



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**

REGION III
2443 WARRENVILLE RD. SUITE 210
LISLE, IL 60532-4352

October 24, 2016

EA-16-188

Mr. Nathan Cox
Radiation Safety Officer
IRISNDT, Inc.
7915 Maryland Avenue
Hammond, IN 46323

SUBJECT: NRC ROUTINE INSPECTION REPORT NO. 03038777/2016001(DNMS) –
IRISNDT, INC.

Dear Mr. Cox:

On August 22, 2016, an inspector from the U.S. Nuclear Regulatory Commission (NRC) conducted a routine inspection at your facility in Hammond, Indiana, with continued in-office review through September 22, 2016. The purpose of the inspection was to review activities performed under your NRC license to ensure that activities were being performed in accordance with NRC requirements. The in-office review included a review of the circumstances of the findings observed during the on-site inspection. The enclosed inspection report presents the results of the inspection.

During this inspection, the NRC staff examined activities conducted under your license related to public health and safety. Additionally, the staff examined your compliance with the Commission's rules and regulations as well as the conditions of your license. Within these areas, the inspection consisted of selected examination of procedures and representative records, observations of activities, and interviews with personnel.

Based on the results of this inspection, one apparent violation of NRC requirements was identified and is being considered for escalated enforcement action in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's website at <http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>. The apparent violation involved the failure to equip radiographers with a direct reading dosimeter and an alarm ratemeter while performing radiographic operations, as required by Title 10 of the *Code of Federal Regulations* (CFR) Section 34.47(a). Specifically, the licensee used a single device (the Mirion Technologies, Inc. RAD-60) to perform the functions of both a direct reading dosimeter and an alarm ratemeter simultaneously. You self-identified this apparent violation.

Enclosure 2 contains Sensitive Unclassified Non-Safeguards Information. When separated from Enclosure 2, Enclosure 1 and its transmittal letter are decontrolled.
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N. Cox

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As corrective action, your company purchased separate alarm ratemeters to be used in conjunction with the combination devices and personnel dosimeters. The corrective action was implemented and compliance was restored, prior to the onsite inspection, on March 24, 2016. Mr. Edward Harvey of my staff discussed the circumstances surrounding this apparent violation, the significance of the issue, and the need for lasting and effective corrective action with you by telephone during the inspection exit meeting on September 26, 2016.

Because the NRC has not made a final determination in this matter, the NRC is not issuing a Notice of Violation for this inspection finding at this time. Before the NRC makes its enforcement decision, we are providing you an opportunity to either: (1) respond in writing to the apparent violation addressed in the enclosed inspection report within 30 days of the date of this letter; or (2) request a Predecisional Enforcement Conference (PEC). **Please contact Aaron T. McCraw, Chief of the Region III Materials Inspection Branch, at 630-829-9650 or Aaron.McCraw@nrc.gov within ten days of the date of this letter to notify the NRC of your intended response.**

If you choose to provide a written response, it should be clearly marked as "Response to the Apparent Violation in Inspection Report No. 03038777/2016001(DNMS); EA-16-188," and should include, for the 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 was or 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 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's 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 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 PEC.

If you choose to request a PEC, it 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 PEC 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. If a PEC is held, it will be open for public observation; the NRC will issue a press release to announce the time and date of the PEC.

Because your facility has not been the subject of escalated enforcement action within the last two years or two inspections, a civil penalty may not be warranted in accordance with Section 2.3.4 of the Enforcement Policy. In addition, based upon NRC's understanding of the facts and your corrective actions, it may not be necessary to conduct a PEC in order to enable the NRC to make a final enforcement decision. Our final decision will be based on your confirming on the license docket that the corrective actions previously described to the staff have been or are being taken.

N. Cox

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Please be advised that the number and characterization of the apparent violation described in the enclosed inspection report may change as a result of further NRC review. You will be advised by separate correspondence of the results of our final determination on this matter.

In addition to the apparent violation, the NRC identified one unresolved item regarding the use of Mirion Technologies, Inc. Instadose™ devices to satisfy regulatory requirements for personnel monitoring during radiographic operations. The item is described in the enclosed report. The NRC will continue to review this open item. You will be advised by separate correspondence of the results of our deliberation on this matter. Because this item remains under NRC review, you are not required to respond to this matter at this time.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your response if you choose to provide one, will be made available electronically for public inspection in the NRC's Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC's website at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, any response should not include any personal privacy, proprietary, or safeguards information so that it can be made publicly available without redaction.

Please feel free to contact Edward Harvey of my staff if you have any questions regarding this inspection. Mr. Harvey can be reached at 630-829-9819.

Sincerely,

/RA/

John B. Giessner, Director
Division of Nuclear Materials Safety

Docket No. 030-38777
License No. 13-32791-01

Enclosures:

1. IR 03038777/2016001(DNMS) (Public)
2. Security Addendum (Non-public)

cc w/encls: Kyle Ledbetter
cc w/encl1: State of Indiana

N. Cox

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Please be advised that the number and characterization of the apparent violation described in the enclosed inspection report may change as a result of further NRC review. You will be advised by separate correspondence of the results of our final determination on this matter.

In addition to the apparent violation, the NRC identified one unresolved item regarding the use of Mirion Technologies, Inc. Instadose™ devices to satisfy regulatory requirements for personnel monitoring during radiographic operations. The item is described in the enclosed report. The NRC will continue to review this open item. You will be advised by separate correspondence of the results of our deliberation on this matter. Because this item remains under NRC review, you are not required to respond to this matter at this time.

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cc w/encls: Kyle Ledbetter
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DATE	10/19/2016		10/19/2016		10/21/2016		10/24/2016	

OFFICIAL RECORD COPY

Letter to Nathan Cox from John Giessner dated October 24, 2016.

SUBJECT: NRC ROUTINE INSPECTION REPORT NO. 03038777/2016001(DNMS)
IRISNDT, INC.

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**U.S. Nuclear Regulatory Commission
Region III**

Docket No. 030-38777

License No. 13-32791-01

Report No. 03038777/2016001(DNMS)

EA No. EA-16-188

Licensee: IRISNDT, Inc.

Locations: 7915 Maryland Avenue
Hammond, Indiana

Temporary Job Site
Niles, Michigan

Inspection Date: August 22, 2016

Exit Meeting Date: September 26, 2016

Inspector: Edward Harvey, Health Physicist

Approved By: Aaron T. McCraw, Chief
Materials Inspection Branch
Division of Nuclear Materials Safety

Enclosure 2 contains Sensitive Unclassified Non-Safeguards Information. When separated from Enclosure 2, Enclosure 1 and its transmittal letter are decontrolled.
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Enclosure 1

EXECUTIVE SUMMARY

IRISNDT, Inc. NRC Inspection Report 03038777/2016001(DNMS)

This was a routine, unannounced inspection of a non-destructive testing company authorized by U.S. Nuclear Regulatory Commission (NRC) License No. 13-32791-01 to use byproduct material for industrial radiography. The purpose of the inspection was to ensure that all licensed activities performed by the licensee were conducted safely and in accordance with NRC requirements. The inspection included a review of licensed activities at the company's main office in Hammond, Indiana, and at a temporary job site in Niles, Michigan.

During the inspection, the licensee informed the inspector of one self-identified apparent violation involving the failure to equip radiographers with a direct reading dosimeter and an alarm ratemeter while performing radiographic operations, as required by Title 10 of the *Code of Federal Regulations* (CFR) Section 34.47(a). Specifically, the licensee used a single device (the Mirion Technologies, Inc. RAD-60) to perform the functions of both a direct reading dosimeter and an alarm ratemeter simultaneously.

The root cause of the apparent violation was a misunderstanding that the combination dosimetry device did not meet the requirements of 10 CFR 34.47(a) when used to serve the functions of an alarm ratemeter and a direct reading dosimeter simultaneously. As corrective action, the licensee purchased separate alarm ratemeters to be used in conjunction with the combination devices and personnel dosimeters. The corrective action was implemented and compliance was restored, prior to the onsite inspection, on March 24, 2016.

In addition, the inspector identified one unresolved item regarding the licensee's use of Mirion Technologies, Inc. Instadose™ devices to satisfy regulatory requirements for personnel monitoring during radiographic operations. This unresolved item remains under NRC review.

REPORT DETAILS

1 Program Overview and Inspection History

IRISNDT, Inc. (licensee) is authorized by NRC Materials License No. 13-32791-01 to possess sealed sources for industrial radiography at temporary job sites. At the time of the inspection, the licensee employed 19 radiographers and 3 radiographer's assistants. The licensee possessed 6 radiographic exposure devices; 4 that contained iridium-192 (Ir-192), 1 that contained selenium-75 (Se-75), and 1 that contained cobalt-60 (Co-60). The Ir-192 and Se-75 devices were used for radiography approximately 2-3 times per week. The Co-60 device was recently purchased prior to the inspection and had not been used yet.

The NRC last inspected the licensee on August 21, 2015, with no violations identified. The previous inspection was conducted on August 1, 2014. The NRC identified two Severity Level IV violations during this inspection.

2 Personnel Radiation Monitoring

2.1 Inspection Scope

The inspector reviewed the elements of the licensee's personnel radiation monitoring by interviewing the radiation safety officer (RSO) and a selection of radiographers. In addition, the inspector reviewed a selection of licensee documents, including calibration records and reports from the dosimetry vendor.

2.2 Observations and Findings

On August 22, 2016, the inspector interviewed the RSO in regard to the personnel monitoring methods used by the licensee. The RSO explained that, prior to March 24, 2016, all radiographers and their assistants were furnished with a personnel dosimeter that is processed by an accredited National Voluntary Laboratory Accreditation Program (NVLAP) processor and one Mirion Technologies, Inc. RAD-60 (RAD-60); which was used as both a direct reading dosimeter and an alarm ratemeter.

Title 10 of the *Code of Federal Regulations* (10 CFR) Section 34.47(a) requires, in part, that the licensee may not permit any individual to act as a radiographer or a radiographer's assistant unless, at all times during radiographic operations, each individual wears, on the trunk of the body, a direct reading dosimeter, an operating alarm ratemeter, and a personnel dosimeter. The licensee's use of a single device, the RAD-60, is an apparent violation of 10 CFR 34.47(a).

The RSO identified this apparent violation from other publicly available NRC inspection reports where combination dosimetry devices were used to serve more than one function simultaneously. The root cause of the apparent violation was a misunderstanding that the RAD-60 did not meet the requirements of 10 CFR 34.47(a) when used to serve the functions of an alarm ratemeter and a direct reading dosimeter simultaneously. Upon self-identifying this violation, the licensee purchased NDS RA-500 alarm ratemeters to be used in conjunction with the RAD-60 and a personnel dosimeter to restore compliance with 10 CFR 34.47(a). The corrective action was implemented

and compliance was restored as of March 24, 2016. The inspector verified that the radiographers were equipped with a personal dosimeter, a RAD-60 direct reading dosimeter, and an NDS RA-500 alarming ratemeter during a temporary job site inspection in Niles, Michigan, on August 22, 2016.

In addition, the inspector identified that the licensee used Mirion Technologies, Inc. Instadose™ (Instadose™) direct ion storage dosimeters to determine the dose of record for radiographers and radiographers' assistants for approximately 4 years. The licensee discontinued the use of film badges exchanged monthly shortly after implementing use of the Instadose™ dosimeters. Given the nature of "processing" an Instadose™ dosimeter (plugging the dosimeter into a USB port on a personal computer), the licensee did not exchange, or replace, these devices periodically.

Title 10 CFR Section 34.47(a)(3) states that film badges must be replaced at periods not to exceed one month and other personnel dosimeters processed and evaluated by an accredited NVLAP processor must be replaced at periods not to exceed three months. The use of Instadose™ devices relative to compliance with 10 CFR 34.47(a)(3) is an unresolved item, which remains under NRC review.

The inspector reviewed occupational exposure records for pertinent licensee staff. The maximum annual whole-body exposures were 421 millirem in 2015, and 96 millirem in 2016 to date. The inspector also reviewed documentation of the electronic direct reading dosimeter and alarming ratemeter calibrations.

2.3 Conclusions

The licensee self-identified one apparent violation of 10 CFR 34.47(a), involving the licensee's failure to equip radiographers with an independent direct reading dosimeter and alarm ratemeter while performing radiographic operations. In addition, the inspector identified one unresolved item regarding the licensee's use of Instadose™ dosimeter to satisfy regulatory requirements for personnel monitoring during radiographic operations.

3 **Other Areas Inspected**

3.1 Inspection Scope

On August 22, 2016, toured the licensee's main office in Hammond, Indiana, observed conduct of radiographic operations at a temporary job site, conducted interviews with members of its radiation safety staff, examined a selection of radiographic equipment, and reviewed a selection of relevant records.

3.2 Observations and Findings

The inspector observed a team of radiographers conduct radiographic operations at a temporary job site located in Niles, Michigan. The inspector observed the radiographers demonstrate adequate knowledge of radiation safety principles as they established and maintained a controlled boundary for the radiation area, wore all required dosimetry, and properly used calibrated survey meters during radiographic operations. The inspector reviewed the shipping papers and utilization log, with no issues noted.

At the main office, the inspector conducted independent surveys using a Thermo Fisher Scientific RadEye G meter (calibrated on January 19, 2016). Readings at the surface of the licensee's QSA 880 Delta cameras were consistent with those indicated in the applicable Safety Evaluation in the Sealed Source and Device Registry. Readings in unrestricted areas in the vicinity of the camera storage area were indistinguishable from background.

The inspector reviewed records of leak tests, quarterly equipment maintenance, source exchanges, weekly inventories, and training, with no issues noted.

3.3 Conclusions

The inspector identified no violations of NRC requirements.

4 **Exit Meeting Summary**

The NRC inspector presented preliminary inspection findings following the onsite inspection on August 23, 2016. The licensee acknowledged the findings presented. A final telephonic exit meeting between the NRC and the RSO was conducted on September 26, 2016.

PARTIAL LIST OF PERSONNEL CONTACTED

- # Nathan Cox, RSO
Kyle Ledbetter, Branch Manager
- # Attended telephonic exit meeting on September 26, 2016

INSPECTION PROCEDURES USED

87121: Industrial Radiography Programs