



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

November 18, 2020

EA-20-084

CampCo, Inc.  
Smith & Wesson Watch Division  
ATTN: Motti Slodowitz, President  
4625 West Jefferson Blvd.  
Los Angeles, CA 90016

SUBJECT: U.S. NUCLEAR REGULATORY COMMISSION'S INSPECTION REPORT 030-36619/2017-001 AND OFFICE OF INVESTIGATIONS INVESTIGATION REPORT NO. 4-2017-036 - CAMPCO, INC

Dear Mr. Slodowitz:

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 at your facility in Los Angeles, California, on May 11, 2017, with subsequent records review, conducted by NRC staff from May 11, 2017, to September 3, 2020. The purpose of the investigation and inspection was to examine activities conducted under your license and to determine CampCo, Inc. (CampCo) compliance with the Confirmatory Order Modifying License, dated June 20, 2016, issued under Enforcement Action EA-14-080.

Based on the information developed during the investigation, inspection, and subsequent records review, 10 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 can be grouped into four focus areas: (1) repeat failures to comply with the license and regulations, (2) other failures to comply with the license and regulations, (3) failure to provide complete and accurate information to the NRC, and (4) failures to comply with the Confirmatory Order. The apparent violations and relevant details are listed in Enclosure 1.

The repeat apparent violations (from EA-14-080) involving failure to comply with the license and regulations include: (A) distributing watch models not authorized on the license; (B) failure to provide complete and accurate annual reports; and (C) failure to have certificates for each shipment.

Other apparent violations for failure to comply with the license and regulations include: (D) failure to perform quality assurance testing as committed to in the license application; (E) distributing watches containing tritium over the authorized limits; and (F) failure to label timepiece containers as required. The apparent violation for failure to provide complete and accurate information to the NRC involved: (G) CampCo's continued distribution of tritium timepieces after stating to the NRC that all distribution of tritium timepieces had been halted.

The apparent violations involving failure to comply with the Confirmatory Order include: (H) failure to submit initial training material for key employees to the NRC for review and failure to address compliance responsibilities in the revised training materials, and failure to incorporate NRC comments on the document; (I) failure to create written procedures and/or checklists; and (J) failure to incorporate the NRC requested changes to all three articles under items 1 - 3 d in the submission dated February 16, 2017 ([ML17220A340](#)).

The NRC has significant concerns about CampCo's apparent failures to comply with regulatory requirements, the specific conditions of the license, and the Confirmatory Order. The investigation and inspection results indicate inadequate management oversight. These failures, in particular the repeated failures, are significant because compliance with these requirements ensures that the products are safe for distribution to members of the general public. The failure to submit timely and complete required annual reports to NRC, and the failure to provide complete and accurate information to NRC, are significant because they inhibit the process of regulatory oversight.

During a telephonic exit meeting conducted by Mr. Jason Dykert on November 18, 2020, the NRC informed you of the violations, the significance of the issues, and the need for lasting and effective corrective actions. As discussed, the NRC has not made a final determination on this matter; therefore, an enforcement action is not being issued at this time.

Before the NRC makes its enforcement decision, we are providing you an opportunity to: (1) respond in writing to the apparent violations described in the enclosure within **thirty (30)** calendar days of the date of this letter, or (2) request a Pre-decisional Enforcement Conference (PEC). If you decide to participate in a PEC, please contact David Alley at [david.alley@nrc.gov](mailto:david.alley@nrc.gov) or at 301-415-2178 within **fourteen (14)** calendar days of the date of this letter. A PEC session would 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 030-36619/2017-001 and Investigation Report No. 4-2017-036; EA-20-084." 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-notices/1996/in96028.html>. Your response may reference or include previously docketed correspondence, if it adequately addresses the required information. 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 to request 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 actions, you should be aware that the promptness and comprehensiveness of your corrective actions will be considered in assessing any civil penalty for the apparent violations. The guidance in NRC Information Notice 96-28, referenced above, may also be helpful.

If a PEC is held, it will be closed to public observation because information related to an Office of Investigations report will be discussed and the report has not been made public. 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 a PEC within the time specified above, or 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 Title 10 of the *Code of Federal Regulations* (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-20-084", and addressed to the NRC's Document Control Center, with a copy mailed to David Alley, Chief, Material Safety and Tribal Liaison Branch, 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. A courtesy copy may also be sent via email to [david.alley@nrc.gov](mailto:david.alley@nrc.gov).

Should you have any questions, please contact David Alley, of my staff, at [david.alley@nrc.gov](mailto:david.alley@nrc.gov) or at 301-415-2178

Sincerely,

**Kevin Williams**

Digitally signed by Kevin  
Williams  
Date: 2020.11.18 13:25:00  
-05'00'

Kevin Williams, Director  
Division of Materials Safety, Security, State,  
and Tribal Programs  
Office of Nuclear Materials Safety  
and Safeguards

Enclosures:

1. Apparent Violations Being Considered  
for Escalated Enforcement, and Basis for Apparent Violations
2. NRC Information Notice 96-28

SUBJECT: NRC INSPECTION REPORT 030-36619/2017-001 AND OI INVESTIGATION  
REPORT NO. 4-2017-036 - CAMPCO, INC DATED: NOVEMBER 18, 2020

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<b>NAME</b>	SXu Via email	DAlley Via email	JDykert Via email	PSilva Via email	LHowell Via email	KWilliams Via email
<b>DATE</b>	09/21/20	10/20/20	09/21/20	10/14/20	10/27/20	10/23/20
<b>OFC</b>	NMSS/EC	OE	OGC	NMSS/MSST/D		
<b>NAME</b>	MBurgess	JPeralta	RCarpenter	KWilliams		
<b>DATE</b>	10/27/20	11/13/20	11/13/20	11/18/2020		

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## **APPARENT VIOLATIONS BEING CONSIDERED FOR ESCALATED ENFORCEMENT, AND BASIS FOR APPARENT VIOLATIONS**

On May 11, 2017, the U.S. Nuclear Regulatory Commission (NRC) performed an inspection at the licensee's facility in Los Angeles, California, with subsequent records review, conducted by NRC staff from May 11, 2017, to September 3, 2020. On August 17, 2017, the NRC, Office of Investigations (OI), Region IV (RIV), initiated an investigation into the repeat violations.

The purpose of the investigation and inspection was to examine activities conducted under your license and to determine CampCo, Inc. (CampCo or licensee) compliance with the Confirmatory Order Modifying License, dated June 20, 2016, issued under Enforcement Action EA-14-080. Based on the information developed during the investigation, inspection, and subsequent records review, 10 apparent violations were identified.

### **Repeat failures to comply with the license and regulations:**

#### **Apparent Violation A:**

License Condition 10 of Materials License 04-23910-01E, Amendments No. 3 and No. 4, require, in part, that the licensee distribute only the timepiece model numbers that are specifically authorized on the license.

Contrary to the above, from October 8, 2014 through January 23, 2018, the licensee failed to distribute only the timepiece model numbers that were specifically authorized on the license. Specifically, CampCo distributed six tritium timepieces which were not listed in License Condition 10, models: HMV-W-ZT1; SWW-77; SWW-MP18; UZI-18B; UZI-26; and UZI-32.

#### **Basis for Apparent Violation A:**

The onsite inspection at CampCo's facility in Los Angeles, California, on May 11, 2017, identified that two models of timepieces were being distributed that were not specifically listed on the license. The Office of Investigations (OI) identified that four additional models were distributed but not listed on the license.

While Enforcement Action EA-14-080 cited CampCo for distributing timepieces with tritium sources that were not authorized by the license, Apparent Violation A pertains to CampCo's distribution of timepiece models that were not authorized on the license.

Apparent Violation A is repetitive because the violations both involve distributing timepieces not authorized by the license as cited in EA-14-080. CampCo was cited for this violation in 2015 and acknowledged the violation in 2016; however, the licensee continued to distribute timepieces not authorized by the license through January 23, 2018.

#### **Apparent Violation B:**

Title 10 of the *Code of Federal Regulations* (10 CFR) 30.9(a) requires, in part, that information provided to the Commission by a licensee be complete and accurate in all material respects.

10 CFR 32.16 requires, in part, each person licensed under 10 CFR 32.14 shall maintain records of all transfers of byproduct material, and file a report identifying the products transferred which must include identification of each product, the model numbers, and the number of units of each type of product transferred during the reporting period by model number.

Contrary to the above, reports filed by the licensee for calendar years 2010 - 2017 were not complete and accurate in all material respects, and failed to include identification of each product, the model numbers, and the number of units of each type of product transferred during the reporting period by model number. Specifically, the licensee's annual reports did not identify that model numbers: SWW-10 and SWW-32 in 2010; SWW39 and SWW-PRO-OI in 2012; HMV-W-ZT1 in 2013; SWW-MP18 and UZI-18B in 2014, 2015, and 2016; or that UZI-32 in 2017 had been transferred.

Additionally, the annual reports submitted for calendar years 2006 - 2016 have an incorrect activity per model, and incorrect listing of total tritium transferred annually, specifically for timepieces: UZI-001; SWW-12T; SWW-MP18; SWW-900; SWW-1864T; SWW-GRH-1; or SWW-88; SWW-357; and SWW450.

#### **Basis for Apparent Violation B:**

During the onsite inspection on May 11, 2017, and during the OI investigation, the NRC identified that the annual reports did not include all required information; specifically, a listing of all models that had been distributed domestically.

Enforcement Action EA-14-080 cited CampCo for failing to include all required information in its annual reports filed with the NRC. In comparison, Apparent Violation B involves the failure to include complete and accurate information in its annual reports filed with the NRC. CampCo was cited for this violation in 2015 and acknowledged the violation in 2016; however, CampCo did not accurately correct the annual reports.

#### **Apparent Violation C:**

License Condition 11 of Materials License 04-23910-01E, Amendments No. 3 and No. 4, require, in part, that each lot of timepieces, hands, and dials received, containing tritium for distribution pursuant to 10 CFR 30.15, must be accompanied by a certificate which attests that, the timepieces were manufactured in accordance with recognized industry standards, and that the amount of tritium on the timepieces is not in excess of the amounts authorized in 10 CFR 30.15(a).

Contrary to the above, five shipments of lots in 2014, six shipments of lots in 2015, three shipments of lots in 2016, and four shipments of lots in 2018, all of which contained timepieces containing tritium for distribution, were received by the licensee and were not accompanied by a certificate which attests that the timepieces were manufactured in accordance with recognized industry standards, and that the amount of tritium on the timepieces is not in excess of the amounts authorized in 10 CFR 30.15(a).

### **Basis for Apparent Violation C:**

The onsite inspection on May 11, 2017, identified that the licensee had not received certificates in the most recent lot of timepieces. The OI investigation identified that the lots received from 2014 - 2018 were not accompanied by the required certificates.

Enforcement Action EA-14-080 cited CampCo for failing to ensure that each lot of timepieces received was accompanied by the required certificate. In comparison, Apparent Violation C involves failing to ensure that each lot of timepieces received was accompanied by the required certificate. CampCo was cited for this violation in 2015 and acknowledged the violation in 2016; however, CampCo did not ensure that each lot of timepieces received was accompanied by the required certificates as of March 7, 2018.

### **Other failures to comply with the license and regulations:**

#### **Apparent Violation D:**

License Condition 15 A of Materials License 04-23910-01E, requires, in part, that the licensee conduct its program in accordance with the statements, representations, and procedures contained in the license application.

CampCo's license renewal application, dated April 23, 2014, commits to the statements made in the initial license application dated July 9, 2004. In the Checklist section of the initial license application, CampCo committed to implement quality assurance measures that include visually inspecting each watch containing tritium upon receipt under natural light for visual defects and then in a completely dark room to verify that all tritium markings are glowing consistently and that there are no leaks visible. In Appendix B of the application, CampCo committed to keeping a logbook registering the date and time of each receipt of product, and to record the number of watch units received and their activity on the inventory record logbook.

Contrary to the above, from issuance of the initial license on October 12, 2004, up until at least the closure of the OI investigation on April 10, 2020, CampCo failed to conduct its program in accordance with the statements, representations, and procedures contained in the license application. Specifically, upon receipt, each watch has not been visually inspected in a completely dark room to verify that all tritium markings are glowing consistently, and a logbook has not been kept that registers the date and time of each receipt of product, the number of units, and the activity of these products.

#### **Basis for Apparent Violation D:**

Upon receipt of timepieces, the only actions taken by CampCo were performing an inventory of each timepiece in a well-lit warehouse space, then securing timepieces in a locked case. The NRC inspection and OI investigation found that CampCo did not visually inspect each watch in a completely dark room, and did not have procedures for the warehouse staff to follow upon receipt of tritium timepieces. CampCo did not have a logbook the NRC could review as described in the license application. A computerized inventory system was demonstrated to the NRC inspectors, but the system could not separate the tritium products from the rest of the inventory and did not record the activity of each product.

### **Apparent Violation E:**

10 CFR 30.15(a)(1)(i) requires, in part, that timepieces may not contain more than 25 millicuries of tritium per timepiece.

10 CFR 32.14(c) requires, in part, that each product will contain no more than the quantity of byproduct material specified for that product in 10 CFR 30.15.

License Condition 10 of Materials License 04-23910-01E, Amendment No. 3 requires, in part, that the Hydrogen-3 activity for an individual timepiece shall not exceed 19 millicuries (mCi).

Contrary to the above, as of January 1, 2017, CampCo distributed timepiece models: UZI-001; SWW-12T; SWW-MP18; SWW-900; SWW-1864T; and SWW-GRH-1 with a Hydrogen-3 activity exceeding 19 mCi, and models: SWW-88; SWW-357; and SWW-4503 with a Hydrogen-3 activity exceeding 25 mCi.

### **Basis for Apparent Violation E:**

CampCo's annual reports submitted for calendar years 2017 - 2019 demonstrate that the models listed in the reports were distributed with an activity greater than permitted by the license, ranging from 20.95 mCi to 24.73 mCi, and three models distributed in 2017 had an activity of 51.2 mCi.

CampCo's license does not allow for distribution of timepieces with an activity greater than 19 mCi.

### **Apparent Violation F:**

10 CFR 32.15(d)(1) requires, in part, that the licensee label each unit's container so that the manufacturer or initial transferor of the product and the byproduct material in the product can be identified.

Contrary to the above, since August 29, 2016, the licensee failed to label each timepiece container so that the manufacturer or initial transferor of the product and the byproduct material in the product can be identified. Specifically, labeling was placed on disposable cardboard outer packaging instead of directly on the timepiece container, and the outer cardboard packaging for each timepiece was incorrectly labeled as a product manufactured under the safety criteria found in 10 CFR 32.22.

### **Basis for Apparent Violation F:**

During the May 11, 2017, onsite inspection it was observed that the licensee put labels on the outer disposable packaging that stated "*This product is manufactured under the safety criteria in NRC regulation 10 CFR 32.22. The user is exempt from any requirement.*" The licensee was not aware that the incorrect regulation was referenced. The inspectors requested that the labels be changed.

On May 17, 2017, the licensee emailed updated labels to the inspectors which stated "*This product is manufactured under the safety criteria in NRC regulation 10 CFR 30.15. The user is exempt from any requirement.*" The inspectors noted to the licensee that the

products are initially distributed under 32.14 as described in CampCo's license, and that the end users are exempt from requirements as described in 10 CFR 30.15.

The inspectors notified the licensee that the labels were not adequate and should contain information similar to: *"CampCo, Inc. Smith & Wesson Watch Division has manufactured this timepiece under the safety criteria found in NRC regulation 10 CFR 32.14 and NRC License 04-23910-01E. Under 10 CFR 30.15, the end user is exempt from any requirements regarding the byproduct material, Hydrogen-3 (tritium), contained within this timepiece."* CampCo has not documented the completed corrective actions related to this violation since it was identified on May 11, 2017, during the onsite inspection.

### **Failures to provide accurate information to the NRC:**

#### **Apparent Violation G:**

10 CFR 30.9(a) requires, in part, that information provided to the Commission by a licensee shall be complete and accurate in all material respects.

Contrary to the above, on August 14, 2014, information provided to the Commission by CampCo was not complete and accurate in all material respects. Specifically, CampCo provided testimony under oath that all distribution of tritium timepieces was halted after July 30, 2013. However, 1,360 timepieces were distributed from July 30, 2013 through February 20, 2014.

#### **Basis for Apparent Violation G:**

The president of CampCo stated under oath, to an NRC OI investigator during the investigation for EA-14-080, that CampCo had halted distribution of all tritium timepieces from July 30, 2013 through February 20, 2014.

However, documentary evidence obtained by OI disclosed that CampCo distributed in total, 1,360 of the following tritium timepieces (HMV-W-ZT, SWW-1864T, SWW-12T, SWW-357, SWW-450, SWW-900, SWW-GRH-1, SWW-MP18, SWW-PRO, UZI-00, UZI-18B, UZI-26, and UZI-32) domestically from July 30, 2013 through February 20, 2014.

### **Failures to comply with the Confirmatory Order:**

#### **Apparent Violation H:**

Confirmatory Order Modifying License number 04-23910-01E, issued on June 20, 2016, Section V, item 6, requires CampCo to engage a third party independent consultant to provide initial training to key employees on NRC compliance responsibilities for exempt distribution licenses, as well as the specific requirements and obligations associated with CampCo's NRC license, and within 9 months to submit a draft of the training content to the NRC for review and approval, and incorporate any comments.

Contrary to the above, prior to March 20, 2017, 9 months from issuance of the Order, CampCo failed to submit a draft of the training content to the NRC for review and approval, and incorporate any comments. Specifically, the training material was not submitted for review until after May 25, 2017, the wrong regulations were referenced, the training material did not cover any CampCo procedures or the importance of compliance with NRC and

Agreement State requirements, or cover any of CampCo's specific compliance responsibilities as a distributor of tritium timepieces

**Basis for Apparent Violation H:**

Training materials required by the Confirmatory Order have not been approved by the NRC. The materials that have been received by the NRC are not adequate, and updated versions have not addressed the NRC's comments on the original version. After the NRC approves the training materials, CampCo must provide the training to employees, as required by the Confirmatory Order.

**Apparent Violation I:**

Confirmatory Order Modifying License number 04-23910-01E, issued on June 20, 2016, Section V, item 11, requires CampCo to develop written procedures and/or checklists identifying NRC compliance responsibilities for exempt distribution licenses in accordance with the regulations, as well as the specific requirements and obligations associated with CampCo's NRC license.

Contrary to the above, since March 20, 2017, CampCo has failed to develop written procedures and/or checklists identifying NRC compliance responsibilities for exempt distribution licenses in accordance with the regulations, as well as the specific requirements and obligations associated with CampCo's NRC license. Specifically, written procedures and/or checklists were not developed to include, for example, the process to be followed should there be a change in sources or watches to be distributed by CampCo, what actions to take if a lot of timepieces is received without the required certificates, written instructions detailing the models authorized for distribution, and employee responsibilities for the timing and content of annual reports.

**Basis for Apparent Violation I:**

During the May 11, 2017, onsite inspection, the inspectors requested to review the procedures developed under item 11 of the Order. CampCo's employees and President stated that the procedures had not been developed.

The inspectors prompted CampCo to start developing the procedures, as required by the Confirmatory Order. A checklist for the distribution manager and warehouse supervisor was emailed to NRC inspectors on May 24, 2017. The inspectors noted the good start, on May 30, 2017, to the licensee, however the checklist was a "shipment receipt report," that did not address compliance responsibilities.

**Apparent Violation J:**

Confirmatory Order Modifying License number 04-23910-01E, issued on June 20, 2016, Section V, items 1.d. through 3.d., require CampCo to incorporate any NRC comments into: (1) an article that the President of CampCo will submit via social media outlets to consumers of tritium watches; (2) the written notifications that the President of CampCo will send to watch manufacturers and assemblers in China and other international locations; and (3) the article for industry publication written by the President of CampCo.

Contrary to the above, from February 16, 2017 to October 5, 2017, the licensee failed to incorporate NRC comments into the article to consumers of tritium watches under item 1.d., the written notifications to manufacturers and assemblers under item 2.d., and the article for industry publication under item 3.d. Specifically, NRC provided comments to all three articles on January 23, 2017, and CampCo did not incorporate NRC-requested changes to any of the three articles under items 1 – 3.d. in the submission dated February 16, 2017.

**Basis for Apparent Violation J:**

The initial submission of the articles by CampCo did not accurately incorporate the elements required by the Confirmatory Order, and CampCo did not incorporate the initial NRC comments provided on January 23, 2017.

# 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 Title 10 of the *Code of Federal Regulations* (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?