

January 20, 2012

Ali Regimand, President  
InstroTek/CPN International, Inc.  
5908 Triangle Drive  
Raleigh, NC 27617

SUBJECT: U.S. NUCLEAR REGULATORY COMMISSION INVESTIGATION REPORT  
NO.4-2010-058, CPN INTERNATIONAL, INC. EA-11-242

Dear Mr. Ali Regimand:

This letter refers to the investigation conducted by the U.S. Nuclear Regulatory Commission's (NRC) Office of Investigations (OI), from June 7, 2010 until September 23, 2011, at the InstroTek/CPN International facility in Concord, CA. The purpose of the investigation was to evaluate CPN's export of NRC regulated materials to embargoed destinations on multiple occasions.

This investigation examined activities conducted under NRC regulations, as they relate to safety, security, and compliance with the Commission's rules and regulations. Within these areas, the investigation consisted of a selected examination of procedures and representative records, observations of activities, and interviews with personnel.

Based on the results of this investigation, two apparent violations were identified and are collectively 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) three instances of a failure to obtain an NRC specific license prior to exporting moisture density gauges containing byproduct material (i.e. americium-241) to embargoed destinations; and (2) ten instances of failing to provide required annual reports of americium-241 exports under general license. The failure to obtain appropriate license authorization to export byproduct material and the failure to submit required annual reports are significant because they resulted in security concerns related to radioactive materials being sent to countries of concern, as well as impacting the NRC's ability to fulfill its regulatory responsibilities to ensure the safety and security of the general public.

The basis for these apparent violations is discussed in Enclosure 1. These apparent violations were discussed with you on January 19, 2012.

Since the NRC has not made a final determination in this matter, a Notice of Violation 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. You will be advised by separate correspondence of the results of our deliberations on this matter.

You should be aware that Section 2.3.4 of the NRC Enforcement Policy states that for violations involving the loss, abandonment, or improper transfer or disposal of a sealed source or device, the NRC should normally exercise discretion when proposing the imposition of a civil penalty of at least the base amount. Since the apparent violation involves the improper transfer of 1.85 GBq of Am-241 in a moisture density tester, the NRC is considering proposing imposition of a civil monetary penalty.

Before the NRC makes its enforcement decision, we are providing you an opportunity to: (1) respond to the apparent violations addressed in Enclosure 1 within 30 days of the date of this letter; or (2) request a Pre-decisional Enforcement Conference (PEC). If a PEC is held, it will be open for public observation and the NRC will issue a press release to announce the time and date of the conference. If you decide to participate in a PEC, please contact Brian Wittick at 301-415-2496 within 10 days of the date of this letter. A PEC should be held within 30 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 EA-11-242" and should be addressed to: The U.S. Nuclear Regulatory Commission, Office of International Programs, Export Control and International Operations Branch, Washington, DC 20555, Attn: Mr. Scott Moore. Your response 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 to avoid further violations; and (4) the date when full compliance will be achieved. In presenting your corrective actions, you should be aware that the promptness and comprehensiveness of your actions will be considered in assessing any civil penalty for the apparent violation. The guidance in the enclosed excerpt from NRC Information Notice 96-28, "SUGGESTED GUIDANCE RELATING TO DEVELOPMENT AND IMPLEMENTATION OF CORRECTIVE ACTION," may be helpful. 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 by the NRC, the NRC will proceed with its enforcement decision or schedule a predecisional enforcement conference.

If you choose to request a PEC, the conference will afford you the opportunity to provide your perspective on the apparent violation and any other information that you believe the NRC should take into consideration before making an enforcement decision. The topics discussed during the conference may include the following: information to determine whether a violation occurred, information to determine the significance of a violation, information related to the identification of a violation, and information related to any corrective actions taken or planned to be taken. In presenting your corrective actions, you should be aware that the promptness and comprehensiveness of your actions will be considered in assessing any civil penalty for the apparent violation(s).

In addition, please be advised that the number and characterization of apparent violations described in Enclosure 1 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.

If you have any questions concerning this matter, please contact Brian Wittick of my staff at 301-415-2496.

Sincerely,

***/RA/***

Scott W. Moore, Deputy Director  
Office of International Programs

Enclosures:

1. Basis for Apparent Violations
2. NRC Information Notice 96-28

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Sincerely,

*/RA/*

Scott W. Moore, Deputy Director  
Office of International Programs

Enclosures:

1. Basis for Apparent Violations
2. NRC Information Notice 96-28

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See attached page.

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**Letter to InistroTek/CPN International, Inc., dated:            January 20, 2011**

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## **BASIS FOR APPARENT VIOLATIONS**

In May 2010, the NRC became aware of an export by InstroTek/CPN International, Inc. (CPN), of a moisture density tester containing NRC regulated material (americium-241) to the Republic of Sudan, an embargoed destination. CPN had not obtained the required NRC specific license for export of regulated material to an embargoed destination.

On June 7, 2010, the U.S. Nuclear Regulatory Commission's (NRC) Office of Investigations (OI), Field Office Region IV, initiated an investigation to determine whether CPN personnel willfully exported or attempted to export moisture density equipment to NRC embargoed destinations without obtaining the required license from the NRC. These exports involved the following shipments: (1) Invoice No. 31647, dated May 5, 2010 to Sudan; (2) Invoice No. 91533DM, dated November 20, 2008 to Iraq; and (3) Invoice No. 20754DM, dated December 28, 2006 to Sudan.

Based on the investigation and inspections, a violation of NRC regulatory requirements with regard to exports to embargoed destinations that occurred three times and a violation of regulatory requirements with regard to annual reporting of americium-241 exports that occurred ten times were identified. The exports to embargoed destinations included:

- December 28, 2006; export to Juba, Southern Sudan
- November 20, 2008; export to Baghdad, Iraq
- May 5, 2010; export to Khartoum, Republic of Sudan

The failure to submit required annual report for americium exports occurred on February 1, 2001 – February 1, 2010, for exports occurring in the previous calendar year.

### **Statement of Violations**

#### **Apparent Violation 1:**

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

10 CFR 110.9, "List of nuclear equipment and material under NRC export licensing authority," includes byproduct material (i.e. americium-241).

10 CFR 110.20(a) states "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 §§ 110.21 through 110.27. If an export or import is not covered by the NRC general licenses described in §§ 110.21 through 110.27, a person must file an application with the Commission for a specific license in accordance with §§ 110.31 through 110.32."

10 CFR 110.23(a) states, in part, "A general license is issued to any person to export byproduct material (see Appendix L to this part) to any country not listed in § 110.28..."

10 CFR 110.28 identifies Cuba, Iran, Iraq, North Korea, Sudan and Syria as embargoed destinations.

Contrary to the above, on December 28, 2006, November 20, 2008, and May 5, 2010, CPN exported americium 241, a byproduct material subject to NRC licensing jurisdiction, to embargoed destinations (i.e. Sudan, Iraq and Sudan, respectively), without a specific license as required by 10 CFR 110.5.

**Apparent Violation 2:**

10 CFR 110.23(a)(5)(iii) states “All exports of americium are subject to the reporting requirements listed in § 110.54(b).”

10 CFR 110.54(b) states, in part, “Persons making exports under the general license established by § 110.23(a) or under a specific license shall submit by February 1 of each year one copy of a report of all americium and neptunium shipments during the previous calendar year....”

Contrary to the above, CPN failed to make annual reports of americium exports for calendar years 2000 - 2009, during which years americium exports were performed.

# 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?

This information notice requires no specific action or written response. If you have any questions about the information in this notice, please contact one of the technical contacts listed below.

Robert C. Pierson, 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  
Office of Nuclear Material Safety and Safeguards

Technical contacts: (Updated as of November 22, 2005)  
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