

**UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION**

In the Matter of)	Docket No. 030-39071
Harman International Industries, Inc.)	License No. 04-35446-01E
Northridge, California)	EA-18-033

**CONFIRMATORY ORDER MODIFYING LICENSE
(EFFECTIVE UPON ISSUANCE)**

I

Harman International Industries, Incorporated, (Harman or Licensee) is the holder of Materials License No. 04-35446-01E issued on December 15, 2017, by the U.S. Nuclear Regulatory Commission (NRC) pursuant to Part 30 of Title 10 of the *Code of Federal Regulations* (10 CFR), *Rules of General Applicability to Domestic Licensing of Byproduct Material*. The license authorizes Harman to distribute lamps containing byproduct material (krypton-85) to persons exempt from the regulations. Harman was located in Elkhart, Indiana (IN), prior to June 2018, and is currently located in Northridge, California (CA), with a distribution facility located in Moreno Valley, CA.

This Confirmatory Order is the result of an agreement reached during an Alternative Dispute Resolution (ADR) mediation session conducted on August 16, 2018.

II

The NRC conducted a review on October 2016 through February 2018, related to the import, possession, and distribution of licensed materials (lamps containing krypton-85) by Harman in areas of NRC jurisdiction without having the required NRC licenses.

On June 7, 2018, the NRC issued a letter to Harman that identified the results of the records review and outlined three apparent violations. The apparent violations involved:

(1) initially transferring, for sale or distribution, lamps containing krypton-85 without an NRC license for such activity pursuant to 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 (U.S.) without an NRC or 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).

In the June 7, 2018, letter, the NRC offered Harman the choice to: (1) attend a Pre-decisional Enforcement Conference (PEC); or (2) participate in an ADR mediation session in an effort to resolve these concerns.

In response to the NRC's letter, Harman requested ADR. On August 16, 2018, Harman and the NRC met in an ADR session mediated by a professional mediator, arranged through Cornell University's Institute on Conflict Resolution. The ADR process is one in which a neutral mediator, with no decision-making authority, assists the parties in reaching an agreement on resolving any differences regarding the dispute. This Confirmatory Order is issued pursuant to the agreement reached during the ADR process.

III

During the ADR session, Harman and the NRC reached a preliminary settlement agreement. The elements of the agreement included Harman acceptance of the violations for a period of non-compliance from approximately March 2016 to February 2017, corrective actions that Harman stated were completed as described below, agreed upon future actions, and general provisions as follows:

Harman Completed Corrective Actions to Restore Compliance:

1. As of mid-February 2017, Harman stopped the shipment into the U.S. of finished products containing krypton-85 lamps and krypton-85 spare bulbs.
2. As of mid-February 2017, Harman stopped the shipment to dealers, end users, etc. in the U.S. of Harman's finished products containing krypton-85 lamps and krypton-85 spare bulbs.
3. As of April 2017, the licensee quarantined all remaining product in the Quality Assurance cage (QA cage) to further ensure no product would be distributed (which requires the Quality Manager signature to release).
4. As of May 18, 2017, no radioactive material remained at the Elkhart, IN, location, and all remaining imported bulbs in Elkhart were shipped back to the manufacturer.
5. On June 29, 2017, Harman submitted an application to the State of California, and on December 15, 2017, received a California license for possession of krypton-85 at Harman's facility located in Moreno Valley, CA.
6. Harman submitted an application for a distribution license in September 2017, and on December 15, 2017, NRC issued to Harman distribution license No. 04-35446-01E.
7. Harman engaged the services of a consultant to assist with the NRC license application.
8. Harman has established the position of Compliance Manager. This role is in addition to the Radiation Safety Officer (RSO) for the license. The Compliance Manager is responsible for ensuring compliance with NRC requirements.

9. Harman has established the New Product Introduction/Product Lifecycle Management (NPI/PLM) process.
 - a. The NPI/PLM is a multistep process that includes determination of whether NRC requirements apply, and ensures compliance with NRC requirements.
 - b. All new or changed products (to overall or component design), new or changed processes, or transfers of product undergo the process.
 - c. When radioactive material is identified, the Compliance Manager and the RSO must approve that the process/component changes are consistent with NRC requirements.

Harman Future Actions to Enhance Compliance:

1. Harman will maintain the position of Compliance Manager. This role is in addition to the RSO for the license. The Compliance Manager is responsible for ensuring compliance with NRC requirements.
2. Harman will maintain the NPI/PLM process as described above.
3. Within 90 days of the date of this Confirmatory Order, Harman will ensure that:
 - a. The documented NPI/PLM process prompts the identification and application of NRC requirements (including regulatory, license, and Order).
 - b. Applicable documents define the roles and responsibilities of the Compliance Manager and RSO, in the NPI/PLM process, as they relate to NRC requirements.
4. Within 90 days of the date of this Confirmatory Order, Harman will issue a letter from the Compliance Manager to the President, Vice Presidents, and the Directors who report to the Vice President for Operations and Procurement, to ensure awareness of the violations and actions taken. The letter will include:
 - a. A description of the violations, including a copy of the NRC letter dated June 7, 2018.

- b. The actions taken to restore compliance, including a copy of this Confirmatory Order.
- 5. Within 90 days of the date of this Confirmatory Order, Harman will issue a communication to foreign suppliers of lighting products to Harman to promote awareness of the NRC requirements.
 - a. The communication will include:
 - i. That there are U.S. requirements for products containing radioactive material that will be imported and distributed within the U.S.
 - ii. That selling product to customers could result in putting those entities in non-compliance with U.S. requirements.
 - iii. Contact information for the NRC.
 - iv. A request to pass the communication to the suppliers' affiliates and potentially impacted customers.
 - b. Harman will provide a copy of the letter to NRC, 30 days in advance of issuance.
- 6. Harman will conduct training for the participants in the NPI/PLM process.
 - a. Harman will review and modify, if not already included, the current Compliance Training to ensure that it contains the following:
 - i. NRC regulatory framework.
 - ii. Applicable requirements for the activities being conducted.
 - iii. The role of each NPI/PLM participant in ensuring compliance and the specific role of the Compliance Manager and RSO.
 - b. The training will include an initial training and annual periodic training.
 - c. The initial training will be completed within 180 days of the date of this Confirmatory Order.
 - d. Harman will maintain documentation of individuals trained.
- 7. Harman will continue to conduct training for all employees handling radioactive material.

- a. Content will include radiation safety and NRC requirements.
 - b. The training will include an initial training and annual periodic training.
 - c. The next training will be completed within 90 days of the date of this Confirmatory Order.
 - d. Harman will maintain documentation of individuals trained.
8. Beginning in calendar year 2020, Harman will perform an annual audit to ensure compliance with NRC requirements. The audit will be completed in the first quarter of each calendar year.
9. By March 31, 2019:
 - a. Harman will conduct an audit using an independent third-party consultant to evaluate compliance with NRC requirements.
 - b. The audit will not commence prior to December 31, 2018.
 - c. The audit will:
 - i. Include review of compliance with NRC requirements.
 - ii. Be documented by an audit report, including the scope, observations, and findings.
 - d. Harman will provide to the NRC a copy of the consultant report, and a description of any corrective actions taken as a result of the audit.

General provisions:

1. For the purposes of this agreement, the term “requirements” includes NRC rules, license and Order requirements.
2. Unless otherwise specified, all dates are calendar days from the date of issuance of this Confirmatory Order.
3. Unless otherwise specified, all documents required to be submitted to the NRC will be sent to: Director, Division of Materials Safety, Security, State and Tribal Programs, Office of Nuclear Material Safety and Safeguards, Two White Flint North, 11545 Rockville Pike,

Rockville, MD 20852-2738, with copies to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852-2738, and to the Branch Chief, Materials Safety Licensing Branch, Division of Materials Safety, Security, State and Tribal Programs, Office of Nuclear Material Safety and Safeguards, Two White Flint North, 11545 Rockville Pike, Rockville, MD 20852-2738. Harman will also endeavor to provide courtesy electronic copies to the above individuals, at their NRC email addresses.

4. NRC agrees not to issue a separate Notice of Violation.
5. NRC will categorize the violations as one Severity Level III problem, with a civil penalty of half the base in the amount of \$7,250.
6. The Confirmatory Order will be considered escalated action consistent with the current NRC Enforcement Policy for future enforcement.
7. In the event of the transfer of the possession and/or distribution licenses of Harman to another entity, the terms and conditions set forth hereunder shall continue to apply to the new entity and accordingly survive any transfer of ownership or license.
8. Based on the completed actions described above, and the commitments described in Section V below, the NRC agrees to not pursue any further enforcement action based on the apparent violations identified in the NRC's June 7, 2018, letter.

On September 21, 2018, Harman consented to issuing this Confirmatory Order with the commitments, as described in Section V below. Harman further agreed that this Confirmatory Order is to be effective upon issuance, the agreement memorialized in this Confirmatory Order settles the matter between the parties, and that it has waived its right to a hearing.

IV

I find that the Harman actions completed, as described in Section III above, combined with the commitments as set forth in Section V, are acceptable and necessary, and conclude that with these commitments the public health and safety are reasonably assured. In view of the foregoing, I have determined that public health and safety require that Harman's commitments be confirmed by this Confirmatory Order. Based on the above and Harman's consent, this Confirmatory Order is effective upon issuance.

V

Accordingly, pursuant to Sections 81, 161(b), 161(i), 161(o), 182, and 186 of the Atomic Energy Act of 1954, as amended, and the Commission's regulations in 10 CFR 2.202 and 10 CFR Part 30, IT IS HEREBY ORDERED, EFFECTIVE UPON ISSUANCE, THAT LICENSE NO. 04-35446-01E IS MODIFIED AS FOLLOWS:

1. Harman will maintain the position of Compliance Manager. This role is in addition to the Radiation Safety Officer (RSO) for the license. The Compliance Manager is responsible for ensuring compliance with NRC requirements.
2. Harman will maintain the New Product Introduction/Product Lifecycle Management (NPI/PLM) process as described in Section III above.
3. Within 90 days of the date of this Confirmatory Order, Harman will ensure that:
 - a. The documented NPI/PLM process prompts the identification and application of NRC requirements (including regulatory, license, and Order).
 - b. Applicable documents define the roles and responsibilities of the Compliance Manager and RSO, in the NPI/PLM process, as they relate to NRC requirements.
4. Within 90 days of the date of this Confirmatory Order, Harman will issue a letter from the Compliance Manager to the President, Vice Presidents, and the Directors who report to the Vice President for Operations and Procurement, to ensure awareness of the

violations and actions taken. The letter will include:

- a. A description of the violations, including a copy of the NRC letter dated June 7, 2018.
 - b. The actions taken to restore compliance, including a copy of this Confirmatory Order.
5. Within 90 days of the date of this Confirmatory Order, Harman will issue a communication to foreign suppliers of lighting products to Harman to promote awareness of the NRC requirements.
 - a. The communication will include:
 - i. That there are U.S. requirements for products containing radioactive material that will be imported and distributed within the U.S.
 - ii. That selling product to customers could result in putting those entities in non-compliance with U.S. requirements.
 - iii. Contact information for the NRC.
 - iv. A request to pass the communication to the suppliers' affiliates and potentially impacted customers.
 - b. Harman will provide a copy of the letter to NRC, 30 days in advance of issuance.
6. Harman will conduct training for the participants in the NPI/PLM process.
 - a. Harman will review and modify, if not already included, the current Compliance Training to ensure that it contains the following:
 - i. NRC regulatory framework.
 - ii. Applicable requirements for the activities being conducted.
 - iii. The role of each NPI/PLM participant in ensuring compliance and the specific role of the Compliance Manager and RSO.
 - b. The training will include an initial training and annual periodic training.
 - c. The initial training will be completed within 180 days of the date of this

Confirmatory Order.

- d. Harman will maintain documentation of individuals trained.
- 7. Harman will continue to conduct training for all employees handling radioactive material.
 - a. Content will include radiation safety and NRC requirements.
 - b. The training will include an initial training and annual periodic training.
 - c. The next training will be completed within 90 days of the date of this Confirmatory Order.
 - d. Harman will maintain documentation of individuals trained.
- 8. Beginning in calendar year 2020, Harman will perform an annual audit to ensure compliance with NRC requirements. The audit will be completed in the first quarter of each calendar year.
- 9. By March 31, 2019:
 - a. Harman will conduct an audit using an independent third-party consultant to evaluate compliance with NRC requirements.
 - b. The audit will not commence prior to December 31, 2018.
 - c. The audit will:
 - i. Include review of compliance with NRC requirements.
 - ii. Be documented by an audit report, including the scope, observations, and findings.
 - d. Harman will provide to NRC a copy of the consultant report, and a description of any corrective actions taken as a result of the audit.
- 10. Harman will pay a civil penalty in the amount of \$7,250.

For the purposes of this agreement, the term “requirements” includes NRC rules, license and Order requirements.

Unless otherwise specified, all dates are calendar days from the date of issuance of the Confirmatory Order.

Unless otherwise specified, all documents required to be submitted to the NRC will be sent to: Director, Division of Materials Safety, Security, State and Tribal Programs, Office of Nuclear Material Safety and Safeguards, Two White Flint North, 11545 Rockville Pike, Rockville, MD 20852-2738, with copies to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852-2738, and to the Branch Chief, Materials Safety Licensing Branch, Division of Materials Safety, Security, State and Tribal Programs, Office of Nuclear Material Safety and Safeguards, Two White Flint North, 11545 Rockville Pike, Rockville, MD 20852-2738. Harman will also endeavor to provide courtesy electronic copies to the above individuals, at their NRC email addresses.

The Confirmatory Order will be considered escalated action consistent with NRC current Enforcement Policy for future enforcement.

In the event of the transfer of the possession and/or distribution licenses of Harman to another entity, the terms and conditions set forth hereunder shall continue to apply to the new entity and accordingly survive any transfer of ownership or license.

The Director, Office of Enforcement, NRC, may, in writing, relax or rescind any of the above conditions upon written request by Harman, and demonstration by Harman or its successors of good cause.

VI

In accordance with 10 CFR 2.202 and 10 CFR 2.309, any person adversely affected by this Confirmatory Order, other than Harman, may request a hearing within thirty (30) calendar days of the date of issuance of this Confirmatory Order. Where good cause is shown, consideration will be given to extending the time to request a hearing. A request for extension of time must be made in writing to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and include a statement of good cause for the extension.

All documents filed in NRC adjudicatory proceedings, including a request for hearing, a petition for leave to intervene, any motion or other document filed in the proceeding prior to the submission of a request for hearing or petition to intervene (hereinafter "petition"), and documents filed by interested governmental entities participating under 10 CFR 2.315(c), must be filed in accordance with the NRC's E-Filing rule (72 FR 49139; August 28, 2007, as amended by 77 FR 46562, August 3, 2012). The E-Filing process requires participants to submit and serve all adjudicatory documents over the internet, or in some cases to mail copies on electronic storage media. Participants may not submit paper copies of their filings unless they seek an exemption in accordance with the procedures described below.

To comply with the procedural requirements of E-Filing, at least ten (10) calendar days prior to the filing deadline, the participant should contact the Office of the Secretary by e-mail at hearing.docket@nrc.gov, or by telephone at 301-415-1677, to (1) request a digital identification (ID) certificate, which allows the participant (or its counsel or representative) to digitally sign submissions and access the E-Filing system for any proceeding in which it is participating; and (2) advise the Secretary that the participant will be submitting a petition or other adjudicatory document (even in instances in which the participant, or its counsel or representative, already holds an NRC-issued digital ID certificate). Based upon this information, the Secretary will

establish an electronic docket for the hearing in this proceeding if the Secretary has not already established an electronic docket.

Information about applying for a digital ID certificate is available on the NRC's public Web site at <http://www.nrc.gov/site-help/e-submittals/getting-started.html>. Once a participant has obtained a digital ID certificate and a docket has been created, the participant can then submit adjudicatory documents. Submissions must be in Portable Document Format (PDF). Additional guidance on PDF submissions is available on the NRC's public Web site at <http://www.nrc.gov/site-help/electronic-sub-ref-mat.html>. A filing is considered complete at the time the document is submitted through the NRC's E-Filing system. To be timely, an electronic filing must be submitted to the E-Filing system no later than 11:59 p.m. Eastern Time on the due date. Upon receipt of a transmission, the E-Filing system time-stamps the document and sends the submitter an e-mail notice confirming receipt of the document. The E-Filing system also distributes an e-mail notice that provides access to the document to the NRC's Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to participate in the proceeding, so that the filer need not serve the document on those participants separately. Therefore, applicants and other participants (or their counsel or representative) must apply for and receive a digital ID certificate before adjudicatory documents are filed so that they can obtain access to the documents via the E-Filing system.

A person filing electronically using the NRC's adjudicatory E-Filing system may seek assistance by contacting the NRC's Electronic Filing Help Desk through the "Contact Us" link located on the NRC's Public Web site at <http://www.nrc.gov/site-help/e-submittals.html>, by e-mail to MSHD.Resource@nrc.gov, or by a toll-free call at 1-866-672-7640. The NRC Electronic Filing Help Desk is available between 9 a.m. and 6 p.m., Eastern Time, Monday through Friday, excluding government holidays.

Participants who believe that they have good cause for not submitting documents electronically must file an exemption request, in accordance with 10 CFR 2.302(g), with their initial paper filing stating why there is good cause for not filing electronically and requesting authorization to continue to submit documents in paper format. Such filings must be submitted by: (1) first class mail addressed to the Office of the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, Attention: Rulemaking and Adjudications Staff; or (2) courier, express mail, or expedited delivery service to the Office of the Secretary, 11555 Rockville Pike, Rockville, Maryland, 20852, Attention: Rulemaking and Adjudications Staff. Participants filing adjudicatory documents in this manner are responsible for serving the document on all other participants. Filing is considered complete by first-class mail as of the time of deposit in the mail, or by courier, express mail, or expedited delivery service upon depositing the document with the provider of the service. A presiding officer, having granted an exemption request from using E-Filing, may require a participant or party to use E-Filing if the presiding officer subsequently determines that the reason for granting the exemption from use of E-Filing no longer exists.

Documents submitted in adjudicatory proceedings will appear in the NRC's electronic hearing docket which is available to the public at <https://adams.nrc.gov/ehd>, unless excluded pursuant to an Order of the Commission or the presiding officer. If you do not have an NRC-issued digital ID certificate as described above, click "Cancel" when the link requests certificates and you will be automatically directed to the NRC's electronic hearing dockets where you will be able to access any publicly available documents in a particular hearing docket. Participants are requested not to include personal privacy information, such as social security numbers, home addresses, or personal phone numbers in their filings, unless an NRC regulation or other law requires submission of such information. For example, in some instances, individuals provide

home addresses in order to demonstrate proximity to a facility or site. With respect to copyrighted works, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application, participants are requested not to include copyrighted materials in their submission.

The Commission will issue a notice or order granting or denying a hearing request or intervention petition, designating the issues for any hearing that will be held and designating the Presiding Officer. A notice granting a hearing will be published in the *Federal Register* and served on the parties to the hearing.

If a person (other than Harman) requests a hearing, that person shall set forth with particularity the manner in which his interest is adversely affected by this Confirmatory Order and shall address the criteria set forth in 10 CFR 2.309(d) and (f).

If a hearing is requested by a person whose interest is adversely affected, the Commission will issue an Order designating the time and place of any hearings. If a hearing is held, the issue to be considered at such hearing shall be whether this Confirmatory Order should be sustained.

Pursuant to 10 CFR 2.202(c)(2)(i), any person adversely affected by this Order, may, in addition to demanding a hearing, at the time the answer is filed or sooner, move the presiding officer to set aside the immediate effectiveness of the Order on the ground that the Order, including the need for immediate effectiveness, is not based on adequate evidence but on mere suspicion, unfounded allegations, or error. In the absence of any request for hearing, or written approval of an extension of time in which to request a hearing, the provisions specified in Section V above shall be final thirty (30) calendar days from the date of issuance of this Confirmatory Order without further order or proceedings. If an extension of time for requesting a hearing has been

approved, the provisions specified in Section V shall be final when the extension expires if a hearing request has not been received.

A REQUEST FOR HEARING SHALL NOT STAY THE EFFECTIVENESS OF THIS ORDER.

For the Nuclear Regulatory Commission,

/RA/

Anne T. Boland, Director
Office of Enforcement

Dated this 27th day of September 2018

cc: The State of California