UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE RD. SUITE 210
LISLE, IL 60532-4352
October 29, 2014

EN 50499
NMED 140545 (Closed)

Mr. Larry Crittenden, Chief Executive Officer
High Energy Devices, LLC
26 Hollenberg Court
Bridgeton, MO 63044

SUBJECT: NRC SPECIAL INSPECTION REPORT NOS. 03032563/2014001(DNMS) AND 03033623/2014001(DNMS) AND NOTICE OF VIOLATION – HIGH ENERGY DEVICES, LLC

Dear Mr. Crittenden:

On October 6 through 7, 2014, a U.S. Nuclear Regulatory Commission (NRC) inspector conducted a special inspection at the High Energy Devices, LLC, Bridgeton, Missouri facility, with continued NRC in-office review through October 20, 2014. The purpose of this inspection was to review the circumstances, root and contributing causes, and proposed corrective actions for a krypton-85 gas release event that your staff reported to the NRC on September 30, 2014. The in-office review included receipt and review of information that was unavailable during the onsite inspection, including your calculated maximum dose to a hypothetical individual as a result of a krypton-85 gas release and results of your physical inventory of licensed material. The preliminary findings of the inspection were discussed with you and Joseph Koch, your Radiation Safety Officer, at the conclusion of the on-site inspection and during a final, telephonic exit meeting with Joseph Koch on October 20, 2014. The enclosed report presents the results of this inspection (Enclosure 2).

During this inspection, the NRC staff examined activities conducted under your license related to public health and safety. Additionally, the staff examined your compliance with the Commission's rules and regulations as well as the conditions of your license. Within these areas, the inspection consisted of selected examination of procedures and representative records, observations of activities, and interviews with personnel.

Based on the results of this inspection, the NRC has determined that two Severity Level IV violations of NRC requirements occurred. The violations were evaluated in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's website at http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html. The violations concerned the licensee's failure to: (1) comply with NRC license possession limits; and (2) conduct quarterly physical inventories of sealed gas tubes that contained licensed material as required by the NRC license. The violations are cited in the enclosed Notice of Violation (Notice)(Enclosure 1). The NRC is citing the violations in the Notice because the inspector identified them.

The NRC has concluded that information regarding the reason for the violations, the corrective actions taken and planned to correct the violations and prevent recurrence, and the date when

full compliance was achieved is already adequately addressed on the docket in the enclosed inspection report. 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.

In accordance with Title 10 of the *Code of Federal Regulations* (CFR) 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosures, and your response, if you choose to provide one, will be made available electronically for public inspection in the NRC's Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC's website 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 publicly available without redaction.

Please feel free to contact Robert Gattone of my staff if you have any questions regarding this inspection. Mr. Gattone can be reached at 630-829-9823.

Sincerely,

/RA/

Aaron T. McCraw, Chief
Materials Inspection Branch
Division of Nuclear Materials Safety

Docket Nos. 03032563 and 03033623
License Nos. 24-26366-01 and 24-26366-02E

Enclosures:
1. Notice of Violation
2. IR 03032563/2014001(DNMS) and
   IR 03033623/2014001(DNMS)

cc w/ encls: Joseph Koch, Ph.D., RSO
State of Missouri
State of South Carolina

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Sincerely,

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Aaron T. McCraw, Chief
Materials Inspection Branch
Division of Nuclear Materials Safety

Docket Nos. 03032563 and 03033623
License Nos. 24-26366-01 and 24-26366-02E

Enclosures:
1. Notice of Violation
2. IR 03032563/2014001(DNMS) and
   03033623/2014001(DNMS)

cc w/ encls: Joseph Koch, Ph.D., RSO
State of Missouri
State of South Carolina

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NOTICE OF VIOLATION

High Energy Devices, LLC
Bridgeton, Missouri

License No. 24-26366-01
Docket No. 030-32563

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted October 6 through 7, 2014, with continued in-office review through October 20, 2014, two violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

10 CFR 30.34(c) requires, in part, that each licensee confine his possession and use of byproduct material to the locations and purposes authorized by the license.

1. NRC License 24-26366-01, Amendment 07, (dated August 28, 2013), Subitems 6.C, 7.C, and 8.C authorize the licensee to possess, at any one time, up to 5 millicuries of any chemical form of krypton-85.

   Contrary to the above, on September 26, 2014, the licensee possessed 125 millicuries of krypton-85 gas, a quantity in excess of 5 millicuries.

This is a Severity Level IV violation (Section 6.3.d.).

2. NRC License 24-26366-01, Amendment 07, (dated August 28, 2013), Condition 18 requires, in part, that the licensee shall conduct its program in accordance with the statements and procedures contained in the documents that are listed, including a facsimile dated November 1, 2012. That facsimile states, in part, that a computer program is in place that keeps a daily inventory of all sealed gas tubes that are in the storeroom with a physical inventory done quarterly.

   Contrary to the above, as of October 6, 2014, the licensee had not conducted a physical inventory of sealed gas tubes that contained licensed material since July 10, 2013, a period that exceeds three months – the duration of a calendar quarter.

This is a Severity Level IV violation (Section 6.3.d.).

The NRC has concluded that information regarding the reason for the violations, the corrective actions taken and planned to correct the violations and prevent recurrence, and the date when full compliance was achieved, is already adequately addressed on the docket in the subject inspection report. However, you are required to submit a written statement or explanation pursuant to Title 10 of the *Code of Federal Regulations* (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, Inspection Report Nos. 03032563/2014001(DNMS) and 03033623/2014001 (DNMS)" and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001 with a copy to the Regional Administrator, Region III, within 30 days of the date of the letter transmitting this Notice.

If you choose to respond, your response will be made available electronically for public inspection in the NRC's Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC's website 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 publicly available without redaction.

If you contest this enforcement action, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

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 October 2014.

U.S. Nuclear Regulatory Commission
Region III

Docket Nos.:	030-32563 & 030-33623
License Nos.:	24-26366-01 & 24-26366-02E
Report Nos:	03032563/2014001(DNMS) & 03033623/2014001(DNMS)
Licensee:	High Energy Devices, LLC
Location:	26 Hollenberg Court Bridgeton, Missouri
Dates of Inspection:	October 6 and 7, 2014, with continued in-office review through October 20, 2014
Exit Meeting:	October 20, 2014
Inspector:	Robert G. Gattone, Jr., Senior Health Physicist Materials Inspection Branch
Reviewed By:	Aaron T. McCraw, Chief Materials Inspection Branch Division of Nuclear Materials Safety

EXECUTIVE SUMMARY

High Energy Devices, LLC
Bridgeton, Missouri
Inspection Report Nos. 03032563/2014001(DNMS)
and 03033623/2014001(DNMS)

On October 6 and 7, 2014, an inspector from the U.S. Nuclear Regulatory Commission (NRC) conducted a special inspection, with continued in-office review through October 20, 2014, to review the facts and circumstances associated with a krypton-85 gas release event that High Energy Devices, LLC (the licensee) reported to the NRC on September 30, 2014. The in-office review included receipt and review of information that was unavailable during the onsite inspection, including the licensee's calculated maximum dose to a hypothetical individual as a result of the release event and results of its physical inventory of licensed material.

The inspector determined that the licensee released 125 millicuries of krypton-85 gas from an air effluent stack to the atmosphere. Based on worst-case scenario dose calculations to determine the maximum dose to a hypothetical individual standing on the roof of the building next to the air stack at the point of the krypton-85 gas release to the atmosphere, the hypothetical individual would receive 6 millirem.

The root cause of the release event was that the pressure in the krypton-85 gas cylinder was too low. A contributing factor was that the release event was the first and only time that radioactive gas was used in this process/system (the vacuum furnace). Another contributing factor for the release event was that the licensee did not consider the pressure of the krypton-85 gas that needed to be used in this process for it to be completed successfully. As corrective action to prevent a similar release event, the licensee committed to no longer use radioactive gas in the vacuum furnace.

The inspector identified violations of NRC regulatory requirements involving the licensee's failure to: (1) comply with NRC license possession limits; and (2) conduct quarterly physical inventories of sealed gas tubes that contained licensed material. The licensee implemented corrective actions to prevent similar violations.

REPORT DETAILS

1 Program Scope and Inspection History

NRC License Number 24-26366-01 authorizes the licensee to use cesium-137, nickel-63, and krypton-85 for manufacturing gas discharge tubes. The license also permits possession of those radionuclides incident to distribution of electron tubes to persons exempt from the requirements for a license under Title 10 of the *Code of Federal Regulations* (CFR) Section 30.15, or equivalent provisions of any Agreement State. Such distribution is authorized by NRC License Number 24-26366-02E.

The licensee primarily used small amounts of nickel-63 and krypton-85 for spotting gas discharge tubes incident to processing. The licensee primarily stored material in the form of gas discharge tubes.

On July 10, 2013, the NRC conducted a routine inspection of the licensee, with continued in-office review through July 18, 2013. Based on the results of the inspection, the licensee was cited for three Severity Level IV violations involving the licensee's failure to: (1) have an RSO as required by License Condition 11 of NRC License 24-26366-01; (2) perform monthly surveys and wipe tests as required by License Condition 18 of NRC License 24-26366-01; and (3) file byproduct material transfer reports for calendar year 2008 through 2012 as required by 10 CFR Section Part 32.16(a).

On September 22, 2009, the NRC conducted a routine inspection. Within the scope of the inspection, no violations of NRC regulatory requirements were identified.

2 Sequence of Events and Licensee Investigation

2.1 Inspection Scope

The inspector observed reenactments of the krypton-85 gas release event and interviewed the authorized user (AU), the radiation safety officer (RSO), and the chief engineer (CE) to determine the sequence of events that resulted in the release event. In addition, the inspector reviewed selected licensee records, licensee procedures, and the licensee's compliance with regulatory requirements relative to krypton-85 use.

2.2 Observations and Findings

a. Release Event Details

Prior to the release event, the licensee had ordered low millicurie quantities of krypton-85 for manufacturing discharge tubes for ultimate distribution to persons exempt from the requirements for a license under 10 CFR 30.15, or equivalent provisions of any Agreement State. When the krypton-85 was used for discharge tubes, the licensee purchased it in concentrations of 0.5 microcuries per liter, 5 microcuries per liter, and 10 microcuries per liter. The discharge tubes each contained 0.5 microcuries of krypton-85.

Recently, the licensee planned to use krypton-85 for gas discharge tubes again. In August 2014, the CE corresponded with Nova Gas Technologies, Inc. (NGT) regarding purchase options for krypton-85 gas. The CE advised the AU to order the minimum quantity of krypton-85 gas. The CE assumed that the AU would determine the quantity of krypton-85 to be ordered, and the CE did not think about compliance with the krypton-85 gas possession limits on the NRC license because he requested the AU to order the minimum quantity of krypton-85 gas. In addition, the CE did not consider the pressure of the krypton-85 gas that was to be ordered.

The AU ordered 25 liters of krypton-85 gas with a concentration of 5 millicuries per liter for a total of 125 millicuries. When ordering the material, the AU was focused on the need for krypton-85 for the discharge tubes and, due to oversight, did not consider the NRC license total possession limit of 5 millicuries for krypton-85 in any form. On September 26, 2014, the AU received the package that contained 125 millicuries of krypton-85 gas.

NRC License 24-26366-01, Amendment 07, (dated August 28, 2013), Subitems 6.C, 7.C, and 8.C authorize the licensee to possess, at any one time, up to 5 millicuries of any chemical form of krypton-85. Contrary to that requirement, on September 26, 2014, the licensee possessed 125 millicuries of krypton-85 gas, a quantity in excess of 5 millicuries. As such, the inspector identified a Severity Level IV violation of the license possession limits.

The root cause of the violation was oversight on the part of the AU who ordered the krypton-85 gas. Specifically, the AU was focused on the need for krypton-85 for the discharge tubes and did not consider the NRC license total possession limit of 5 millicuries for krypton-85 in any form. A contributing factor for the violation was the CE not thinking about compliance with the krypton-85 gas possession limits on the NRC license because he requested the AU to order the minimum quantity of krypton-85 gas. Another contributing factor for the violation was that NGT sent the 125 millicuries of krypton-85 gas to the licensee even though the licensee was not authorized to receive it.

On September 26, 2014, the licensee achieved compliance with its license possession limits as a result of the release event. As corrective action to prevent a similar violation, on October 6, 2014, the licensee completed training of all applicable staff including, in part, the need to: (1) compare the type and quantity of radioactive material being ordered with that authorized on the NRC license to ensure compliance with the NRC license possession limits; (2) verify that that the company that will send the ordered material has a current copy of the licensee's NRC license; and (3) compare the packing list with the purchase order upon receipt of the material, and notify the RSO if there is a discrepancy. In addition, the licensee instituted a requirement for individuals who order radioactive material such that those individuals must verify with the RSO that receipt of the radioactive material to be ordered will be in compliance with the license possession limits.

On September 26, 2014, the cylinder containing 125 millicuries of krypton-85 gas was connected to a vacuum furnace. The licensee energized a compressor to

create 18 pounds per square inch (PSI) positive pressure inside of the vacuum furnace for processing; however, the licensee was only able to achieve a 5 PSI pressure because the pressure within the cylinder containing the krypton-85 gas was too low. Because the licensee could not create 18 pounds per square inch (PSI) positive pressure inside of the vacuum furnace for processing, the AU had only two options. One option was to release the krypton-85 gas from the tank to the room, and the other option was to release the gas to the atmosphere through an air effluent stack. The AU chose to release the krypton-85 gas through the air effluent stack to the atmosphere because he thought that it would result in the lowest radiation dose to an individual.

The root cause of the release event was that the pressure in the krypton-85 gas cylinder was too low. A contributing factor was that the release event was the first and only time that radioactive gas was used in the vacuum furnace. Another contributing factor for the release event was that the licensee did not consider the pressure of the krypton-85 gas that needed to be used in this process for it to be completed successfully. As corrective action to prevent a similar release event, the licensee committed to no longer use radioactive gas in the vacuum furnace.

b. Release Event Assessment and Notification

The AU identified the release event on Friday, September 26, 2014, at 4:00 p.m. Central Time. The AU notified the RSO on Monday, September 29, 2014, at approximately 1:00 p.m. Central Time. On September 29, 2014, the RSO assessed the release and noted that the release could have resulted in an intake in excess of one occupational annual limit on intake if an individual had been present for 24 hours; therefore, the RSO notified the NRC Operations Center about the release event by telephone on September 30, 2014, at 2:44 pm Central Time as required by 10 CFR 20.2202(b)(2).

Subsequently, the RSO conducted worst-case scenario dose calculations to determine the maximum dose to a hypothetical individual standing on the roof of the building next to the air stack at the point of the krypton-85 gas release to the atmosphere. Based on the RSO's calculations, the hypothetical individual would receive less than 1 microrem.

NRC staff members conducted independent, worst-case scenario dose calculations to determine the maximum dose to a hypothetical individual standing on the roof of the building next to the air stack at the point of the krypton-85 gas release to the atmosphere. Based on the NRC staff members' calculations, the hypothetical individual would receive 6 millirem; therefore, the maximum dose to a hypothetical individual as a result of the release event was less than the 10 millirem constraint on air emissions referenced in 10 CFR 20.1101(d).

2.3 Conclusions

The licensee implemented corrective actions to prevent future release events. The inspector determined that the licensee's response to and assessment of the release event were adequate. The inspector also determined that the licensee's notification of the release event was timely. A violation of NRC regulatory requirements was identified involving licensee failure to comply with NRC license possession limits. The licensee implemented corrective action to prevent a similar violation.

3 Licensed Material Inventory Control

3.1 Inspection Scope

The inspector reviewed the licensee's means of controlling its licensed material inventory by interviewing the RSO and observing the AU conduct a physical inventory of items containing licensed material that were randomly selected as a sample by the inspector.

3.2 Observations and Findings

The licensee had not conducted a quarterly physical inventory of sealed gas tubes that contained licensed material since July 10, 2013. Based on the inspector's observation of the AU conducting a physical inventory of items containing licensed material that were randomly selected as a sample by the inspector, two of the six selected items could not be immediately accounted for.

NRC License 24-26366-01, Amendment 07, (dated August 28, 2013), Condition 18 requires, in part, that the licensee shall conduct its program in accordance with the statements and procedures contained in the documents that are listed, including a facsimile dated November 1, 2012. Page 3 of that facsimile states, in part, that a computer program is in place that keeps a daily inventory of all sealed gas tubes that are in the storeroom with a physical inventory done quarterly. The licensee's failure to conduct quarterly physical inventories of sealed gas tubes that contained licensed material since July 10, 2013, is a Severity Level IV violation of Condition 18 of NRC License No. 24-26366-01.

The cause of the violation was that the RSO did not have a copy of the facsimile dated November 1, 2012; therefore, he was unaware of the requirement. In addition, the RSO misinterpreted that the byproduct material transfer reports required by 10 CFR 32.16(a) sufficed as physical inventories. During the onsite inspection, the inspector provided a copy of the facsimile to the RSO.

As corrective action, the licensee completed a physical inventory on October 10, 2014; therefore, the licensee achieved compliance with the physical inventory requirement on that date. The two aforementioned items that were not immediately accounted for during the onsite inspection were identified. In addition, the licensee found some discrepancies between its physical inventory database and the completed physical inventory findings. The licensee determined that most of the items associated with the discrepancies were

acquired by the licensee incident to High Energy Devices' purchase of a division from CP Clare in 2001, and they were not properly inventoried at the time of the purchase. The physical inventory also showed that the licensee was well below the NRC license possession limits. The licensee planned to conduct quarterly physical inventories of sealed gas tubes unless and until its planned NRC license amendment request is approved to authorize annual physical inventories of sealed gas tubes.

3.3 Conclusions

A violation of NRC regulatory requirements was identified involving licensee failure to conduct quarterly physical inventories of sealed gas tubes that contained licensed material. The licensee implemented corrective action to prevent a similar violation.

4 Follow-Up of Previously Identified Violations

4.1 Inspection Scope

The inspector reviewed the effectiveness of the licensee's corrective actions taken to prevent violations that were cited as a result of the previous inspection by interviewing selected licensee staff members, including the RSO; reviewing selected records; and observing the AU demonstrate how he had conducted monthly area surveys.

4.2 Observations and Findings

As discussed in Section 1 above, based on the results of the previous inspection, the licensee was cited for three Severity Level IV violations involving the licensee's failure to: (1) have an RSO as required by License Condition 11 of NRC License 24-26366-01; (2) perform monthly surveys and wipe tests as required by License Condition 18 of NRC License 24-26366-01; and (3) file byproduct material transfer reports for calendar year 2008 through 2012 as required by 10 CFR 32.16(a).

During followup of the violation involving the licensee's failure to have an RSO as required by the license, the inspector observed that the licensee's RSO was the same individual whom the licensee appointed as its RSO as short-term corrective action to achieve compliance with NRC License 24-26366-01. In addition, the inspector noted that the licensee made plans to take action to ensure that if the RSO leaves that position, the licensee will notify the NRC and hire a qualified replacement RSO to avoid a lapse of having an RSO that is not authorized on the license. This previous violation is closed.

During followup of the violation involving the licensee's failure to perform monthly surveys and wipe tests as required by the license, the inspector noted that the licensee made the RSO responsible for ensuring that the surveys were conducted as required. The RSO also visited the licensee once per month to verify that the monthly surveys were conducted as required. In addition, the inspector noted that the AU conducted the surveys. The inspector also reviewed selected records of monthly survey results that were obtained since the previous inspection and noted that the results did not indicate poor control of licensed material. In addition, the inspector observed the AU

demonstrate how he had conducted the monthly surveys with survey instruments that were calibrated annually by an authorized firm. This previous violation is closed.

During followup of the violation involving the licensee's failure to file byproduct material transfer reports for calendar years 2008 through 2012 as required by 10 CFR 32.16(a), the inspector interviewed the RSO and reviewed copies of the licensee's byproduct material transfer reports for calendar years 2008 through 2013. In addition, the inspector noted that the RSO had a computer software calendar reminder to help him provide timely byproduct material transfer reports as required; however, the RSO subsequently replaced his operating system software which erased his calendar reminders. The inspector observed the RSO re-make the calendar reminders on his computer to help him provide timely byproduct material transfer reports. This previous violation is closed.

4.3 Conclusions

The inspector determined that the licensee implemented adequate corrective actions to prevent recurrence of the violations that were cited as a result of the previous inspection; therefore, the previous violations are closed.

5 Exit Meeting

At the completion of the on-site inspection, the inspector discussed the preliminary inspection findings in this report with licensee management during an exit meeting. The licensee did not identify any information reviewed during the inspection and proposed for inclusion in this report as proprietary in nature. A final telephonic exit meeting was conducted on October 20, 2014.

Attachment: List of Personnel Contacted
Inspection Procedures Used

LIST OF PERSONNEL CONTACTED

Al Bazerian, Chief Engineer
+Larry Crittenden, Chief Executive Officer and Authorized User
^+Joseph Koch, Ph.D., Radiation Safety Officer

+ Attended the on-site exit meeting October 7, 2014
^ Participated in the telephone exit meeting on October 20, 2014

INSPECTION PROCEDURES USED

87103: Materials Licensees Involved in an Incident or Bankruptcy Filing
87125: Materials Processor/Manufacturer Programs