UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
1600 EAST LAMAR BOULEVARD
ARLINGTON, TEXAS 76011-4511

November 5, 2021

EA-21-119

Ms. Heather Viele
Radiation Safety Officer
KRONUS, Inc.
170 South Seneca Springs Way
Suite 105
Star, Idaho 83669

SUBJECT: NRC INSPECTION REPORT 030-35244/2021-001

Dear Ms. Viele:

This letter refers to the announced inspection conducted remotely from April 22, 2021, through October 14, 2021, of licensed activities performed at your facility in Star, Idaho. The inspection was an examination of activities conducted under your license as they relate to public health and safety, to confirm compliance with the U.S. Nuclear Regulatory Commission (NRC) rules, regulations, and with the conditions of your license. Within these areas, the inspection consisted of a selected examination of procedures and representative records, and interviews with personnel. The preliminary inspection findings were discussed with you on July 12, 2021, and a final exit meeting was held telephonically with you on October 20, 2021. The enclosed report presents the results of the inspection.

Based on the results of this inspection, the NRC has determined that an apparent violation 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 website at http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html. The apparent violation involved the failure to perform adequate surveys to evaluate potential radiological hazards at your facility. The circumstances surrounding the apparent violation, the significance of the issues, and the need for lasting and effective corrective action were discussed with you, during the telephonic exit meeting on October 20, 2021.

Before the NRC makes its enforcement decision, we are providing you an opportunity to: (1) respond in writing to the apparent violation addressed in the inspection report within 30 days of the date of this letter; or (2) request a predecisional enforcement conference (PEC). If a PEC is held, it will be open for public observation and the NRC may issue a press release to announce the time and date of the conference. If you decide to participate in a PEC, please contact Dr. Lizette Roldán-Otero at 817-200-1455 or by email at Lizette.Roldan-Otero@nrc.gov within 10 days of the date of this letter. A PEC should be held within 30 days of the date of this letter.

If you choose to provide a written response, it should be clearly marked as a "Response to an Apparent Violation in NRC Inspection Report 030-35244/2021-001; EA-21-119" and should include: (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. Your response may reference or include previously docketed correspondence, if the correspondence adequately addresses the required response. Additionally, your response should be sent to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001, with a copy mailed to Ms. Mary C. Muessle, Director, Division of Nuclear Materials Safety, Region IV, 1600 East Lamar Boulevard, Arlington, Texas, 76011, and emailed to R4Enforcement@nrc.gov within 30 days of the date of this letter. 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, the conference will afford you the opportunity to provide your perspective on this matter 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.

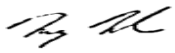
In presenting your corrective actions, you should be aware that the promptness and comprehensiveness of your actions will be considered in assessing any civil penalty for the apparent violations. The guidance in NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," may be helpful in preparing your response. You can find the Information Notice on the NRC website at: http://pbadupws.nrc.gov/docs/ML0612/ML061240509.pdf.

Please be advised that the 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 on our deliberations in this matter.

In accordance with 10 CFR 2.390 of the NRC's "Agency Rules of Practice and Procedure," 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 Public Document Room and from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC website at http://www.nrc.gov/reading-rm/adams.html. To the extent possible, your response should not include any personal privacy or proprietary information so that it can be made available to the public without redaction.

If you have any questions concerning this matter, please contact Dr. Lizette Roldán-Otero of my staff at 817-200-1455.

Sincerely,



Signed by Muessle, Mary
on 11/05/21

Mary C. Muessle, Director
Division of Nuclear Materials Safety

Docket No. 030-35244
License No. 11-27646-01

Enclosure:
NRC Inspection Report 030-35244/2021-001
cc w/Enclosure:

Mark Dietrich, PE, State Liaison Officer
Idaho Department of Environmental Quality
1410 N. Hilton St.
Boise, ID 83706

SUBJECT: NRC INSPECTION REPORT 030-35244/2021-001 - DATED NOVEMBER 5, 2021

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ADAMS ACCESSION NUMBER: ML21305A108

☒SUNSI Review: By: JCD | ADAMS: ☒ **Yes** ☐ No | ☐ Non-Publicly Available ☒ **Publicly Available** | ☒**Non-Sensitive** ☐ Sensitive | Keyword:

OFFICE	DNMS:MIB	DNMS:C:MIB	ACES: RIV	RC: RIV	D:DNMS	
NAME	JDykert	LRoldanOtero	JGroom	DCylkowski	MCMuessle	
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U.S. NUCLEAR REGULATORY COMMISSION
REGION IV

Docket No.:	030-35244
License No.:	11-27646-01
Inspection Report No.:	030-35244/2021-001
EA No:	EA-21-119
Licensee:	KRONUS, Inc.
Location Inspected:	Remote inspection
Inspection Dates:	April 22, 2021 through October 14, 2021
Exit Meeting Date:	October 20, 2021
Inspector:	Jason Dykert, Health Physicist Materials Inspection Branch Division of Nuclear Materials Safety, Region IV
Approved By:	Lizette Roldán-Otero, PhD, Chief Materials Inspection Branch Division of Nuclear Materials Safety, Region IV
Attachment:	Supplemental Inspection Information

Enclosure

EXECUTIVE SUMMARY

KRONUS, Inc.
NRC Inspection Report 030-35244/2021-001

On April 22, 2021, the U.S. Nuclear Regulatory Commission (NRC) began a remote inspection of KRONUS, Inc. (Kronus or licensee), with continued inspection and review through October 14, 2021. The inspection was an examination of activities conducted under the license, including review of procedures and records, and interviews with licensee personnel.

Program Overview

Kronus is authorized to manufacture and distribute in-vitro diagnostic test kits, each containing up to 10 microcuries of iodine-125 (I-125), bound in a freeze-dried gel within sealed vials. NRC Materials License 11-27646-01 authorized Kronus to perform quality control testing and handling of the non-volatile, unsealed I-125 that was obtained from tested kits. (Section 1)

Inspection Findings

As a result of this inspection, an apparent violation was identified involving the failure to perform adequate surveys to evaluate potential radiological hazards, at the licensee's facility in Star, Idaho. The licensee utilized a survey meter with less than 1 percent efficiency for detecting I-125 and the meter would not have detected I-125 at activities lower than 1-2 microcuries. Additionally, wipe tests for removable contamination were not performed at the end of the day when unsealed I-125 was handled. (Section 3)

Corrective Actions

Upon identification of the apparent violation by the inspector, the licensee immediately ordered a new sodium iodide scintillation detector type of survey meter which is more efficient in detecting I-125. Procedures were developed for using the new instrument when conducting the quality control tests on the vials, and for conducting wipe tests for removable contamination at the end of each day material is handled. Training was provided on the new procedures, and the licensee performed a response comparison between the old survey meter, the new scintillation detector, and a sensitive gamma counter that was documented for the inspection. (Section 4)

REPORT DETAILS

1 Program Overview (Inspection Procedure (IP) 87125)

1.1 Program Scope

KRONUS, Inc. (Kronus or licensee) is a manufacturer and distributer of iodine-125 (I-125) in-vitro diagnostic test kits, as authorized by Materials License 11-27646-01. Kronus distributes primarily to specific materials licensees and very rarely to generally licensed physicians, veterinarians, clinical laboratories, or hospitals.

Kronus' Radiation Safety Officer (RSO) and partial company owner employs two quality control (QC) managers authorized to perform lab testing on the kits, and a few other assistants for receiving, storing, and preparing kits for shipment.

1.2 Inspection Scope

The remote inspection consisted of in-office review of required records and authorized procedures under the license, and interviews with personnel regarding licensed activities as they relate to public health and safety, and security.

2 Background (IP 87125)

Kronus performs weekly QC testing on a few vials, each containing up to 10 microcuries of unsealed iodine-125 (I-125) in a lab area. During the QC tests, the unsealed I-125, in a vial, may be run through a centrifuge, pipetted, or transferred from vial to sink as effluent disposal to the sanitary sewer. Handling unsealed I-125 creates the potential for contamination to be present and I-125 has an approximately 60 day, or 2-month long half-life.

An evaluation of whether contamination is present after handling unsealed materials is required. Prior to this inspection, Kronus' evaluation of potential contamination was focused upon known spills or damaged vials and packages as they were initially received. However, after unsealing the material and handling the I-125 during QC testing, Kronus' evaluation did not include a physical survey or measurements to confirm that no concentration of radioactive material was present.

When spills occurred, or if initial receipt of I-125 products indicated a possibility of damage, the licensee utilized a Geiger-Mueller (G-M) pancake detector type of survey meter to evaluate if contamination was present. The G-M pancake detector has a measured efficiency of identifying about 0.07 percent of I-125 that is present. The low efficiency at detecting the soft gamma energy I-125 emits at around 35 KeV (kiloelectron volts) also presents an issue where the G-M detector is not able to reliably identify small amounts of I-125 activity. The evaluations performed by Kronus would not have identified contamination with activity below 1-2 microcuries.

Kronus has used this type of survey meter since the license was issued in 1999 for evaluating known spills or damaged packages. Potential contamination after handling unsealed I-125 was not evaluated with surveys. Compliance with requirements in 10 CFR (*Code of Federal Regulations*) Part 20, regarding exposure limits and waste

disposal requires evaluation of whether small amounts of contamination were present after handling unsealed I-125. Additionally, evaluations of known spills and damaged packages upon receipt requires an appropriate survey meter that can reliably detect I-125 contamination.

3 Observations and Findings (IP 87125)

During this remote inspection one apparent violation of NRC requirements was identified.

3.1 Apparent Violation of 10 CFR 20.1501(a)

Title 10 CFR 20.1501(a) requires, in part, that each licensee shall 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 are reasonable under the circumstances to evaluate the potential radiological hazards of the radiation levels and residual radioactivity detected.

As defined in 10 CFR 20.1003, *Survey* means 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. When appropriate, such an evaluation includes a physical survey of the location of radioactive material and measurements or calculations of levels of radiation, or concentrations or quantities of radioactive material present.

Contrary to the above, from December 1999 to May 2021, the licensee failed to make or cause to be made, surveys of areas to comply with regulations in 10 CFR Part 20 that were reasonable to evaluate the potential radiological hazards of the radiation levels and residual radioactivity detected. Specifically, the licensee failed to make adequate physical surveys with a radiation detection survey meter that could reasonably detect low activity amounts of I-125 contamination and did not perform surveys at the end of the day in areas where unsealed I-125 was handled.

The failure to 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 are reasonable under the circumstances to evaluate the potential radiological hazards of the radiation levels and residual radioactivity detected was identified as an apparent violation of 10 CFR 20.1501(a). (030-35244/2021-001-01)

4 Corrective Actions

Upon identification of the apparent violation by the inspector, the licensee immediately ordered a new sodium iodide scintillation detector type survey meter for appropriately detecting I-125. The licensee developed procedures for using the new instrument when conducting the QC tests on the vials, and for conducting wipe tests for removable contamination at the end of each day material is handled. In addition, the licensee provided training on the new procedures to the staff that performs QC testing. The licensee performed a response comparison between the old survey meter, the new scintillation detector, and a sensitive gamma counter that was documented for the inspection in Agencywide Documents Access and Management System (ADAMS) Accession No. ML21188A119.

5 Exit Meeting Summary

On October 20, 2021, the NRC held an exit meeting summary with Ms. Heather Viele, RSO and Mr. Brian Deis, QC manager. The licensee acknowledged the inspection findings and did not dispute any of the details presented during the call.

Supplemental Inspection Information

PARTIAL LIST OF PERSONS CONTACTED

Heather Viele, Radiation Safety Officer
Brian Deis, Quality Control Manager

INSPECTION PROCEDURE USED

IP 87125 – Materials Processor/Manufacturer Programs

ITEMS OPENED, CLOSED, AND DISCUSSED

Opened

030-35244/2021-001-01	AV	Failure to make adequate surveys (10 CFR 20.1501(a))

Closed

None.

Discussed

None.

LIST OF ACRONYMS USED

10 CFR	Title 10 *Code of Federal Regulations*
ADAMS	Agencywide Documents Access and Management System
AV	Apparent Violation
Iodine-125	I-125
IP	Inspection Procedure
KeV	Kiloelectron volts
G-M	Geiger-Mueller
NRC	Nuclear Regulatory Commission
PEC	Predecisional Enforcement Conference
QC	Quality Control
RSO	Radiation Safety Officer

Attachment