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UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
1600 E. LAMAR BLVD.
ARLINGTON, TX 76011-4511

June 29, 2016

EA-16-041

Mr. Michael McIntire, President
and Radiation Safety Officer
Southwest X-Ray Corporation
P.O. Box 130
Glenrock, WY 82637

SUBJECT: NRC INSPECTION REPORT 030-37579/2015-001 AND FOLLOWUP TO NRC INSPECTION REPORT 030-37579/2014-001

Dear Mr. McIntire:

This letter refers to the routine, unannounced inspection conducted on July 28 and 29, 2015, at your facility in Casper, Wyoming. This inspection examined activities conducted under your license as they relate to public health and safety, the common defense and security, and to confirm compliance with the U.S. Nuclear Regulatory Commission's (NRCs) rules and regulations and with the conditions of your license. Within these areas, the inspection consisted of an examination of selected procedures and representative records, observations of licensed activities, independent radiation measurements, and interviews with personnel.

The enclosed report presents the results of this inspection. The inspectors discussed the preliminary inspection findings with you on July 29, 2015, at the conclusion of the onsite portion of the inspection. Members of NRC management met with you on October 22, 2015, to discuss the apparent violations and your completed and planned corrective actions. A final exit briefing was conducted telephonically with you on April 13, 2016.

Based on the results of this inspection, 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 Web site at http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html. At least one apparent violation involved security requirements in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 37. The circumstances surrounding these apparent violations, the significance of the issues, and the need for lasting and effective corrective action were discussed with you at the conclusion of the onsite portion of the inspection, during the meeting on October 22, 2015, and during the final exit briefing on April 13, 2016.

Attachment 2 of Enclosure 1 contains Sensitive Unclassified Non-Safeguards Information. When separated from Attachment 2, this letter, Attachment 1 of Enclosure 1 and Enclosure 2 are decontrolled.

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Since the NRC has not made a final determination in this matter, a Notice of Violation is not being issued for these inspection findings at this time. In addition, please be advised that the number and characterization of apparent violations described in the enclosed inspection report may change as a result of further NRC review.

Before the NRC makes its enforcement decision, we are providing you an opportunity to (1) request a predecisional enforcement conference (PEC) or (2) request alternative dispute resolution (ADR). If a PEC is held, the NRC will issue a meeting notice to announce the time and date of the conference; however, the PEC will be closed to public observation since Security-Related Information will be discussed. If you decide to participate in a PEC or pursue ADR, please contact Mr. Ray L. Kellar, P.E., Chief, Nuclear Materials Safety Branch A, at 817-200-1191 within 10 days of the date of this letter to notify the NRC of your intended response. A PEC should be held within 30 days and an ADR session within 45 days of the date of this letter.

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 the 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 actions will be considered in assessing any civil penalty for the apparent violations. The guidance in NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," (Enclosure 2) may be helpful. You can find the Information Notice on the NRC Web site at http://pbadupws.nrc.gov/docs/ML0612/ML061240509.pdf.

In lieu of a PEC, 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 employs is mediation. Mediation is a voluntary, informal process in which a trained neutral 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 Cornell University Scheinman Institute on Conflict Resolution (Cornell) has agreed to facilitate the NRC's program as a neutral third party. Please contact Cornell at 877-733-9415 within 10 days of the date of this letter if you are interested in pursuing resolution of this issue through ADR.

In accordance with 10 CFR 2.390 of the NRC's "Agency Rules of Practice and Procedure," a copy of this letter, the enclosed inspection report, and Attachment 1 of the inspection report will be made available electronically for public inspection in the NRC Public Document Room or in the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html.

However, Attachment 2 of the enclosed inspection report contains Security-Related Information in accordance with 10 CFR 2.390(d)(1) and its disclosure to unauthorized individuals could present a security vulnerability. Therefore, Attachment 2 of the enclosed inspection report will not be made available electronically for public inspection in the NRC Public Document Room or from ADAMS.

If you have any questions concerning this matter, please contact Mr. Ray L. Kellar, P.E., of my staff, at 817-200-1191.

Sincerely,

/RA/

Mark R. Shaffer, Director
Division of Nuclear Materials Safety

Docket No. 030-37579
License No. 49-29277-01

Enclosures:
1. NRC Inspection
   Report 030-37579/2015-001
   w/Attachment 1 and 2
2. NRC Information Notice 96-28

cc w/enclosures:
Scott Ramsay
Radiological Services Manager
5500 Bishop Blvd.
Cheyenne, WY 82009

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Enclosures:
1. NRC Inspection
   Report 030-37579/2015-001
   w/Attachment 1 and 2
2. NRC Information Notice 96-28

cc w/enclosures: Scott Ramsay, State of Wyoming

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R4Enforcement@nrc.gov		

ADAMS ACCESSION NUMBER – PUBLIC LETTER AND IR W/ATTACHMENT 1:ML16182A527
ADAMS ACCESSION NUMBER – NON-PUBLIC LETTER W/ATTACHMENT 2: ML16092A316

Cover Letter (w/o Att 2) X SUNSI Review by: **JEV**	ADAMS X Yes ☐ No	X Publicly Available ☐Non-Publicly Available		X Non-Sensitive ☐Sensitive		Keyword: EA-16-041
Cover Letter (w/Att 2) X SUNSI Review by: **JEV**	ADAMS X Yes ☐ No	☐ Publicly Available X Non-Publicly Available		☐ Non-Sensitive X Sensitive		Keyword: **MD A.3**
OFFICE	NMSB-A	NMSB-A	C NMSB-A	ACES TL	RC	OE	D DNMS
NAME	JEvonEhr	JFKatanic	RLKellar	MHay	KFuller	SWoods	MRShaffer
SIGNATURE	**/RA/**	**/RA/**	**/RA/**	**/RA/**	**/RA/**	review	**/RA/**
DATE	04/04/2016	04/04/2016	04/11/2016	06/09/16	06/27/16	06/24/16	06/29/16

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U.S. NUCLEAR REGULATORY COMMISSION
REGION IV

Docket No.	030-37579
License No.	49-29277-01
Report No.	030-37579/2015-001
EA No.	EA-16-041
Licensee:	Southwest X-Ray Corporation
Facilities:	2067 Renauna Avenue Casper, Wyoming
Inspection Dates:	July 28 and 29, 2015, with continued in-office review through April 13, 2016
Exit Meeting Date:	April 13, 2016
Inspectors:	Janine F. Katanic, PhD, CHP Senior Health Physicist Nuclear Materials Safety Branch A Jason E. vonEhr Health Physicist Nuclear Materials Safety Branch A
Approved by:	Ray L. Kellar, P.E., Chief Nuclear Materials Safety Branch A Division of Nuclear Materials Safety

Enclosure 1

EXECUTIVE SUMMARY

Southwest X-Ray Corporation
NRC Inspection Report 030-37579/2015-001

Program Overview

Southwest X-Ray Corporation is authorized to possess and use byproduct material (iridium-192) for industrial radiographic operations within its facility in Casper, Wyoming, and at temporary job sites in areas of NRC jurisdiction. (Section 1)

Inspection Findings

During a routine, unannounced inspection conducted on July 28 and 29, 2015, NRC inspectors identified five apparent violations of NRC requirements related to health and safety. The apparent violations involve the licensee's failure to conduct surveys in accordance with Title 10 of the *Code of Federal Regulations* (10 CFR) 20.1501(a) and 10 CFR 20.1302(a), failure to post a radiation area as required by 10 CFR 34.53, failure to check pocket dosimeters for correct response to radiation in accordance with 10 CFR 34.47(c), and failure to conduct timely refresher training for hazmat employees. (Section 2)

In addition, inspectors identified one or more apparent violations of NRC security requirements in 10 CFR Part 37. These apparent violations are discussed in the non-public attachment to this report (Attachment 2).

Corrective Actions

During the inspection, the licensee took certain steps to address the issues identified during the inspection with regard to radiation safety and safe handling of radioactive materials. On October 22, 2016, during a meeting with NRC management, the licensee's radiation safety officer discussed corrective actions completed and planned to address the inspection findings. NRC management emphasized the importance of compliance with regulatory requirements and the terms and conditions of Southwest X-Ray Corporation's NRC license. (Section 3)

REPORT DETAILS – Health and Safety

1 Program Overview (Inspection Procedure 87121)

1.1 Program Scope

Southwest X-Ray Corporation is authorized to possess and use byproduct material (iridium-192) for industrial radiographic operations. Licensed activities are authorized at the licensee's facility located in Casper, Wyoming, as well as at temporary job sites in areas of NRC jurisdiction. The licensee's radiation safety officer (RSO) is also the President and only radiographer under the license. The licensee has one assistant radiographer. The licensee conducts most of its licensed activities at its Casper, Wyoming, facility. The licensee also conducts licensed activities at temporary job sites in the greater Casper area.

1.2 Observations and Findings

The inspectors observed the performance of industrial radiography at the licensee's facility in Casper, Wyoming, on July 28 and 29, 2015. The inspectors reviewed the licensees operations and written procedures, and interviewed the RSO and the assistant radiographer regarding the performance of industrial radiography and transportation of radioactive materials as they relate to public health and safety to confirm compliance with the NRC's rules, regulations, and the conditions of the NRC license. Collectively, the activities observed and the documents reviewed describe the licensee's implementation of its radiation safety program.

2 Inspection Findings (Inspection Procedure 87121)

2.1 Inspection Scope

The NRC conducted a routine, unannounced inspection on July 28 and 29, 2015, at the licensee's Casper, Wyoming, facility. The inspectors observed the licensee conduct industrial radiography, performed independent radiation measurements, interviewed the RSO and the assistant radiographer, and reviewed records and procedures related to the licensee's implementation of its radiation safety program.

2.2 Observation and Findings

The inspectors identified five apparent violations of NRC health and safety requirements during the inspection. The apparent violations are described below.

Apparent violation of Title 10 of the Code of Federal Regulations (10 CFR) 20.1501(a)

Title 10 CFR 20.1501(a) requires, in part, that the licensee make, or cause to be made surveys of areas that may be necessary for the licensee to comply with the regulations in 10 CFR Part 20 and that are reasonable under the circumstances to evaluate the magnitude and extent of radiation levels and the potential radiological hazards of the radiation levels and residual radioactivity detected.

Title 10 CFR 20.1003 defines *survey* as an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or presence of radioactive material or other sources of radiation.

During the inspection at the licensee's facility, the inspectors took independent radiation measurements while the RSO and the assistant radiographer conducted industrial radiography. Measurements on the neighboring property at and near the licensee's fence on the west side of the licensee's property indicated dose rates that would require the area to be posted as a *Radiation Area* in accordance with 10 CFR 1902(a), during the conduct of radiographic operations. The RSO and the assistant radiographer were conducting industrial radiography inside the licensee's facility near a bay door. The inspectors observed that the licensee could not, with only two individuals present, perform surveys outside of the facility while radiographic operations were conducted inside the facility without being in violation of 10 CFR 34.41(a). Accordingly, the inspectors determined that the licensee had not performed surveys of the area the inspectors surveyed, where the elevated dose rates were measured.

In addition, the inspectors observed no controls to prevent a member of the public, including employees of the neighboring businesses, from accessing the area of the neighboring lot directly adjacent to the licensee's property and it was in this area that the inspectors observed elevated dose rates. The inspectors questioned the RSO regarding surveys conducted to demonstrate compliance with the public dose limits of 10 CFR Part 20. The RSO was not able to demonstrate compliance with the requirements.

Furthermore, the inspectors observed that the radiation measurements they took were related to the licensee's use of a radiographic source that was of a lower activity than other sources possessed by the licensee. Therefore, in the same circumstances, the licensee's use of other sources in its possession could have resulted in higher dose rates along the fence line accessible to members of the public.

The licensee's failure to make, or cause to be made, surveys of areas that may be necessary for the licensee to assure compliance with the posting requirements of 10 CFR 20.1902(a) and that are reasonable under the circumstances to evaluate the magnitude and extent of radiation levels, and the potential radiological hazards of the radiation levels and residual radioactivity detected was identified as an apparent violation of 10 CFR 20.1501(a). (030-37579/2015-001-01)

Apparent violation of 10 CFR 34.53

Title 10 CFR 34.53 requires, in part, that all areas in which industrial radiography is being performed must be conspicuously posted as required by 10 CFR 20.1902(a) and (b).

Title 10 CFR 20.1902(a) requires that the licensee shall post each radiation area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIATION AREA."

Title 10 CFR 20.1003 defines *Radiation area* as an area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.005 rem (0.05 mSv) in 1 hour at 30 centimeters from the radiation source or from any surface that the radiation penetrates.

The inspectors questioned the RSO and the assistant radiographer to determine if surveys had been conducted around the area that radiography was being performed, specifically near the property's west-side fence, to determine the radiation hazards present during operations. As described above, the RSO had not conducted any surveys in that area that would determine the potential radiation hazards during radiographic operations. As a result, the licensee did not have a posting or warning communicating these hazards to members of the public. The RSO stated that they had never posted that area during radiographic operations.

The failure of the licensee to conspicuously post all areas in which industrial radiography was being performed on July 28, 2015, in accordance with 10 CFR 20.1902(a), was identified as an apparent violation of 10 CFR 34.53. (030-37579/2015-001-02)

Apparent violation of 10 CFR 20.1302(a)

Title 10 CFR 20.1302(a) requires, in part, that the licensee make or cause to be made, as appropriate, surveys of radiation levels in unrestricted and controlled areas to demonstrate compliance with the dose limits for individual members of the public in 10 CFR 20.1301.

During interviews with the RSO and his assistant, the RSO was not aware of the ease of access to the neighboring facility, and indicated that he rarely observed any activity at the neighboring facility during normal business hours. The RSO was informed that the inspectors performed radiation measurements at the property's west-side fence line upon arrival at the facility. The inspectors indicated to the RSO that there were no controls to prevent a member of the public from accessing the neighboring lot.

The inspectors also noted that the employees of the neighboring company are considered members of the public. This resulted in the potential for public access to the west side fence of the licensee's facility where the elevated radiation levels were independently measured by the inspectors. The inspectors observed a number of pallets with barrels of chemicals along the neighboring facility's perimeter, which indicates that the employees of the neighboring company may need to access or perform activities in that area.

Based on the observations made during the inspection, it was unlikely that any individual member of the public exceeded the annual public dose limits in 10 CFR 20.1301(a)(1) of 0.1 rem (1 mSv). However, the licensee is required to evaluate and document the radiation hazards associated with its licensed activities.

The failure to make or cause to be made, as appropriate, surveys of radiation levels in unrestricted and controlled areas to demonstrate compliance with the dose limits for individual members of the public in 10 CFR 20.1301 from January 1 through July 28, 2015, was identified as an apparent violation of 10 CFR 20.1302(a). (030-37579/2015-001-03)

Apparent violation of 10 CFR 34.47(c)

Title 10 CFR 34.47(c) requires, in part, that pocket dosimeters must be checked at periods not to exceed 12 months for correct response to radiation. Acceptable dosimeters must read within plus or minus 20 percent of the true radiation exposure.

The inspectors reviewed the licensee's dosimetry program which includes procedures for the calibration of pocket dosimeters. The licensee utilized a dosimeter calibrator, with a cesium-137 source, purchased in 2004 to perform calibration of the pocket dosimeters. The RSO's records dating back to the purchase of the source did not provide a calibrated activity or the calibration date of the cesium-137 source. The inspectors found no labels or markings on the source and the associated shielding to indicate any source strength, date, or a specific dose value (true radiation exposure).

The licensee's procedure involved recording the deflection of the pocket dosimeters from the calibrator source after a set amount of time. However, the licensee did not compare this deflection value with a true radiation exposure because it was unknown. Instead, the licensee compared the deflection value with that from the previous year. If the value was nearly the same, the RSO continued to use the pocket dosimeters.

Because the true radiation exposure was unknown and could not be established, the licensee could not demonstrate that the pocket dosimeters' response to radiation was within plus or minus 20 percent of the true radiation exposure. The inspectors examined the pocket dosimeters in use the day of the inspection and found that the dosimeters did respond to radiation, i.e., there was a deflection following an exposure. However, based on the calibration source used by the licensee, there is no way to determine what the true exposure from the calibration source was, and thus no way to confirm the pocket dosimeter measurement was within the 20 percent range established by 10 CFR Part 34.

The failure to demonstrate that pocket dosimeters correctly respond to radiation within plus or minus 20 percent of the true radiation exposure was identified as an apparent violation of 10 CFR 34.47(c). (030-37579/2015-001-04)

Apparent violation of 10 CFR 71.5(a)

License Condition 17 of NRC License 49-29277-01, Amendment 01, states that the licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

Title 10 CFR 71.5(a) requires, in part, that each licensee who transports licensed material outside the site of usage, as specified in the NRC license, or where transport is on public highways, shall comply with the applicable requirements of the Department of Transportation (DOT) regulations in 49 CFR Parts 107, 171 through 180, and 390 through 397, appropriate to the mode of transport.

Title 49 of the *Code of Federal Regulations* (49 CFR) 172.704(c)(2) requires, in part, that a hazmat employee must receive the training required by 49 CFR Part 172, Subpart H, at least once every 3 years.

The licensee regularly performed radiography at temporary jobsites in areas of NRC jurisdiction, as authorized by License Condition 11 of its NRC license. The licensee transported the radiography camera and associated iridium-192 source to temporary job sites primarily in the Casper area and around the industrial park where the licensee's facility is located.

Through a records review and interviews with the licensee employees, the inspectors determined that the last time the RSO and the assistant radiographer took the refresher training required by 49 CFR 172, Subpart H, was on July 10, 2012. However, the licensee continued to transport licensed byproduct material on public roads after July 10, 2015, a period in excess of 3 years.

The licensee stated that on many occasions, the radioactive material is only transported across the street to another facility, or down the street a few feet and that this is not a public highway but rather a private road. The inspectors determined that the transport route utilized by the licensee is a public road. The transportation of licensed radioactive materials was to facilitate commerce by the licensee. The licensee is therefore subject to the DOT requirements.

The licensee's failure to provide the training required by 49 CFR Part 172, Subpart H, at least once every 3 years to hazmat employees who transport licensed material was identified as an apparent violation of 10 CFR 71.5(a). (030-37579/2015-001-05)

2.3 Conclusions

The inspectors identified five apparent violations of NRC health and safety requirements, involving the licensee's failure to: (1) conduct surveys in accordance with 10 CFR 20.1501(a); (2) conduct surveys in accordance with 10 CFR 20.1302(a); (3) post a *Radiation Area* as required by 10 CFR 34.53; (4) check pocket dosimeters for correct response to radiation in accordance with 10 CFR 34.47(c); and (5) conduct required hazmat training.

3 Corrective Actions

During the inspection, the licensee took actions to address the some of the apparent violations identified by the inspectors. In addition, the RSO discussed the completed and planned corrective actions with NRC management during a meeting on October 22, 2015. NRC management emphasized the importance of compliance with the regulatory requirements and Southwest X-Ray Corporation's license conditions.

In order to address the high dose rates at the property line and beyond, the licensee moved the flatbed truck on which the industrial radiography was being performed and other vehicles and equipment within the bay. This shift of equipment in the area where the licensee performs industrial radiography resulted in a lower dose rate at the licensee's property line, alleviating the immediate health and safety concerns identified during the inspection.

In addition, the licensee placed a posting along the west-side fence line during the inspection, which read "CAUTION/ Radiography in progress/ Radiation Area/ Keep Out." This posting was secured to the fence on a pair of 'S' hooks, and could be readily removed once radiographic operations had completed.

In addition, at the conclusion of the onsite inspection the RSO committed to completing the required hazmat training.

During the NRC management meeting with the RSO on October 22, 2015, the licensee was still considering how they would address the survey requirements in accordance with the provisions of 10 CFR Part 20. The licensee described one potential method, using a pocket dosimeter, to evaluate the dose rates on the outside of the fence line. NRC management expressed a concern about the sensitivity of a pocket dosimeter to develop the data to demonstrate compliance with 10 CFR 20.1301(a).

Also during the meeting on October 22, 2015, the RSO stated that he had purchased a new cesium-137 source for calibrating pocket dosimeters to address the concerns raised during the inspection about the unknown true radiation exposure of the calibrator source used to comply with the requirements in 10 CFR 34.47(c). This will potentially allow the RSO to demonstrate in the future the true radiation exposure of the pocket dosimeters and, thus, confirm that the pocket dosimeters' measurements are within plus or minus 20 percent of the true radiation exposure.

4 Exit Meeting Summary

On April 13, 2016, Linda L. Howell, Deputy Division Director, Division of Nuclear Materials Safety, and the inspectors discussed the apparent violations with the licensee during a telephonic exit briefing. The issues covered in the October 22, 2015, meeting with the licensee were also discussed. Further, the licensee was informed that certain issues identified during the routine inspection conducted in 2014 would be documented in this inspection report. The NRC also described the enforcement process and the options for the licensee moving forward, including its option to attend a PEC or request ADR.

Supplemental Inspection Information – Health and Safety

PARTIAL LIST OF PERSONS CONTACTED

Michael McIntire, President, RSO, and Radiographer
Kurt McIntire, Assistant Radiographer

INSPECTION PROCEDURES USED

87121 Industrial Radiography Programs

ITEMS OPENED, CLOSED, AND DISCUSSED

Opened

030-37579/2015-001-01	APV	The licensee failed to survey as necessary and reasonable under the circumstances to evaluate the magnitude and extent of radiation levels, and the potential radiological hazards of the radiation levels and residual radioactivity detected. (10 CFR 20.1501(a))
030-37579/2015-001-02	APV	The licensee failed to conspicuously posted as required by 10 CFR 20.1902(a). (10 CFR 34.53)
030-37579/2015-001-03	APV	The licensee failed to survey radiation levels in unrestricted and controlled areas to demonstrate compliance with the dose limits for individual members of the public. (10 CFR 20.1302(a))
030-37579/2015-001-04	APV	The licensee failed to demonstrate that pocket dosimeters read within plus or minus 20 percent of the true radiation exposure. (10 CFR 34.47(c))
030-37579/2015-001-05	APV	The licensee failed to ensure that hazmat employees received the training required by 49 CFR Part 172 Subpart H at least once every 3 years. (10 CFR 71.5(a))

Closed

None

Discussed

None

LIST OF ACRONYMS USED

ADAMS	Agencywide Documents Access and Management System
ADR	Alternative Dispute Resolution
APV	Apparent Violation
CFR	*Code of Federal Regulations*
DOT	Department of Transportation
ICR	Institute on Conflict Resolution
NRC	Nuclear Regulatory Commission
PEC	Predecisional Enforcement Conference
RSO	Radiation Safety Officer

NRC INFORMATION NOTICE 96-28

SUGGESTED GUIDANCE RELATING TO DEVELOPMENT AND IMPLEMENTATION OF CORRECTIVE ACTION

Enclosure 2

NOTE: The following information is an updated excerpt from NRC Information Notice 96-28 issued during 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 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.

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