



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

June 7, 2018

EA-18-033

Ms. Beverly Shin
Senior Director, Associate General Counsel
Harman International Industries, Incorporated
8500 Balboa Blvd
Northridge, CA 91329

SUBJECT: U.S. NUCLEAR REGULATORY COMMISSION RECORDS REVIEW,
HARMAN INTERNATIONAL INDUSTRIES, INCORPORATED

Dear Ms. Shin,

This letter refers to the records review initiated on October 2016 through February 2018, by the U.S. Nuclear Regulatory Commission (NRC), related to the import, possession, and distribution of licensed materials by Harman International Industries, Inc. (Harman) in areas of NRC jurisdiction without having the required NRC licenses.

Based on the results of this review, three apparent violations were identified and are being considered for escalated enforcement action in accordance with the NRC Enforcement Policy. The current 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) initially transferring, for sale or distribution, lamps containing krypton-85 without an NRC license for such activity pursuant to Title 10 of the *Code of Federal Regulations* (10 CFR) sections 30.3(a), 30.15(a)(8)(iv), and 32.14; (2) possession of material (krypton-85) without an NRC license for such activity pursuant to 10 CFR 30.3; and (3) importing material (krypton-85) into the United States without an NRC or an Agreement State license for possession of the material containing byproduct material pursuant to 10 CFR 110.5, 110.9a, 110.20(a), and 110.27(a).

The failure to obtain the required licenses for the import, distribution and/or possession of these products prior to distributing these products is significant because it resulted in the NRC not being able to conduct its regulatory responsibilities to ensure that the products were safe for distribution to members of the general public, and inhibits the process of regulatory oversight. The apparent violations are listed in Enclosure 1.

During an April 26, 2018, telephonic exit meeting conducted with Mr. Erik Bowers, Harman's Director of Global Quality, Ms. Samantha Crane of the NRC discussed these apparent violations, the significance of the issues, and the need for lasting and effective corrective action.

As discussed with Mr. Bower, the NRC has not made a final determination regarding the apparent violations or that enforcement action will be taken against Harman; therefore, 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) request a Pre-decisional Enforcement Conference (PEC), or (2) request Alternative Dispute Resolution (ADR). You are required to contact Ms. Samantha Crane at 301-415-6380 within **10** calendar days of the date of this letter to inform the NRC whether you choose a PEC or ADR. The PEC or ADR session should be held within 30 calendar days of the date of this letter.

The purpose of the PEC is to obtain information to assist the NRC in making an enforcement decision and 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 the NRC makes 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. The information 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. In addition, since these apparent violations are similar to violations issued in 2005 to Martin Professional (owned by Harman), this information should also include: (1) the reason why the violations recurred despite corrective actions taken in 2005; and (2) what corrective steps Harman is taking, or has taken, such that NRC should have confidence in Harman's future compliance with regulatory requirements. This information may reference or include previously docketed correspondence. 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. 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. If you choose to request a PEC, the PEC will be open to public observation, and the NRC may issue a meeting notice and/or press release to announce the time and date of this open 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. If you choose ADR, you must 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. If you choose to request ADR, the ADR will be closed to the public; however, the NRC may issue a meeting notice and/or press release to announce the time and date of this closed conference.

If you choose to not respond within the times specified, or an extension of time has not been granted by the NRC, the NRC will proceed with its enforcement decision.

In addition, please be advised that the number and characterization of apparent violations described in the enclosure may change as a result of further NRC review. You will be advised by separate correspondence of the results of our deliberations on this matter.

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, 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-18-033.

Should you have any questions, please contact Ms. Samantha Crane of my staff at (301) 415-6380.

Sincerely,

/RA/

Christian Einberg, Acting Deputy Director
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosures:

1. Apparent Violations Being Considered for Escalated Enforcement
2. Summary of Basis of Apparent Violations
3. NRC Information Notice 96-28

SUBJECT: U.S. NUCLEAR REGULATORY COMMISSION RECORDS REVIEW,
HARMAN INTERNATIONAL INDUSTRIES, INCORPORATED

DISTRIBUTION:

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SHoliday, OE

OEMail Resource

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OFFICE	NMSS/MSST	NMSS/MSST	NMSS/MSST	OIP
NAME	SXu	THerrera for SCrane	MBurgess	SBaker Via email
DATE	5/16/18	5/17/18	5/17/18	5/22/18
OFFICE	NMSS/MSST (prior to OE)	OE	OGC	NMSS/MSST (final concurrence)
NAME	CEinberg	SHoliday Via email	DCylkowski Via email	CEinberg
DATE	5/24/18	5/25/18	5/30/18	6/7/18

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APPARENT VIOLATIONS BEING CONSIDERED FOR ESCALATED ENFORCEMENT

Apparent Violation 1:

Title 10 of the *Code of Federal Regulations* (10 CFR) section 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 30.15(a)(8)(iv) provides an exemption to the requirement for a license in 10 CFR 30.3(a) for persons who receive, possess, use, transfer, own, or acquire electron tubes containing not more than specified quantities of byproduct material. However, the exemption in 10 CFR 30.15(a) excludes "persons... who initially transfer for sale or distribution" such electron tubes.

10 CFR 30.15(b) provides, in part, that any person who desires to initially transfer for sale or distribution the products exempted in 10 CFR 30.15(a) should apply for a specific license pursuant to 10 CFR 32.14, which license states that the product may be distributed by the licensee to persons exempt from the regulations pursuant to 10 CFR 30.15(a).

Contrary to the above, Harman International Industries, Inc. (Harman) distributed material to unlicensed persons without possessing an NRC license to distribute exempt products as required by 10 CFR 30.3(a) and 30.15(b). Specifically, from 2013 through February 2017, Harman initially transferred, for sale or distribution, approximately 10,000 Kr-85 bulbs containing byproduct material to unlicensed persons without obtaining a specific license pursuant to 10 CFR 32.14 authorizing such transfers.

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."

Contrary to the above, Harman received and possessed byproduct material (light bulbs containing Kr-85) without having the required license for possession of the material (a possession license issued by the NRC), and without being able to demonstrate that the bulbs were obtained from an entity licensed to distribute those bulbs as an exempt use product as required by 10 CFR 30.3(a). Specifically, between 2013 and May 26, 2017, Harman received and possessed more than 15,000 bulbs, manufactured by Philips Professional Lamps in Netherlands, Osram GmbH in Germany, and GE Lighting in Denmark and Hungary, containing Kr-85, without having a possession license issued by the NRC, and without being able to demonstrate that the bulbs were obtained from an entity licensed to distribute those bulbs as an exempt use product.

Apparent Violation 3:

10 CFR 110.5 states, in part, "no person may export any nuclear equipment or material listed in § 110.8 and § 110.9, or import any nuclear equipment or material listed in § 110.9a, unless authorized by a general or specific license issued under this part."

10 CFR 110.9a, List of nuclear equipment and material under NRC import licensing authority, includes byproduct material (e.g., Kr-85).

10 CFR 110.20(a) states, "A person may use an NRC general license as authority to export or import nuclear equipment or material, if the nuclear equipment or material to be exported or imported is covered by the NRC general licenses described in §§ 110.21 through 110.27. 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 110.27(a) states, "Except as provided in paragraphs (b) and (c) of this section, a general license is issued to any person to import byproduct, source, or special nuclear material if the U.S. consignee is authorized to receive and possess the material under a general or specific NRC or Agreement State license issued by the Commission or a State with which the Commission has entered into an agreement under Section 274b. of the Atomic Energy Act."

Contrary to the above, Harman imported byproduct material into the United States without being authorized by a general or specific license issued under 10 CFR Part 110. Specifically, between approximately 2013 and 2017, Harman imported approximately 15,000 bulbs, manufactured by Philips Professional Lamps in Netherlands, Osram GmbH in Germany, and GE Lighting in Denmark and Hungary, containing Kr-85, without having a possession license issued by the NRC. Therefore, the import was not authorized under the provisions of a general license.

SUMMARY OF BASIS OF APPARENT VIOLATIONS

Martin Professional is a Danish manufacturer and distributor of stage and architectural lighting and effects fixtures. Martin Professional is headquartered in Aarhus, Denmark, and has US locations in Sunrise, Florida and Elkhart, Indiana. It is owned by Harman International Industries Incorporated (Harman). Harman acquired Martin Professional in 2013.

Harman is an American company that designs and engineers connected products for automakers, consumers and enterprises worldwide, including connected car systems; audio and visual products; enterprise automation; and connected services. Harman is headquartered in Stamford, Connecticut, and maintains major operations in the Americas, Europe, and Asia. Harman markets its products under more than twenty brands, including AKG Acoustics, AMX, Crown Audio, Harman/Kardon, Infinity, JBL, JBL Professional, Lexicon, Mark Levinson, Martin, Revel, Soundcraft and Studer.

Martin Professional possessed and distributed lamps containing Kr-85 without a specific exempt distribution or possession license issued by the NRC from storage and distribution facilities in Elkhart, Indiana. In addition, Martin Professional imported byproduct material into the United States without being authorized to do so by a general or specific license issued under 10 CFR Part 110.

On February 7, 2005, the NRC inspected Martin Professional at its storage and distribution facility in Sunrise, Florida. The inspection report was issued to Martin Professional in May 20, 2005 with one Severity Level IV Violation, citing that Martin Professional distributed specialty electrical light bulbs containing krypton-85 in fixtures without a specific license issued by the NRC pursuant to 10 CFR Part 30.

Martin Professional responded to the NRC regarding the violation in a letter dated June 18, 2005. The letter described Martin Professional's corrective actions, including "Corrective steps that will be taken to avoid further violations," and emphasized: "In order to prevent the violations from continuing, an agreement has been made between our manufacturing facility and the licensed American vendor, to supply licensed bulbs directly from USA to our manufacturing facilities for installation in products intended for sale in US, hence ensuring that all merchandise entering USA will contain only licensed bulbs."

In a letter dated February 22, 2017, Mr. Peter Thieman, consultant for Harman, stated that Harman has imported lamps containing Kr-85 directly from manufacturers in Europe since 2013 and has distributed these lamps to customers in the U.S. These manufacturers include Philips Professional Lamps in the Netherlands, Osram GmbH in Germany, and GE Lighting in Denmark and Hungary. The products were imported to Harman's storage and distribution facilities in Elkhart, Indiana. The letter stated that as of mid-February 2017, Harman stopped the shipment into the United States of finished products containing Kr-85 lamps and Kr-85 spare bulbs. The letter further stated that as of mid-February 2017, Harman stopped the shipment to dealers, end users, etc. in the United States of Harman's finished products containing Kr-85 lamps and Kr-85 spare bulbs.

In an e-mail dated February 15, 2018, Mr. Erik Bowers, Operations/Quality Control Director of Harman Professional Solutions, confirmed:

- Harman has a facility in Elkhardt, IN, at which Harman shutdown manufacturing recently with plans to close out the office by June 2018.
- As of May 26, 2017, the bulbs in Elkhardt were shipped back to their manufacturing site in Pec, Hungary.
- All units in the Moreno, CA facility were received after approvals [licenses issued], or had OSRAM U.S.A, bulbs installed.

From the spreadsheets submitted by Harman in February 2017, it appears that the following imports and distributions were made:

	Import (response to RFI Questions 1c&1d)	Distribution (response to RFI Question 3)
CY13, CY14	8098	8760*
CY15	7696	1474
Total	15794	10234

* Note: The distribution number is higher than the import number. It is assumed that some product was drop shipped directly to the end user and not reflected as possessed by Harman.

Based on the evidence gathered during this records review, it appears that between approximately 2013 to 2017, Harman imported and possessed approximately 15,000 lamps or finished products containing lamps containing krypton-85 without having a general or specific NRC import license or a possession license issued by the NRC, and without being able to demonstrate that the lamps or product were obtained from an entity licensed to initially transfer those bulbs as an exempt-use product. Furthermore, it appears that during this same period, Harman initially transferred approximately 10,000 lamps or finished products to unlicensed persons without having a NRC exempt distribution license.

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.

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 predecisional 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 predecisional 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?

19. Has management communicated its expectations for safety and compliance?
20. Is there a published discipline policy for safety violations, and are employees aware of it? Is it being followed?