



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**

REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, ILLINOIS 60532-4352

January 20, 2010

Tom Russo, President
BRK Brands, Inc.
3901 Liberty Street Road
Aurora, IL 60504-8122

**SUBJECT: NRC ROUTINE INSPECTION REPORT NO. 030-32838/09-01(DNMS)
AND NOTICE OF VIOLATION – BRK BRANDS, INC.**

Dear Mr. Russo:

This refers to the inspection conducted on September 16, 2009, at the 3901 Liberty Street Road and 3920 Enterprise Court, Aurora, Illinois, facilities with continued U. S. Nuclear Regulatory Commission (NRC) in-office review through January 5, 2010. The NRC in-office review included receipt and review of information that was unavailable during the onsite inspection including, but not limited to, information about a bankruptcy and results of a facility close-out survey. The inspection findings were discussed with Ed Duran and Mark Dippner of your staff during an exit meeting teleconference on January 5, 2010.

This inspection was an examination of activities conducted under your license as they relate to safety and compliance with the Commission's rules and regulations and with 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 three Severity Level IV violations of the NRC requirements occurred involving the failure to: (1) obtain an NRC license prior to possession and use of americium-241; (2) notify the NRC of a bankruptcy petition involving an entity that listed the licensee as property of the estate; and (3) file reports to the NRC regarding exempt product transfers. 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 are cited in the enclosed Notice of Violation (Notice). The violations are being cited in the Notice because they were identified by the inspector.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. For your consideration and convenience, an excerpt from NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," is enclosed. The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

The violation involving failure to file reports to the NRC regarding exempt product transfers is a repeat violation because it was cited in a Notice of Violation dated December 7, 2004, as a result of the last inspection that was conducted from November 8 through December 7, 2004.

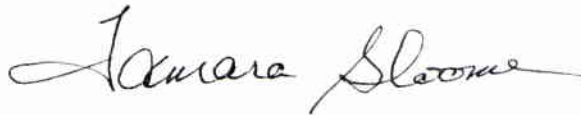
T. Russo

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Therefore, in your response to the repeat violation, discuss why you believe your corrective actions to prevent a similar violation will be more successful than those previously taken.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, it's enclosures, and your response, will be 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 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 available to the Public without redaction.

Sincerely,

A handwritten signature in cursive script that reads "Tamara Bloomer".

Tamara Bloomer, Chief
Materials Inspection Branch

Docket No. 030-32838
License No. 12-23809-01E

Enclosures:

1. Notice of Violation
2. Excerpt from Information Notice 96-28

cc: Mark Dippner, Compliance Engineer

NOTICE OF VIOLATION

BRK Brands, Inc.
Aurora, Illinois

Docket No. 030-32838
License No. 12-23809-01E

During an U.S. Nuclear Regulatory Commission (NRC) inspection conducted on September 16, 2009, three violations of the NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

1. 10 CFR 32.29(c) requires, in part, that the licensee file a report to the NRC that includes specific information about products that were transferred to persons exempt from the requirements for a license. It also requires that the licensee file the report, covering the preceding calendar year, on or before January 31 of each year, and that in its first report after December 17, 2007, the licensee separately include data for transfers in prior years not previously reported to the Commission.

Contrary to the above, from approximately July 22, 2002, to September 16, 2009, the licensee failed to file a report to the NRC that included specific information about products that were transferred to persons exempt from the requirements for a license.

This is a Severity Level IV violation (Supplement VI).

2. 10 CFR 30.34(c) requires, in part, that each licensee confine its possession and use of byproduct materials to the locations and purposes authorized by the license.

Items 6, 7, and 9 of the NRC License No. 12-23809-01E authorize the licensee to distribute specific smoke detector devices containing americium-241 to persons exempt from the requirements for a license. Condition 11 of the license does not authorize the licensee to possess or use licensed material.

Contrary to the above, from approximately July 2004 through December 2006, the licensee possessed several smoke detector devices each containing approximately 1 microcurie of americium-241 at 303 Nelson Avenue, Neosho, Missouri, without an NRC license authorizing possession or use of americium-241 at that location.

This is a Severity Level IV violation (Supplement VI).

3. 10 CFR 30.34(h) requires, in part, that each specific licensee notify the appropriate NRC Regional Administrator, in writing, immediately following the filing of a voluntary or involuntary petition for bankruptcy under any Chapter of Title 11 (Bankruptcy) of the United States Code by or against the licensee.

Contrary to the above, on February 6, 2001, American Household, Inc. filed a petition for bankruptcy under Chapter 11 of Title 11 (Bankruptcy) of the United States Code and the licensee, which was a subsidiary debtor and part of the bankruptcy, failed to

notify the appropriate NRC Regional Administrator in writing immediately after it filed for bankruptcy.

This is a Severity Level IV violation (Supplement VI).

Pursuant to the provisions of 10 CFR 2.201, BRK Brands, Inc. is hereby required to submit a written statement or explanation 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 of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation or severity level; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken to avoid further violations; and (4) the date when full compliance will be achieved. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

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, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

Because your response 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 website at <http://www.nrc.gov/reading-rm/adams.html>, to the extent possible, it should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such material, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). If safeguards information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21.

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days.

Dated this 20th day of January 2010

NOTE: The following information is an updated excerpt from an NRC Information Notice (96-28) issued in 1996.

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 nor written response is required.

Background

On June 30, 1995, NRC revised its Enforcement Policy (NUREG-1600)¹ 60 FR 34381, 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.

¹Copies of NUREG-1600 can be obtained by calling the contacts listed at the end of the Information Notice.

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 an auditable record 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?

This information notice requires no specific action nor written response. If you have any questions about the information in this notice, please contact one of the technical contacts listed below.

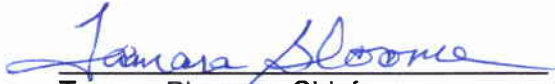
Michael F. Weber, Director
Division of Fuel Cycle Safety and Safeguards
Office of Nuclear Material Safety
and Safeguards

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

Technical contacts: (Updated as of September 30, 2002)

Sally Merchant, Office of Enforcement

Approved


Tammy Bloomer, Chief
Materials Inspection Branch

Date

1/15/00

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

1. AMENDMENTS AND PROGRAM CHANGES:
(License amendments issued since last inspection, or program changes noted in the license)

<u>AMENDMENT #</u>	<u>DATE</u>	<u>SUBJECT</u>
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None

2. INSPECTION AND ENFORCEMENT HISTORY:
(Unresolved issues; previous and repeat violations; Confirmatory Action Letters; and orders)

A Severity Level IV violation of 10 CFR 32.29 (c) was cited as a result of the last inspection. At that time, 10 CFR 32.29 (c) required, in part, that the licensee file a report with the Director of Nuclear Material Safety and Safeguards, U.S. NRC, regarding products transferred to other persons for use under 10 CFR 30.20 or equivalent regulations of an Agreement State within 30 days following five years after filing the previous report or filing an application for renewal of the license under 10 CFR 30.37. Contrary to the above, the licensee failed to file the required report within 30 days following the date that they filed for renewal of the license on July 22, 2002, and the licensee failed to file a report within the previous five years. As corrective action, the licensee committed to issue the required report within 30 days and provide the required five-year report annually in order to ensure that the report is filed appropriately in the future.

No violations were identified during the previous inspection that was conducted on August 31, 1994.

3. INCIDENT/EVENT HISTORY:
(List any incidents, or events reported to NRC since the last inspection. Citing "None" indicates that regional event logs, event files, and the licensing file have no evidence of any incidents or events since the last inspection.)

None

PART II - INSPECTION DOCUMENTATION

1. ORGANIZATION AND SCOPE OF PROGRAM:
(Management organizational structure; authorized locations of use, including field offices and temporary job sites; type, quantity, and frequency of material use; staff size; delegation of authority)

Tom Russo, President
Joe DeLucca, Vice President, New Production Development
Ed Duran, Quality Manager
Vince Mori, RSO
Mike Swieboda, Director of Product Development
Mark Dippner, Compliance Engineer

Note: Mark Dippner replaced Vince Mori on or about September 18, 2009; however, Mark kept his position as Compliance Engineer.

The licensee only conducted research and development, marketing and sales at the 3901 Liberty Street Road, Aurora, Illinois facility. Exempt distribution from the 3920 Enterprise Court, Aurora, Illinois facility was discontinued in 2005. The inspector observed that IEMA License No. IL-01835-01 authorized the licensee to possess and use licensed material at the 3901 Liberty Street Road, Aurora, Illinois facility. The inspector observed that Texas License No. L03725 authorized the licensee to possess and use licensed material at the 25 Spur Drive, El Paso, Texas facility. The licensee conducted exempt distribution activities as authorized. About 10 million devices were distributed per year worldwide. The licensee distributed about 8 million devices per year domestically.

2. SCOPE OF INSPECTION:

(Identify the inspection procedure(s) used and focus areas evaluated. If records were reviewed, indicate the type of record and time periods reviewed)

Inspection Procedure(s) Used: 87126

Focus Areas Evaluated: 03.03, 03.06, and 03.07

3. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:

(Areas surveyed, both restricted and unrestricted, and measurements made; comparison of data with licensee's results and regulations; and instrument type and calibration date)

N/A: The license does not authorize possession or use of licensed material.

4. VIOLATIONS, NCVs, AND OTHER SAFETY ISSUES:

(State the requirement, how and when the licensee violated the requirement, and the licensee's proposed corrective action plan. For NCVs, indicate why the violation was not cited. Attach copies of all licensee documents needed to support violations.)

1. 10 CFR 32.29(c) requires, in part, that the licensee file a report to the NRC that includes specific information about products that were transferred to persons exempt from the requirements for a license. It also requires that the licensee file the report, covering the preceding calendar year, on or before January 31 of each year, and that in its first report after December 17, 2007, the licensee separately include data for transfers in prior years not previously reported to the Commission.

Contrary to the above, from approximately July 22, 2002, to September 16, 2009, the licensee failed to file a report to the NRC that included specific information about

products that were transferred to persons exempt from the requirements for a license.

The violation was caused by staff oversight to ensure that corrective actions for the previous violation (identified during the last inspection) were completed. In addition, the licensee was unaware that the applicable regulation was revised since the last inspection which changed the reporting requirements to annually. As immediate corrective action, the licensee submitted the required information to the required location by letter dated October 22, 2009. As long term corrective action, the licensee planned to incorporate the need to provide the required reports at the required frequency into a Standard Operating Procedure as a means of reminding applicable staff to achieve long-term compliance.

2. 10 CFR 30.34(c) requires, in part, that each licensee confine his possession and use of byproduct materials to the locations and purposes authorized by the license.

Items 6, 7, and 9 of NRC License No. 12-23809-01E authorizes the licensee to distribute specific smoke detector devices containing americium-241 to persons exempt from the requirements for a license. Condition 11 of the license does not authorize the licensee to possess or use licensed material.

Contrary to the above, from approximately July 2004 through December 2006, the licensee possessed several smoke detector devices each containing approximately 1 microcurie of americium-241 at 303 Nelson Avenue, Neosho, Missouri, without an NRC license authorizing possession or use of americium-241 at that location.

The violation occurred because licensee staff incorrectly interpreted that NRC License No. 12-23809-01E authorized possession and use of licensed material. As corrective action, the licensee committed to request an amendment to its license to remove the Neosho, MO location. In addition, the licensee committed to write a Standard Operating Procedure (SOP) that informs applicable staff about the need to obtain an NRC license that authorizes possession and use of radioactive material prior to possession and use of such material in NRC jurisdiction.

In response to the inspector's request, the licensee hired a contractor who conducted a closeout survey of the 303 Nelson Avenue, Neosho, Missouri facility on December 29, 2009. Based on the results of the survey, no radioactive material remained at the facility.

3. 10 CFR 30.34(h) requires, in part, that each specific licensee notify the appropriate NRC Regional Administrator, in writing, immediately following the filing of a voluntary or involuntary petition for bankruptcy under any chapter of title 11 (Bankruptcy) of the United States Code by or against the licensee.

Contrary to the above, on February 6, 2001, American Household, Inc. filed a petition for bankruptcy under chapter 11 of title 11 (Bankruptcy) of the United States Code and the licensee, who was a subsidiary debtor and part of the bankruptcy, failed to notify the appropriate NRC Regional Administrator in writing immediately after it filed for bankruptcy.

The licensee did not realize that, since it was a subsidiary debtor of American Household, Inc. and part of the bankruptcy, it was required to notify the NRC. As corrective action, the licensee informed applicable staff regarding applicable NRC regulatory requirements. In addition, the licensee committed to write a "roles and responsibilities" SOP that informs applicable staff about the requirements in 10 CFR 30.34(h).

Note: The inspector consulted the Regional Counsel regarding the violation of 10 CFR 30.34(h).

5. PERSONNEL CONTACTED:

(Identify licensee personnel contacted during the inspection, including those individuals contacted by telephone.)

- ^* Mark Dippner, Compliance Engineer
- ^ Ed Duran, Quality Manager
- #* Vince Mori, previous RSO
- * Mike Swieboda, Director of Product Development

Use the following identification symbols:

- # Individual(s) present at entrance meeting
- * Individual(s) present at on-site, preliminary exit meeting
- ^ Individual(s) participating in telephonic, final exit meeting on January 5, 2009

-END-