



INDIANA UNIVERSITY

PUBLIC SAFETY
Environmental Health and Safety

January 17, 2023

ATTN: Document Control Desk
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

and

Director, Division of Nuclear Materials Safety
U.S. Nuclear Regulatory Commission, Region III
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

Resource@nrc.gov

**RE: Reply to Notice of Violation (NOV) in the Routine Inspection Report Nos.
03001609/2022001(DRSS) and 03009792/2022001(DRSS); EA-22-107**

Dear Sir/Madam:

Attached please find Indiana University's response to the Notice of Violations as noted in the
aforementioned reports. Should you have any questions, please do not hesitate to contact me.

Sincerely,

Benjamin D. Hunter, Associate Vice President; Superintendent for Public Safety

cc: Christopher P. Harvey, MSPH, MHP – IUMC/IUPUI Radiation Safety Officer
Mark Payne, MD, FAAP, FACC – Chairman, Radionuclide Radiation Safety Committee

RESPONSE TO NOTICE OF VIOLATIONS

Routine Inspection Report Nos. 03001609/2022001(DRSS) and 03009792/2022001(DRSS); EA-22-107

Violations #1 and #2 – Violation #1 - Licensee failed to secure from unauthorized removal or limit access to a unit dose containing approximately 126 microcuries of radium-223 [aka Xofigo] that was stored in a controlled area as required by 10 CFR 20.1801 and Violation #2 - The licensee did not perform an adequate survey before disposing of a unit dose, containing 126 microcuries of radium-223, as normal, non-radioactive waste as required by 10 CFR 20.1501.

1) Reason for the Violation

There are several contributing factors to why this loss of material occurred. Two administrations of Xofigo (radium-223) were scheduled one day apart from each other. The nuclear medicine department received a package containing two (2) unit doses of Xofigo on the day of the first administration. It is unusual to receive the unit dose a day in advance or receive multiple quantities at once. The unit doses are usually delivered on the day of administration. The technologist who threw the package away would have expected a new unit dose to be received the next day for the second administration. As radium-223 is primarily an alpha-emitter, the external dose rate is reasonably low. Therefore, the unit doses do not require lead shielding, making the package significantly lighter than a dose containing lead shielding (see attachment 1). The technologist would not have realized by the weight of the box that there was still a single unit dose left inside. An end-of-day direct radiation survey was completed on the day the package was discarded with the remaining unit dose still inside. However, the material was not detected within the trashcan when performing the end-of-day direct radiation survey using a standard GM meter due to the low level of photon emissions (see attachment 2). Neither did the waste portal at the local waste facility detect the lost material. The expected dose rate at the time of the loss of material at a one-meter distance was approximately 0.02 millirem per hour, the usual background exposure rate in the nuclear medicine area.

2) Corrective Steps That Have Been Taken

There have been no actions to recover the loss of the material, as it was determined to be discarded in the general waste and was no longer retrievable at the time the incident was discovered. The nuclear medicine supervisor initiated an internal investigation and discussed with the nuclear

medicine technologist involved what caused the incident and how to prevent it. The GM survey meter was up to date on calibration at the time of the incident and still within its calibrated date range (see attachment 3). However, the Radiation Safety Office provided the nuclear medicine department with an updated GM survey meter in case of possible issues with the existing meter. As noted above, the expected dose rate was near the background exposure rate at the time of the loss of the material.

3) Corrective Actions Taken to Avoid Further Violations

The procedure in nuclear medicine has been updated such that the nuclear medicine technologist will now completely open and empty all packages of Xofigo (radium-223) at the time the package is received. All unit doses will be placed in the existing rack system to prevent accidental disposal in the future (see attachment 4). This will ensure that no unit doses will be accidentally discarded. The rack system holds radiopharmaceutical unit doses within their shielded containers until the time of administration. Additionally, all nuclear medicine technologists were reminded of the requirements of performing end-of-day direct radiation surveys with an emphasis on surveying inside and outside of all general waste trashcans within the nuclear medicine department.

4) Date When Full Compliance Was Achieved

Full compliance has been achieved as of the date of this response.

Violation #3 – A nuclear medicine physician was approved by the Radiation Safety Office and Radionuclide Radiation Safety Committee for 10 CFR 35.300 uses without evidence of adequate training and experience as required by 10 CFR 35.390.

1) Reason for the Violation

The cause of this violation was human error by the proposed authorized user, the Radiation Safety Office, and the preceptor who signed the form. This is likely because the proposed authorized user was applying for 10 CFR 35.100 and 35.200 uses, in addition to 35.300 uses. Therefore, multiple NRC forms were completed, and the details on the forms were overlooked. The training and experience for 10 CFR 35.300 uses require at least 200 hours of classroom and laboratory training; however, only 100 hours of classroom and laboratory training was entered on the form.

2) Corrective Steps That Have Been Taken

A new NRC Form 313A (AUT) was completed and signed by the preceptor for the proposed authorized user when the error was discovered. Because there were questions about the amount of actual classroom and laboratory training for this proposed authorized user, the Radiation Safety Officer obtained a training case log of the proposed authorized user to demonstrate adequate training. This was completed during the routine NRC inspection in May 2022. Additionally, as noted in the routine inspection report mentioned above, it was determined during the NRC inspection in May 2022 that the proposed authorized user had the required training prior to their approval.

3) Corrective Actions Taken to Avoid Further Violations

An internal review process for the approval of authorized users was implemented. The review process includes an in-depth review of all application materials by the Radiation Safety Office and a comparison with the NRC requirements. The Radiation Safety Office will create a packet with all application materials to be submitted to the Radionuclide Radiation Safety Committee for review. Once completed, the packet will be reviewed by a second member of the Radiation Safety Office before being submitted to the Radionuclide Radiation Safety Committee for review and preliminary voting. After preliminary approval, the committee will provide a final approval at the following committee meeting. This internal review process was provided in writing to the NRC inspectors as a part of their in-office review through November 29, 2022 (see attachment 5).

4) Date When Full Compliance Was Achieved

Full compliance has been achieved as of the date of this response.

Violation #4 – Two individuals were observed to be handling radioactive materials without wearing gloves contrary to the licensee’s written procedures for the safe use of unsealed byproduct material.

1) Reason for the Violation

During the routine NRC inspection in May 2022, the inspectors took facility tours and spoke with personnel who handle radioactive materials. In two instances during the weeklong inspection, personnel were observed handling radioactive materials without gloves while providing demonstrations to inspectors. There is no excuse for personnel not wearing gloves.

2) Corrective Steps That Have Been Taken

During the inspection, the inspectors immediately pointed out to the users that they were not wearing gloves while handling radioactive materials. The Radiation Safety Office also reminded the personnel of the requirement to wear disposable gloves while handling radioactive materials as outlined in the Radiation Safety Procedures Manual under the Contamination Control section. The users acknowledged their non-compliance and understanding of the requirements. The Radiation Safety Office also provided the inspectors with a copy of this section of the Radiation Safety Procedures Manual as a part of their in-office review (see attachment 6). In April 2021, contamination control refresher training was provided to all radioactive material users (see attachment 7). In April 2022, all radioactive material users were required to acknowledge that they had reviewed the most recent version of the Radiation Safety Procedures Manual, which was updated in February 2022 (see attachment 8).

3) Corrective Actions Taken to Avoid Further Violations

The Radiation Safety Procedures Manual was established to illustrate the requirements of working with radioactive materials. This manual is reviewed and upgraded as needed regularly. The manual is made available to all users on our website and in paper form when required. In addition to the Radiation Safety Procedures Manual, the Radiation Safety Office also provides training to all radioactive material users before using radioactive materials. The Radiation Safety Office also conducts routine radiation safety audits at all locations listed on our NRC licenses. During these audits, the members of the Radiation Safety Office observe all users while handling radioactive materials to ensure that they follow all requirements. The Radiation Safety Office has counseled the the personnel who were observed not wearing gloves during the May 2022 inspection. These users were given verbal warnings.

4) Date When Full Compliance Was Achieved

Full compliance has been achieved as of the date of this response.

Violation #5 – The licensee did not perform full calibration measurements (length of the source transfer tubes and the length of the applicators) on HDR units on the source transfer tubes and the applicators.

1) Reason for the Violation

The cause of this violation was the result of the requirements of 10 CFR 35.633 being unintentionally overlooked by the personnel who perform the routine quality assurance (QA) checks on the HDR machine and source. Additionally, the lack of full calibrations measurements was not identified by the Radiation Safety Office during routine radiation safety audits. Daily and quarterly QA checks have always been completed for the HDR unit and each time the source is exchanged.

2) Corrective Steps That Have Been Taken

The transfer tube lengths for the HDR unit were measured and verified on May 19, 2022, and for each quarter since the May 2022 inspection (see attachment 9). The applicator lengths have been measured prior to each procedure since the May 2022 inspection (see attachment 10).

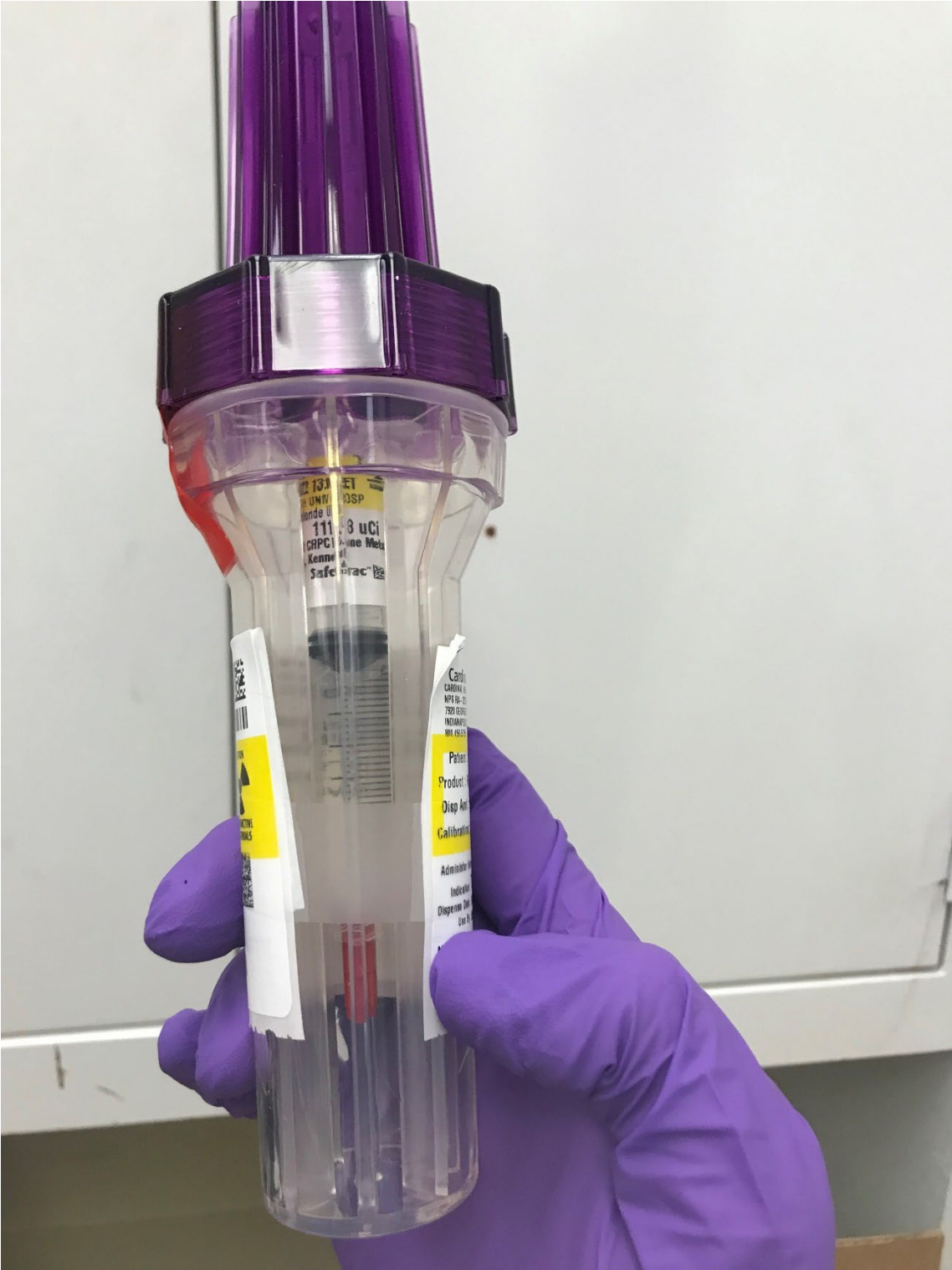
3) Corrective Actions Taken to Avoid Further Violations

Moving forward, all HDR transfer tube lengths will be measured and documented with the quarterly HDR QA checks. The procedure to measure the applicator length will be to either measure the applicator length prior to each procedure or measure and document the applicator length quarterly, depending on the specific applicator. Additionally, full calibration measurements will be reviewed and recorded on the quarterly HDR radiation safety audit forms (see attachment 11).

4) Date When Full Compliance Was Achieved

Full compliance has been achieved as of the date of this response.

Attachment 1 – Xofigo Syringe Inside Lightweight Plastic Shielding





Area Monitoring Report

Group Name : DAILY SURVEYS

Date Range : 03-31-2022 To 04-01-2022

Meter Model	Manufacturer Name	Meter S/N	Ck. Src
2	Ludlum	72747	

	2022/03/31 14:21	2022/04/01 14:53
	Tech: AH	Tech: BG
	Bkg: 0.02	Bkg: 0.02
	mR/hr	mR/hr
1. BENCH TOP	0.04	0.02
11. HOOD LEDGE / FACE	0.02	0.12
12. TRASH CAN	0.02	0.02
13. HOOD LEDGE AND FACE	0.02	0.12
14. WASTE	0.10	0.12
15. BENCH TOP	0.06	0.12
16. INJECTION AREA	0.02	0.02
17. TRASH CAN	0.02	0.02
18. FLOOR AROUND CHAIRS	0.02	0.02
19. LINEN CONTAINER	0.02	0.02
2. REFRIDGERATOR	0.02	0.02
20. FLOOR AROUND SYMBIA	0.02	0.02
24. FLOOD AROUND SPECT/CT	0.02	0.02
26. LINEN CONTAINER	0.02	0.02

IU Health University Hospital

Nuclear Medicine Department

Area Monitoring Report : Group Name : DAILY SURVEYS

Date Range : 03-31-2022 To 04-01-2022

	2022/03/31 14:21	2022/04/01 14:53
	Tech: AH	Tech: BG
	Bkg: 0.02	Bkg: 0.02
	mR/hr	mR/hr
27. LINEN CONTAINER*	0.02	0.02
28. FLOOR AROUND E-CAM	0.02	0.02
3. WALL OPPOSITE WASTE	0.12	0.02
4. BENCH TOP	0.08	0.02
5. TRASH CAN	0.02	0.02
6. TREADMILL	0.02	0.02
7. LEFT SIDE OF L-SHIELD	0.02	0.08
8. RIGHT SIDE OF L-SHIELD	0.02	0.08
9. BENCH TOP	0.02	0.02

IU Health University Hospital

Nuclear Medicine Department

Area Monitoring Report : Group Name : DAILY SURVEYS

Date Range : 03-31-2022 To 04-01-2022

Default Trigger Limit : 0.05 mR/hr**Current Area Trigger Limits (mR/hr):**

1. BENCH TOP - 2.00	2. REFRIDGERATC - 2.00	3. WALL OPPOSIT - 2.00
4. BENCH TOP - 2.00	5. TRASH CAN - 2.00	6. TREADMILL - 2.00
7. LEFT SIDE OF - 2.00	8. RIGHT SIDE C - 2.00	9. BENCH TOP - 2.00
11. HOOD LEDGE - 2.00	12. TRASH CAN - 2.00	13. HOOD LEDGE - 2.00
14. WASTE - 2.00	15. BENCH TOP - 2.00	16. INJECTION A - 2.00
17. TRASH CAN - 2.00	18. FLOOR AROUN - 2.00	19. LINEN CONTA - 2.00
20. FLOOR AROUN - 2.00	24. FLOOD AROUN - 2.00	26. LINEN CONTA - 2.00
27. LINEN CONTA - 0.05	28. FLOOR AROUN - 2.00	

Tech Information:

Tech	Complete Tech Name
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BG	██████████
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AH	██████████
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The above report indicates all of the values UNDERLINED did not pass .

Technologist Signature: - _____

R.S.O. Signature: - _____

Report Printed: 4/6/2022 12:17:15PM

Authorized Calibration Personnel Information

Name (printed:) <div style="background-color: black; width: 100px; height: 15px; margin-top: 5px;"></div>	Signature:	Permit Holder, Location: Sims (UHNM01) UH Hot Lab	Calibration Date: 06/10/21
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Instrument Information

Make: Ludlum	Model: 2	Serial: 72747	Probe Type: <input type="checkbox"/> Pancake <input checked="" type="checkbox"/> End Window <input type="checkbox"/> N/A <input type="checkbox"/> Side Window <input type="checkbox"/> Internal
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Source Information

Manufacturer: Tech Ops	Model: 773	Serial: S509	Cal Date: 11/20/84	Cal Activity: 153 mCi	mR/hr@1m (on cal date): 49.00	mR/hr@1m (today): 21.09
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Gamma Calibration Data

Scale	Calculated Exposure (mR/hr)	Calculated Distance (cm)	Filter	Observed Exposure Rate (mR/hr)	Adjusted Exposure Rate (mR/hr)	Correction Factor
X	140.00	38.8	0			
	70.00	54.9	0			
X 10	14.00	122.7	0	13.50		N/A
	7.00	173.6	0	6.75		N/A
X 1	1.40	122.7	1	1.30		N/A
	0.70	173.6	1	0.70		N/A
X 0.1	0.14	122.7	2	0.15		N/A
	0.07	173.6	2	0.06		N/A

Beta Calibration Data

Nuclide	Emax (MeV)	Activity (μCi)	Assay Date	Calculated dpm	Observed cpm	Efficiency
¹⁴ C	0.156	0.098	8/1/1978	216,435	3500	2%
⁹⁹ Tc	0.292	0.039	2/24/1978	86,568	6750	8%
³⁶ Cl	0.719	0.0208	3/30/1978	46,131	6000	13%
²¹⁰ Pb	1.16	0.02005	4/1/2001	22,413	3000	13%
¹²⁹ I	0.15	0.082	8/25/1982	182,040		

Additional Checks

Check Source Reading: N/A	Battery Condition: <input type="checkbox"/> Okay <input checked="" type="checkbox"/> Replaced	Speaker Working? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	Next Calibration Due: 06/30/22
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Comments:

UHNM indicated erratic readings. Could not replicate.

RADIATION SURVEY INSTRUMENT CALIBRATION REPORT

Authorized Calibration Personnel Information

Name (printed:) <div style="background-color: black; width: 100px; height: 15px;"></div>	Signature: <div style="background-color: black; width: 100px; height: 15px;"></div>	Permit Holder, Location: Sims (UHNM01)	Calibration Date: 06/29/22
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Instrument Information

Make: Ludlum	Model: 2	Serial: 72747	Probe Type: <input type="checkbox"/> Pancake <input checked="" type="checkbox"/> End Window <input type="checkbox"/> N/A <input type="checkbox"/> Side Window <input type="checkbox"/> Internal
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Source Information

Manufacturer: Tech Ops	Model: 773	Serial: S509	Cal Date: 11/20/84	Cal Activity: 153 mCi	mR/hr@1m (on cal date): 49.00	mR/hr@1m (today): 20.58
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Gamma Calibration Data

Scale	Calculated Exposure (mR/hr)	Calculated Distance (cm)	Filter	Observed Exposure Rate (mR/hr)	Adjusted Exposure Rate (mR/hr)	Correction Factor
X 10	33.00	79.0	0	30.00		N/A
	16.00	113.4	0	16.00		N/A
X 1	3.30	79.0	1	3.70		N/A
	1.60	113.4	1	1.70		N/A
X 0.1	0.33	79.0	2	3.40		0.10
	0.16	113.4	2	0.17		N/A

Beta Calibration Data

Nuclide	Emax (MeV)	Activity (μCi)	Assay Date	Calculated dpm	Observed cpm	Efficiency
¹⁴ C	0.156	0.098	8/1/1978	216,407	1000	0%
⁹⁹ Tc	0.292	0.039	2/24/1978	86,567	5000	6%
³⁶ Cl	0.719	0.0208	3/30/1978	46,130	3500	8%
²¹⁰ Pb	1.16	0.02005	4/1/2001	21,626	1000	5%
¹²⁹ I	0.15	0.082	8/25/1982	182,040		

Additional Checks

Check Source Reading: N/A	Battery Condition: <input checked="" type="checkbox"/> Okay <input type="checkbox"/> Replaced	Speaker Working? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	Next Calibration Due: 06/30/23
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Comments:

Attachment 4 – Photo of the Dose Rack in Nuclear Medicine





INDIANA UNIVERSITY

PUBLIC SAFETY

Environmental Health and Safety

REVIEW PROCESS FOR APPROVAL OF AUTHORIZED USERS (AIRP, AROP, ANMP) AND MEDICAL PHYSICISTS (AMP) BY THE RADIONUCLIDE RADIATION SAFETY COMMITTEE (RRSC)

1. The proposed AU or AMP completes the A-03 form for the appropriate use and submits to the radiation safety office (RSO) for review.
2. In addition to the completed A-03 form, the following documents may be required, as necessary:
 - a. Copy of license showing previous authorization
 - b. Copy of board certification
 - c. Letter of other appropriate documentation from residency/fellowship
 - d. Copy of license showing preceptor authorized uses
 - e. Case log
 - f. Curriculum vitae
 - g. Any other documenting appropriate training and experience
3. The RSO reviews the content of the application and each document for consistency across all documents. The RSO verifies all submitted training and experience meets requirements outlined in the appropriate section of 10 CFR 35. For Perfexion or TheraSphere uses, the RSO verifies training and experience meet requirements outlined in the current NRC Licensing Guidance for these uses.
4. The RSO creates a “packet” of information in a single PDF format containing the submitted information. Additionally, the RSO will include excerpts from regulatory requirements, highlighting pertinent parts, in this packet for RRSC review. The RSO will additionally notate any areas requiring extra scrutiny, such as unusual alternate pathway approvals.
5. Once completed, a second member of the RSO reviews the packet prior to submission the RRSC.
6. The RSO distributes the packet to the RRSC via email for review and voting. This may be facilitated by the Office of Research Compliance or other appropriate mechanisms.
7. After review of the complete study application, the RRSC members may:
 - a. Vote for “provisional” approval, if appropriate (for example, a user may be provisionally approved pending completion of annual device-specific emergency procedure training)
 - b. Vote for “preliminary” approval if all submitted information is satisfactory
 - c. Vote for disapproval if information is unsatisfactory, with an explanation of what the member deemed unsatisfactory

8. If the majority of RRSC members vote for approval, the RSO issues a preliminary or provisional approval letter as an attachment to an email to the applicant with copies to appropriate parties. Any additional requirements for a provisional approval are explicitly noted. RSO investigates any disapprovals to ensure any disqualifying issues are resolved.
9. The AU or AMP may begin working in their requested role following preliminary approval.
10. The RRSC will initiate a formal approval vote at the next scheduled RRSC meeting. Following the meeting, the RSO issues a final approval letter as an attachment to an email to the applicant with copies to appropriate parties.

11. Contamination Control

A. General Procedures

- i. The control of contamination is important in the prevention of the uptake and spread of radioactive material. The following precautions must be implemented to help control contamination:
 - a. Work over a spill tray or lay absorbent paper over lab benches and spill trays to limit the spread of contamination and aid in the clean-up of contaminated areas.
 - b. Label containers or instruments used in radioactive processes with a radioactive symbol (e.g. radioactive tape).
 - c. Confine radioactive material use as much as possible within designated areas of the lab (e.g. a fume hood).
 - d. Complete radiation surveys in the laboratory after radioactive materials use according to permit requirements.
 - e. Use extra precaution when chemicals may become volatilized (e.g. ^{35}S amino acids in incubators, ^3H water storage in freezers).
 - f. Wear disposable gloves when handling any radioactive material. Monitor the gloves frequently using a radiation survey meter (if applicable) and change them frequently, especially if contamination is suspected.
 - g. Wear lab coats to protect clothing. Survey lab coats periodically. If not contaminated, lab coats may be laundered without special precautions.
 - h. Do not eat, drink, smoke, store consumables, and/or apply cosmetics in labs or other areas approved for radioactive material use.
 - i. Do not pipette radioactive material by mouth.
 - j. Survey hands and clothing periodically during and after procedures involving the use of radioactive material. Such surveys may be in the form of a direct radiation survey with a portable survey instrument and/or a wipe survey, depending on the requirements of the permit.
 - k. Use fume hoods for procedures involving the generation of volatile radioactive material.
 - l. Minimize exposure by storing the radionuclide away from constantly occupied areas. Additional shielding is required if the exposure rate is greater than 2 mR/hr (or equivalent count rate) at 30 cm from the source.
 - m. Bioassays may be required for individuals utilizing large quantities of radioactive material and/or certain volatile radionuclides (e.g. ^{125}I sodium iodide). The RSO may also require bioassays in the event of an accident involving personal contamination.
- ii. Any additional requirements, such as a specific fume hood filtration for a specific chemical form, will be stated in the radionuclide use permit.
- iii. For new procedures, dry runs without the use of radioactive material are recommended to improve technique and minimize time of exposure. For extremely hazardous operations, dry runs under the supervision of the RSO may be required.
- iv. Tongs or forceps should be used for the direct handling of unshielded vials containing more than a few microcuries of activity. Vessels containing millicurie quantities should rarely be handled directly with the fingers.
- v. A direct radiation survey may be required during and after procedures involving certain quantities of radioactivity depending on the radionuclides in use.

B. Iodination

- i. Due to the volatile nature of certain chemical forms of radioiodine, charcoal filtration of the airstream is required to minimize the release of radioiodine to the environment. Such filtration must be accomplished by at least one of the following methods:
 - a. Use a fume hood equipped with a charcoal filter. A list of these currently-approved hoods is on file in the RSO.
 - b. Use a charcoal filtered "mini-hood" within or vented to an existing chemical hood. This arrangement may require a site visit by the RSO for approval.
 - c. Perform the iodination procedure in a closed system utilizing a charcoal vent trap within an existing chemical fume hood.
- ii. The PH must inform the RSO in writing regarding which type of filtration will be employed and the location where the iodination procedures will be performed. If the procedures will be carried out in a lab not currently listed on a radionuclide use permit, a Form A-4: *Application for Radionuclide Laboratory Approval* must be submitted to the RSO. In addition, if the iodination will take place in another PH's laboratory, written approval must be obtained from that PH and provided to the RSO.
- iii. Studies have shown that release of volatile radioiodine is most often associated with the initial opening of sealed vials of radioiodine and during the iodination reaction itself. Although additional releases during other phases of the procedure are thought to be minimal, it is recommended that such procedures be carried out in a standard chemical fume hood. In addition, the volatile radioiodine stock vial should be stored in a hood when not being used. If the iodination will be carried out in the RSO hood, the stock vial will be kept at the RSO.
- iv. In addition to the volatility problem, contamination control is a primary concern associated with iodination procedures. Some specific precautions to limit the spread of contamination include:
 - a. Verify that the fume hood is operating properly.
 - b. Wear appropriate protective attire (e.g. lab coat, protective eyewear).
 - c. Use a spill tray lined with absorbent paper.
 - d. Double glove and change the outer gloves frequently.
 - e. Monitor hands frequently with a portable survey instrument.
 - f. Be careful not to contaminate the instrument.
 - g. Wash hands after iodinating.
 - h. Due to the increased likelihood of contamination associated with iodination as well as the fact that iodination is frequently carried out in a single location by more than one PH, perform and document direct radiation and contamination (wipe) surveys after each iodination.
- v. If an individual has no prior experience iodinating, a minimum of three iodinations must be performed in the presence of an experienced authorized user or a member of the RSO staff.
- vi. Routine thyroid bioassays are required for all persons who handle volatile forms of radioiodine. Before the first iodination by an individual, they must schedule a baseline thyroid bioassay with the RSO. Following each iodination, a bioassay must be performed between 24 and 72 hours after the iodination.

C. Radioactive Material in Animals

- i. For acute in-vivo animal studies (i.e. animals sacrificed shortly after administration of the radioactive material), the PH is generally responsible for all radiation safety aspects of the procedure including post-procedure surveys, radwaste collection, etc. The PH's permit will

reflect any specific requirements or restrictions with regard to the study.

- ii. Animals administered PET radiopharmaceuticals must have their cages posted with the Form A-10a: *Precautions for Animals Containing PET Radiopharmaceuticals*. This form may be removed and filed with the animal care center once the animal is deemed nonradioactive.
- iii. The requirements for chronic in-vivo animal studies which require the animal(s) to be housed in an "animal care facility" are more rigorous. These requirements are as follows:
 - a. Following initial review and approval, a Form A-10: *Precautions for Animals Containing Radioactive Materials* will be prepared by the RSO. Rules and restrictions will be specified in Sections II and III of the form.
 - b. Once animals are administered radioactive material, the remaining information on the Form A-10 must be completed by the PH. This information generally includes:
 - 1. Date and time of administration
 - 2. Exposure rate at 10 cm and 1 meter (for gamma- and high energy beta- emitting radionuclides)
 - 3. Number of animals per cage
 - 4. Total activity per cage per day which would be found in any animal bedding if the radioactive material is excreted
 - c. A new Form A-10 must be affixed to each cage/pen as additional administrations of radioactive material are carried out.
 - d. The Form A-10 is valid for 60 days from the signed date on the form. After the unused forms have expired, they may be discarded, and new ones must be obtained from the RSO.
 - e. When the animals are transferred or removed from a cage and the contamination levels of the cage are found to be within acceptable limits, the completed Form A-10 should be transferred to another cage along with the animal(s) or left in the animal care facility office if the animal(s) is/are either no longer radioactive or they are to be sacrificed.
 - f. If a survey of the cage/pen is required per Section III of the Form A-10 after the animal(s) is/are removed, the survey must be performed by the PH or their designee with the results recorded on a Form A-11: *Contamination Survey for Animal Care Facilities*.
 - g. Once the survey is completed and contamination levels are within acceptable limits, the Form A-11 should be attached to the Form A-10 and forwarded to the animal care facility office.
- iv. Forms A-10 are approved specifically for the procedures which were initially reviewed and approved by the RSO. Therefore, any changes in the protocol (e.g. different radionuclide or amount administered) require an amendment, approval, and issuance of a new Form A-10 by the RSO.
- v. If radioactivity is excreted by the animals, Section III of the Form A-10 specifies how the excreta must be handled. In most cases, animal care personnel may dispose of the excreta. However, the PH has the following responsibilities regarding animal excreta which must be collected:
 - a. The PH must provide the animal care facility with a solid radioactive waste disposal container, obtainable from the RSO, and a completed Form A-12: *Log Sheet For Animal Bedding Contaminated With Radioactive Materials* with the appropriate information completed.
 - b. Once the disposal container is full or upon completion of the study (whichever comes first), the plastic liner must be sealed, the Form A-12 placed on the container, and the container transported to the RSO by the PH or his/her designee. The RSO must be

contacted prior to delivering the waste.

- c. If the animal care facility personnel are responsible for placing the contaminated bedding in the disposal container, the PH will be notified when the container is full and must remove it from the animal care facility within 48 hours of notification.
- d. The PH is responsible for the collection and transportation of contaminated animal excreta to the RSO if a metabolism cage is specifically required by the RSO to collect such excreta. If the PH requests the use of a metabolism cage but such cage is not required by the RSO, information will be provided on the Form A-10 regarding the collection of excreta. In this situation, ultimate disposal of the contaminated excreta is still the responsibility of the PH.

Radiation Safety Refresher Training

April 2021

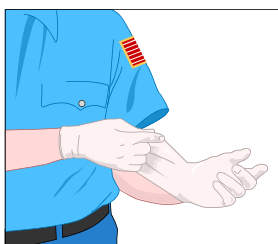
Contamination Control

"Are you taking your work home with you?"

In most laboratory settings, contamination control is the primary concern with respect to using radioactive material. Unless large activities of high energy beta or gamma-emitting radionuclides are used, the external radiation exposure one receives from routine procedures is easily controlled. However, avoiding internal contamination is important in all uses of unsealed radioactive material. The following guidelines outline measures that should be taken to control contamination and prevent internal exposure to radioactive material:

- (1) Lab coats and disposable gloves should always be worn when handling radioactive material or equipment that is used in radioactive procedures. In addition, protective eyewear should be worn when procedures may disperse radioactive material to the face (e.g., grinding or using large volumes of radioactive liquid). It is also advisable to avoid shorts and open-toed shoes. The use of radiochemical fume hoods may also be necessary to control airborne contamination.
- (2) Prior to beginning your radioactive procedure, label all pipettes, vials, etc. with "Radioactive" tape if there is a potential that they may become contaminated.
- (3) Remember to remove your gloves if you are interrupted during your procedures (e.g., the phone rings) or if you need to open a freezer, incubator, etc.
- (4) If the radionuclide that you are working with can be detected by a survey meter, perform a survey of yourself and your work area periodically and at the end of your experiment. Decontaminate as necessary in accordance with established limits (see Radiation Safety Procedures Manual).
- (5) Remember that eating, drinking, smoking and application of cosmetics are prohibited in laboratories.

If you have any questions about contamination control, please contact the RSO at [REDACTED]
PLACE A COPY OF THIS DOCUMENT IN YOUR RADIONUCLIDE INVENTORY AND SURVEY BOOK.



Radiation Safety Refresher Training

April 2022

Radiation Safety Procedures Manual Update

In February 2022, the Radiation Safety Procedures Manual was updated. Every section had at least a few changes. Use this Refresher Training in order to familiarize yourselves with the updated version. A tracked-change copy of each section is available upon request, but the largest changes are highlighted below:

- Review the Table of Contents to ensure you can quickly find information you need. In the PDF version, click page numbers to move to that section.
- Review clarifications: Section 1.B, “should/may” vs. “shall/must” language. Previously the manual used “should” even when a statement was a requirement. This version of the manual attempts to clarify when an action is recommended (“should” or “may”) and when an action is required (“shall” or “must”).
- Review change: Section 4.F, *Renewal, Closure, or Inactivation of Radionuclide User Permits*. The differences in closing vs. inactivating a permit have been added to the manual.
- Review clarifications: Section 11.A, *General Procedures*. Contamination prevention procedures were clarified using shall/must and should/may language.
- Review clarifications: Section 16, *Radionuclide Inventory and Survey Book*. Required sections of the binder have been clarified.
- Review change: Section 17, *Audits*. Previously, discrepancies were noted as a “violation” or an “area of concern.” The language has been changed to “major violation” and “minor violation.” A new form, Form A-18, *Notice of Violation*, has been introduced to more easily track corrective actions.
- Review Section 18, *Emergency Procedures*.

If you have any questions about anything discussed here, please contact the RSO at [REDACTED]
PLACE A COPY OF THIS DOCUMENT IN YOUR RADIONUCLIDE INVENTORY AND SURVEY BOOK.

Return the signed verification form to [REDACTED] by April 29, 2022.

Elekta Flexitron HDR s/n FT00643

Flexitron Ir-192 Source s/n **D85E8349**

Date: **5/19/22** Time: **13:00** Physicist: **YY/CH**

Well Chamber IVB1000 (s/n H042677) ADCL calibration: **4.540** E5 Gy m²/h/A Date: **7/29/2020**

MAX4000 (s/n E042748) ADCL calibration for HIGH Scale: **1.000** nC/Rdg Date: **7/12/2020**

Source Positioning Simulator and Autoradiograph test within 1 mm Yes No

Temp (C): **20.3** Press (mm Hg): **736** TP_{CF}: **1.027**

Source Calib Date: **5/13/22** time (CET): **18:00** AKR (mGy/h@1m): **48.530**
 Current AirKerma Activity: **45.983** mGy/h = **11.266** Ci Eastern time = e.g. 8:01AM CI

Plan: monthly source strength HDR

OUTPUT D310: **98.050** nA D315: **98.49** nA D320: **98.74** nA
 D325: **98.85** nA D330: **98.86** nA D335: **98.8** nA D: distance of driving length

Calibrated Air Kerma: R-max*ADCL calib*TP_{CF}* ECF = **0.046** Gy/h **11.289** Ci

Source Activity measured/expected : **0.21%**

TIMER TEST

Plan: monthly timer 01s-30s HDR using Fixed dwell time

Timer Set (s)	Rdgs nC	Avg (nC)	(s)	diff (s)
30	3062.7 3063.5	3063.1	30.98	0.98
10	1081.2 1081.3	1081.3	10.94	0.94
5	585.9 585.9	585.9	5.93	0.93
2	288.8 288.9	288.9	2.92	0.92
1	189.9 189.9	189.9	1.92	0.92

140cm

Avg Transit Time: **0.938** graph: 0.917 LINEARITY: 1.002 Acceptable? Yes No

59.69 Diff **-0.52%** Satisfactory? Yes No

TIMER ACCURACY 60 sec Rdg: **6138.2**

Plan: monthly timer 60s HDR

- 5. Source retraction with backup battery upon power failure (vendor checked) Satisfactory? Yes No
- 6. Integrity of applicators and transfer tubes (Sterilized instruments are checked as they are opened) Satisfactory? Yes No
- 7. Backup battery check – radiation monitor Satisfactory? Yes No
- 8. Source position simulator (SPS) tests (1 mm tolerance) Inspect SPS cable assembly for damage Satisfactory? Yes No

9. End Effect: 60 sec exposure interrupting beam four times.

Reading_x: **6403.6** nC
 End effect: **0.65564861** s <0.8

Plan: monthly timer 60s HDR

10. Radiation area monitor: Operational Yes No Operational w/o power supply Yes No

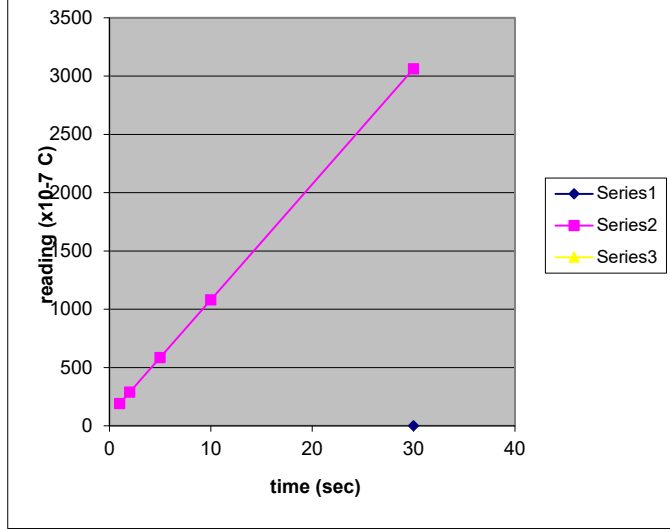
Maze: Yes No Remote: Yes No

- 11. Door Interlock operational: Yes No
- Console Emergency operational: Yes No
- Wall Emergency operational: Yes No

12. Radiation room survey: front above side
 5cm from afterloader **0.07** mR/hr **0.03** mR/hr **0.09** mR/hr
 30 cm from afterloader **0.03** mR/hr

Deliver the morning QA plan to record the dwell position centers: Planned 800 1400

Reading (C) vs time



Transfer Tube Length Measurement

Date 5/19/2022

Physicist YY/CH

Transfer tube type

Manufacture length 1000.0 mm

Tube #	Length (mm)
1	1000.0
2	1000.0
3/33	1000.0
4	1000.0
5	1000.0
6	1000.0
7/37	1000.0
8	1000.0
9	1000.0
10	1000.0
11/31	1000.0
12	1000.0
13	1000.0
14	1000.0
15	1000.0
16	1000.0
17	1000.0
18	1000.0
19	1000.0
20	1000.0
21	1000.0
22	1000.0
23	1000.0
24	1000.0
25	1000.0

Elekta Flexitron HDR s/n FT00643

Flexitron Ir-192 Source s/n **D85E8825**

Date: **8/9/22** Time: **10:00** Physicist: **YY/SN**

Well Chamber IVB1000 (s/n H042677) ADCL calibration: **4.549** E5 Gy m²/h/A Date: **7/4/2022**

MAX4000 (s/n E042748) ADCL calibration for HIGH Scale: **1.000** nC/Rdg Date: **7/1/2022**

Source Positioning Simulator and Autoradiograph test within 1 mm Yes No

Temp (C): **23.8** Press (mm Hg): **743** TP_{CF}: **1.029**

Source Calib Date: **7/20/22** time (CET): **12:00** AKR (mGy/h@1m): **47.540**
 Current AirKerma Activity: **39.495** mGy/h = **9.676** Ci Eastern time = e.g. 8:01AM CI

Plan: monthly source strength HDR
 OUTPUT D310: **84.450** nA D315: **84.79** nA D320: **85.01** nA
 D325: **85.09** nA D330: **85.091** nA D335: **85.029** nA D: distance of driving length

Calibrated Air Kerma: R-max*ADCL calib*TP_{CF}* ECF = **0.040** Gy/h **9.760** Ci

Source Activity measured/expected : **0.86%**

TIMER TEST

Plan: monthly timer 01s-30s HDR using Fixed dwell time

Timer Set (s)	Rdgs nC	Avg (nC)	(s)	diff (s)
30	2619.6	2619.7	30.79	0.79
10	915.1	915.1	10.75	0.75
5	489.1	489.1	5.75	0.75
2	233.5	233.5	2.74	0.74
1	148.4	148.4	1.74	0.74

140cm

Avg Transit Time: **0.755** graph: 0.741 LINEARITY: 1.001 Acceptable? Yes No

60.3 Diff **0.50%** Satisfactory? Yes No

TIMER ACCURACY 60 sec Rdg: **5176.9**

Plan: monthly timer 60s HDR

5. Source retraction with backup battery upon power failure (vendor checked) Satisfactory? Yes No

6. Integrity of applicators and transfer tubes (Sterilized instruments are checked as they are opened) Satisfactory? Yes No

7. Backup battery check – radiation monitor Satisfactory? Yes No

8. Source position simulator (SPS) tests (1 mm tolerance) Inspect SPS cable assembly for damage Satisfactory? Yes No

9. End Effect: 60 sec exposure interrupting beam four times.

Reading_x: **5430** nC
 End effect: **0.74242832** s <0.8

Plan: monthly timer 60s HDR

10. Radiation area monitor: Operational Yes No Operational w/o power supply Yes No

Maze: Yes No Remote: Yes No

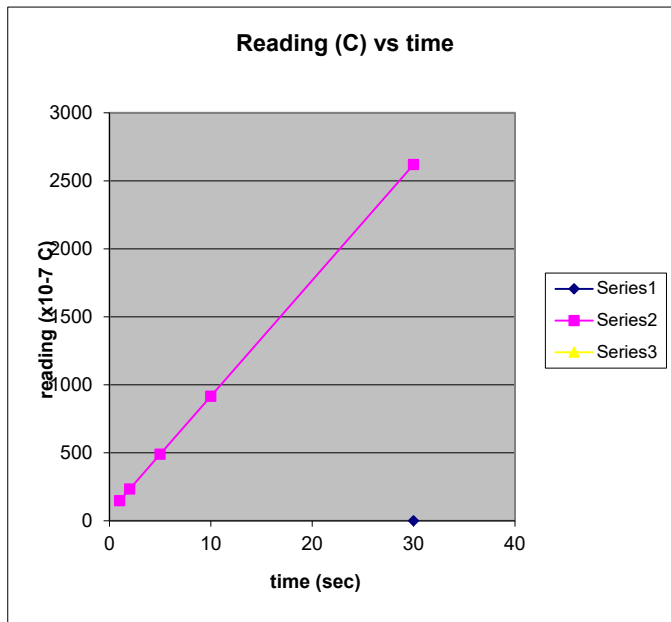
11. Door Interlock operational: Yes No

Console Emergency operational: Yes No

Wall Emergency operational: Yes No

12. Radiation room survey: front above side
 5cm from afterloader **0.07** mR/hr **0.03** mR/hr **0.09** mR/hr
 30 cm from afterloader **0.03** mR/hr

Deliver the morning QA plan to record the dwell position centers: Planned 800 1400



Transfer Tube Length Measurement

Date 8/9/2022

Physicist YY/SN

Transfer tube type

Manufacture length 1000.0 mm

Tube # Length (mm)

1	1000.0
2	1000.0
3	1000.0
4	1000.0
5	1000.0
6	1000.0
7	1000.0
8	1000.0
9	1000.0
10	1000.0
11/31	1000.0
12	1000.0
13	1000.0
14	1000.0
15	1000.0
16	1000.0
17	1000.0
18	1000.0
19	1000.0
20	1000.0
21	1000.0
22	1000.0
23	1000.0
24	1000.0
25	1000.0

Elekta Flexitron HDR s/n FT00643

Flexitron Ir-192 Source s/n **D85E9462**

Date: **12/7/22** Time: **14:00** Physicist: **YY/SN**

Well Chamber IVB1000 (s/n H042677) ADCL calibration: **4.549** E5 Gy m²/h/A Date: **7/4/2022**

MAX4000 (s/n E042748) ADCL calibration for HIGH Scale: **1.000** nC/Rdg Date: **7/1/2022**

Source Positioning Simulator and Autoradiograph test within 1 mm Yes No

Temp (C): **21.1** Press (mm Hg): **747.5** TP_{CF}: **1.014**

Source Calib Date: **11/8/22** time (CET): **18:00** AKR (mGy/h@1m): **48.360**
 Current AirKerma Activity: **36.922** mGy/h = **9.046** Ci Eastern time = e.g. 8:01AM CI

Plan: montly source strength HDR
 OUTPUT D310: **79.673** nA D315: **79.955** nA D320: **80.114** nA
 D325: **80.174** nA D330: **80.169** nA D335: **79.999** nA D: distance of driving length

Calibrated Air Kerma: R-max*ADCL calib*TP_{CF}* ECF = **0.037** Gy/h **9.057** Ci

Source Activity measured/expected : **0.12%**

TIMER TEST

Plan: montly timer 01s-30s HDR using Fixed dwell time

Timer Set (s)	Rdgs nC	Avg (nC)	(s)	diff (s)	
30	2464.2	2464.5	2464.4	30.74	0.74
10	860.4	860.5	860.5	10.73	0.73
5	459.3	459.4	459.4	5.73	0.73
2	218.6	218.6	218.6	2.73	0.73
1	138.4	138.4	138.4	1.73	0.73

140cm

Avg Transit Time: **0.730** graph: 0.727 LINEARITY: 1.000 Acceptable? Yes No

59.59 Diff **-0.68%** Satisfactory? Yes No

TIMER ACCURACY 60 sec Rdg: **4876.3**

Plan: montly timer 60s HDR

- 5. Source retraction with backup battery upon power failure (vendor checked) Satisfactory? Yes No
- 6. Integrity of applicators and transfer tubes (Sterilized instruments are checked as they are opened) Satisfactory? Yes No
- 7. Backup battery check – radiation monitor Satisfactory? Yes No
- 8. Source position simulator (SPS) tests (1 mm tolerance) Inspect SPS cable assembly for damage Satisfactory? Yes No

9. End Effect: 60 sec exposure interrupting beam four times.

Reading_x: **5109.3** nC
 End effect: **0.7253972** s <0.8

Plan: montly timer 60s HDR

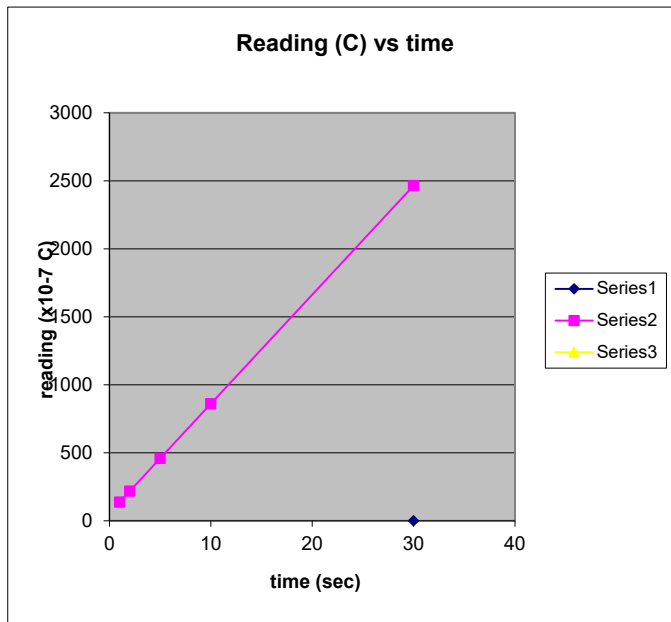
10. Radiation area monitor: Operational Yes No Operational w/o power supply Yes No

Maze: Yes No Yes No
 Remote: Yes No Yes No

- 11. Door Interlock operational: Yes No
- Console Emergency operational: Yes No
- Wall Emergency operational: Yes No

12. Radiation room survey: front above side
 5cm from afterloader **0.11** mR/hr **0.08** mR/hr **0.09** mR/hr
 30 cm from afterloader **0.05** mR/hr

Deliver the morning QA plan to record the dwell position centers: Planned 200 400



Transfer Tube Length Measurement

Date 12/7/2022

Physicist YY/SN

Transfer tube type

Manufacture length 1000.0 mm

Tube #	Length (mm)
1	1000.0
2	1000.0
3	1000.0
4	1000.0
5	1000.0
6	1000.0
7	1000.0
8	1000.0
9	1000.0
10	1000.0
11/31	1000.0
12	1000.0
13	1000.0
14	1000.0
15	1000.0
16	1000.0
17	1000.0
18	1000.0
19	1000.0
20	1000.0
21	1000.0
22	1000.0
23	1000.0
24	1000.0
25	1000.0



Indiana University Health



**Methodist Hospital – Radiation Therapy
HDR Prostate Special Physics Report**

Date: 6/30/22 Prescription Dose: 15 Gy

Today's Air-Kerma Strength: 30974.88 cGy-cm²/hr @ 8:30

Print: Prostate Brachytherapy Written Directive, Prostate Brachytherapy Checklist and Treatment Record, Radiation Treatment Survey Forms

- Assemble Table Mount for Stepper
- Prep US probe 8848
- Setup US Unit and Oncentra Prostate Cart

US unit

- Probe 8848 selected
- Prog. 1..7/A..G 5mm template selected (offset 3 mm out)
- Transverse plane: verify 7.3 cm depth
- Sagittal plane: verify 7.4 cm depth
- ECRM operational
- Stepper encoder operational
- Epiphan Capture tool operational

Applicator length

Needle 1 length: 237.5 mm 1237.5 = 1000 + 237.5

Needle 2 length: 237.5 mm 1237.5

- All needle length verified

Oncentra Prostate

Verify the following options are selected in the dialogue box:

- Fixed Template
- Template: Prostate Stepper Template 6F (HDR,LDR)
- Catheters: ProGuide 6F Trocar L=240 mm Flexitron (HDR)
- Afterloader: Flexitron HDR
- Sources Flexcitron HDR
- Date and time are correct.
- Green light appears for (1) US hardware or frame grabber, and (2) scanner positioning hardware.

Start Planning button

- Enter Patient and Study

3D US Acquisition

- Select correct **Preference**
- Probe and depth have been detected
- US template overlays virtual OP template
- Set origin plane, set stepper dial to zero

Turn US template off

Inject Contrast
Catheter Reconstruction

Enter probe to template distance (192.6 mm - distance from
template to silver ring)

$$\begin{array}{r} 192.6 \\ - 90.5 \\ \hline = 102.1 \end{array}$$

$$\begin{array}{r} 192.6 \\ - 90.0 \\ \hline = 102.6 \end{array}$$

$$\begin{array}{r} 192.6 \\ - 77.0 \\ \hline = 115.6 \end{array}$$

$$\begin{array}{r} 192.6 \\ 79 \\ \hline 113.6 \end{array}$$

Catheter #	Location	Free Length	Reconst	Free Length Measured (mm)	Free length < 2 mm measured
15	Ⓢ a 4	132.0	<input type="checkbox"/>	132	<input type="checkbox"/>
16	a d 4	133.0	<input type="checkbox"/>	133	<input type="checkbox"/>
13	Ⓢ c 3.5	130.0	<input type="checkbox"/>	130	<input type="checkbox"/>
14	e 3.5	130.0	<input type="checkbox"/>	131	<input type="checkbox"/>
b 3.5					
11	f 2.5	124.0	<input type="checkbox"/>	125	<input type="checkbox"/>
8	e 2.0	122.0	<input type="checkbox"/>	122	<input type="checkbox"/>
12	b 3.0	127.0	<input type="checkbox"/>	129	<input type="checkbox"/>
5	b 2.0	123.0	<input type="checkbox"/>	123	<input type="checkbox"/>
1	Ⓢ c 1.5	118.0	<input type="checkbox"/>	119	<input type="checkbox"/>
4	e 1.5	115.0	<input type="checkbox"/>	115	<input type="checkbox"/>
9	Ⓢ c 2.5	128.0	<input type="checkbox"/>	129	<input type="checkbox"/>
10	e 2.5	122.0	<input type="checkbox"/>	121	<input type="checkbox"/>
6	Ⓢ c 2.0	124.0	<input type="checkbox"/>	124	<input type="checkbox"/>
7	d 2.0	123.0	<input type="checkbox"/>	123	<input type="checkbox"/>
2	Ⓢ c 1.5	114.0	<input type="checkbox"/>	114	<input type="checkbox"/>
3	a 1.5	118.0	<input type="checkbox"/>	118	<input type="checkbox"/>
			<input type="checkbox"/>		<input type="checkbox"/>
			<input type="checkbox"/>		<input type="checkbox"/>
			<input type="checkbox"/>		<input type="checkbox"/>
			<input type="checkbox"/>		<input type="checkbox"/>

Ⓢ





- Lock template, remove obturators, wipe test of obturators
- Enter and verify measured needle length into Oncentra Prostate
- Add calculation points
- Indexer length of 1234 mm verified with Source Position Simulator
- Verify catheter parameters
 - Indexer length = 1234 mm
 - Tip to 1st dwell position = 6 mm
- Diff Plan U (cGy-cm²/hr) / Today's U (cGy-cm²/hr) < 2%

$$\frac{30974}{30940} < 2\%$$

- Export Treatment Plan
- Export Plan to RadCalc
- Transfer tube/catheter connections verified
- Field photo taken

Physicist: [Signature] Radiation Oncologist: [Signature] 6-30-22 12:10pm
 6/30/2022 12:09pm

R:\Physics\Medical Physics\Brachytherapy\Oncentra Prostate\QA Forms\HDRProstateSpecialPhysicsReport.doc

Oral Prescriptions/Written and Oral Revisions

1. Oral revisions to an existing written directive were documented immediately and the revised written directive was signed and dated by an authorized staff physician within 2 working days:

Yes No NA

2. Written revisions to written directives are signed and dated by an authorized staff physician:

Yes No NA

HDR CHECKS

Daily spot checks were performed on each day of use: Yes No

Full calibration was performed on device following source replacement (date: _____), prior to first therapy (date: _____): Yes No

a. Max and avg radiation levels around device do not exceed those specified in SSTR (performed by vendor at installation – see log book on shelf above HDR desk – limits are 50 uSv/h @ 5 cm from unit & 10 uSv/h @ 1m): Yes No

b. Area survey performed (date: _____) following source replacement indicated acceptable levels in surrounding areas: Yes No

Issues of concern noted in Fault Log: Yes No

Operating/Emergency Procedures posted at console: Yes No

HDR room is locked if unattended: Yes No NA

Medical Events noted: Yes (explain below) No

Comments: _____

Audited By: _____ Date: _____