



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

January 9, 2019

EA-18-123

Ms. Tiffany Davis  
Chief Operating Officer  
Solis Tek, Incorporated  
853 Sandhill Avenue  
Carson, CA 90746

SUBJECT: U.S. NUCLEAR REGULATORY COMMISSION INVESTIGATION REPORT  
NO. 1-2017-017, INSPECTION REPORT 030-39036/2018-001, SOLIS TEK,  
INCORPORATED

Dear Ms. Davis:

This letter refers to the investigation initiated by the U.S. Nuclear Regulatory Commission's (NRC's) Office of Investigations on June 20, 2017, and the inspection conducted by NRC staff from July 9, 2018, to August 22, 2018. The purpose of the investigation and inspection was to determine whether Solis Tek, Inc. (Solis Tek) was in compliance with regulatory requirements related to Solis Tek's importation and distribution of bulbs containing radioactive material (krypton-85). This investigation and inspection examined activities conducted under your license as they relate to safety and compliance with the Commission's rules and regulations and with the conditions in your license. The inspector discussed the preliminary inspection findings with you at the conclusion of the on-site portion of the inspection.

Based on the information developed during the investigation and inspection, four apparent violations were identified and are being considered for escalated enforcement action in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's Web site at <http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>.

The apparent violations involve: (1) willful failure to obtain an NRC license authorizing distribution of licensed material to unlicensed persons prior to beginning distribution, (2) non-willful failure to obtain an NRC license authorizing distribution of licensed material to unlicensed persons prior to beginning distribution, (3) non-willful failure to receive authorization to import radioactive material into the United States by a general or specific license under the regulations in Title 10 *Code of the Federal Regulations* (10 CFR) Part 110, prior to importing

such material, and (4) non-willful failure to submit a timely annual report for 2017 on or before January 31, 2018, which contained complete and accurate information. The apparent violations, and the basis for those apparent violations, are listed in Enclosure 1.

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

During a January 8, 2019 telephonic exit meeting conducted with you, Mr. Hipolito González, of the NRC, discussed these apparent violations, the significance of the issues, and the need for lasting and effective corrective action.

As discussed with you, the NRC has not made a final determination on this matter; therefore, an enforcement action is not being issued at this time. In addition, please be advised that the characterization of the apparent violations may change as a result of further NRC review.

Before the NRC makes its enforcement decision, we are providing you an opportunity to: (1) respond to the apparent violation(s) addressed in this inspection report within **thirty (30)** days of the date of this letter, (2) request a Pre-decisional Enforcement Conference (PEC), or (3) request Alternative Dispute Resolution (ADR). If you decide to participate in a PEC or pursue ADR, please contact Mr. González at 301-415-5637 within **ten (10)** calendar days of the date of this letter. A PEC or ADR session should be held within **thirty (30)** calendar days of the date of this letter.

If you choose to provide a written response, it should be clearly marked as a "Response to Apparent Violations in NRC Inspection Report 030-39036/2018-001; EA-18-123." The information should include for each apparent violation: (1) the reason for the apparent violation or, if contested, the basis for disputing the apparent violation; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken; and (4) the date when full compliance will be achieved. The guidance in NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," may be useful in preparing your response. You can find the information notice on the NRC website at: <http://www.nrc.gov/reading-rm/doc-collections/gen-comm/info-notice/1996/in96028.html>. Your response may reference or include previously docketed correspondence, if the correspondence adequately addresses the required response. If an adequate response is not received within the time specified or an extension of time has not been granted, the NRC will proceed with its enforcement decision or schedule a PEC.

If you choose a PEC, the conference will afford you the opportunity to provide your perspective on these matters and any other information that you believe the NRC should take into consideration before making an enforcement decision. The decision to hold a PEC does not mean that the NRC has determined that a violation has occurred or that enforcement action will be taken. This conference would be conducted to obtain information to assist the NRC in making an enforcement decision. The topics discussed during the conference may include information to determine whether a violation occurred, information to determine the significance of a violation, information related to identification of a violation, and information related to any corrective actions taken or planned. In presenting your corrective action, you should be aware that the promptness and comprehensiveness of your actions will be considered in assessing

any civil penalty for the apparent violations. The guidance in the NRC Information Notice 96-28, referenced above, may also be helpful.

If a PEC is held, since information related to an Office of Investigations report will be discussed and the report has not been made public, this conference will be closed to public observation. The NRC may issue a meeting notice and/or press release to announce the time and date of this closed conference.

In lieu of a PEC or written response, you may request ADR with the NRC in an attempt to resolve this issue. ADR is a general term encompassing various techniques for resolving conflicts using a neutral third party. The technique that the NRC has decided to employ is mediation. Mediation is a voluntary, informal process in which a trained neutral third party (the "mediator") works with parties to help them reach resolution. If the parties agree to use ADR, they select a mutually agreeable neutral mediator who has no stake in the outcome and no power to make decisions. Mediation gives parties an opportunity to discuss issues, clear up misunderstandings, be creative, find areas of agreement, and reach a final resolution of the issues. Additional information concerning the NRC's program can be obtained at <http://www.nrc.gov/about-nrc/regulatory/enforcement/adr.html>. The Institute on Conflict Resolution (ICR) at Cornell University has agreed to facilitate the NRC's program as a neutral third party. Please contact ICR at (877) 733-9415 within **ten (10)** calendar days of the date of this letter if you are interested in pursuing resolution of this issue through ADR. If you choose to request ADR, the ADR will be closed to the public; however, the NRC may issue a meeting notice and/or press release to announce the time and date of this closed conference.

If you do not contact us regarding your participation in either a PEC or request ADR within the time specified above, nor submit a written response within the time specified above, and the NRC has not granted an extension of the contact time, we will make an enforcement decision based on available information.

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

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosure(s), and your response, if you choose to provide one, will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System, accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction. Any information forwarded to NRC should be clearly labeled on the first page with the case reference number: EA-18-123, and should be sent to the NRC's Document Control Center (Ref: 10 CFR 30.6 Communications, <https://www.nrc.gov/reading-rm/doc-collection3s/cfr/part030/part030-0006.html>), with a copy mailed to Andrea Kock, 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.

Should you have any questions, please contact Mr. Hipolito González, of my staff at (301) 415-5637.

Sincerely,

***/RA Kevin Williams for/***

Andrea Kock, Director  
Division of Materials Safety, Security, State  
and Tribal Programs  
Office of Nuclear Material Safety  
and Safeguards

Enclosures:

1. Apparent Violations Being Considered  
for Escalated Enforcement
2. Inspection Report 030-39036/2018-001
3. Factual Summary of Office of  
Investigations Report 1-2017-017
4. NRC Information Notice 96-28

SUBJECT: U.S. NUCLEAR REGULATORY COMMISSION INVESTIGATION REPORT  
 NO. 1-2017-017, INSPECTION REPORT 030-39036/2018-001, SOLIS TEK, INCORPORATED  
 DATE: January 9, 2019

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OFC	NMSS/MSST	NMSS/MSST/BC	RIV/DNMS	RIV/DNMS/BC	RIV/DNMS	NMSS/MSST (prior to OE)
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DATE	9/26/18	9/27/18	9/20/18	9/27/18	10/16/18	10/3/18
OFC	NMSS/EC	OE	OGC	NMSS/MSST/D		
NAME	MBurgess	SWoods for JPeralta	KGamin	KWilliams for AKock		
DATE	11/02/18	12/21 /18	12/21/18	1/9/19		

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## **APPARENT VIOLATIONS BEING CONSIDERED FOR ESCALATED ENFORCEMENT**

### **Apparent Violation 1:**

Title 10 of the *Code of Federal Regulations* (10 CFR) section 30.3(a), "Activities requiring license" states, in part, that "no person shall manufacture, produce, transfer, receive, acquire, own, possess, or use byproduct material except as authorized in a specific or general license issued in accordance with the regulations in this chapter."

10 CFR § 30.15(a)(8)(iv), states, in part, that there is an exemption to the requirement for a license in 10 CFR § 30.3(a) for persons who receive, possess, use, transfer, own or acquire electron tubes containing not more than specified quantities of byproduct material. However, the exemption in 10 CFR § 30.15(a) excludes "persons ... who initially transfer for sale or distribution" such electron tubes.

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

Contrary to the above, Solis Tek willfully distributed material to unlicensed persons without an NRC license to distribute. Specifically, from February 24, 2017 through June 12, 2017, Solis Tek willfully transferred for sale or distribution from the New Jersey location, approximately 1785 Kr-85 bulbs containing byproduct material to unlicensed persons without obtaining a specific license pursuant to 10 CFR § 32.14 authorizing such transfers.

### **Apparent Violation 2:**

10 CFR § 30.3(a), "Activities requiring license" provides, in part, that "no person shall manufacture, produce, transfer, receive, acquire, own, possess, or use byproduct material except as authorized in a specific or general license issued in accordance with the regulations in this chapter."

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

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

Contrary to the above, Solis Tek distributed material to unlicensed persons without obtaining a specific license pursuant to 10 CFR § 32.14 authorizing such transfers. Specifically, from January 2014 through February 5, 2018, Solis Tek initially transferred for sale or distribution from the Keegan Avenue, Carson, CA location, approximately 80,000 Kr-85 bulbs containing byproduct material to unlicensed persons without obtaining a specific license pursuant to 10 CFR § 32.14 authorizing such transfers. In addition, from November 2014 through

February 23, 2017, Solis Tek initially transferred for sale or distribution from the NJ location, approximately 11,913 Kr-85 bulbs containing byproduct material to unlicensed persons without obtaining a specific license pursuant to 10 CFR § 32.14 authorizing such transfers.

### **Apparent Violation 3:**

10 CFR § 110.5 states, in part, that no person may export any nuclear equipment or material listed in 10 CFR § 110.8 and 10 CFR § 110.9, or import any nuclear equipment or material listed in 10 CFR § 110.9a, unless authorized by a general or specific license issued under 10 CFR Part 110.

10 CFR § 110.9a(d) provides, in part, a list of nuclear equipment and material under NRC import licensing authority, includes byproduct material (i.e. krypton-85).

10 CFR § 110.20(a) states, in part, that a person may use an NRC general license as authority to export or import nuclear equipment or material, if the nuclear equipment or material to be exported or imported is covered by the NRC general licenses described in 10 CFR § 110.21 through 10 CFR § 110.27. If an export or import is not covered by the NRC general licenses described in 10 CFR § 110.21 through 10 CFR § 110.27, a person must file an application with the Commission for a specific license in accordance with 10 CFR § 110.31 through 10 CFR § 110.32.

10 CFR § 110.27(a) states, in part, that except as provided in 10 CFR § 110.27(b) and 10 CFR § 110.27(c), a general license is issued to any person to import byproduct, source, or special nuclear material if the U.S. consignee is authorized to receive and possess the material under the relevant NRC or Agreement State regulations.

Contrary to the above, Solis Tek imported byproduct material into the United States without being authorized by a general or specific license issued under the regulations in 10 CFR Part 110. Specifically, on November 21, 2014, Solis Tek imported approximately 1804 bulbs, and on January 28, 2015 imported approximately 5028 bulbs, containing Kr-85, manufactured by Zhuhai Relite Tech Co., Ltd. in China, to their NJ location without having a possession license issued by the NRC or an Agreement State for that location, or without first obtaining a specific import license from the NRC. In addition, on approximately 38 occasions from January 8, 2014, to October 6, 2017, the licensee imported a total of approximately 82,885 bulbs containing Kr-85, manufactured by Zhuhai Relite Tech Co., Ltd. in China, to their Keegan Avenue, Carson, CA location without having a possession license issued by the NRC or an Agreement State for that location, or without first obtaining a specific import license from the NRC.

### **Apparent Violation 4:**

10 CFR § 32.16(a) and (c)(1) require, in part, that each person licensed shall maintain records of all transfers of byproduct material and shall file a report, covering the preceding calendar year, on or before January 31 of each year.

10 CFR § 32.16(a) and (b) require, in part that the report: (a)(1) must include the license number; (a)(2) must indicate that products are transferred for use under 10 CFR § 30.15, giving the specific paragraph designation; and (b)(2) must include for each radionuclide in each type of product and each model number, if applicable, the total quantity of the radionuclide.

Contrary to the above, Solis Tek failed to submit annual reports for 2017 on or before January 31 of the following year. In addition, the licensee's report, which was filed on June 15, 2018, failed to include the following required information: (1) that the products were transferred for use under 10 CFR § 30.15 giving the specific paragraph designation; and (2) the radionuclide in each type of product and each model number; and the total quantity of the radionuclide.



**Inspection Report 030-39036/2018-001**

**Factual Summary  
Office of Investigations  
OI Report 1-2017-017**

On June 20, 2017, the U.S. Nuclear Regulatory Commission (NRC), Office of Investigations (OI), Region I, initiated an investigation to determine whether Solis Tek willfully distributed grow lamps containing Kr-85 without authorization. The investigation was completed on June 28, 2018, and documented in OI Report 1-2017-017.

The OI investigation revealed that a Solis Tek manager was informed multiple times from March 2015 through February 2017 by a representative from the New Jersey Bureau of Environmental Protection that an NRC distribution license was required, including an electronic mail in February 2017 stating that Solis Tek should immediately cease distribution of the Kr-85 light bulbs. Additional electronic mailings to the manager from U.S. Nuclear Regulatory Commission (NRC) representatives in February and March 2017 identified the need for the NRC distribution license and included statements that Solis Tek was not permitted to distribute any licensable products before obtaining an NRC distribution license. On February 24, 2017, Solis Tek applied for an NRC exempt-distribution license. The NRC license for the NJ location was issued on July 20, 2017. However, Solis Tek continued to distribute the Kr-85 lamps during the months February through June 2017, i.e., before the license was issued.

The manager admitted that, after receiving the notifications from New Jersey and NRC representatives, the choice was not to immediately stop distribution in order to provide a period of time to inform Solis Tek's customers that shipments were going to stop.

Based on the evidence obtained during the OI investigation, it appears that the Solis Tek manager deliberately continued to distribute the Kr-85 bulbs after being informed that an NRC distribution license was required. Specifically, the involved manager appears to have violated 10 CFR § 30.10, causing Solis Tek to be in apparent violation of 10 CFR § 30.3(a) and § 30.15(b) when the manager continued to deliberately ship Kr-85 bulbs from February through June 2017 while aware that Solis Tek did not have the required NRC exempt distribution license.

# **NRC INFORMATION NOTICE 96-28**

UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS  
WASHINGTON, D.C. 20555

May 1, 1996

NRC INFORMATION NOTICE 96-28:      SUGGESTED GUIDANCE RELATING TO  
DEVELOPMENT AND IMPLEMENTATION OF  
CORRECTIVE ACTION

## Addressees

All material and fuel cycle licensees.

## Purpose

The U.S. Nuclear Regulatory Commission (NRC) is issuing this information notice to provide addressees with guidance relating to development and implementation of corrective actions that should be considered after identification of violation(s) of NRC requirements. It is expected that recipients will review this information for applicability to their facilities and consider actions, as appropriate, to avoid similar problems. However, suggestions contained in this information notice are not new NRC requirements; therefore, no specific action or written response is required.

## Background

On June 30, 1995, NRC revised its Enforcement Policy, to clarify the enforcement program's focus by, in part, emphasizing the importance of identifying problems before events occur, and of taking prompt, comprehensive corrective action when problems are identified. Consistent with the revised Enforcement Policy, NRC encourages and expects identification and prompt, comprehensive correction of violations.

In many cases, licensees who identify and promptly correct non-recurring Severity Level IV violations, without NRC involvement, will not be subject to formal enforcement action. Such violations will be characterized as "non-cited" violations as provided in Section VI.A of the Enforcement Policy. Minor violations are not subject to formal enforcement action. Nevertheless, the root cause(s) of minor violations must be identified and appropriate corrective action must be taken to prevent recurrence.

If violations of more than a minor concern are identified by the NRC during an inspection, licensees will be subject to a Notice of Violation and may need to provide a written response, as required by 10 CFR 2.201, addressing the causes of the violations and corrective actions taken to prevent recurrence.

In some cases, such violations are documented on Form 591 (for materials licensees) which constitutes a notice of violation that requires corrective action but does not require a written response. If a significant violation is involved, a predecisional enforcement conference may be held to discuss those actions.

The quality of a licensee's root cause analysis and plans for corrective actions may affect the NRC's decision regarding both the need to hold a predecisional enforcement conference with the licensee and the level of sanction proposed or imposed.

### Discussion

Comprehensive corrective action is required for all violations. In most cases, NRC does not propose imposition of a civil penalty where the licensee promptly identifies and comprehensively corrects violations. However, a Severity Level III violation will almost always result in a civil penalty if a licensee does not take prompt and comprehensive corrective actions to address the violation.

It is important for licensees, upon identification of a violation, to take the necessary corrective action to address the noncompliant condition and to prevent recurrence of the violation and the occurrence of similar violations. Prompt comprehensive action to improve safety is not only in the public interest, but is also in the interest of licensees and their employees. In addition, it will lessen the likelihood of receiving a civil penalty. Comprehensive corrective action cannot be developed without a full understanding of the root causes of the violation.

Therefore, to assist licensees, the NRC staff has prepared the following guidance, that may be used for developing and implementing corrective action. Corrective action should be appropriately comprehensive to not only prevent recurrence of the violation at issue, but also to prevent occurrence of similar violations. The guidance should help in focusing corrective actions broadly to the general area of concern rather than narrowly to the specific violations. The actions that need to be taken are dependent on the facts and circumstances of the particular case.

The corrective action process should involve the following three steps:

1. Conduct a complete and thorough review of the circumstances that led to the violation.  
Typically, such reviews include:

Interviews with individuals who are either directly or indirectly involved in the violation, including management personnel and those responsible for training or procedure development/guidance. Particular attention should be paid to lines of communication between supervisors and workers.

Tours and observations of the area where the violation occurred, particularly when those reviewing the incident do not have day-to-day contact with the operation under review. During the tour, individuals should look for items that may have contributed to the violation as well as those items that may result in future violations. Reenactments (without use of radiation sources, if they were involved in the original incident) may be warranted to better understand what actually occurred.

Review of programs, procedures, audits, and records that relate directly or indirectly to the violation. The program should be reviewed to ensure that its overall objectives and requirements are clearly stated and implemented. Procedures should be reviewed to determine whether they are complete, logical, understandable, and meet their objectives (i.e., they should ensure compliance with the **current** requirements). Records should be reviewed to determine whether there is sufficient documentation of necessary tasks to provide a record that can be audited and to determine whether similar violations have occurred previously. Particular attention should be paid to training and qualification records of individuals involved with the violation.

2. Identify the root cause of the violation.

Corrective action is not comprehensive unless it addresses the root cause(s) of the violation. It is essential, therefore, that the root cause(s) of a violation be identified so that appropriate action can be taken to prevent further noncompliance in this area, as well as other potentially affected areas. Violations typically have direct and indirect cause(s). As each cause is identified, ask what other factors could have contributed to the cause. When it is no longer possible to identify other contributing factors, the root causes probably have been identified. For example, the direct cause of a violation may be a failure to follow procedures; the indirect causes may be inadequate training, lack of attention to detail, and inadequate time to carry out an activity. These factors may have been caused by a lack of staff resources that, in turn, are indicative of lack of management support. Each of these factors must be addressed before corrective action is considered to be comprehensive.

3. Take prompt and comprehensive corrective action that will address the immediate concerns **and** prevent recurrence of the violation.

It is important to take immediate corrective action to address the specific findings of the violation. For example, if the violation was issued because radioactive material was found in an unrestricted area, **immediate** corrective action must be taken to place the material under licensee control in authorized locations. After the immediate safety concerns have been addressed, timely action must be taken to prevent future recurrence of the violation. Corrective action is sufficiently comprehensive when corrective action is broad enough to reasonably prevent recurrence of the specific violation as well as prevent similar violations.

In evaluating the root causes of a violation and developing effective corrective action, consider the following:

1. Has management been informed of the violation(s)?
2. Have the programmatic implications of the cited violation(s) and the potential presence of similar weaknesses in other program areas been considered in formulating corrective actions so that both areas are adequately addressed?
3. Have precursor events been considered and factored into the corrective actions?
4. In the event of loss of radioactive material, should security of radioactive material be enhanced?
5. Has your staff been adequately trained on the applicable requirements?
6. Should personnel be re-tested to determine whether re-training should be emphasized for a given area? Is testing adequate to ensure understanding of requirements and procedures?

7. Has your staff been notified of the violation and of the applicable corrective action?
8. Are audits sufficiently detailed and frequently performed? Should the frequency of periodic audits be increased?
9. Is there a need for retaining an independent technical consultant to audit the area of concern or revise your procedures?
10. Are the procedures consistent with current NRC requirements, should they be clarified, or should new procedures be developed?
11. Is a system in place for keeping abreast of new or modified NRC requirements?
12. Does your staff appreciate the need to consider safety in approaching daily assignments?
13. Are resources adequate to perform, and maintain control over, the licensed activities? Has the radiation safety officer been provided sufficient time and resources to perform his or her oversight duties?
14. Have work hours affected the employees' ability to safely perform the job?
15. Should organizational changes be made (e.g., changing the reporting relationship of the radiation safety officer to provide increased independence)?
16. Are management and the radiation safety officer adequately involved in oversight and implementation of the licensed activities? Do supervisors adequately observe new employees and difficult, unique, or new operations?
17. Has management established a work environment that encourages employees to raise safety and compliance concerns?
18. Has management placed a premium on production over compliance and safety? Does management demonstrate a commitment to compliance and safety?
19. Has management communicated its expectations for safety and compliance?
20. Is there a published discipline policy for safety violations, and are employees aware of it? Is it being followed?