

PART I-LICENSE, INSPECTION, INCIDENT/EVENT, AND ENFORCEMENT HISTORY

1. AMENDMENTS AND PROGRAM CHANGES:

<u>AMENDMENT #</u>	<u>DATE</u>	<u>SUBJECT</u>
Amendment No. 6	1/14/2013	Change in mailing address

2. INSPECTION AND ENFORCEMENT HISTORY:

None

3. INCIDENT/EVENT HISTORY:

None

PART II – INSPECTION DOCUMENTATION

1. ORGANIZATION AND SCOPE OF PROGRAM:

High Energy Devices, LLC (HED) is authorized under NRC Materials License No. 24-26366-01 to possess and distribute licensed material in the manufacture of gas discharge tubes and spark gap arrestors for distribution in accordance with NRC License No. 12-26366-02E. The licensee is a small company with one authorized location of use in Bridgeton, Missouri, and employs three staff members (two of which are authorized to use material). HED primarily uses small amounts of nickel-63 and krypton-85 for spotting gas discharge tubes incident to processing. On average, the licensee ships approximately 100-150 units (only about 1/3 of the units sold contain radioactive material) each month. HED has ceased producing units with cesium-137, but is still authorized for its possession in accordance with the license. The licensee primarily stores material in the form of previously spotted tubes and arrestors. Material is used infrequently; according to the licensee's records, the last time material was used, was two months prior to the time of the inspection. The company's CEO is listed as an authorized user on the license, and performs spotting.

Additionally, the Radiation Safety Officer (RSO) listed on the license is Michael Brower; however, at the time of the inspection, he was no longer employed at HED. On February 28, 2013, the RSO was laid off; however, the licensee failed to appoint an RSO and notify the NRC. The licensee's failure to appoint a new RSO, is a violation of NRC requirements (for more information, see Section 4. below).

2. SCOPE OF INSPECTION:

Inspection Procedure Used: 87125
Focus Areas Evaluated: 3.01-3.07

The inspection consisted of interviews with licensee personnel, review of selected records, and a tour of the manufacturing and distribution facility. This was an inspection of both the byproduct materials license and exempt distribution license for HED. Specifically, the inspector observed: (1) staff demonstrate their procedures for packaging and receiving licensed material; (2) markings on individual units with the

manufacturer's name, type, and activity of radioactive material inside the product; (3) material tracking methods and a staff member perform an inventory crosscheck; (4) procedures for handling radioactive liquids and performing spotting inside the hot lab area; and (5) that survey instruments were calibrated.

A staff member demonstrated how surveys were conducted in the hot lab after each use, and provided records of end-of-the-day surveys for that area. After tubes have been spotted with radioactive liquid and allowed time to dry, the material is stored in locked cabinets designated for its storage until it is processed in the production area. After the tubes have been processed, the licensee stores them in a designated, fenced in storage area. The inspector reviewed a utilization log maintained by the licensee and used each time material is taken out of the storage area and returned. All storage locations are locked at all times.

The inspector reviewed dosimetry records and the licensee's evaluation to discontinue the issuance of personal monitoring badges. The last monitoring period captured in a dosimetry report was from April 10 to May 9, 2011; the maximum whole body (TEDE) and extremity (SDE) exposures in this last report were "minimal."

Additionally, the inspector reviewed the licensee's monthly survey and wipe test records; however, the licensee's staff did not adhere to their approved procedure in accordance with the license application dated June 27, 2012. This item is discussed in greater detail in Section 4, below. As part of the review of the exempt distribution license, the inspector also discovered that the licensee failed to file an annual report of byproduct material transfers required by Title 10 of the Code of Federal Regulations (CFR) 32.16. The licensee had failed to file the reports for 2008 through 2012. This item is discussed in greater detail in Section 4 below.

3. INDEPENDENT AND CONFIRMATORY MEASUREMENTS

The inspector performed independent measurements taken with a calibrated survey meter within the licensee's hot lab and radioactive material storage areas. The inspector did not identify any dose rate measurements in excess of background levels.

4. VIOLATIONS, NCVs, AND OTHER SAFETY ISSUES:

- A. Condition 11 of NRC License No. 24-26366-01, Amendment No. 6, states that the Radiation Safety Officer for this license is Michael C. Brower.

Contrary to the above, between March 1 and July 10, 2013, this individual was not the RSO for the license. Specifically, the RSO had been laid off on February 28, 2013; since that time, the licensee had not notified the NRC or submitted an amendment request to appoint a new RSO. The staff's unfamiliarity with NRC requirements was the root cause of the violation. As an immediate corrective action, the licensee requested that their consultant (listed as an RSO on another NRC license in the area) be named the RSO on HED's license and submit an amendment request in order to do so. The amendment request was sent and received on July 10, 2013.

- B. Condition 18 of NRC License No. 24-26366-01 requires, in part, that the licensee conduct its program in accordance with the statements, representations, and procedures contained in specified documents, including the facsimile dated November 1, 2012.

Item 10 of the facsimile states that a survey is conducted on a monthly basis throughout the entire production area.

Contrary to the above, between February 28 and July 10, 2013, the licensee failed to perform monthly surveys throughout the entire production area. Specifically, the last survey and wipe test of the entire production area was conducted on February 27, 2013. The root cause of the violation was the licensee's lack of an RSO and the staff's unfamiliarity with the survey and wipe test procedures. As immediate corrective action, the licensee conducted a survey and wipe test during the on-site inspection. The licensee also submitted an amendment request to name a new RSO. Part of the duties of that individual will be to ensure that the licensee is in compliance with all regulations and license requirements, including survey and wipe test requirements.

- C. Title 10 CFR 32.16(a) requires, in part, that each person licensed under 10 CFR 32.14 maintain records of all transfers of byproduct material and file a report with the Director of the Office of Federal and State Materials and Environment Management Programs (FSME).

Title 10 CFR 32.16(c)(1) requires, in part, that the licensee shall file the report, covering the preceding calendar year, on or before January 31 of each year. In its first report after December 17, 2007, the licensee shall separately include data for transfers in prior years not previously reported to the Commission.

Contrary to the above, from February 1, 2009, until July 10, 2013, the licensee failed to file a report, covering the preceding calendar year, on or before January 31 of each year to the Director of FSME. Specifically, the last byproduct material transfer report was submitted on May 8, 2008, which covered the 2007 transfers; therefore, the licensee failed to file a byproduct material transfer report for Calendar Years 2008 through 2012. The root cause of the violation was the licensee's incomplete understanding of the filing requirements. As an immediate corrective action, the licensee submitted the transfer reports for Calendar Years 2008, 2009, 2010, 2011, and 2012 to the Director of FSME on July 10, 2013.

5. PERSONNEL CONTACTED:

#*Larry Crittenden, CEO
#Sheila Hayes

Individual(s) present at entrance meeting
* Individual(s) present at exit meeting

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