



### Materials Inspection Report

<b>1. Licensee/Location Inspected:</b>  H3D, Inc. 812 Avis Drive Ann Arbor, MI 48108  Report Number(s) 2023-001	<b>2. NRC/Regional Office</b>  Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352
---	--

<b>3. Docket Number(s)</b> 030-38932	<b>4. License Number(s)</b> 21-35314-01	<b>5. Date(s) of Inspection</b> 01/27/23; exit 04/10/23
---	--	--

**LICENSEE:**

The inspection was an examination of the activities conducted under your license as they relate to radiation safety and to compliance with the Nuclear Regulatory Commission (NRC) rules and regulations and the conditions of your license. The inspection consisted of selective examinations of procedures and representative records, interviews with personnel, and observations by the inspector. The inspection findings are as follows:

- 1. Based on the inspection findings, no violations were identified.
- 2. Previous violation(s) closed.
- 3. During this inspection, certain of your activities, as described below and/or attached, were in violation of NRC requirements, and were assessed at Severity Level IV, in accordance with the NRC Enforcement Policy.

A. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, corrective action was or is being taken, and the remaining criteria in the NRC Enforcement Policy were satisfied.

(Non-cited violation(s) was/were discussed involving the following requirement(s)

(1) Contrary to Condition 14 of NRC License No. 21-35314-01, between 12/17/20 and 07/29/22, H3D, Inc. did not conduct physical inventories to account for all sealed sources possessed under the license every six month. As corrective action, the licensee completed physical inventories on 07/29/22 and 01/27/23; all sources were accounted for on both occasions. The licensee also revised its inventory documentation to include source quantities and established an electronic tracking mechanism to ensure timely completion of future inventories. [continued on next page]

B. The following violation(s) is/are being cited in accordance with NRC Enforcement Policy. This form is a NOTICE OF VIOLATION, which may be subject to posting in accordance with 10 CFR 19.11.  
(Violations and Corrective Actions)

Contrary to 10 CFR 20.1101(c), between 02/13/18 and 01/27/23, H3D, Inc. did not review the content and implementation of its radiation protection program at least annually. Specifically, between these dates it only reviewed the content and implementation of its program once, in 2020. As corrective action for this Severity Level IV violation, the licensee committed to complete a program audit in April 2023, and to establish an electronic tracking mechanism to ensure timely completion of future audits.

**Statement of Corrective Actions**

I hereby state that, within 30 days, the actions described by me to the Inspector will be taken to correct the violations identified. This statement of corrective actions is made in accordance with the requirements of 10 CFR 2.201 (corrective steps already taken, corrective steps which will be taken, date when full compliance will be achieved). I understand that no further written response to NRC will be required, unless specifically requested.

TITLE	PRINTED NAME	SIGNATURE AND DATE
LICENSEE'S REPRESENTATIVE	Brian Kitchen	05/02/2023
NRC INSPECTOR	Ryan Craffey	Digitally signed by Ryan J. Craffey Date: 2023.05.01 14:21:56 -0400
BRANCH CHIEF	Rhex Edwards	Digitally signed by Rhex A. Edwards Date: 2023.05.01 13:23:55 -0500

## Materials Inspection Report (Continued)

[continued from section 3.A]

(2) Contrary to Condition 13.A of NRC License No. 21-35314-01, between 03/06/19 and 01/27/23, H3D, Inc. did not test five sources designed primarily to emit neutron or gamma radiation and containing more than 10 uCi of alpha-emitting material or 100 uCi of gamma-emitting material for leakage or contamination at the required interval of six months. Specifically, three such sources were initially tested by the manufacturer on 09/05/18, 12/15/18, and 04/01/19, respectively, and were not tested again until 11/03/22; one was initially tested on 01/01/21 and not again until 08/20/21, and one was initially tested on 04/15/22 and had not yet been tested again since.

As corrective action for this Severity Level IV violation, the licensee had all five sources tested on 02/28/23, with no leakage or contamination noted. The licensee also confirmed that the provider would now send leak test kits on a recurring basis, and committed to establish an electronic tracking mechanism to ensure timely completion of future leak tests.

As long-term corrective action for all findings in Section 3 of this report, the licensee hired a Certified Health Physicist with extensive radiation protection experience, and on February 17, 2023, submitted a request to the NRC to approve this individual as RSO. The licensee also committed to create an electronic action tracking database for radiation safety program matters.



### Materials Inspection Record

1. Licensee Name: H3D, Inc.		2. Docket Number(s): 030-38932		3. License Number(s) 21-35314-01	
4. Report Number(s): 2023-001			5. Date(s) of Inspection: January 27, 2023; exit April 10, 2023		
6. Inspector(s): Ryan Craffey		7. Program Code(s): 03620	8. Priority: 5	9. Inspection Guidance Used: IP 87126	
10. Licensee Contact Name(s): Brian Kitchen, PhD - RSO Dave Nessel, CHP		11. Licensee E-mail Address: brian@h3dgamma.com dnestle@h3dgamma.com		12. Licensee Telephone Number(s): 734-661-6416 x122 734-661-6416 x173	
13. Inspection Type: <input type="checkbox"/> Initial <input checked="" type="checkbox"/> Routine <input type="checkbox"/> Announced <input type="checkbox"/> Non-Routine <input checked="" type="checkbox"/> Unannounced		14. Locations Inspected: <input type="checkbox"/> Hybrid <input checked="" type="checkbox"/> Main Office <input type="checkbox"/> Field Office <input type="checkbox"/> Temporary Job Site <input type="checkbox"/> Remote		15. Next Inspection Date (MM/DD/YYYY):  01/27/2028 <input checked="" type="checkbox"/> Normal <input type="checkbox"/> Extended <input type="checkbox"/> Reduced <input type="checkbox"/> No change	
16. Location(s) Inspected List:  812 Avis Drive, Ann Arbor, MI					
17. Scope and Observations: H3D, Inc. manufactured high-performance imaging spectrometers using CZT detectors for nuclear power, CBRNE, defense, waste, and medical imaging applications. The licensee was authorized to use a wide variety of sealed and plated sources for research and development and for calibration and testing of its instruments, including as a commercial service, at its facility in Ann Arbor, Michigan. At the time of the inspection, the licensee had around 40 employees, most of whom were trained in radiation safety.  The inspector toured the facility in Ann Arbor. All areas were properly posted, and all licensed material was adequately secured. Readings from independent and confirmatory surveys found no evidence of residual contamination or exposures above limits to members of the public in unrestricted areas. The inspector observed the use of several sources for product testing and validation, and the conduct of a physical inventory. The inspector interviewed the RSO and staff to discuss the conduct of instrument calibrations, area surveys for exposure levels and contamination, and oversight of the radiation protection program. The inspector also reviewed a selection of records including documentation of physical inventories, sealed source leak tests, area survey results, radiation safety training, and program audits.  During discussions of program oversight, the licensee acknowledged several recent self-identified findings (below). The licensee determined that the root cause of all three was inadequate oversight of the program; the RSO acknowledged that he struggled to keep up with RSO duties along with others which had expanded recently. As long-term corrective action for all findings, the licensee hired a Certified Health Physicist with extensive radiation protection experience, and on February 17, 2023, submitted a request to the NRC to approve this individual as RSO. The licensee also committed to create an electronic action tracking database for radiation safety program matters.  (1) The licensee identified that between 12/17/20, and 07/29/22, it had not conducted physical inventories to account for all sealed sources possessed under the license, as required by LC 14. The licensee had already taken adequate corrective action by the date of the inspection; therefore, this finding met the criteria to be considered an NCV.					

**Materials Inspection Record (Continued)**

(2) The licensee identified it had not tested four sources designed primarily to emit neutron or gamma radiation and containing more than 10 uCi of alpha-emitting material or 100 uCi of gamma-emitting material for leakage or contamination every six months, as required by LC 13.A. Specifically, three sources containing 50 uCi of Cf-252, 100 uCi of Am-241 and 90 uCi of Am-241 were initially tested by the manufacturer on 09/05/18, 12/15/18, and 04/01/19, respectively, and were not tested again until 11/03/22; and one source containing 480 uCi of Eu-152 was initially tested on 01/01/21 and not again until 08/20/21 and 11/03/22. Although the licensee had already taken adequate corrective action by the date of the inspection for these four sources, it did not identify that one additional source containing 900 uCi of Co-57 had not been tested as required (it was initially tested on 04/15/22 and had not yet been tested again since). However, the licensee: previously identified the programmatic non-compliance with leak testing; committed during the inspection to fully correcting the violation within a reasonable period of time by testing all five sources for leakage within 30 days; and confirmed that the leak test service provider would now send leak test kits on a recurring basis and that tests would be performed promptly thereafter. These actions were completed on 02/28/23; therefore, this finding met the criteria to be considered an NCV.

(3) The licensee identified that between 02/13/18 and 01/27/23, it did not review the content and implementation of its radiation protection program at least annually, as required by 10 CFR 20.1101(c). Specifically, between these dates it only reviewed the content and implementation of its program once, in 2020 (the audit itself was undated). The 2020 audit identified the lack of an audit the year before, but since the violation occurred again in 2021 and 2022, and additional corrective action was needed to restore compliance and address the potential for recurrence, this finding did not meet the criteria to be considered an NCV and was therefore cited as a SLIV violation.

Signature and Date - Branch Chief



Digitally signed by Rhex A. Edwards  
Date: 2023.05.01 13:23:40 -05'00'