syncor™
TENTH ANNIVERSARY

July 17, 1985

U.S. Nuclear Regulatory
Commission
Region I
Material Licensing
Section B
631 Park Avenue
King of Prussia, PA 19406

Re: Amendment to License Number 06-19661-01,01MD
Syncor Corporation, Hartford CT.

Dear Sir:

Please amend license number 06-19661-01MD Syncor Corp., Hartford CT. to show the following changes:

1. Increase the maximum limit for 133-Xenon (item 8 F) from 1 Curie to 2 Curies. See attached evaluation for this limit.

2. Add the enclosed updated Bioassay Procedure to our licensed application.

3. In a letter dated November 6, 1984 we noted that 131-Iodine is transferred from one stoppered vial to another stoppered vial. This situation has changed due to recent requests for 131-Iodine in screwtop vials. This change will not affect the calculations submitted with the letter dated Nov. 6, 1984.

Applicant Dept II I
Check No. 24202
Amount/Fee Category $230 (3C)
Type of Fee AMD
Date Check Rec'd 9/18/85
Received By

RECEIVED
'85 SEP 18 A10:19
U.S. NRC REGION I
LIC. FEE MANAGEMENT BRANCH

Thank you for your time and consideration in this matter. If there are any questions concerning this request, please contact me at (301) 459-8909.

Sincerely,

Frank Demeis
Frank Demeis
Health Physics Group

8510230071 850930
REG1 LIC30
06-19661-01MD PDR

"OFFICIAL RECORD COPY"

Encl.: Check $230.00
133-Xenon Evaluation
Bioassay Procedure

104360

ML10 SEP 06 1985

Syncor International Corporation
Medical Services Group
10033-M George Palmer Highway
Lanham, Maryland 20706
(301) 459-8905

Adequacy of Facility for Handling Xenon-133

A. Quantities to be used

1. State the desired possession limit.

The desired possession limit is 2 Ci of Xenon-133 in gas and/or saline form. The only forms of Xenon-133 we are requesting are sealed glass vials of the New England Nuclear, and Medi-Physics type of glass vial containing gas, or the Mallinckrodt cartridge of Xenon-133 in saline. The rubber septums on these vials will not be punctured nor the contents of the vials altered in any way. These vials will be shipped from the nuclear pharmacy in the same containers and form in which they are shipped to the pharmacy, reducing the possibility of Xenon-133 leaks, spills or contamination essentially to zero.

B. Use and storage areas

1. Describe the area in which you plan to use and store Xenon-133.

When the pharmacy receives shipments of Xenon-133, the gas or gas in saline will be in sealed glass vials which will be shipped to authorized users without being opened or without the septum being punctured by anyone in the pharmacy. The sealed vials will be stored in a fume hood, nevertheless, and will remain inside the lead containers used by the manufacturer for shipment of the Xenon-133. Please see attached floor plan diagram for the location of the fume hood. The nearest uncontrolled area is the side entrance which is over 25 feet away.

2. Describe the ventilation in all areas where Xenon-133 is stored and dispensed. See attached sketch. The total supply to the dispensing area (fume hood location) is 900 CFM, the exhaust from the fume hood is 900 CFM with no return air vents located in this area.

Xenon-133 is not to be used in the pharmacy; it will be stored and dispensed in the fume hood only. The exhaust fan from the fume hood is used to maintain a high flow rate through the hood. The fume hood has a * measured air flow of 900 CFM.

Total supply (dispensing area) = 900 CFM*
Return = 0
Exhaust = 900 CFM

* The Air supply to the fume hood will be drawn from the air space above the ceiling when the door to the fume hood is closed. When the door to the fume hood is open air will be drawn from the facility.

3. The fume hood will be checked every six months with a volumeter to determine if the fume hood is operating according to specifications in our Xenon-133 protocol.

C. Procedures for routine use

1. Describe the procedures to be followed for routine use of Xenon-133 giving particular attention to radiological safety factors.

No patient procedures will be performed in the nuclear pharmacy. The Xenon-133 gas or gas in saline being ordered will be sealed in glass vials with rubber septums by the manufacturer. The septum will not be punctured nor the sealed vial opened in any way. The vials will be stored in the original shipping containers composed of lead, and they will be stored in the fume hood at all times. When an authorized user orders a quantity of Xenon-133 gas or gas in saline, the vials will be dispensed in their original containers to the physician.

D. Emergency procedures

1. Describe the emergency procedures to be used in case of accidental release of Xenon-133. This should include such considerations as temporary evacuation of the area or increasing the ventilation of the area.

Since we are not performing ventilation studies on patients, and since we are not opening or puncturing the septum in these vials, there is virtually no chance of an accidental release of Xenon-133. Should some unexpected accident occur, we will be monitoring the area in front of the fume hood, and if levels should increase, the room will be evacuated until levels return to background.

E. Air concentrations of Xenon-133 for unrestricted areas.

1. All Xenon-133 gas will be handled and dispensed in the fume hood.

a. Estimate the maximum amount of activity to be used per week (A).

b. Estimate the fraction of Xenon-133 that is lost during use and storage (f).

c. Determine the ventilation rate in the area of interest and calculate the volume of air available per week for dilution of Xenon-133 (V).

2. The maximum amount of activity to be used per week in mCi is 2000. This will be the maximum amount stored in the fume hood. Due to the location, we consider the hot storage lab as a "restricted area" even though no Xenon-133 would be intentionally released into this area.

3. In the past we have used as a 0.5% per day value for vial leakage. The value was supplied by NEN. We have now evaluated actual vial leakage and feel that leakage actually averages about 0.04% leakage per day when averaged over a seven day period. We rarely if ever maintain a maximum possession limit on hand for more than a few hours to one day. From the data we see a trend of increased leakage the longer the material is stored. We therefore feel that 0.04% leakage is a reasonable value to use in calculating either fume hood flow or the necessary time that a fume hood must be left on to insure that maximum permissible concentration of 133-Xenon are not released to an unrestricted area. We therefore submit the following calculations and request authorization to run the fume hood at this location 3 hours per day. Note that the fume hood will be turned on whenever 133-Xenon or 131 Iodine is handled.

$$F = \frac{0.04\%}{day} \times \frac{7\ days}{week} \qquad F = 2.8 \times 10^{-3}/week$$

4. The exhaust across the fume hood is 900 cubic feet per minute. Calculating (V) in metric terms:

$$V = \frac{900\ cubic\ ft}{min} \times \frac{60\ min}{hr} \times \frac{24\ hr}{da} \times \frac{7\ da}{wk} \times \frac{1728\ cu\ in}{cu\ ft} \times \frac{16.39\ ml}{cu\ in}$$

$$V = 900 \times (1.008 \times 10^{4}) \times (2.83 \times 10^{4})\ \frac{ml}{wk}$$

$$V = \underline{2.57 \times 10^{11}}\ ml/wk$$

5. For unrestricted area, Section 20.106 of 10 CFR, Part 20 requires that the maximum allowed concentration is:

$$\frac{A}{V} \times f = 3 \times 10^{-7}\ \mu Ci/ml$$

In our case:

$$\frac{A}{V} \times f = \frac{2 \times 10^{6}\ \mu Ci}{2.57 \times 10^{11}} \times \frac{2.8 \times 10^{-3}}{ml/wk\ wk} = \underline{2.18 \times 10^{-8}}\ \mu Ci/ml$$

$$\text{Fume Hood on time} = 168\ \frac{Hrs}{Wk} \times \frac{2.18 \times 10^{-8}}{3.7 \times 10^{-7}} = 9.9\ \frac{Hrs}{Wk}$$

Item 9
DATE: 7/15/85

F. Methods for Xenon-133 disposal

1. Xenon-133 vials not marketed to hospitals will be held for decay and will be disposed of in the normal trash when monitoring with a low level survey meter shows the vials to be at background radiation levels.

G. Please note that Xenon-133 will not be used in the radiopharmacy. It will be assayed in a dose calibrator and repackaged in its original shipping container and distributed to authorized recipients.

H. If one considers that 5.6 mCi of Xenon-133 escapes through the fume hood exhaust vent per week, then the table on page 10-8-54 of the NRC Guide 10-8 indicates that the exhaust rate of 900 CFM operated for 3.0 hrs per week will be more than adequate to ensure that the average concentration of Xenon-133 released to an unrestricted area will be less than 3×10^{-7} µCi/ml. The exhaust stack from the fume hood is exclusive for this fume hood, and is located over 10 meters from the nearest intake vent or access to the building.

* Measured with an Alenor Jr. Air Flow Meter (Anemometer).

Attached is raw data that has just been collected on two manufacturers 133-Xenon. We feel that the constant movement of air over the vials does contribute to our leakage information. We plan to do one more week of evaluation with NEN the product to see why the great discrepancy for the week of 6/28/85.

XENON-133 LEAKAGE DATA SHEET

Dose Calibrator CAPINTEC Serial # 10859

Calibration Factor _____ Xenon-133 Background 0.1 uCi

Activity Loaded 523.8 mCi Date 5/31/85 Time 1200

	Date	Time of Filter Removal and Replacement	Net Xenon Activity in Charcoal Filters 1(uCi)	2(uCi)	3(uCi)	Total
1.	6/1/85	1200	0.3	0.1	0.3	0.7 μCi
2.	6/2/85	1200	0.1	0.1	0.2	0.4 μCi
3.	6/3/85	1200	3.2	1.2	0.7	5.1 μCi
4.	6/4/85	1200	2.0	1.3	0.8	4.1 μCi
5.	6/5/85	1200	2.6	1.5	1.7	5.8 μCi
6.	6/6/85	1200	6.3	5.5	3.8	15.6 μCi
7.	6/7/85	1200	6.1	4.8	3.7	14.6 μCi
		Totals	20.6	14.5	11.2	46.3 μCi

COMMENTS: THE ABOVE VALUES WERE FROM 10 x 10 mCi AND 8 x 20 mCi MEDI-PHYSICS XENON VIALS

Signature [signature]

Date 6/7/85

syncor

Medi-Physics 10 mCi & 20 mCi Xe-133 vials

Xenon-133 Leakage Study Start: 5/31/85 End: 6/7/85

SOURCE	INITIAL ASSAYED ACTIVITY (mCi)	FINAL ASSAYED ACTIVITY (mCi)	CALCULATED FINAL ACTIVITY (mCi)	AMOUNT LOST IN 7 DAYS (mCi)
A	21.9	8.43	8.45	0.020
B	21.0	8.16	8.15	-0-
C	20.7	8.06	8.03	-0-
D	19.8	7.68	7.68	-0-
E	20.2	7.87	7.84	-0-
F	20.8	8.06	8.07	0.010
G	20.4	7.95	7.92	-0-
H	21.6	8.40	8.38	-0-
I	21.7	8.39	8.42	0.030
J	21.1	8.22	8.19	-0-
K	39.1	15.25	15.17	-0-
L	38.9	15.24	15.09	-0-
M	42.4	16.68	16.45	-0-
N	38.5	14.96	14.94	-0-
O	41.4	16.12	16.06	-0-
P	38.3	14.85	14.86	0.010
Q	38.7	15.12	15.02	-0-
R	37.3	14.55	14.47	-0-
			203.24 mCi	0.070 mCi

% LOSS IN 7 DAYS = $\frac{0.070}{203.24} \times 100 = 0.0344\%$

AVERAGE LOSS PER DAY = 0.0049%

By: Verne Y. Tabacon

Date: 6/7/85

Syncor International Corporation
Medical Services Group
1141 Air Way
Glendale, California 91201
(213) 245-5751

XENON-133 LEAKAGE DATA SHEET

Dose Calibrator CAPINTEC Serial # 10859

Calibration Factor _____ Xenon-133 Background _____ uCi

Activity Loaded 417.38 mCi Date 7/5/85 Time 10:00

	Date	Time of Filter Removal and Replacement	Net Xenon Activity in Charcoal Filters 1(uCi)	2(uCi)	3(uCi)	Total
1.	7/6/85	10:00	40.4	7.3	0.3	48.0
2.	7/7/85	10:00	13.3	0.9	0.0	14.2
3.	7/8/85	10:00	12.0	1.2	0.4	13.6
4.	7/9/85	10:00	57.5	36.5	4.0	98.0
5.	7/10/85	10:00	50.8	14.7	11.7	77.2
6.	7/11/85	10:00	28.8	17.7	10.8	57.3
7.	7/12/85	10:00	36.9	23.0	9.3	69.2
		Totals	239.7	101.3	36.5	377.5

COMMENTS: 10 x 10 mCi } NEN Xenon Vials
8 x 20 mCi }

Signature _____

Date 7/12/85

syncor

XENON-133 LEAKAGE STUDY

NEN 10 mCi & 20 mCi Xe-133 Vials START: 7/5/85 END: 7/12/85

SOURCE	INITIAL ASSAYED ACTIVITY (mCi)	FINAL ASSAYED ACTIVITY (mCi)	CALCULATED FINAL ACTIVITY (mCi)	AMOUNT LOST IN 7 DAYS (mCi)
A	16.50	6.53	6.54	0.01
B	16.58	6.56	6.58	0.02
C	17.00	6.70	6.74	0.04
D	16.81	6.62	6.67	0.05
E	17.10	6.77	6.78	0.01
F	16.69	6.59	6.62	0.03
G	16.67	6.61	6.61	-0-
H	17.03	6.75	6.75	-0-
I	16.48	6.51	6.54	0.03
J	16.72	6.62	6.63	0.01
K	30.7	12.17	12.18	0.01
L	30.9	12.20	12.25	0.05
M	31.1	12.21	12.33	0.12
N	31.1	12.30	12.33	0.03
O	30.2	11.96	11.98	0.02
P	32.5	12.87	12.89	0.02
Q	32.1	12.70	12.73	0.03
R	31.2	12.36	12.37	0.01
			165.52 mCi	0.49 mCi

$$\% \text{ LOSS IN 7 DAYS} = \frac{0.49}{165.52} \times 100 = 0.296\%$$

AVERAGE LOSS PER DAY = 0.042%

Syncor International Corporation
Medical Services Group
1141 Air Way
Glendale, California 91201
(213) 245-5751

By: Verne Y. Tabacon

Date: July 12, 1985

XENON-133 LEAKAGE DATA SHEET

Dose Calibrator CAPINTEC Serial # 10859

Calibration Factor _____ Xenon-133 Background _____ uCi

Activity Loaded 428.1 mCi Date 6/28/85 Time 10:00

	Date	Time of Filter Removal and Replacement	Net Xenon Activity in Charcoal Filters 1(uCi)	2(uCi)	3(uCi)	Total
1.	6/29/85	10:00	12.9	3.9	3.8	20.6
2.	6/30/85	10:00	10.6	9.1	9.7	29.4
3.	7/1/85	10:00	30.6	11.3	10.4	52.3
4.	7/2/85	10:00	44.4	17.2	9.1	70.7
5.	7/3/85	10:00	62.2	44.2	10.3	116.7
6.	7/4/85	10:00	15.6	2.3	0.2	18.1
7.	7/5/85	10:00	25.0	2.1	1.1	28.2
		Totals	201.3	90.1	44.6	336.0

COMMENTS: 10 x 10 } NEN Xenon Vials
8 x 20 }

Signature _____

Date 7/5/85

syncor

XENON-133 LEAKAGE STUDY

NEN 10 mCi & 20 mCi Xe-133 vials START: 6/28/85 END: 7/5/85

SOURCE	INITIAL ASSAYED ACTIVITY (mCi)	FINAL ASSAYED ACTIVITY (mCi)	CALCULATED FINAL ACTIVITY (mCi)	AMOUNT LOST IN 7 DAYS (mCi)
A	16.8	6.45	6.52	0.07
B	16.7	6.42	6.48	0.06
C	16.6	6.42	6.44	0.02
D	16.6	6.39	6.44	0.05
E	16.8	6.45	6.52	0.07
F	15.7	6.04	6.09	0.05
G	16.5	6.36	6.40	0.04
H	16.6	6.40	6.44	0.04
I	16.2	6.27	6.28	0.01
J	16.1	6.23	6.25	0.02
K	32.6	12.56	12.65	0.09
L	32.7	12.56	12.68	0.12
M	33.1	12.71	12.84	0.13
N	33.4	12.79	12.96	0.17
O	33.1	12.74	12.84	0.10
P	33.0	12.71	12.80	0.09
Q	33.3	12.89	12.95	0.06
R	32.3	12.39	12.53	0.14
			166.11 mCi	1.33 mCi

% LOSS in 7 DAYS = $\frac{1.33}{166.11}$ x 100 = 0.8006%

AVERAGE LOSS PER DAY = 0.114%

By: Verde Y. Tabacon

Date: July 5, 1985

Syncor International Corporation
Medical Services Group
1141 Air Way
Glendale, California 91201
(213) 245-5751

Item 10.j Precautionary Measures for Handling Millicurie Quantities of Liquid Radioiodine

Personnel dispensing therapeutic quantities of liquid 131-I Iodine will be instructed to wear gloves and to perform this operation in the fume hood. There will be an L-Block drawing station in the fume hood with 2" leaded glass and 2" lead. The Iodine will be drawn behind it. (See Iodine fume hood information 10. j.)

Discussion: Bioassay must be performed in accordance with NRC Regulatory Guide 8.20. A copy of this guide should be filed with your bioassay results so that it may be used as a reference should thyroid burden action levels be exceeded. Urine bioassay will be performed monthly as a backup procedure to assess the need for further in vivo procedures.

In Vivo Thyroid Bioassay

1. Equipment necessary:

   a. Scintillation counting system with

   b. Thyroid neck phantom

   c. 131-I capsule

2. Procedure:

   131-I energy = 364 KEV
   Analyzer window = 100 KEV

   With the 131-I capsule, peak the analyzer by adjusting the detector voltage until maximum count rate is achieved.

   a. Obtain background of counting system

   b. Obtain standard count by placing neck phantom containing capsule centered on detector face.

   c. Obtain counts over the thyroid. Place the detector against the front of the neck at midline in three vertical positions. For your calculations use the positions which gives you the highest count rate.

EXAMPLE

d. Calculate thyroid activity from:

131-I thyroid activity =

$$\frac{\text{(neck CPM - Bg CPM) (uCi of capsule)}}{\text{Capsule CPM - Bg CPM}} = \text{uCi in thyroid}$$

3. Comment: Since NRC Guide 8.20 specifies an action level with respect to thyroid burden of 0.04 uCi, it will be necessary for you to determine the sensitivity of your equipment, and the thyroid counting time necessary to demonstrate a level of 0.04 uCi in the thyroid. This may be done in the following manner:

a. From the data obtained when counting the 131-I capsule for thyroid bioassay, express the sensitivity of your counting system in CPM per uCi. Example: a 5.0 uCi 131-I capsule is counted in the thyroid neck phantom on the detector face and counts 20,000 CPM, then:

$$CF = \frac{20{,}000 \text{ CPM}}{5 \text{ uCi}} = 4000 \text{ CPM/uCi}$$

b. Sample calculations: Minimum detectable activity *

Prior to any thyroid bioassay procedure, it is necessary to verify that the requisite MDA can be achieved. The MDA is given by:

$$MDA = \frac{3.3 \sqrt{2R_b/t_b}}{CF}$$

R_b = the background counting rate

t_b = time taken to count the background

CF = calibration factor, i.e., the counts per minute per uCi of a standard source

In the above example, CF = 4000 CPM/uCi.

If background was counted for 10 minutes and yielded 2400 total counts, then the MDA is determined to be:

$$MDA = 3.3 \times \sqrt{\frac{(2 \times 240 \text{ cmp})/10 \text{ min.}}{4000 \text{ cpm/uCi}}} = MDA = 0.0052 \text{ uCi}$$

which is approximately 15% of the re[illegible]ce sensitivity.

It is apparent that this thyroid counting system would be capable of detecting quantities of 131-I below that required for adequate monitoring of health and safety.

The quantity of radioactive material (Q) deposited in the thyroid is simply:

$$Q = \frac{\text{Net thyroid cpm}}{CF}$$