

Radiation Safety Information for Caregivers of SIERRA Study Patients Treated with Iodine-131



Prepared by the Department of Environment Health and Safety
Radiation Safety Section



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What is the Actinium SIERRA Study?

- Iomab-B (CD45) (apamistamab-I-131) is a substance that is currently being studied in the pivotal Phase 3 SIERRA (Study of Iomab-B in Relapsed or Refractory AML) trial, a 150-patient, randomized controlled clinical trial in patients with relapsed or refractory acute myeloid leukemia (AML) who are age 55 and above.
- Radioactive iodine (I-131) is chemically attached to the monoclonal antibody BC8, of Iomab-B, which targets CD45, an antigen widely expressed on leukemia and lymphoma cancer cells, B cells and stem cells.
- The dose from the radioactive I-131 irradiates and kills the cancer cells and bone marrow cells before the bone marrow transplant process is initiated.
- (paraphrased from <https://www.actiniumpharma.com/product-pipeline/iomab-b>)
- Clinical Trial



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What is the Actinium SIERRA Study?

- Elderly Patients
- Acute Myeloid Leukemia (AML)
- Substitute I-131 to kill blood cancer cells & bone marrow (instead of Chemotherapy & Radiation Therapy)
- Prepare Patient for Bone Marrow Transplant
- Dosimetric Dose (@5-15 mCi) determines Therapeutic Dose activity
- Therapeutic Dose 1 week later (500-1000 mCi)
- Upon Release: Transfer to Bone Marrow Unit



Iodine-131

- 8.0197 day half life
- Decay
 - @606 keV Beta
 - @364 keV Gamma
- Bound to apamistamab-I-131 (no positive worker thyroid bioassay results)



Estimated Exposure Rates

Point Source I-131 1000 mCi

		At 1 meter	At 2 meter	At 3 meter
Day 0	100 %	220 mrem/h	55 mrem/h	24 mrem/h
Day 1	57 %	125 mrem/h	31 mrem/h	14 mrem/h
Day 2	33 %	73 mrem/h	18 mrem/h	8 mrem/h
Day 3	19 %	42 mrem/h	11 mrem/h	5 mrem/h
Day 4	11 %	24 mrem/h	6 mrem/h	3 mrem/h
Day 5	6 %	13 mrem/h	3 mrem/h	< 2 mrem/h



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UNC Hospitals SIERRA Study Patients

	Male 70 y/o	Female 66 y/o	Male 71 y/o
In house radiation isolation	7 days	7 days	9 days
Activity infused	960 mCi (-450 mCi)	521 mCi	758 mCi
Dose Rate at 1 meter Day 1	44 mR/hr	40 mR/hr	62 mR/hr
Dose Rate at Release	1.6 mR/hr	1.85 mR/hr	1.9 mR/hr

The median dose of lomab-B was **636 mCi** (range 354-1027 mCi) and the median radiation dose delivered to the marrow in the lomab-B group was **14.9 Gy** (range 4.6 – 32 Gy).

Actinium website: https://www.sierratrial.com/wp-content/uploads/sites/2/2018/10/SIERRA_clinical_trial_patient_doctor_summary.pdf



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UNC Hospitals SIERRA Study Patients

	Male 70 y/o	Female 66 y/o	Male 71 y/o
In house radiation isolation	7 days	7 days	9 days
Activity infused	960 mCi (-450 mCi)	521 mCi	758 mCi
	Infusion Spill**	MS Biology	
	"Mr. Fixit"	Unhappy with release limit	Chest Pains
	Salivary Gland	Wanted to exercise	EKG Heart Monitor
	Diarrhea	Possessions Return	Chest X-Ray
** Deliver enough isotope to the patient for targeted treatment without damaging the Critical Organ (Liver)			



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UNC Hospitals SIERRA Study Patients Planning

- Departments possibly affected
- Training
- Physical Facilities
- Room Preparation
- Area Surveys
- Contamination Control
- Radioactive Waste Management



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UNC Hospitals SIERRA Study Patients

Preparation and Training Issues

- Departments possibly affected
 - RN Staff (6 Women's)
 - Principal Investigator
 - Bone Marrow
 - ICU
 - Determine which ICU maintains jurisdiction
 - Rapid Response Team
 - Multiple departments
 - Multiple disciplines
 - Pathology & Clinical Laboratory



UNC Hospitals SIERRA Study Patients

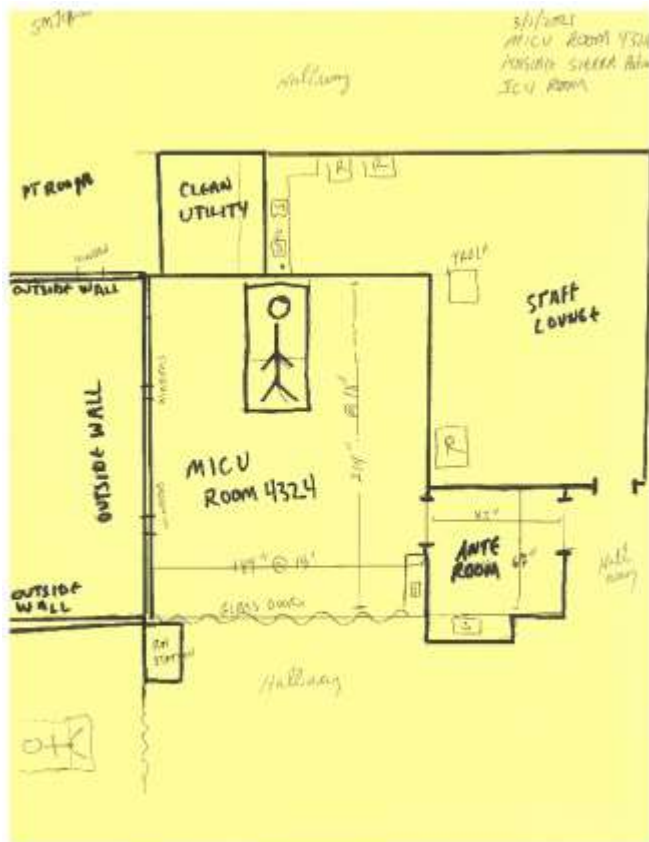
TRAINING

- 6 Women's: Physical patient care (@ 30 RNs)
 - Inservice updates
 - Badged radiation workers
- Multiple M.D.s from several departments
- ICU: Potential Patient Care (Managers – opted for Printed Copies)
 - Non-radiation workers
 - Patient relocation selection
- Rapid Response Team/Code Team: Potential Patient Transport (Managers)
 - Non-radiation workers from multiple disciplines
- Pathology/Lab
 - Samples must be labeled “Caution: Radioactive Material” (> 1 microcurie)
 - Sample Storage (Multiple/Daily: Blood, Sputum, Urine, Stool, Nasal Swipe, Anal Swipe)
 - Confirmatory Surveys
 - Sample retrieval/Radioactive Waste



UNC Hospitals SIERRA Study Patients Facilities

- MICU Did not require use (No patient Codes or Medical Emergencies)



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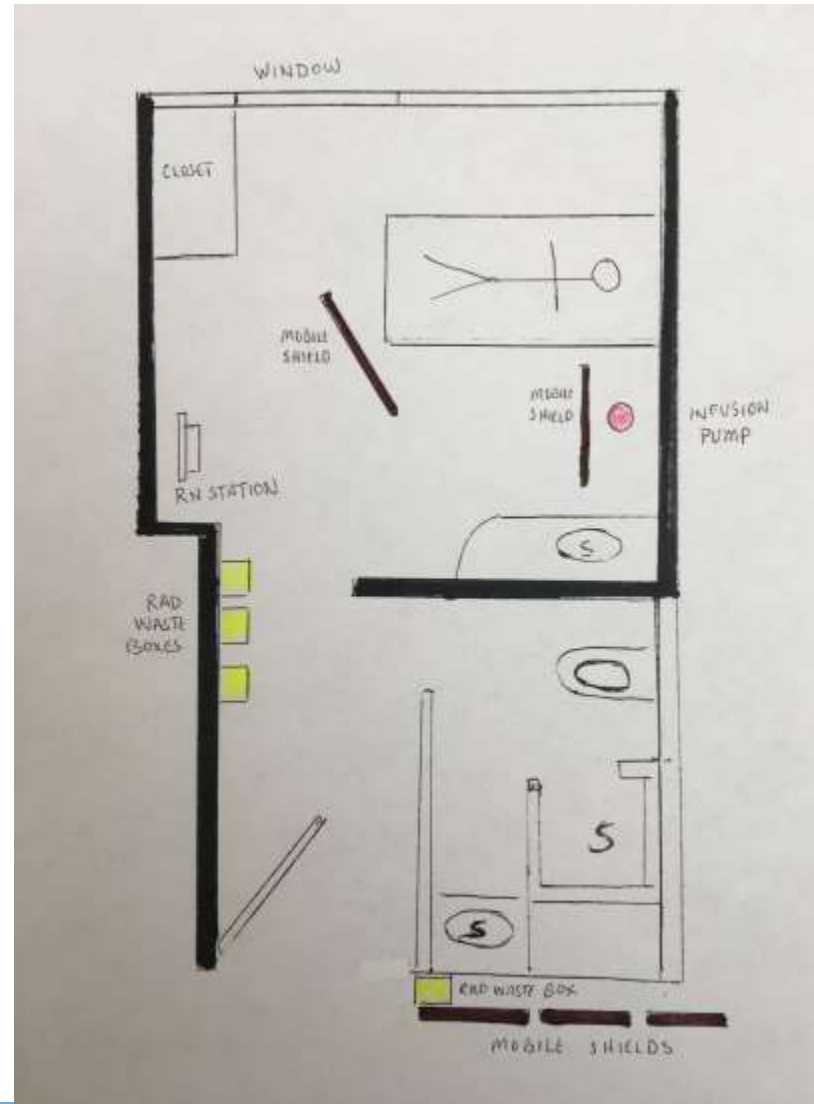


UNC Hospitals SIERRA Study Patients Facilities

- UNC Hospitals 6 Women's
- 4 Shielded Rooms
- 3" Steel Shielding in walls
- Lead Shielded Door
- Bathroom/Hall Wall Unshielded
- Required mobile shields in hallway
- Required 2 mobile shields in room
- Adjacent rooms vacant
- Hallway restricted



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ROOM PREPARATION



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ROOM PREPARATION



Averaged
4–10 rad
waste
boxes per
day



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Postings

3 Required

Posted On Door

Posted inside Patient's Room

Front of Patient Chart

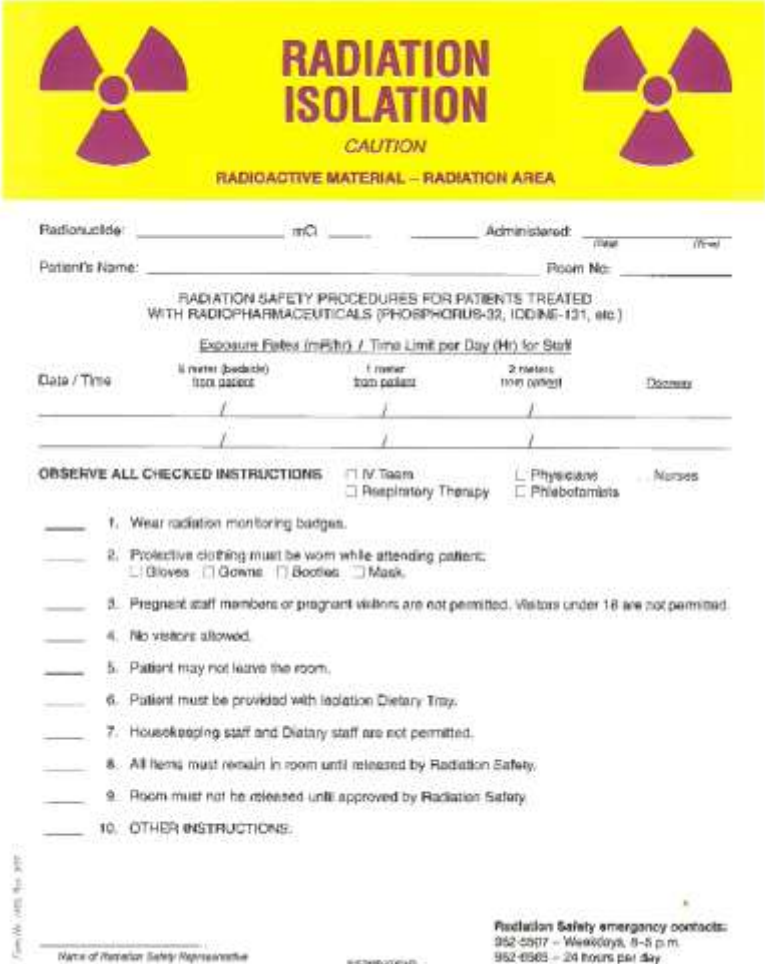
Daily Surveys Required

Daily Instructions Required

Pregnant Staff Prohibited

Visitors Prohibited

Non-essential Staff Prohibited



The image shows a yellow radiation warning sign with two black trefoil symbols and the text "RADIATION ISOLATION CAUTION RADIOACTIVE MATERIAL - RADIATION AREA". Below the sign is a form titled "RADIATION SAFETY PROCEDURES FOR PATIENTS TREATED WITH RADIOPHARMACEUTICALS (PHOSPHORUS-32, IODINE-131, etc.)". The form includes fields for Radionuclide, mCi, Administered, Patient's Name, and Room No. It also has a table for Exposure Rates (mR/hr) and Time Limit per Day (Hr) for Staff, with columns for 0.1 mCi (bedside), 1 mCi (room), and 2 mCi (room). The form lists 10 instructions to be observed, including wearing radiation monitoring badges, protective clothing, and restrictions on pregnant staff, visitors, and non-essential staff. It also includes a section for "OTHER INSTRUCTIONS" and "Radiation Safety emergency contacts".

Radionuclide: _____ mCi _____ Administered: _____ (date) _____ (time)

Patient's Name: _____ Room No: _____

RADIATION SAFETY PROCEDURES FOR PATIENTS TREATED WITH RADIOPHARMACEUTICALS (PHOSPHORUS-32, IODINE-131, etc.)

Exposure Rates (mR/hr) / Time Limit per Day (Hr) for Staff

Date / Time	0.1 mCi (bedside) 1000 patients	1 mCi (room) 100 patients	2 mCi (room) 100 patients	Doctors
_____	_____	_____	_____	_____
_____	_____	_____	_____	_____
_____	_____	_____	_____	_____

OBSERVE ALL CHECKED INSTRUCTIONS

☐ IV Team ☐ Physician ☐ Nurses

☐ Respiratory Therapy ☐ Phlebotomists

1. Wear radiation monitoring badges.
2. Protective clothing must be worn while attending patient:
☐ Gloves ☐ Gown ☐ Boots ☐ Mask.
3. Pregnant staff members or pregnant visitors are not permitted. Visitors under 18 are not permitted.
4. No visitors allowed.
5. Patient may not leave the room.
6. Patient must be provided with Isolation Dietary Tray.
7. Housekeeping staff and Dietary staff are not permitted.
8. All items must remain in room until released by Radiation Safety.
9. Room must not be released until approved by Radiation Safety.
10. OTHER INSTRUCTIONS: _____

Name of Radiation Safety Representative

Signature

Radiation Safety emergency contacts:
952-5517 - Weekdays, 8-5 p.m.
952-5563 - 24 hours per day



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UNC Hospitals SIERRA Study Patients

- PPE
- Dosimetry
- Contamination Control



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PPE Requirements



- Similar to Required Covid PPE:
- **Add** 1 pair Gloves
- **Add** Booties/shoe Covers
- **Dispose** (Doff) all in Waste before leaving room.
- **Immediately Survey** yourself with Geiger Counter



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How will I know how much radiation exposure I have received?

- You will be provided with a personnel dosimeter badge
- This device measures the dose you receive during your entire interaction with the patient.
- The badges are individually assigned and worn by the assignee.
- The badges must be returned for manufacturer evaluation after treatment is complete.
- MAX DOSES RECEIVED
 - RSO Staff (WB) 119 mrem/month
 - RN (WB) 126 mrem/month
 - Pharmacist (WB/R) 49 WB 1172 R mrem/month



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How will I know how much radiation exposure I have received?

- You will be provided with an electronic personnel dosimeter (called an EPD).
- This is a device that measures cumulative radiation dose similar to how an odometer measures mileage in a car.
- The EPD reads out in radiation dose units of mR (mrem).



Radiation monitor

- Radiation detectors
- Radiation level indicators



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Future SIERRA Treatments

- SIERRA Study has been completed and has been reported to have been a successful Clinical Trial
- Actinium expects full FDA Approval in 2022 or 2023.



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