

New Britain  
General Hospital

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New Britain  
Connecticut 06050  
203/224-5011

Laurence A. Tanner  
President

May 28, 1997

U.S. Nuclear Regulatory Commission  
Document Control Desk  
Washington, D.C. 20555

Docket No. 030-01250

License No. 06-02388-01

Dear Sir:

The following is a response to the Notice of Violation based on Inspection No. 030-01250/97-001 conducted by Mr. Louis Manning on March 17 and 18, 1997.

**ITEM A. 10 CFR 35.315(a)(7)**

1. **Response:** The room was released by the nursing staff prior to the completion of decontamination by the nuclear medicine personnel.
2. **Corrective Steps Taken:** The policy and procedures for the administration of therapeutic I-131 has been reviewed by the Radiation Safety Committee. The policy has been reviewed to include a "released notification" to be posted on the room door at the completion of monitoring and decontamination. This form will advise nursing that the room may be reassigned. (Attachment 1 is enclosed.)
3. **To Avoid Further Violations:** It has been discussed with the staff to not remove radioactive caution signs until decontamination is complete, and to post a formal notification upon the room door indicating the room has been released to the nursing unit.
4. **Date for Compliance:** Full compliance achieved 5/21/97, with the review by the Radiation Safety Committee.

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**ITEM B. 10 CFR 35.315(a)(4)**

1. **Response:** Exposure rate surveys were performed on the dates cited, but were not performed inside the adjacent patient room (a contiguous unrestricted area). Mr. Manning communicated his concern if the surveys may have shown greater than 2 mR/hr in the adjacent room, and that an exposure assessment be promptly performed to demonstrate compliance with 10 CFR 20.
2. **Corrective Steps Taken:** Measurements have been performed to ensure that exposure rates did not exceed the 2 mR/hr limit. A summary of the results of those measurements had been transmitted to Mr. Manning. (See Attachment 2.)
3. **To Avoid Further Violations:** Future administrations will include survey measurements in restricted and unrestricted contiguous areas. The adjacent space survey will be performed even if in-room surveys show less than 2 mR/hr. (Attachment 3, form including adjacent room measurement, is enclosed.)
4. **Date for Compliance:** Full compliance achieved 5/21/97, with the review by the Radiation Safety Committee.

**ITEM C. 10 CFR 35.415(a)(4)**

1. **Response:** Exposure rate surveys were performed on the dates cited, but were not performed inside the adjacent room (a contiguous unrestricted area). Mr. Manning communicated his concern was if these surveys may have shown greater than 2 mR/hr in the adjacent room, and that an exposure assessment be promptly performed to demonstrate compliance with 10 CFR 20.
2. **Corrective Steps Taken:** Measurements have been performed to ensure that exposure rates did not exceed the 2 mR/hr limit. A summary of the results of those measurements had been transmitted to Mr. Manning. (See Attachment 2.)
3. **To Avoid Further Violations:** Future administrations will include survey measurements in restricted and unrestricted contiguous areas. The adjacent space survey will be performed even if in-room surveys show less than 2 mR/hr. (Attachment 3, form including adjacent room measurement, is enclosed.)

**ITEM D. 10 CFR 35.205(e)**

1. **Response:** A monthly check of the operation of the reusable collection system for radioactive

gases had not been in place at the time of the inspection.

2. **Corrective Steps Taken:** A procedure which demonstrates the efficacy of the trapping system has been developed by the RSO. The nuclear medicine supervisor and staff will perform the test procedure once a month. (Attachment 4, the new procedure and forms for this test, are enclosed.)
3. **To Avoid Further Violations:** A written procedure and corresponding technical information have been provided to ensure its correct implementation. Suitable logs and record keeping forms have been generated and are located in the Nuclear Medicine section (see Attachment 4). The medical physicist was present for the first demonstration, which yielded satisfactory results. This requirement has been input into the computer-based nuclear medicine information manager which provides a status of the tasks to be performed.
4. **Date for Compliance:** Full compliance achieved 4/28/97.

**ITEM E. 10 CFR 35.70(b)**

1. **Response:** After 1/6/96, the survey of the waste storage area was not conducted on a weekly basis. It was never part of the nuclear medicine information system.
2. **Corrective Steps Taken:** A weekly survey program was implemented.
3. **To Avoid Further Violations:** This requirement has been input into the computer-based nuclear medicine information manager which provides a status of the tasks to be performed. A survey of the decay-in-storage area is to be performed weekly. I-131 wastes shall be held for a minimum of 10 half-lives prior to disposal if indistinguishable from background radiation levels.
4. **Date for Compliance:** Full compliance achieved 3/25/97.

**ITEM F. CONDITION 21 OF LICENSE NO. 06-02388-01**

This item of the Notice of Violation is contested.

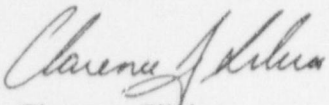
Thyroid burdens of the personnel involved in the therapeutic administrations of I-131, in amounts exceeding 30 mCi, were performed. The results though, were recorded as a "percent uptake" from 6/15/95 until August 1996 when the error was noticed and corrected. Those results may be recalculated to uCi, if so deemed necessary, because the data was acquired.



The uptake probe use for thyroid burdens was reviewed by the RSO and a suitable calibration factor was determined for the bioassay procedure. Our perspective on the matter is that the intent of the regulation for conducting bioassay measurements and identifying a positive uptake was met. Also, we self-identified an error in our program and corrected it in a timely manner.

**Date for Compliance:** Full compliance was achieved prior to September 6, 1996, when a bioassay was required of the personnel.

Submitted by



Clarence Silvia  
Senior Vice President, Operations

/js

cc: Peter J. Mas, M.S., Radiation Safety Officer

**NOTIFICATION FOR  
RELEASE OF ROOM FROM RADIATION PRECAUTIONS**

Room Number \_\_\_\_\_

☐ is released from the Radiation Precaution category

☐ is to remain on Radiation Precautions until further notice

Signature \_\_\_\_\_/per RSO

Date \_\_\_\_\_

Title \_\_\_\_\_

**POLICY FOR ADMISSION AND TREATMENT OF PATIENTS RECEIVING  
GREATER THAN 30 mCi OF I-131**

**A. NUCLEAR MEDICINE**

1. Nuclear Medicine Staff shall be responsible for notifying

- a. Admitting Office
- b. Environmental Services
- c. N-4 Nursing Staff
- d. Radiation Safety Officer
- e. Physicist

on the date and time the iodine patient will be treated. This notification should be made at least one week before the treatment day.

2. Nuclear Medicine shall be responsible for renotifying all the staff in (a) - (e) should there be any cancellation or change in the originally scheduled date and time.
3. All iodine therapy patients shall be admitted in room N424 or N425.
4. Nuclear Medicine Staff (NMS) shall brief the patient on clinical procedure of the treatment.
5. NMS shall assay the dose in the presence of the authorized user/physicist.
6. NMS shall administer the dosage to the patient.
7. Shall measure thyroid burden of all personnel who were present during loading, transportation and administration of the prescribed dose to the patient.
8. Post room-door with "Radioactive Materials" sign.
9. Post patient chart with "Radioactive Materials" sign.
10. Decontaminate, check wipe and survey results with physicist/RSO, and upon the approval of the physicist/RSO, remove all contaminated materials to the storage for decay.
11. Remove the "Radioactive Materials" signs from the room-door and chart.
12. Post room-door with "Notification of Release" sign. File room survey records, patient discharge information and thyroid burden values.



Policy for Admission & Treatment of Patients Receiving Greater than 30 mCi of I-131 p. 2

**B. NURSES**

1. Shall order minimal DISPOSABLE table service; tray may not be left with the patient. (Discard cups, spoon, etc. into Box No. 2.)
2. Provide about 12 cans of soda (ask patient the type he/she likes, discard empty cans into Box No. 2).
3. Provide shoe covers and hand gloves outside room.
4. Provide gloves for patient's use inside the room. (Discard patients' used gloves in Box No. 1.)
5. Use pocket detector properly whenever you enter the room:
  - a. Turn detector ON, record initial reading, enter the room.
  - b. Exit room, record final reading, turn detector OFF.
6. Prefer NO visitors.
7. If possible avoid records of vital signs or protect the stethoscope and blood pressure cuff with plastic.
8. Avoid bed bath (may provide small warm towel for patient to clean face and discard in contaminated Box No. 1).
9. Change bedding **only** if soiled, discard in Box No. 1.
10. Change gowns **only** if soiled, discard in Box No. 1.
11. Used shoe covers should be placed in Box No. 3, outside the room.
12. Used gloves should be placed in Box No. 2, inside the room.
13. Patient should surrender all items used in the room before discharge.

**C. ENVIRONMENTAL SERVICES**

1. Clear the room of unneeded items, e.g.: chairs, trash bags, etc.
2. Shall cover large room surfaces with one-side absorbent and one-side plastic material with the absorbent side exposed, eg: floor, table, mattress, pillow, bed rails, night stand.

Policy for Admission & Treatment of Patients Receiving Greater than 30 mCi of I-131 p. 3

3. Cover small surfaces with absorbent paper or plastic bags, e.g.: phone, TV control, sink, toilet seat, door knob or handle, or other items the patient may touch.
4. Provide two biohazard boxes marked 1 and 2 inside the room and one box marked 3 outside the room.
5. Remove all contaminated coverings, uncontaminated room trash and clean up the room AFTER:
  - a. Patient has been discharged
  - b. The RSO has declared the room free of any contamination
  - c. All radiation signs have been removed

**D. RADIATION SAFETY OFFICER/PHYSICIST**

1. Shall inspect room covering before treatment starts.
2. Provide "Nursing Instructions" for patient's chart.
3. Post "Room/Patient Survey Record" on room-door.
4. Provide pocket dosimeter for nursing staff.
5. Provide personnel dosimeter record form for the nursing staff.
6. Answer radiation safety questions, if any.
7. Perform survey measurements in restricted and unrestricted contiguous areas.
8. Measure the exposure rates daily as required by NCRP 37.
9. Re-survey room and record background readings.
10. Release room for cleaning.
11. Upon approval of wipe and survey results, release room from radiation precautions.
12. Notify nurse manage of release of room, ensure "Notification for Release" sign is in place.



New Britain General Hospital  
Radiation Safety Office  
Room Survey Dose Assessment

Attachment 2

March 26, 1997

The equivalent thickness of concrete was assessed to establish attenuation factors. The ratio of transmitted wall exposure rate (I) to in air exposure rate (I<sub>o</sub>) for a 25 mg-Ra-Eq Cs 137 source serves as a measured transmission factor for this isotope.

Using this measurement data, the equivalent concrete wall thickness can be arrived at by inversely solving the attenuation equation:  $I / I_o = \exp(-mt)$ , where m is the linear attenuation coefficient for Cs-137 and concrete, for thickness t.

Other isotope transmission factors can be calculated using the resultant equivalent concrete thickness and known linear attenuation coefficients for each respective isotope.

The in air measurement for the setup was 0.805 R/hr. The resulting measurements for the wall adjacent to room N425 was 0.280 R/hr. For room C525, the resulting measurement was 0.330 R/hr. Data is summarized in the following tables.

<u>Room</u>	<u>R/hr Wall Transmission</u>	<u>R/hr in Air</u>	<u>Cs-137 Atten. Factor</u>	<u>cm Concrete Equivalence</u>
N-425	0.280	0.805	0.348	7.31
C-525	0.330	0.805	0.41	6.18

<u>Isotope</u>	<u>Concrete HVL (cm)</u>	<u>m (cm-1)</u>	<u>N425 Wall Attenuation</u>	<u>C525 Wall Attenuation</u>
Cs-137	4.8	0.1444	0.348	0.41
Ir-192	4.3	0.1612	0.308	0.369
I-131	4.1	0.1690	0.290	0.352

<u>Date</u>	<u>Isotope</u>	<u>Room</u>	<u>mR/hr recorded in Room</u>	<u>mR/hr calculated to adjacent Room</u>	<u>Duration of Implant (hr)</u>
11-Dec-96	Cs-137	C523	2.9	1.19	48
16-Jul-96	I-131	N425	13.8	1.52 *	30
8-Jul-96	Ir-192	C525	2.6	0.96	50
28-May-96	Cs-137	C525	2.5	1.03	48
5-Feb-96	Cs-137	C525	4.2	1.72	26.5
9-Jan-96	I-131	N425	3.8	1.10	51

\*Calculated mR/hr with inverse square from a distance of 4 feet to a distance of 6.5 feet. This is the only assessment point to include inverse square correction.

Mark Young, MS  
Medical Radiation Physicist

Peter J. Mas, MS  
Health Physicist & RSO

# RADIOPHARMACEUTICAL THERAPY RECORD & NURSING INSTRUCTIONS SUMMARY

(Phosphorus-32, Strontium-89, Iodine-131, or, Gold-198)

Patient's name: \_\_\_\_\_, Room: \_\_\_\_\_, MD: \_\_\_\_\_, Auth. user: \_\_\_\_\_

Radioisotope administered: \_\_\_\_\_, Date & time: \_\_\_\_/\_\_\_\_/\_\_\_\_ @ \_\_\_\_:\_\_\_\_ AM-PM.

Dose received: \_\_\_\_\_ mCi, Method of administration: \_\_\_\_\_

## Exposure Rates (mR/hr):

Date & time	Bedside	at 3 ft	at 10 ft	% Retention	mCi assay
_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____

Surveys: N = \_\_\_\_\_, S = \_\_\_\_\_, E = \_\_\_\_\_, W = \_\_\_\_\_, Patient = \_\_\_\_\_ at 1m  
when discharged, linens = \_\_\_\_\_, room = \_\_\_\_\_, wipes  $\leq$  \_\_\_\_\_ dpm.

## Comply with all checked items:

- \_\_\_\_ 1. Radiation dosimeter badges must be worn (film, TLD, XETEX, or EPD-2).
- \_\_\_\_ 2. The following tag(s) are present: \_\_\_\_ door, \_\_\_\_ bed, \_\_\_\_ chart, \_\_\_\_ wrist.
- \_\_\_\_ 3. Do not change linens unless necessary. Place laundry in linen bag and retain in the room.
- \_\_\_\_ 4. Non-medical care personnel may not enter the room (housekeeping, engineering, etc.).
- \_\_\_\_ 5. Patient may not leave their private room.
- \_\_\_\_ 6. Patient must use disposable utensils with their meals.
- \_\_\_\_ 7. Visitors under 18 yr of age, &/or, that may be pregnant are not permitted.
- \_\_\_\_ 8. Visitors must remain a minimum of 3 feet distance from patient.
- \_\_\_\_ 9. Daily visiting time permitted: 0.5 hr at 3 ft distance, or, 2 hr at 6 ft distance.
- \_\_\_\_ 10. All items must remain in room until approved for removal by the Radiation Safety Officer.
- \_\_\_\_ 11. Room is not to be released to the Admitting Office until surveyed and approved by the Radiation Safety Officer.
- \_\_\_\_ 12. No patient specimens unless it is a STAT emergency, or, you have the approval of the Nuclear Medicine consultant physician.
- \_\_\_\_ 13. In case of an emergency, contact for:
  - a) Medical Nuc. Medicine physician.
  - b) Radiation Safety- the RSO or designate,  
Mark Young, M. S., Physicist  
Ext. 5520, or, tel. \_\_\_\_\_

Nuc Med MD: \_\_\_\_\_, M. D. RSO: Mr. Peter J. Mas, M. S.

Ext. 6260, or, tel. \_\_\_\_\_ Ext. 5520, Page # 299-8390, Home tel. 635-7050

### ROOM AIR MONITORING QA

This procedure is followed **daily** for the use of Xenon-133 gas. It is based upon the manufacturer's recommended use of a XenAlert unit for the monitoring of Xe-133. Place the unit in the area where you will be working with Xe-133. Reset the XenAlert to 0 (zero) at the start of each week, or, at 80 MPC-HOURS (whichever occurs first).

1. Background Adjustment. Background radiation may vary and affect your Xe-133 measurements due to the presence of other isotopes in the imaging area. Check the background-subtract compensation periodically and adjust it as necessary. The background should be  $\leq 0.5$  MPC.

Adjust: Place METER MULTIPLIER switch on TEST. To adjust background, move toggle switch to BKG position. Wait 4 minutes, and record the background reading as it appears on the meter. Move the toggle switch to SUB BKG position. If necessary, with a screwdriver turn the ADJUST screw until the meter reads the same as it did in the BKG position.

Verify: Place the METER MULTIPLIER switch in the X1 position. The background has been subtracted from both the meter and digital readouts if the meter reads between 0 - 0.1 MPC.

2. Press the RESET button on rear of instrument. MPC-HOURS and HOURS should now read 0 (zero).
3. The AUDIBLE ALARM may be switched to the "ON" position.
4. At the end of the working day, toggle the INTEGRATE and BLOWER switches to TRAP/STANDBY. Record the day's readings in the logbook.

Note: Do not unplug the XenAlert from its power source. Accumulated data is lost when power is removed.

### XENALERT OPERATIONAL QA

This procedure is performed **weekly** for the use of Xenon-133 gas. It is based upon the manufacturer's recommended use of a XenAlert unit for the monitoring of Xe-133. Place the unit in the area where you will be working with Xe-133.

1. Keeping the Cs-137 vial source within the vial shield, place this source directly over the top-rear of the XenAlert and on the label which reads: "Place Check Source Here".
2. Record the MPC reading shown on the XenAlert. Verify the constancy of this reading with the previous week's reading.
3. Notify the RSO if the XenAlert does not appear to be working correctly.



### GAS TRAP MONITORING QA

This procedure is performed **monthly** for the use of Xenon-133 gas and is required by the NRC for compliance with 10 CFR 35.205 (e). Place the unit in the area where you will be working with Xe-133.

1. To measure the concentration in the effluent from a gas trap, place one end of a 1" (inner diameter) hose on the XenAlert air intake port, and, the other end over the Xenon trap exhaust port. Gas trap measurements should be made during the washout phase of a ventilation study.
2. Move the METER MULTIPLIER switch to the X1000 position, and, place the INTEGRATE and BLOWER switches to TRAP/STANDBY.
3. During the washout phase you should observe the MPC meter reading. If it reads less than 100 MPC, move the switch to the X100 position.
4. Record the results and calculate the activity in the trap effluent by using the formula:  
$$A = \text{MPC} \times 10^{-5} \times V \times T$$
, where  
A = effluent activity in uCi,  
MPC = reading from analog meter,  
 $10^{-5} = 1 \text{ MPC in uCi/ml}$ ,  
V = trap flow velocity in ml/minute,  
T = washout time in minutes.
5. Remove the gas trap hose connection. Toggle the BLOWER switch to "ROOM AIR" until the MPC meter reads 0 (zero), which indicates that all the Xenon (from the trap) is out of the XenAlert unit. This should take about 5 minutes.
6. Toggle the INTEGRATE switch to "ROOM AIR" to continue monitoring the imaging area air.

# NEW BRITAIN GENERAL HOSPITAL

NUCLEAR MEDICINE SERVICE  
Monthly Xe-133 Gas Trap Q. A.

Year: \_\_\_\_\_

Trap Effluent Activity (uCi) =  $\text{MPC} \times 10e-5 \times V \times T$

Mo/Day	MPC Rdg * 10e-5 uCi/ml	Volume ml/min	Time, min	Calc Act, uCi	Initials
Jan/					
Feb/					
Mar/					
Apr/					
May/					
Jun/					
Jul/					
Aug/					
Sep/					
Oct/					
Nov/					
Dec/					

Year: \_\_\_\_\_

Trap Effluent Activity (uCi) =  $\text{MPC} \times 10e-5 \times V \times T$

Mo/Day	MPC Rdg * 10e-5 uCi/ml	Volume ml/min	Time, min	Calc Act, uCi	Initials
Jan/					
Feb/					
Mar/					
Apr/					
May/					
Jun/					
Jul/					
Aug/					
Sep/					
Oct/					
Nov/					
Dec/					

NEW BRITAIN GENERAL HOSPITAL  
Medical Physics Services

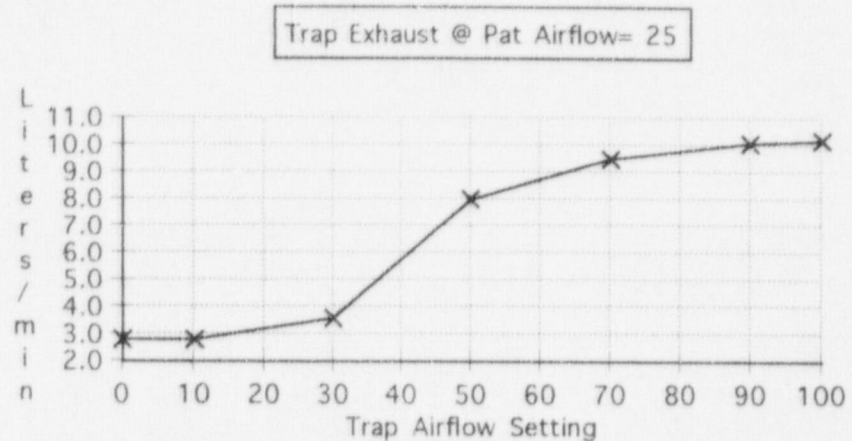
NUCLEAR MEDICINE SERVICE

Pulmonex Xe-133 Gas Trapping System Measured Airflow Rates (liters/min)

4/1/97

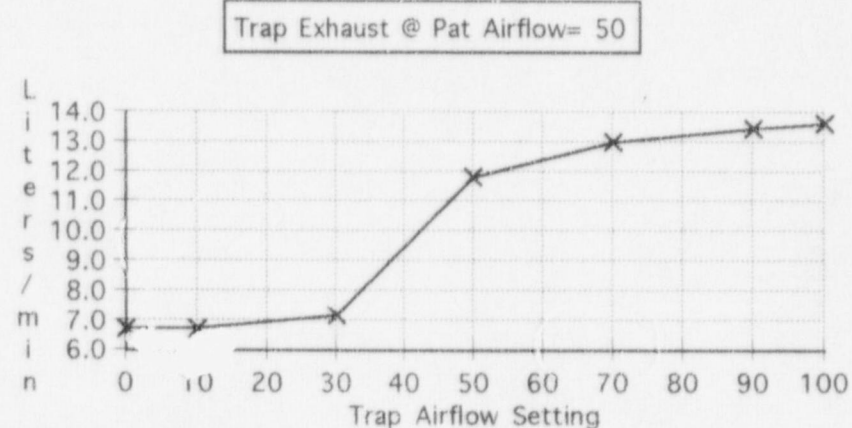
Patient Airflow Setting of 25:

Trap Setting of:	l/min
0	2.8
10	2.8
30	3.6
50	8.0
70	9.5
90	10.1
100	10.2



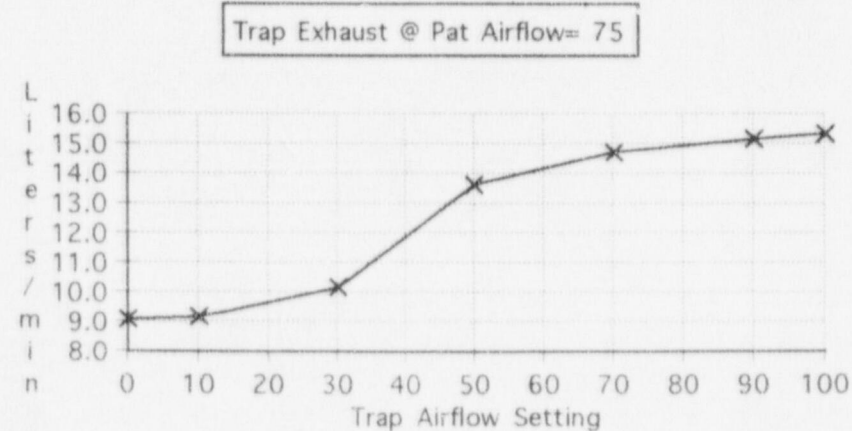
Patient Airflow Setting of 50:

Trap Setting of:	l/min
0	6.7
10	6.7
30	7.2
50	11.8
70	13.0
90	13.5
100	13.6



Patient Airflow Setting of 75:

Trap Setting of:	l/min
0	9.1
10	9.2
30	10.2
50	13.6
70	14.7
90	15.2
100	15.4





# NEW BRITAIN GENERAL HOSPITAL

## NUCLEAR MEDICINE SERVICE

### Weekly XenAlert Q. A.

Cs-137 vial chk srce = \_\_\_\_\_ MPC. Initials: \_\_\_\_\_

Room Air Log for Week starting on: \_\_\_\_/\_\_\_\_/\_\_\_\_

Complete this record for each day of use of Xe-133 gas.

Day	Total scans	Total mCi		MPC Hours	Hours
Mon.			@ Start	_____	_____
			@ Finish		
			Difference		
Tues.			@ Start	_____	_____
			@ Finish		
			Difference		
Wed.			@ Start	_____	_____
			@ Finish		
			Difference		
Thurs.			@ Start	_____	_____
			@ Finish		
			Difference		
Fri.			@ Start	_____	_____
			@ Finish		
			Difference		
Sat.			@ Start	_____	_____
			@ Finish		
			Difference		
Sun.			@ Start	_____	_____
			@ Finish		
			Difference		

Cs-137 vial chk srce = \_\_\_\_\_ MPC. Initials: \_\_\_\_\_

Room Air Log for Week starting on: \_\_\_\_/\_\_\_\_/\_\_\_\_

Complete this record for each day of use of Xe-133 gas.

Day	Total scans	Total mCi		MPC Hours	Hours
Mon.			@ Start	_____	_____
			@ Finish		
			Difference		
Tues.			@ Start	_____	_____
			@ Finish		
			Difference		
Wed.			@ Start	_____	_____
			@ Finish		
			Difference		
Thurs.			@ Start	_____	_____
			@ Finish		
			Difference		
Fri.			@ Start	_____	_____
			@ Finish		
			Difference		
Sat.			@ Start	_____	_____
			@ Finish		
			Difference		
Sun.			@ Start	_____	_____
			@ Finish		
			Difference		