference or include previously docketed correspondence, if the correspondence adequately addresses the required response. Additionally, your response should be sent to the NRC's Document Control Center, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; with a copy mailed to Daniel Collins, 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 this letter. If an adequate response is not received within the time specified or an extension of time has not been granted by the NRC, the NRC will proceed with its enforcement decision.

If you choose to request a PEC, the conference will afford you the opportunity to provide your perspective on these matters and any other information that you believe the NRC should take into consideration before making an enforcement decision. The decision to hold a PEC does not mean that the NRC has determined that a violation has occurred or that enforcement action will be taken. The PEC is being held to obtain information to assist the NRC in making an enforcement decision. This may include information to determine whether a violation occurred, information to determine the significance of any violation, and information related to any corrective actions taken or planned. For each apparent violation, you should be prepared to address: (1) the reason for the apparent violation, or, if contested, the basis for disputing the apparent violation; (2) the corrective steps that have been taken and the results achieved; and (3) the corrective steps that will be taken to avoid further violations. You may reference

previously docketed correspondence, if the correspondence adequately addresses the required response. If a PEC is held, it will be open for public observation and the NRC will issue a press release to announce the time and date of the conference.

In lieu of a PEC, you may request ADR with the NRC in an attempt to resolve this issue. ADR is a general term encompassing various techniques for resolving conflicts using a neutral third party. The technique that the NRC has decided to employ is mediation. Mediation is a voluntary, informal process in which a trained neutral third party (the "mediator") works with parties to help them reach resolution. If the parties agree to use ADR, they select a mutually agreeable neutral mediator who has no stake in the outcome and no power to make decisions. Mediation gives parties an opportunity to discuss issues, clear up misunderstandings, be creative, find areas of agreement, and reach a final resolution of the issues. Additional information concerning the NRC's program can be obtained at <http://www.nrc.gov/about-nrc/regulatory/enforcement/adr.html>. The Institute on Conflict Resolution (ICR) at Cornell University has agreed to facilitate the NRC's program as a neutral third party. Please contact ICR at (877) 733-9415 within 10 days of the date of this letter if you are interested in pursuing resolution of this issue through ADR.

In presenting any corrective actions, you should be aware that the promptness and comprehensiveness of the actions will be considered in assessing any civil penalty for the apparent violation. A separate civil penalty can be assessed for each violation issued. Based on the information that NRC has at this time, NRC would consider a base civil penalty of up to \$14,000 per violation. The guidance in the enclosed excerpt from NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," may be helpful.

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, if you choose to provide one, will be made available electronically for public inspection in the NRC Public Document Room or from 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. Any information forwarded to NRC should be clearly labeled on the first page with the case reference number: EA-16-097.

K. Ho

-4-

Should you have any questions, please contact Mr. Hipolito Gonzalez of my staff at (301) 415-5637.

Sincerely,

/RA/

Pamela J. Henderson, Deputy Director
Division of Material Safety, State, Tribal
and Rulemaking Programs
Office of Nuclear Material Safety
and Safeguards

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

Enclosures:

1. Basis of Apparent Violation
2. Apparent Violations
3. NRC Information Notice 96-28

cc: State of California

K. Ho

-4-

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DISTRIBUTION:

See next page

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OFC	MSTR	MSTR	MSTR	OE	MSTR
NAME	MBurgess	HRodriguez-Luccioni	H González	RFretz	PHenderson
DATE	05/05/16	05/06 /16	05/10/16	08/09/16	8/23/16

OFFICIAL RECORD COPY

Letter to K. Ho from Pamela Henderson dated August 29, 2016

SUBJECT: U.S. NUCLEAR REGULATORY COMMISSION RECORDS INSPECTION, JENBO
USA, LLC.

DISTRIBUTION:

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Basis of Apparent Violations

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 a report detailing distributions made under 10 CFR 32.14. Annual reports covering the preceding calendar year must be filed on or before January 31 of each year. In 2014 the U.S. Regulatory Commission (NRC) staff conducted a review and discovered that Jenbo USA LLC., (Jenbo) failed to submit the annual reports since the exempt distribution license (No. 04-23986-01E) was issued in February 1, 2011. In August 4, 2014, the NRC issued a letter to Jenbo requesting copies of annual reports detailing all transfers of byproduct material, pursuant to 10 CFR 32.16 for the reporting periods of 2011, 2012, 2013. In September 15, 2015, a second letter was issued to Jenbo, requesting copies of annual reports for the reporting periods of 2011, 2012, 2013 and 2014. The letter was returned to the NRC because Jenbo was no longer located in 3672 Edison Way, Fremont, California.

In December 16, 2015, the State of California informed the NRC that Jenbo submitted a request to terminate their possession license with the State of California. State of California reviewed the Jenbo exempt distribution license and identified that the location under license Condition No.11 was no longer Jenbo's address. The State of California informed the NRC that Jenbo amended their possession license in 2014, when Jenbo decommissioned the location in Fremont in 2014, and moved to a new location at 21393 Curtis Street, Hayward, California. Jenbo did not request an amendment to their NRC exempt distribution license.

The NRC exempt distribution license Condition No. 11 authorizes Jenbo to distribute only from its facilities located at 3675 Edison Way, Fremont, California. In 2014, Jenbo decommissioned the Fremont facilities and changed location to 21393 Curtis Street, Hayward, California. Jenbo failed to submit a license amendment request to change location of distribution in its license Condition No. 11. Jenbo annual reports indicate that Jenbo distributed lamps containing Kr-85 in 2014. Based on this information, it appears that Jenbo distributed lamps from location not authorized on its license.

Apparent Violations

Apparent Violation 1:

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).

Apparent Violation 2:

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 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, Jenbo changed the location authorized on the license without submitting and obtaining prior authorization from NRC.

Apparent Violation 3:

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, California to Hayward, California. Licensee annual reports indicate that Jenbo distributed lamps containing Kr-85 in 2014.

NRC INFORMATION NOTICE 96-28

UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS
WASHINGTON, D.C. 20555

May 1, 1996

NRC INFORMATION NOTICE 96-28: SUGGESTED GUIDANCE RELATING TO
DEVELOPMENT AND IMPLEMENTATION OF
CORRECTIVE ACTION

Addressees

All material and fuel cycle licensees.

Purpose

The U.S. Nuclear Regulatory Commission (NRC) is issuing this information notice to provide addressees with guidance relating to development and implementation of corrective actions that should be considered after identification of violation(s) of NRC requirements. It is expected that recipients will review this information for applicability to their facilities and consider actions, as appropriate, to avoid similar problems. However, suggestions contained in this information notice are not new NRC requirements; therefore, no specific action or written response is required.

Background

On June 30, 1995, NRC revised its Enforcement Policy, to clarify the enforcement program's focus by, in part, emphasizing the importance of identifying problems before events occur, and of taking prompt, comprehensive corrective action when problems are identified. Consistent with the revised Enforcement Policy, NRC encourages and expects identification and prompt, comprehensive correction of violations.

In many cases, licensees who identify and promptly correct non-recurring Severity Level IV violations, without NRC involvement, will not be subject to formal enforcement action. Such violations will be characterized as "non-cited" violations as provided in Section VI.A of the Enforcement Policy. Minor violations are not subject to formal enforcement action. Nevertheless, the root cause(s) of minor violations must be identified and appropriate corrective action must be taken to prevent recurrence.

If violations of more than a minor concern are identified by the NRC during an inspection, licensees will be subject to a Notice of Violation and may need to provide a written response, as required by 10 CFR 2.201, addressing the causes of the violations and corrective actions taken to prevent recurrence.

Enclosure 3

In some cases, such violations are documented on Form 591 (for materials licensees) which constitutes a notice of violation that requires corrective action but does not require a written response. If a significant violation is involved, a pre-decisional enforcement conference may be held to discuss those actions.

The quality of a licensee's root cause analysis and plans for corrective actions may affect the NRC's decision regarding both the need to hold a pre-decisional enforcement conference with the licensee and the level of sanction proposed or imposed.

Discussion

Comprehensive corrective action is required for all violations. In most cases, NRC does not propose imposition of a civil penalty where the licensee promptly identifies and comprehensively corrects violations. However, a Severity Level III violation will almost always result in a civil penalty if a licensee does not take prompt and comprehensive corrective actions to address the violation.

It is important for licensees, upon identification of a violation, to take the necessary corrective action to address the noncompliant condition and to prevent recurrence of the violation and the occurrence of similar violations. Prompt comprehensive action to improve safety is not only in the public interest, but is also in the interest of licensees and their employees. In addition, it will lessen the likelihood of receiving a civil penalty. Comprehensive corrective action cannot be developed without a full understanding of the root causes of the violation.

Therefore, to assist licensees, the NRC staff has prepared the following guidance, that may be used for developing and implementing corrective action. Corrective action should be appropriately comprehensive to not only prevent recurrence of the violation at issue, but also to prevent occurrence of similar violations. The guidance should help in focusing corrective actions broadly to the general area of concern rather than narrowly to the specific violations. The actions that need to be taken are dependent on the facts and circumstances of the particular case.

The corrective action process should involve the following three steps:

1. Conduct a complete and thorough review of the circumstances that led to the violation.
Typically, such reviews include:

Interviews with individuals who are either directly or indirectly involved in the violation, including management personnel and those responsible for training or procedure development/guidance. Particular attention should be paid to lines of communication between supervisors and workers.

Tours and observations of the area where the violation occurred, particularly when those reviewing the incident do not have day-to-day contact with the operation under review. During the tour, individuals should look for items that may have contributed to the violation as well as those items that may result in

future violations. Reenactments (without use of radiation sources, if they were involved in the original incident) may be warranted to better understand what actually occurred.

Review of programs, procedures, audits, and records that relate directly or indirectly to the violation. The program should be reviewed to ensure that its overall objectives and requirements are clearly stated and implemented. Procedures should be reviewed to determine whether they are complete, logical, understandable, and meet their objectives (i.e., they should ensure compliance with the **current** requirements). Records should be reviewed to determine whether there is sufficient documentation of necessary tasks to provide a record that can be audited and to determine whether similar violations have occurred previously. Particular attention should be paid to training and qualification records of individuals involved with the violation.

2. Identify the root cause of the violation.

Corrective action is not comprehensive unless it addresses the root cause(s) of the violation. It is essential, therefore, that the root cause(s) of a violation be identified so that appropriate action can be taken to prevent further noncompliance in this area, as well as other potentially affected areas. Violations typically have direct and indirect cause(s). As each cause is identified, ask what other factors could have contributed to the cause. When it is no longer possible to identify other contributing factors, the root causes probably have been identified. For example, the direct cause of a violation may be a failure to follow procedures; the indirect causes may be inadequate training, lack of attention to detail, and inadequate time to carry out an activity. These factors may have been caused by a lack of staff resources that, in turn, are indicative of lack of management support. Each of these factors must be addressed before corrective action is considered to be comprehensive.

3. Take prompt and comprehensive corrective action that will address the immediate concerns **and** prevent recurrence of the violation.

It is important to take immediate corrective action to address the specific findings of the violation. For example, if the violation was issued because radioactive material was found in an unrestricted area, **immediate** corrective action must be taken to place the material under licensee control in authorized locations. After the immediate safety concerns have been addressed, timely action must be taken to prevent future recurrence of the violation. Corrective action is sufficiently comprehensive when corrective action is broad enough to reasonably prevent recurrence of the specific violation as well as prevent similar violations.

In evaluating the root causes of a violation and developing effective corrective action, consider the following:

1. Has management been informed of the violation(s)?

2. Have the programmatic implications of the cited violation(s) and the potential presence of similar weaknesses in other program areas been considered in formulating corrective actions so that both areas are adequately addressed?
3. Have precursor events been considered and factored into the corrective actions?
4. In the event of loss of radioactive material, should security of radioactive material be enhanced?
5. Has your staff been adequately trained on the applicable requirements?
6. Should personnel be re-tested to determine whether re-training should be emphasized for a given area? Is testing adequate to ensure understanding of requirements and procedures?
7. Has your staff been notified of the violation and of the applicable corrective action?
8. Are audits sufficiently detailed and frequently performed? Should the frequency of periodic audits be increased?
9. Is there a need for retaining an independent technical consultant to audit the area of concern or revise your procedures?
10. Are the procedures consistent with current NRC requirements, should they be clarified, or should new procedures be developed?
11. Is a system in place for keeping abreast of new or modified NRC requirements?
12. Does your staff appreciate the need to consider safety in approaching daily assignments?
13. Are resources adequate to perform, and maintain control over, the licensed activities? Has the radiation safety officer been provided sufficient time and resources to perform his or her oversight duties?
14. Have work hours affected the employees' ability to safely perform the job?
15. Should organizational changes be made (e.g., changing the reporting relationship of the radiation safety officer to provide increased independence)?
16. Are management and the radiation safety officer adequately involved in oversight and implementation of the licensed activities? Do supervisors adequately observe new employees and difficult, unique, or new operations?
17. Has management established a work environment that encourages employees to raise safety and compliance concerns?

18. Has management placed a premium on production over compliance and safety? Does management demonstrate a commitment to compliance and safety? Has management communicated its expectations for safety and compliance?
19. Is there a published discipline policy for safety violations, and are employees aware of it? Is it being followed?

This information notice requires no specific action or written response. If you have any questions about the information in this notice, please contact one of the technical contacts listed below.

Robert C. Pierson, Director
Division of Fuel Cycle Safety and Safeguards
Office of Nuclear Material Safety and Safeguards

Donald A. Cool, Director
Division of Industrial and Medical Nuclear
Office of Nuclear Material Safety and Safeguards

Technical contacts: (Updated as of November 22, 2005)

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