



170 S. Seneca Springs Way, Suite 105 • Star ID 83669

November 22, 2021

Dr. Lizette Roldán-Otero & Jason Dykert
Division of Nuclear Materials Safety
US NRC Region IV

Subject: Response to an Apparent Violation in NRC Inspection Report 030-35244/2021-001;
EA-21-119

To: Dr. Roldán-Otero and Mr. Dykert

This letter is in response to the violations found during the NRC's recent remote inspection at KRONUS. This response has been divided in to two sections to address the NRC's two concerns; namely the appropriateness of the instrument being used for routine ^{125}I contamination surveys and the frequency of contamination surveys being conducted in the laboratory.

Appropriateness of KRONUS' Survey Meter

In an email KRONUS received on 04/26/2021, Mr. Jason Dykert indicated that the NRC was concerned with the TBM-3 survey meter being utilized for shipment inspections and contamination surveys. Mr. Dykert stated that the TBM-3 instruments had a very low detection efficiency for ^{125}I and that this unit may not be adequate for its intended use at KRONUS.

On 5/14/2021, during a phone call, Mr. Dykert confirmed that it was the NRC's opinion that the TBM-3 meter was not suitable for detecting ^{125}I and advised KRONUS that a meter paired with an NaI scintillator capable of approximately 30% to 40% efficiency would be appropriate.

As an immediate correction to address this violation, KRONUS researched and identified survey meters that met the required specifications as indicated by Mr. Dykert. On 5/17/21, KRONUS ordered a Ludlum 3000 meter paired with a Ludlum 44-21 detector. Specifications for the 44-21 beta-gamma detector indicated an efficiency of 38% for ^{125}I . Immediately after ordering the new instrument, KRONUS advised Mr. Dykert via email of the purchase and informed him we were expecting the instrument to be calibrated and shipped from the manufacturer in the next week. KRONUS received the calibrated survey meter on 6/1/21.

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A root cause analysis concluded that, from the information regarding the use of the TBM-3 survey meter provided to the NRC during past application submissions and on-site inspections, KRONUS believed the TBM-3 was an acceptable meter and that the company was in regulatory compliance.

Corrective actions to address this violation included assessing the performance and suitability of the Ludlum instrument, training personal on how to operate the unit and to put the survey meter into service.

The Ludlum meter and detector were found to be suitable for use at KRONUS and a copy of our suitability assessment report was provided to Mr. Dykert on 6/29/21.

The new Ludlum survey meter was first put into service on 6/7/21. The new meter was used in parallel with the TBM-3 meter (i.e. surveys were conducted with both meters) through 7/19/21. The TBM-3 meters were then removed from service and the Ludlum meter was used solely thereafter.

Training for the new instrument occurred for staff who regularly conduct contamination surveys and shipment inspections on 6/7/21. Effectiveness of this training was evaluated on 7/1/21. Effectiveness criteria was based upon observation of survey procedures and a review of survey records. Staff was found to be proficient and the training was found to be effective.

Additional survey meter training for all staff who handle radioactive material occurred on 9/8/21 during KRONUS' annual ¹²⁵I and radioactive materials training. This training was evaluated and found to be effective on 10/7/2021.

All corrective actions associated with this non-conformity were assessed on 10/21/21 and were found to be effective with no occurrence of unintended consequences. As such, this matter is considered closed by KRONUS.

Frequency of Laboratory Contamination Survey

During a phone call on 7/12/21, Mr. Dykert informed KRONUS that weekly contamination surveys of the laboratory area were inadequate and that end of day surveys should be conducted every time ¹²⁵I is utilized in the lab.

As an immediate correction to address this non-conformity KRONUS reviewed 10 CFR 20 subpart F to ensure the NRC requirements were fully understood.

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A root cause analysis determined that, from the information provided to the NRC during past application submissions and on-site inspections regarding the use of ^{125}I material in the lab and related contamination survey procedures, KRONUS believed its survey procedure was in regulatory compliance.

Corrective actions identified consisted of adding an end of day contamination survey procedure to KRONUS' ^{125}I handling SOP (SOP 12) and to provide training to laboratory staff.

An end of day survey procedure was added to KRONUS' ^{125}I handling SOP on 7/19/21. Training of laboratory staff and implementation of the new end of day survey procedure occurred on 7/27/21. This training was evaluated for effectiveness on 8/9/21 by observing the laboratory survey procedure and through examining survey records. Laboratory staff was found to be proficient and training was deemed effective. Further training of the laboratory procedure was provided for all staff that handles ^{125}I on 9/8/21 during KRONUS' annual ^{125}I and radioactive materials training. This training was evaluated and found to be effective on 10/7/2021.

The corrective actions associated with this violation were assessed on 10/21/21 and were found to be effective with no occurrence of unintended consequences. As such, this matter is considered closed by KRONUS.

An updated copy SOP 12 describing the end of day survey procedure (See *Monitoring* on page 3) and the related survey form are attached as they have not been previously submitted to the NRC.

KRONUS looks forward to hearing the NRC's comments regarding the corrective actions implemented to address these violations and to receiving additional information about the NRC's final decision regarding enforcement of these violations.

Sincerely,

A handwritten signature in black ink, appearing to read "H. Viele", with a long horizontal flourish extending to the right.

Heather Viele
Vice President, Regulatory & Technical Affairs / Radiation Safety Officer
KRONUS, Inc.

