

From: [Lizette Roldan-Otero](#)
To: kimberly.daniel@fda.hhs.gov
Cc: [Leo Wardrobe](#)
Subject: NRC Inspection Report and Notice of Violation
Date: Friday, December 8, 2023 1:12:13 PM
Attachments: [DHHS.FDA.NRC 591M NOV Revised.pdf](#)

Dear Kimberly Daniel –

As discussed earlier, editorial errors were identified within the context of the report and Notice of Violation (NOV) during my review. The report with the NOV was issued to you by Leo Wardrobe. You acknowledged and signed the report on November 14, 2023. I have incorporated the editorial changes to the NOV. Please sign and return the report to me.

Thanks,

Lizette Roldán-Otero, Ph.D., Chief

RIV/DRSS/MIB

Office: 817-200-1455

Cell: 630-453-3812



Materials Inspection Report

1. Licensee/Location Inspected: Department of Health Human Services Food and Drug Administration National Center for Toxicological Research 3900 NCTR Road, HFT-2 Jefferson, AR 72079 Report Number(s) 2023-001	2. NRC/Regional Office Region IV U. S. Nuclear Regulatory Commission 1600 E. Lamar Boulevard Arlington, TX 76011-4511
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3. Docket Number(s) 030-08559	4. License Number(s) 03-15093-01	5. Date(s) of Inspection 10/11/2023, 11/7/2023
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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.


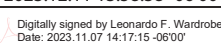

3. During this inspection, certain of your activities, as described below and/or attached, were in violation of NRC requirements, and were assessed at Severity Level IV, in accordance with the NRC Enforcement Policy.

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))

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)
See Continuation Page.

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	Kimberly Daniel - RSO	 Digitally signed by Kimberly D. Daniel -5 Date: 2023.12.11 13:58:38 -06'00'
NRC INSPECTOR	Leonardo Wardrobe	 Digitally signed by Leonardo F. Wardrobe Date: 2023.11.07 14:17:15 -06'00'
BRANCH CHIEF	Lizette Roldán-Otero, PhD	 Digitally signed by Lizette Roldan-Otero Date: 2023.12.08 12:50:00 -06'00'

Materials Inspection Report (Continued)

License Condition 22B of NRC License 03-15093-01, states that the licensee is authorized to hold radioactive material with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal in ordinary trash:

A record of each such disposal permitted under this license condition shall be retained for 3 years. The record must include the date of disposal, the date on which the byproduct material was placed in storage, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.

Contrary to the above, since August of 2023, the licensee failed to maintain a record of disposal for radioactive material with a physical half-life of less than or equal to 120 days. Specifically, in August of 2023, the licensee started using fluorine -18, a radioactive material with a physical half-life of less than or equal to 120 days, and failed to maintain records of disposal.

This a Severity Level IV Violation (Enforcement Policy 6.3.d)

The licensee committed to commence records of disposal for their F-18 waste and also to update their waste disposal procedure to ensure all new studies are evaluated for waste disposal requirements.



Materials Inspection Report

1. Licensee/Location Inspected: Department of Health Human Services Food and Drug Administration National Center for Toxicological Research 3900 NCTR Road, HFT-2 Jefferson, AR 72079 Report Number(s) 2023-001	2. NRC/Regional Office Region IV U. S. Nuclear Regulatory Commission 1600 E. Lamar Boulevard Arlington, TX 76011-4511	
3. Docket Number(s) 030-08559	4. License Number(s) 03-15093-01	5. Date(s) of Inspection 10/11/2023, 11/7/2023

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))

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TITLE	PRINTED NAME	SIGNATURE AND DATE
LICENSEE'S REPRESENTATIVE	Kimberly Daniel - RSO	 Digitally signed by Kimberly D. Daniel -S Date: 2023.11.14 09:29:30 -06'00'
NRC INSPECTOR	Leonardo Wardrobe	Leonardo F. Wardrobe Digitally signed by Leonardo F. Wardrobe Date: 2023.11.07 14:17:15 -06'00'
BRANCH CHIEF	Lizette Roldán-Otero, PhD	

Materials Inspection Report (Continued)

License Condition 22 of NRC License 03-15093-01 states that the licensee is authorized to hold radioactive material with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal in ordinary trash:

B. A record of each such disposal permitted under this license condition shall be retained for 3 years. The record must the date of disposal, the date on with the byproduct material was placed in storage, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.

Contrary to the above, the licensee failed to maintain a record of disposal for radioactive material with a physical half-life of less than or equal to 120 days. Specifically, since August, 2023, the licensee has used Fluorine -18, a radioactive material with a physical half-life of less than or equal to 120 days, and failed to maintain records of disposal.

This a Severity Level IV Violation (Enforcement Policy 6.3.d)

The licensee committed to commence records of disposal for their F-18 waste and also to update their waste disposal procedure to ensure all new studies are evaluated for waste disposal requirements.