



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**
REGION I
475 ALLENDALE ROAD, SUITE 102
KING OF PRUSSIA, PA 19406-1415

December 20, 2024

EA-24-093

Braden Case, WPS Manager
Agilent Technologies, Inc.
2850 Centerville Road
Wilmington, DE 19808

SUBJECT: AGILENT TECHNOLOGIES, INC. - NRC INSPECTION REPORT 030-
32792/2024-002

Dear Braden Case,

This letter refers to the reactive inspection by the U.S. Nuclear Regulatory Commission (NRC) conducted between July 2, 2024, and August 30, 2024, at your Wilmington, DE facility. The purpose of the inspection was an examination of activities related to NRC-licensed byproduct material. The enclosed report presents the results of this inspection. A final exit briefing was conducted (telephonically) with David S. Bennett of your staff on December 6, 2024.

Based on the results of the inspection, the NRC identified one apparent violation which is being considered for escalated enforcement action in accordance with the NRC's Enforcement Policy. The current Enforcement Policy is included on the NRC's website at: <https://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>. The apparent violation, which is described in the Enclosure, involves the apparent failure to control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage in accordance with Title 10 *Code of Federal Regulations* (10 CFR) 20.1802. The inspection was opened following the event notification you submitted on July 2, 2024, regarding the loss of licensed radioactive material on June 5, 2024. This inspection also includes the 30-day report you submitted on July 30, 2024, and the telephone call conversation that occurred on August 30, 2024, regarding the loss of a sealed source containing 15mCi of Nickel-63. The inspection consisted of a selected examination of representative records and interviews with personnel. The circumstances surrounding these apparent violations, the significance of the issues, and the need for lasting and effective corrective action were discussed with members of your staff at the inspection exit meeting on December 6, 2024.

Since the apparent violation involves the improper transfer for disposal of licensed material (15mCi of Ni-63), the NRC is considering proposing imposition of a civil monetary penalty. Section 2.3.4, Civil Penalty, of the NRC Enforcement Policy states that for violations where a licensee has lost required control of its regulated licensed material for any period of time, the NRC normally will impose at least a base civil penalty. The NRC may exercise its discretion to mitigate or escalate a civil penalty amount based on the merits of a specific case. However, the NRC will not normally decrease the civil penalty to an amount below the lowest base civil penalty for such cases (i.e., \$9,000).

Since the NRC has not made a final determination in this matter, a Notice of Violation is not being issued at this time. 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 review. You will be advised by separate correspondence of the results of our deliberations on this matter.

Before the NRC makes its enforcement decision, we are providing you an opportunity to (1) respond to the apparent violation addressed in this inspection report in writing within 30 days of the date of this letter, (2) request a Pre-decisional Enforcement Conference (PEC), or (3) request Alternative Dispute Resolution (ADR). If a PEC is held, it will be open for public observation and the NRC will issue a press release to announce the time and date of the conference. If you decide to participate in a PEC or pursue ADR, please contact **Monica Ford at (610) 337-5214 or via email at Monica.Ford@nrc.gov** within 10 days of the date of this letter. 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 provide a written response, it should be clearly marked as a "Response to Apparent Violations in NRC Inspection Report (030-32792/2024-002); EA-24-093," and should include: (1) the reason(s) 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 U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001, with a copy mailed to Paul G. Krohn, Director, Division of Radiological Safety & Security, U.S. Nuclear Regulatory Commission Region I, 475 Allendale Road, Suite 102, King of Prussia, PA, 19406, and emailed to R1Enforcement@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.

If you choose to request a PEC, the conference will include an opportunity for you 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 Pre-decisional Enforcement Conference 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 PEC 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 action, 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 the enclosed excerpt from NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," may be helpful in preparing for your response. You can find the information notice on the NRC website at <https://www.nrc.gov/reading-rm/doc-collections/gen-comm/info-notices/1996/in96028.html>.

In lieu of a PEC or written response, 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 has decided to employ is mediation: a voluntary, informal process in which a trained neutral (the "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 ADR program can be obtained at <https://www.nrc.gov/about-nrc/regulatory/enforcement/adr/post-investigation.html>. The Institute on Conflict Resolution (ICR) at Cornell University has agreed to facilitate the NRC program as a neutral third-party. Please contact ICR 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, its enclosures, 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 Document 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 regarding this matter, please contact Monica Ford of my staff at (610) 337-5214, or via electronic mail at Monica.Ford@nrc.gov.

Sincerely,

Paul G. Krohn, Director
Division of Radiological Safety and Security
Region I

Docket No. 030-32792
License No. 07-28762-01

Enclosures:

1. NRC Inspection Report 030-32792/2024-002
2. NRC Information Notice 96-28

cc w/ Enclosure:
David S. Bennett, Radiation Safety Officer

SUBJECT: AGILENT TECHNOLOGIES, INC. - NRC INSPECTION REPORT 030-32792/2024-002 DATED DECEMBER 20, 2024

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R1Enforcement.Resource

[https://usnrc.sharepoint.com/teams/Region-I-CIRDA/Inspection Documentation/Inspection Documentation - Final/Agilent Technologies Inc Choice Letter EA-24-093.docx](https://usnrc.sharepoint.com/teams/Region-I-CIRDA/Inspection%20Documentation/Inspection%20Documentation%20-%20Final/Agilent%20Technologies%20Inc%20Choice%20Letter%20EA-24-093.docx)

ADAMS ACCESSION NUMBER: ML24353A222

<input checked="" type="checkbox"/> SUNSI Review/ MJW		<input checked="" type="checkbox"/> Non-Sensitive <input type="checkbox"/> Sensitive			<input checked="" type="checkbox"/> Publicly Available <input type="checkbox"/> Non-Publicly Available	
OFFICE	RI/DRSS	RI/DRSS	RI/ORA	RI/ORA	OE	OGC
NAME	M Wutkowski	M Ford	R Chazell	J Nick	SWoods	RAugustus
DATE	10/18/2024	10/18/24 (MLF)	10/18/2024	10/21/2024	11/21/2024	11/21/2024
OFFICE	RI/DRSS					
NAME	P Krohn					
DATE	12/20/2024					

OFFICIAL RECORD COPY

**U.S. NUCLEAR REGULATORY COMMISSION
REGION I**

Docket: 030-32792

License: 07-28762-01

Report: 2024-002

EA No.: EA-24-093

Licensee: Agilent Technologies, Inc.

Locations Inspected: Little Falls Center
2850 Centerville Road
Wilmington, Delaware, 19808

Inspection Dates: July 2, 2024, through December 6, 2024

Inspector: Michael Wutkowski, Health Physicist
Commercial, Industrial, R&D and Academic Branch
Division of Radiological Safety and Security

Approved By: Monica Ford, Chief
Commercial, Industrial, R&D and Academic Branch
Division of Radiological Safety and Security

Attachment: Supplemental Inspection Information

EXECUTIVE SUMMARY

Agilent Technologies, Inc.
NRC Inspection Report 030-32792/2024-002

Program Overview

At the time of the occurrence, Agilent Technologies, Inc. (Agilent) was a manufacturer and distributor of generally licensed devices at its Wilmington, Delaware, location under NRC license 07-28762-01. These devices were distributed via their distribution license 07-28762-02G. In addition to manufacturing and initial distribution, Agilent received generally licensed devices for servicing and redistribution to other customers. The licensee typically manufactured and distributed Nickel-63 sources inside Electron Capture Detector (ECD) devices.

Inspection Findings

One apparent violation was identified through a non-routine, unplanned, and reactive inspection of the activities performed by Agilent and its performance of these activities within the Nuclear Regulatory Commission's (NRC's) jurisdiction. The inspection was initially opened following the event notification (EN57205) Agilent submitted to the Headquarters' Operations Center on July 2, 2024, regarding the loss of licensed radioactive material on June 5, 2024. This inspection also includes the 30-day report you submitted on July 30, 2024 (ML24239A343), and the telephone call conversation on August 30, 2024, (ML24243A062) regarding the loss of a sealed source containing 15 mCi of Nickel-63.

The apparent violation, as identified during this inspection, involved the failure to control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage in accordance with Title 10 *Code of Federal Regulations* (10 CFR) 20.1802.

Corrective Actions

Upon the licensee self-identifying the violation, the licensee initiated steps to implement corrective actions. In the July 30, 2024, report (ML24239A343), the licensee identified that management would review with lab employees the necessity to comply with proper handling steps identified in the referenced procedure. Agilent stated this was completed on June 5, 2024. The licensee also committed that management would close gaps associated with employee training. This will include retraining staff on the procedure with both verbal and written instruction. This portion of the corrective measures was completed on November 26, 2024. Lastly, in the telephone conversation dated August 30, 2024 (ML24243A062), the licensee confirmed that they will commit to performing annual training with an employee sign-off of performing the training. These corrective actions were confirmed during the exit meeting held on December 6, 2024.

REPORT DETAILS

1. Program Overview

1.1 Program Scope

At the time of the inspection, Agilent Technologies, Inc. (Agilent) was a manufacturer and distributor of generally licensed devices at its Wilmington, Delaware, location under NRC license 07-28762-01. These devices were distributed via their distribution license 07-28762-02G. In addition to manufacturing and distribution, Agilent received generally licensed devices for servicing and redistribution to other customers. Agilent typically manufactured and distributed Nickel-63 sources inside ECD devices.

1.2 Inspection Scope

The inspection was an examination of activities conducted within the jurisdiction of the Nuclear Regulatory Commission (NRC), as they related to NRC-licensed byproduct material. Within this area, the inspection consisted of a selected examination of representative records and interviews with personnel.

2. Background

Agilent manufactures generally licensed, 15 mCi ECDs at its site in Wilmington, DE, under NRC license 07-28762-01. The devices are distributed by Agilent via their distribution license 07-28762-02G. In addition to manufacturing and distribution, Agilent transfers ECDs for customers from location to location. Agilent received a shipment of ECDs for transfer from a customer in North Carolina, with the eventual intent of transferring them to another customer in Canada. During incoming processing, it was discovered that the number of ECDs claimed by the customer did not match Agilent's count. Per a telephone conversation with the Radiation Safety Officer (RSO) (ML24243A062), it was verified that the licensee transferring the device confirmed that they do not possess the device, but Agilent could not fully confirm with 100 percent accuracy that they were in possession of the material. The devices, once sealed, are indistinguishable from background even at centimeter distance. The source was lost in a shielded position.

Agilent's process for receiving customer transfers is covered under Agilent procedure GCECD033 [Receiving Radioactive Sources]. That procedure requires that the lab technician handling the transfer "Retain all boxes and packaging materials in (the) inner lab until sources are verified." The technician performing the task normally follows that process, but for this instance, failed to do so before transferring the packaging materials to a trash bin in the hallway. The contents of that bin were then transferred to the site's trash compactor/dumpster by house cleaning services.

Upon discovering there was a discrepancy between the count provided by the customer and the count of ECDs in the lab, the technician attempted to retrieve the packaging material from the trash bin, but it had been transferred to the site's compactor and rammed into the adjoining dumpster. The technician notified the RSO, of the incident on the morning of June 5, 2024. The RSO sealed off the dumpster and attempted to retrieve the wrapping materials, but by that time, the previous day's trash had been added to the dumpster and compacted. Attempts to remove the trash were unsuccessful

due to the level of compaction within the container. Surveys of the dumpster using a survey meter were unable to detect the source as even from a minimum distance (i.e., 1 centimeter) when the source is in the shielded position, the source is essentially undetectable.

The licensee believes that the most likely cause of the loss of material involves the ECD being disposed of in the dumpster, and that dumpster subsequently being taken to a landfill. No exposure to the public is expected unless the integrity of the device is tampered with and deliberately compromised.

3. Observations and Findings

During an inspection initiated on July 2, 2024, with continued in office review through December 6, 2024, the inspector reviewed licensed activities pertinent to the transfer and storage of sealed sources found in the licensee's electron capture devices. During this inspection, one apparent violation of NRC requirements was identified as follows.

3.1. Apparent Violation of 10 CFR 20.1802

10 CFR 20.1802 requires, in part, that the licensee shall control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage.

Contrary to the above, on June 5, 2024, Agilent, a holder of a specific NRC license to manufacture and distribute Electron Capture devices, failed to maintain control of licensed material that is in a controlled or unrestricted area that is not in storage. Specifically, during incoming processing of a shipment of Electron Capture Devices, a technician failed to follow Agilent procedure GCECD033 "Receiving Radioactive Sources," that requires the lab technician verify that the number of devices claimed by the customer to be in the package matched the receipt count performed by the technician prior to disposing of all boxes and packaging materials. As a result, one ECD containing a 15 millicurie Ni-63 sealed source was lost when Agilent transferred the source for disposal to an unlicensed entity and could not be recovered.

4. Corrective Actions

Upon self-identification that the loss of radioactive material from their facility occurred, the licensee initiated an internal review to identify the root cause and implement corrective actions. The licensee identified that the lab technician involved in the loss of material was familiar with the need to confirm counts vs. customer information but failed in this instance to follow that procedure. Furthermore, the licensee identified that formal manufacturing training is not being implemented for new employees as in the past. Previous employees were trained in area manufacturing procedures and those employees signed off on their understanding of those procedures. The current technician had only received verbal instructions in how to perform their tasks.

After determining these root causes, the licensee began to implement and commit to corrective actions to prevent further loss of radioactive material by having: (1) management review with lab employees the necessity to comply with proper handling steps identified in the referenced procedure (Completion: June 5, 2024); (2) The management would close gaps associated with employee training. (Completion date:

November 26, 2024); and (3) complete annual training with an employee sign-off of training receipt. These corrective actions were confirmed during the exit meeting held on December 6, 2024.

5. Exit Meeting Summary

On December 6, 2024, the NRC held an exit meeting summary with the RSO David S. Bennett. Agilent acknowledged the inspection findings, confirmed that all corrective actions were complete and fully implemented by November 26, 2024. Agilent did not dispute any of the details presented during the call.

SUPPLEMENTAL INSPECTION INFORMATION

LIST OF PERSONS CONTACTED

Licensee

Braden Case, WPS Manager
David D. Bennett, Radiation Safety Officer

INSPECTION PROCEDURES USED

87125– Materials Processor/Manufacturer Programs
87141– Limited Scope Academic and Research & Development Programs Including Animal Use

ITEMS OPENED, CLOSED, AND DISCUSSED

Opened

030-32792/2024-002	AV	Failure to control and maintain constant surveillance of licensed material that is in an unrestricted area (10 CFR 20.1802).
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Closed

None

Discussed

None

LIST OF ACRONYMS

ADAMS	Agencywide Documents Access and Management System
AU	Authorized User
AV	Apparent Violation
CFR	<i>Code of Federal Regulations</i>
ECD	Electron Capture Detector
LC	License Condition
NRC	Nuclear Regulatory Commission
PEC	Pre-decisional Enforcement Conference