DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Main Street, Suite 7200 Dallas, TX 75202 (214)253-5200 Fax:(214)253-5314	3/9/2026-3/13/2026
	FEI NUMBER 3021621451

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Alexander J. Whyte, Regional Manager

FIRM NAME	STREET ADDRESS
Isorx Cyclotron Center	4009 19th St Ste A
CITY, STATE, ZIP CODE, COUNTRY Lubbock, TX 79410-1004	TYPE ESTABLISHMENT INSPECTED PET Radiopharmaceutical Drug Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:
Production System

OBSERVATION 1

Permitted variations in the amount of component necessary are not reasonable and not specified in the master production and control records.

Your master production and control records did not include a statement of action limits on radiochemical yield. Your master production and control records did not include complete special notations and precautions to be followed.

Specifically,

A. You did not include the recording and reconciliation of all inputs and outputs in your production batch records to demonstrate that your production process is in a state of control and that you can consistently produce predictable batch yield and quality. For example, the following batches have varied cyclotron irradiation times from (b) (4) ; varied cyclotron charge amount; cyclotron calculated radioactivity generated; and resulting (b) (4) radioactivity at Start of Synthesis (SOS); final product vial (FPV) radioactivity at end of synthesis (EOS); and assay concentration from (b) (4) .

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Date	Batch #	Cyclotron Irrad. Time (min:sec)	Cyclotron charge (uAh)	Cyclotron Calc. Activity (mCi)	(b) (4) Radioactivity (SOS) (mCi)	FPV Radioactivity (EOS) (mCi)	FPV Assay (mCi/mL)
(b) (4)							

The firm has not included the cyclotron inputs in the batch record as a function of batch scale and has not reconciled that with the final product yield to demonstrate consistent and expected results.

B. The batch records produced by the firm lack consistent information and process. Batches were produced with varied cyclotron power from (b) (4) charge and varied irradiation times from (b) (4) The radiation dose produced in the final product vial varied from (b) (4) The firm has not calculated an acceptable lowest and acceptable highest range of input and finished product output, that can realistically accommodate patient doses. The inconsistent production processes and record do not provide a valid evaluation for process control.

C. The batch records lack a stated purpose designating the production as development, engineering, or GMP. After errors were identified in some batch records, the firm reported that some batches

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were for R&D, development, engineering runs, or because there was a long gap in production activity, or that the firm did not have a specific reason for the batch. This reason was given for use of expired reagents, varied cyclotron power and run times, and missing information between batch records. But this is not justified with intended purpose or batch scale planned prior to the execution of the batch. Additionally, batch records do not include information about deviations or environmental monitoring excursions and sometimes have missing forms for incoming material log.

OBSERVATION 2

Your batch production record did not include labeling.

Specifically,

During the review of batch records we found inconsistencies with batch record product and shield/packaging labels.

For example:

PPQ batch records (b) (4) and batch (b) (4) contain a single product vial label with lot number, date, total activity, volume, and expiration date and time.

Batch records (b) (4) contain a single vial label but this label is different from the [(b)] batches above as it only contains lot number, date, and expiry date and time, but not activity.

Batch (b) (4) did not have any product labels.

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Batch record (b) (4) contains a vial label and shield label, but the expiration times were inconsistent and the total activity at End of Synthesis (EOS) was incorrectly reporting the larger activity for start of synthesis.

OBSERVATION 3

You did not review production records to determine whether errors had occurred.

Specifically,

A. Expired reagents and materials were used in the production of PET batches, including but not limited to the following:

Batch Record (b) (4) was produced using (b) (4) expired (b) (4) Lot (b) (4) expired 10/2025, and (b) (4) unit Lot (b) (4) expired 2025/09. This was not documented in the batch record as a deviation nor was it noted on the deviation log.

Batch Record (b) (4) labeling discrepancies. Product vial label has expiry time of (b) (4) at (b) (4) label had expiry time (b) (4) Also, the incorrect (b) (4) activity @ EOS (b) (4) is the starting level however the label should have the level after the process was completed which was (b) (4) no documentation in the batch record as a deviation nor was it noted on the deviation log.

Expired (b) (4)" (b) (4) Lot (b) (4) expired 2025-12-31 were used with no documentation in the

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batch record as a deviation nor was it noted on the deviation log.

B. The firm lacks an effective material management and inventory tracking system to prevent mix-ups of expired materials and reagents from being used for GMP production and does not designate non-GMP development batches with planned deviations to account for use of expired materials.

Quality System

OBSERVATION 4
You did not establish and follow written quality assurance procedures.

Specifically,

Your firm did not establish adequate environmental monitoring procedures to ensure that the ISO-5, ISO-7, and ISO-8 classified areas used to produce (b) (4) PET drugs are consistently made in safe environmental conditions.

- Standard Operating Procedure DOC-417, Environmental Monitoring Policy, version 1.1, effective 11/18/2025, describes that environmental monitoring sampling and testing will be conducted after (b) (4) (b) (4) and by third party vendor (b) (4) HEPA filter recertifications, and additionally (b) (4) even when there is not activity.

  (b) (4) EM has not been done over the past 2 years, from the period of 4/24/2024, when the

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(b) (4) PPQ batches were produced, up to 2/15/2026.

- The firm has not conducted and trended EM results to demonstrate that the cleaning and disinfection procedures and (b) (4) EM monitoring is adequate.

A summary of HEPA filter recertification and EM results by (b) (4) is listed in the table below. Microbial excursions and HEPA filter failures were reported for the 6 months from June – December 2025, but the firm has not completed a comprehensive CAPA to address potential root cause(s).

Date of Test / Activity	Results	Filter Number, Area
3/4/2026	Pass	HEPA recertification
12/29/2025	Pass	HEPA recertification
12/15/2025	Remodel / Ceiling Tiles removed, new HEPA filter(s) installed. *No cleaning records, no environmental monitoring records.	
10/30/2025	Fail	HEPA recertification. (b) (4) ISO-7 Cleanroom
	Fail	Leak test, ISO-7 Cleanroom
9/17/2025	Out of Compliance	(b) (4) HEPA check. 12 CFUs, Viable Active Air, ISO-7 Cleanroom
6/9/2025	Out of Compliance	(b) (4) HEPA check.

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		11 CFUs, Viable Active Air, ISO-7 Cleanroom
	Alert	2 CFUs Viable Active Air and 2 CFUs Viable Surface, ISO-8 Ante Room
3/26/2025	Pass	HEPA Recertification

- The firm has not conducted and documented thorough cleaning and disinfection of ISO-5, ISO-7, and ISO-8 classified areas after significant interventions by non-employees. This includes 6 instances over the past year when (b) (4) technicians conducted HEPA filter recertification and 2 instances of smoke studies. This includes construction / remodeling done in December 2025 to remove ceiling tiles in the ISO-7 cleanroom, exposure of the classified space to the ceiling crawlspace, installation of new HEPA filter(s), reinstalling ceiling tiles, application of (b) (4) sealants and paint.

- During the inspection of the ISO-7 cleanroom between 3/10-12/2026, deficiencies were observed with the cleanroom. For example:
  - The ISO-7 cleanroom is not constructed to ensure controlled separation between the ISO-7 space and the uncontrolled air in the shipping room. The outgoing (b) (4) had gaps between the (b) (4) on the inside room (b) (4) door. The outer (b) (4) (b) (4) door was warped resulting in a gap of space of approximately 2-3mm.
  - Rust was observed on the bolts of the outer (b) (4)
  - Sealant and smeared paint was observed on the walls and ceiling tiles in the ISO-7 cleanroom.

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OBSERVATION 5

You did not have written production and process control procedures to ensure that any deviations from the procedures are justified.

Specifically, **2026-0217-1** - CAPA still open with outstanding work not completed and no additional comments of status or when it will be completed. Doc 131 Inventory Management SOP was supposed to be finalized by the end of February. As of this inspection it has not be completed and the CAPA has not been updated with current information

Additionally, the Change Control Program 102 states that changes in operating procedures are not recorded as change controls but instead are listed under change Document Request Policy 111, but this practice is also used for implementation of new procedures. The nature of the change or policy and significance or risk assessment is not included the determination of whether a change control or a document change request is used. This decision between the two processes does not cover criticality or process changes.

OBSERVATION 6

You did not establish written procedures describing the identification of components.

Specifically, your procedure unique document # 132 entitled Materials Acceptance effective Feb 16, 2026, states you will use a unique unit control number to identify all incoming lots of components and if you received several shipments of the same product with the same lot number on the same day each shipment would get its own unique identifier. Your SOP does not address receiving the same product with the same lot number on a different day.

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During the review of the following batch records they all used (b) (4) lot (b) (4) however you are not able to determine which shipment the lot of (b) (4) was a part of, nor does it have a unique identifier used in the batch record.

(b) (4)	used	(b) (4)	lot	(b) (4)
(b) (4)	used	(b) (4)	lot	(b) (4)
(b) (4)	used	(b) (4)	lot	(b) (4)

OBSERVATION 7

You lack personnel with the necessary training and experience to perform their assigned functions.

Specifically,

The firm has begun to provide basic GMP training, however, the managers acknowledged lack of awareness of GMP documentation, the need for consistent production processes, and to establish in-house evaluations and validations of microbiological, cleaning, and other procedures. No validation studies were performed in-house for cleaning and disinfectant efficacy, environmental monitoring, microbial media incubation conditions, or other relevant procedures with scientific bases to support the reason for the procedures used.

Training on standard operating procedures is not documented. A review of the training record for the assistant cyclotron operator to be cross-trained to perform QC testing lacked documentation and evaluative assessment of the understanding of the relevant standard operating procedures. Complete training records for all employees covering common or specific work activities was not available. For

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example, receipt of materials, record keeping, good documentation, principles of data integrity, preventing chemical or microbial cross contamination, and other practices were lacking.

X Ronda R Loyd Jones
Investigator
Signed By: RONDA R. LOYD-JONES -S
Date Signed: 03-13-2026 11:20:57

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The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."