ST. JOSEPH'S HOSPITAL

September 26, 1985

United States Nuclear Regulatory Commission
Region III
799 Roosevelt Road
Glen Ellyn, Illinois 60137

Attention Control Number 79265

Gentlemen:

Enclosed please find our response to the letter received September 6, 1985, concerning renewal of our Byproduct Material License Number 13-00418-02. We will respond to each of the questions in the same order as addressed in the September 6th correspondence.

I. In regards to 10 CFR Part 35, requiring a representative of the Nursing Staff to be on the Medical Isotopes Committee:

A. A representative of the Nursing Staff, Mary Jane Shank, R.N., has been appointed to the Nuclear Medicine/Radiation Safety Committee as of March 9, 1984. (See Attached).

II. The following procedure has been developed regarding the precautionary measures and bioassay procedures required in handling liquid Iodine-131:

A. Therapeutic doses of I-131 will be ordered from reputable suppliers and received precalibrated ready for dispensing to patients.

B. These materials will be stored until time for use in the Isotope storage area behind sufficient shielding to reduce the Radiation levels to 2.0 mR/hr at a distance where occupational workers can conveniently stand.

C. All liquid sources will be opened in a fume hood with the fan activated.

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D. All personnel handling the Radioactive material will be instructed to wear rubber gloves.

E. Routine thyroid bioassays will be performed on all personnel involved with the administration of liquid Iodine-131 totaling more than 10 mCi. A baseline bioassay will be performed prior to administration of the Radionuclide on all personnel that will be present during the administration of the therapeutic dose. Followup bioassays will be performed at 24 hours post administration and whenever deemed necessary by the Radiation Safety Officer.

The bioassay will be performed according to the following procedure:
1. Peak the thyroid uptake system according to manufacturer's specifications for Iodine 131.
2. Set the counting window to 50% with a threshold of 339.
3. Count the Thyroid Region for three minutes using the standard neck to crystal distance of 25 cm. convert to CPM.
4. Count background for three minutes. Convert to CPM.
5. Calculate the standard deviation for the background CPM as follows:

$$S.D = \sqrt{\frac{\text{Background CPM}}{3}}$$

6. If the thyroid CPM from step 3 is not greater then the background CPM plus 3 standard deviations, then there is no statistically detectable Iodine 131 in the thyroid. Record the measured thyroid burden as .009 microcuries, which is the minimum detectable Activity for this protocol. (As per prior calculations by our Radiation Physicist).
7. If the thyroid CPM from step 3 is greater than the background CPM plus 3 standard deviations, calculate the thyroid burden (in microcuries) by multiplying times the net thyroid CPM (thyroid CPM from step 3 minus background CPM from step 4) times 1861. (CPM/microcurie by our determinations).
As soon as possible, refer the individual to appropriate medical consultation for recommendations regarding therapeutic procedures that may be carried out to accelerate removal of Radioactive Iodine from the body. Continue bioassays until the Radioiodine concentration has reached a background level or as approved by the Radiation Safety Officer.

III. The Dose calibrator utilized at our institution is a Capintec Model CRC-17.

IV. Instructions for opening packages containing Radioactive Material.

1. Packages containing Radioactive material are to be opened only in the Nuclear Medicine hot lab by authorized individuals.
2. Individual opening package will wear protective clothing and gloves.
3. Note external condition of package and record. If package is wet or stained, immediately wipe test the package surface with filter paper on alcohol prep and forcep. Place wipe in a test tube and count in well spectrometer. If counts are above 22,000 DPM, notify Radiation Safety Officer.
4. All packages must be surveyed with a GM Survey Meter prior to opening. Record results.
   A. Measure exposure rate at three feet from package surface with thin-window GM detector. If this reading is 10 mR/hr, proceed with caution and immediately notify Radiation Safety Officer.
   B. Measure the exposure rate at the package surface. If this reading is 200 mR/hr, proceed as in step A (above).
5. Carefully open outer shipping container and remove the Radionuclide and packing slip. Open inner package to verify contents (compare requisition, packing slips, and label on bottle) and check the integrity of the final source container (inspect for breakage of seals or vials, loss of liquid, discoloration of packing material). Measure the exposure rate at the surface of the empty shipping container and record result. If this reading is greater than twice background, the final container must be wipe tested and the results recorded.
   A. Wipe test with filter paper on alcohol prep and forceps. Place wipe in a test tube and count in the well spectrometer. If counts are above 22,000 DPM, notify the Radiation Safety Officer immediately.
6. After package has been surveyed, complete the remaining sections on the package receipt form.
7. If package and/or packing material are contaminated, treat as Radioactive waste. If not, obliterate Radiation warning labels and Discard as normal waste.

V. Regarding our ALARA Program as required by the NRC, please find enclosed a copy of St. Joseph's Hospital ALARA Program that was instituted November 16, 1979.

VI. In response to the questions regarding the addition of Gadolinium-153 and Iodine-125 as sealed sources for use in Bone Mineral Analysis:

A. Dr. Fouad Halaby - an approved Group I, II, III, IV, V, & VI user, as per license number 13-00418-02 - will supervise and direct the use of the Gd-153 and I-125 sealed sources. Under Dr. Halaby's direct supervision, the following individuals will be involved with the Bone Mineral Analysis:

Richard Bauman, M.D.	Approved for Groups I, II, & III.
John Pasalich, M.D.	Approved for Groups I, II, & III.
Stephen Phillipp, M.D.	Approved for Groups I, II, & III, and in Vitro Studies.
Marc Thomas, M.D.	Approved for Groups I, II, & III, and in Vitro Studies.

B. The manufacturer of the Iodine-125 sealed source will be AECL and model number C324. The I-125 source will be utilized in Lunar Radiation Device SP2, NRC device Registration number NR-430-D-102-S. The manufacturer of the Gadolinium-153 source will be Gulf Nuclear, their model GD-1. We also seek permission to purchase the equivalent material from Amersham, their model number GDC 10410 to be supplied in Lunar Radiation holder NRC Number GDC, CYI, New England Nuclear Model number NER-430 or Lunar GD Series. These sealed sources will be used for the Lunar Radiation Model DP3 spine scanner. This device has NRC registration number NR-430-D-101-S.

C. The Lunar Radiation Corporation will provide two days of on-site training with installation of the DP3 and SP2. This will include instructions on the installation and replacement of the sealed sources. Actual installation and replacement of the source will occur only under the direct supervision of Dr. Halaby and Dr. Pasalich (our Radiation Safety Officer), or their designees, all of whom will have been trained by the Manufacturer's Representative. No source will be installed prior to this training.
In addition to area monitoring and personal monitoring devices required under our license, leak testing of the Gd-153 in the DP3 Scanner and I-125 in the SP2 Scanner will be performed per 10 CFR 35.14 by the Radiation Safety Officer or his designee in accordance with the instructions from the Lunar Radiation Corporation to be provided at time of installation. The wipes will be either sent to a certified laboratory for counting or counted in a well counting system in the department and the results kept in units of microcuries for inspection by the Commission.

D. Enclosed please find manufacturer's recommended procedures for installation and removal of the Gd-153 and I-125 sealed sources. Instructions for the replacement of the Gd-153 source can be found in the Lunar DP3 Technical Manual, pages 22-23. (See enclosed).
Instructions for the replacement of the Iodine-125 source can be found in the Lunar SP2 Technical Manual pages 12-13. (See enclosed).

E. At the time of a new source replacement, depleted sources will be returned to the original supplier in appropriate shipping containers as per supplier instructions.

F. Lunar Radiation Corporation will provide complete service to the SP2/DP3 Bone Mineral Analyzers. Service will include all maintenance to the units, including the source holders and shutter mechanisms.

G. Security in Nuclear Medicine areas (including the Bone Mineral Analyzer areas) will include:

1. Caution Radiation Area signs posted appropriately on doors to rooms in which Radionuclides are used or stored in accordance with NRC Regulations.
2. During the hours of operation of the Nuclear Medicine Area, Nuclear Medicine personnel are present at all times to prevent access of unauthorized persons.
3. During the hours that the Nuclear Medicine Area is not in operation, the doors to the Nuclear Medicine Areas are locked.
4. Emergency phone numbers are posted for the notification of the Radiation Safety Officer and necessary personnel in case of emergencies.

If you have any questions or require clarification on any of the information stated above, you may contact us at the above address or at (219) 425-3977.

Sincerely,

Lee Jaeger

Lee Jaeger
Assistant Executive Director

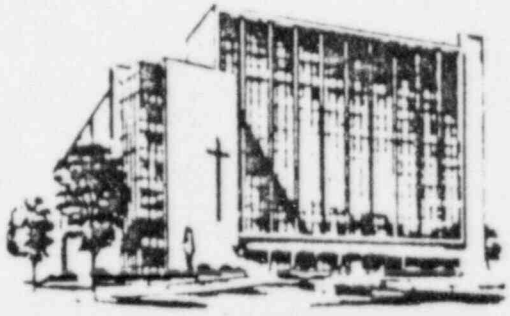
LJ/dac

ST. JOSEPH'S HOSPITAL

ST. JOSEPH'S HOSPITAL - FORT WAYNE, INDIANA

Nuclear Medicine Committee Members

John Pasalich, M.D. - Radiologist
Richard Bauman, M.D. - Radiologist
Peter Casey, M.D. - Pathologist
John Crawford, M.D. - Oncologist
Fouad Halaby, M.D. - Radiologist
John McCallister, M.D. - Surgeon
Stephen Phillipp, M.D. - Radiologist
David Sorg, M.D. - Internal Medicine
Marc Thomas, M.D. - Radiologist
Irene Spindler - Administrative Assistant
Sandy Seibert - Director of Radiology
John Helmer - Supervisor of Nuclear Medicine
Donald Rumschlag - Manager of Laboratory
Mary Jane Shank, R.N. - Director of Critical Care
Mary Ellen Luther - Director, Quality Review



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Attachment A

ST. JOSEPH'S HOSPITAL

11-16-79

I. Management Commitment

a. We, the management of St. Joseph's Hospital are committed to the program described in this paper for keeping exposures (individual and collective) as low as reasonably achievable (ALARA). In accord with this commitment, we hereby establish an administrative organization for radiation safety and develop the necessary written policy procedures and instructions to foster the ALARA concept within our institution. The organization will include an Isotope Committee and a Radiation Safety Officer (RSO). We are also commited to following the guidance provided by U.S. Nuclear Regulatory Guides 8.10 and 8.18.

b. We will perform a formal audit annually to determine how exposures might be lowered. This shall include reviews of operating procedures and past exposure records, inspections, etc., and consultations with the radiation protection staff or outside consultants. A brief summary of the audit will be prepared covering the scope of the review and the conclusions reached.

c. Modification to operating and maintenance procedures and to equipment and facilities will be made where they will significantly reduce exposures at reasonable costs. We will be able to demonstrate that improvements have been sought, that modifications have been considered, and that they have been implemented where practicable. Where modifications have been considered but not implemented, we will be prepared to describe the reasons for not implementing them.

d. In addition to maintaining doses to individuals as far below the limits as is reasonably achievable, the sum of the doses received by all exposed individuals will also be maintained at the lowest practicable level. It would not be desirable, for example, to hold the highest doses to individuals to some fraction of the applicable limit if this involved exposing additional people and significantly increasing the sum of radiation doses received by all involved individuals.

II. Isotope Committee

a. Review of Proposed Users and Uses

1. The Isotope Committee will thoroughly review the qualifications of each potential authorized user with respect to the types and quantities of materials and uses for which he has applied to assure that the user will be able to take appropriate measures to maintain exposure ALARA.

2. When considering a new use of byproduct material, the Isotope Committee will review the efforts of the authorized user to maintain exposure ALARA. The user should have systematized procedures to ensure ALARA, and should have considered the use of special equipment such as syringe shields, rubber gloves, etc., in his proposed use.

3. The Isotopes Committee will ensure that the user justifies his procedures and that they will result in ALARA doses (individual and collective).

b. Delegation of Authority

1. The Isotope Committee will delegate sufficient authority to the RSO for enforcement of the ALARA concept.

2. The Isotopes Committee will support the RSO in those instances where it is necessary for the RSO to assert his authority. Where the RSO has been overruled, the Committee will record the basis for its action.

c. Review of ALARA Program

The Isotopes Committee of our medical facility will perform an annual review of all radiation safety programs. This review will be performed independently of that performed by management.

1. The Isotopes Committee will encourage all users to review current procedures and develop new procedures as appropriate for ways to implement the ALARA concept.

2. The Isotopes Committee will review all instances of deviations from the ALARA philosophy. Information in support of the review will normally be supplied by the RSO.

3. The Isotopes Committee will evaluate our Institution's overall efforts for maintaining exposures ALARA. This review will include the efforts of the RSO, authorized users, and workers as well as those of management.

d. Public Statement of Commitment by the Isotopes Committee to ALARA

All elements of our institution will be informed of the Isotopes Committee commitment to the ALARA concept.

1. The Isotopes Committee will ensure that employees are aware of the Isotopes Committee commitment to the ALARA philosophy.

2. The Isotopes Committee will demonstrate its commitment to the ALARA concept through the methods employed in its review of proposed users and uses.

III. Radiation Safety Officer (RSO)

a. Periodic Review and Audit of the Radiation Safety Program for Compliance with ALARA Concepts. Frequent reviews of procedures will be conducted.

1. The RSO will review and audity, on a regular basis (at least annually), the effectiveness of his own radiation protection programm in maintaining doses (individual and collective) ALARA.

2. The RSO will review exposures of authorized users and occupational workers to determine that their exposures are ALARA.

3. The RSO will review radiation levels in unrestricted and restricted areas and releases of effluents to unrestricted areas to determine that they are at ALARA level.

b. The RSO's Education Responsibilities for an ALARA Program

1. The RSO will schedule briefings and educational sessions to inform workers of ALARA program efforts.

2. The RSO will assure that authorized users, occupational workers and ancillary personnel understand the ALARA philosophy and know that management, the Isotopes Committee and the RSO are committed to implementing the ALARA concept.

c. Cooperative Efforts for Development of ALARA Procedures

Individuals who must work with ALARA concepts will be given opportunities to participate in formulation of the procedures that they will be required to follow.

1. The RSO will maintain close contact with all users and workers in order to develop ALARA procedures for working with radioactive materials.

2. The RSO will establish procedures to encouraging, receiving, and evaluating the suggestions of individual workers for improving health physics practices.

d. Reporting and Reviewing Instances of Deviation from Good ALARA Practices

1. The RSO will investigate all instances of deviation from good ALARA practices; and, if possible, determine the causes. When the cause is known, the RSO will propose changes in the program to maintain exposures ALARA.

2. The RSO will report all significant instrances of deviation from ALARA concepts to the Isotopes Committee for review.

IV. Authorized Users

a. New Procedures Involving Potential Radiation Exposures

1. The authorized user will consult the RSO and Isotope Committee before using radioactive materials for a new procedure.

2. The authorized user will consider all procedures thoroughly before using radioactive materials to ensure that exposures will be kept ALARA. This may be enhanced through the application of trial runs.

b. Responsibility of the Authorized User to Those He Supervises

1. The authorized user will thoroughly explain the ALARA concept and his commitment to maintain exposures ALARA to all of those he supervises.

2. The authorized user will ensure that his occupational workers are trained and educated in good health physics practices and in maintaining exposures ALARA.

3. The authorized user will be responsible to the radiation safety concerns of the individuals that he supervises.

c. Continuing Review of ALARA Concepts by the Authorized User

1. The authorized user will continuously review his procedures to ensure that his ALARA program is optimal.

2. The authorized user will maintain contact with the RSO to ensure that he is aware of and employs the most current methods to maintain exposures ALARA.

V. Occupational Worker

a. What the Occupational Worker Must Consider about ALARA

1. The worker will implement ALARA procedures developed by the authorized user and the RSO.

2. The occupational worker will know what recourses are available if he feels that ALARA is not being promoted on the job.

3. The occupational worker will understand that ALARA concept and will review his own working conditions and those of his fellow workers for the implementation of ALARA principles.

VI. Establishment of Action Levels in Order to Achieve Reductions in Individual Occupational Exposures

St. Joseph's Hospital hereby establishes exposure action levels for specific kinds of classes of operations which, when exceeded, will trigger investigation by the Radiation Safety Committee and/or the Radiation Safety Officer. The exposure action levels that we have established are listed in Section VII below. These levels apply to the exposure of individual workers. The exact levels have been determined based on our institution's radiation exposure history and a thorough analysis of our current program. We will maintain on file at our institution an account of the considerations used in establishing action levels.

Written justification is appended to this program for any exposure action levels that exceed 10% of MPD (10 CFR 20.201). This justification includes details of the past exposure history at this institution for the particular kind or class of operation, a summary of efforts taken to reduce this exposure, and an explanation of why further dose reductions are not feasible.

We will investigate the causes of personnel exposures that exceed our established exposure action levels. In the event of a personnel exposure that exceeds our established action levels or 10% of MPD, whichever is higher, we will maintain accounts of our investigation for inspection by the NRC. As a minimum, these accounts will include the cause of the exposure, the action taken to correct the situation and the follow-up action taken.

The specific action levels established by St. Joseph's Hospital are as follows:

Kind or Class of Operation	Action Level
1. Clinical Nuclear Medicine	10%
2. Group VI Radiation Therapy	10%
3. Teletherapy	10%

VIII Signature of Certifying Official

I hereby certify that St. Joseph's Hospital is committed to the ALARA Program set forth above.

Lee Jaeger
Signature

Lee Jaeger
Name (print or type)

Assistant Executive Director
Title

St. Joseph's Hospital
700 Broadway
Fort Wayne, Indiana 46802

C. DETAILED OPERATING PROCEDURES

C.1 INSTALLING AND REMOVING THE SOURCE

CAUTION: Only personnel trained in the principles of radiation safety and protection should conduct these procedures. The technician should study the following procedures before attempting an actual source transfer. The press-on label with the warning "CAUTION - RADIOACTIVE MATERIALS" should be affixed to the table of the scanner in a location where it can be seen by the operator, patients, and/or visitors to the area where measurements are done.

All steps should be conducted without tools. Do not use pliers, clamps, etc. to parts. The "source" consists of a capsule containing 125-I in solid form. This source is located in a brass source holder (Figure 5). Sources are not supplied by LRC.

PROCEDURE

1. Have container that he source is shipped in nearby.
2. Turn off SP2.
3. Unplug SP2 power cord.
4. Unlock the locks that hold down the top (FIG 6).
5. Remove top, do not bump the detector.
6. Turn shutter to open position and hold there. Avoid beam if a source has been installed earlier.
7. Turn source holder arbor counterclockwise to remove. (Avoid beam if source was attached previously).
8. Remove old source holder from arbor.
9. Screw protective cap (supplied with each source holder) onto old source holder. If a new source holder is not to be installed, screw the arbor back into the plate to avoid loss. Follow standard procedures for source disposal.
10. Unscrew cap from new source holder.
11. Screw source holder into the arbor.

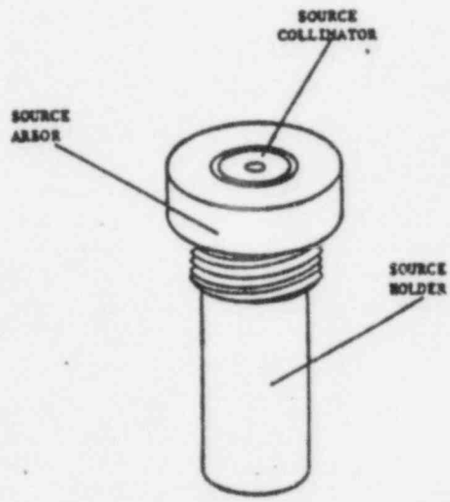

FIGURE 5
SOURCE HOLDER ASSEMBLY

TABLE 1. CABLE INTERCONNECTIONS ON THE SP2-SYSTEM

DEVICE	ORIGIN LABEL	DESTINATION	CABLE TYPE
Advantage Computer	SP2	SP2 Enclosure	15-Wire (D-Type)
	AC Power	Outlet Strip	3-Conductor
	DP3	DP3 Enclosure	15-Wire (D-Type)
	Printer	Epson FX-80 Printer	25-Wire (D-Type)
Detector Electronics AMP/DCA	CH 1 OUT	CH 1 (Advantage)	RG-59/U (Coaxial)
	CH 2 OUT	CH 2 (Advantage)	RG-59/U (Coaxial)
	SP2 OUT	Event (Advantage)	RG-59/U (Coaxial)
	AC Power	Outlet Strip	3-Conductor
SP2 Scanner Enclosure	AC Power	Outlet Strip	3-Conductor
	SP2 Signal	SP2 IN (AMP/DCA)	RG-62/U (Coaxial)
DP3 Scanner Enclosure	AC Power	Outlet Strip	3-Conductor
	DP3 Signal	DP3 IN (AMP/DCA)	RG-62/U (Coaxial)

12. Screw arbor into the scanner and be sure it is properly seated. Be sure the lead shutter can swing freely over the arbor.

13. Replace the top and lock into position.

14. Plug the power cord in and turn scanner on.

If the Atomic Energy of Canada Limited (AECL) sources are used in AECL holder C236, then an additional source collimator is used in the arbor. This can be inserted in the arbor prior to insertion of the source holder. Use of this additional collimator reduces the beam size at the table thereby lowering radiation exposure and scattered radiation. The SRC-0100-1 source holder does not require the extra collimator since the source holder itself provides sufficient collimation.

Once the old source is removed, the protective cap must be screwed onto the top of the old source holder. The old source should then be packed into the original shipping container. Send the depleted source in the source holder back to the supplier of that source using the recommended shipping procedures for this type of material.

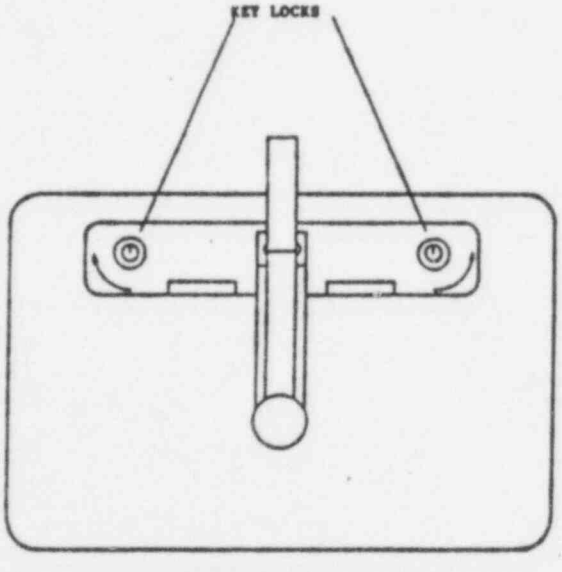

FIGURE 6
UNLOCKING SP2 TOP

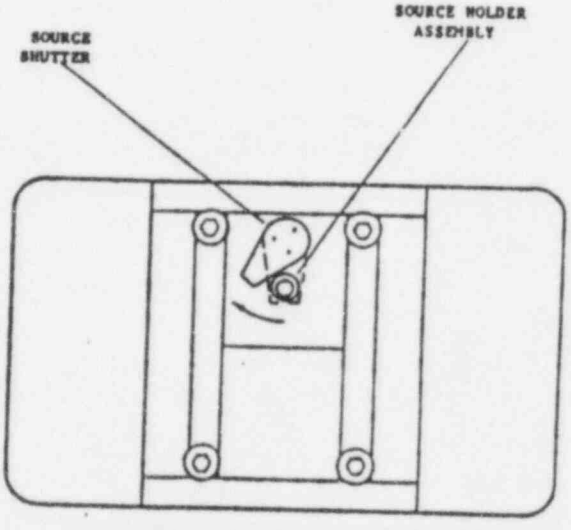

FIGURE 7
SOURCE LOCATION & REMOVAL
NOTE: "DASHED" lines refer to shutter in "occluded" position.

C.2 START-UP AND SHUT-DOWN

Initial Start-Up Procedure

1. Verify that the system is interconnected properly.

2. Verify that no diskettes are in either drive of the computer.

3. Verify that the outlet strip is turned off, and plug the cord into a grounded 120VAC/60Hz outlet (220VAC/50Hz for European models).

4. Turn ON the outlet strip, computer, printer, AMP/DCA, and scanner.

5. Insert the disk labelled "ADVANTAGE DEMO-DIAGNOSTIC" in drive #1. Depress the "ENTER" key. Select the diagnostic option. Select the single block test mode and test all sub systems except the SIO.

6. Reset the computer (User Manual) and load the SP2 system disk in drive #1. Depress the <RETURN> key and run the "PEAK" and "STANDARD D/A" programs (User Manual).

SHUTDOWN PROCEDURE

If the SP2 will not be used for SEVERAL MONTHS, turn off all the components. The system should not be shut down needlessly, however, since the components are most stable when maintained in a steady state. If a source is in place when the SP2 is shut down the user should check that the shutter is occluding the radiation beam (Figure 7 pg. 13).

1. Remove the SP2 system diskette from drive #1 and data diskette from drive #2 of the computer and store in a vertical position in their protective jackets.

2. Turn "OFF" the switch on the outlet strip.

3. Unplug the AC power cord supplying the outlet strip.

C.2 INSTALLING AND REMOVING THE SOURCE

CAUTION: Only personnel trained in the principles of radiation safety and protection should conduct these procedures. The technician should study the following procedures before an actual source transfer is attempted. A press-on label with the warning "CAUTION - RADIOACTIVE MATERIALS" should be displayed in a location where it can be seen by the operator, patients and/or visitors to that area where measurements are done.

WARNING: All steps should be conducted without tools. Use of pliers, clamps, etc. may cause irreparable damage to parts.

C.2.a Removing the Source

1. Remove the pad if it is on the table. Using the key provided with the system, unlock the lucite insert and remove it from the table.

2. Select OPTION 5 (STATIC COUNTER) of the "DP3 SYSTEM" diskette menu to position the arm and source at the center of the window.

3. Place a lead source holder cap onto the source collimator (Fig. 10 and 11).

4. Select the "SHUTTER OPEN" command of OPTION 5. Alternatively, the shutter can be manually opened. Be careful to keep hands and other body parts clear of the actual radiation beam. If the shutter is opened manually, do not force the shutter blade to swing more than 35 degrees; then tape the shutter in this (open) position.

5. Turn the chuck ring (Fig. 12) counterclockwise until the collimator is loose in the chuck. Do not completely loosen the chuck ring.

6. Slide the source collimator (Fig. 13), which will have the source holder attached to the end of it, out of the chuck. The source collimator and holder can now be handled as a unit.

7. Holding the source collimator and source holder upright (as they are positioned in the scanner assembly enclosure), unscrew the source holder from the collimator. Immediately put a lead cap on the source holder and tape it in place.

   CAUTION: RADIATION PRESENT! After the collimator is removed and before the lead cap is positioned a broad beam of high intensity radiation projects from the top of the source holder. Exercise due caution.

   This completes the source removal procedure.

C.2.b Installing a Source

1. Unlock and remove the lucite insert on the scan table.

2. Load and run the "DP3 SYSTEM" diskette. Use the "shutter open" command ("O") of OPTION 5 (STATIC COUNTER). Alternatively the shutter can be manually opened. Be careful to keep hands and other body parts clear of the actual radiation beam. If the shutter is opened manually, do not force the shutter blade to swing more than 35 degrees; then tape the shutter in this (open) position.

3. Remove the lead cap from the source holder and place it on the brass collimator provided with the system. Thread the source holder onto the base of the collimator. Do not force the collimator onto the source holder or it may cross-thread. The source collimator and holder can now be handled as a single unit (Fig. 10).

4. Slide the source collimator/holder assembly into the source chuck (Fig. 12) so the lower pin on the collimator fits into the notch on the source chuck. The collimator shoulder should rest on the top of the chuck (not the chuck ring).

5. Use the "shutter close" command ("C") of OPTION 5 or remove the tape if the shutter is held opened manually.

6. Turn the chuck ring clockwise until the collimator is held firmly in the chuck.

7. Verify that the shutter can swing into the notch on the collimator (Fig. 12) and fully occludes the source beam. Open and close the shutter using the "O" and "C" commands in OPTION 5 (STATIC COUNTER). If actuation is not smooth, adjust the collimator position. If actuation still is not smooth, notify LUNAR. Close the shutter.

8. Remove the source holder (lead) cap from the top of the collimator.

9. Replace and lock the lucite window. NOTE: The "HOME" position should be nearest the scan arm side of the table.

10. Monitor radiation levels around the table to insure operator safety.

11. Return to the computer's main menu and select OPTION 3 - "SCAN STANDARD AND Q/A". All measurements should yield a passing status.

This completes the source installation procedures.

ST. JOSEPH'S HOSPITAL

Applicant ... May 35
Check No. ... 138182
Amount ... $120
Type of ... Cash
Date Check Rec'd ... 5/31/85
Received by ...

Medical Licensing Branch
U.S. Nuclear Regulatory Commission, Region III
799 Roosevelt Road
Glen Ellyn, Illinois 60137

Gentlemen:

Please amend our byproduct materials license number 13-00418-02 to incorporate the relocation of Nuclear Medicine to new facilities within the hospital. A thorough exposure rate and contamination survey of the current Nuclear Medicine rooms will be performed when they are vacated and prior to their release as unrestricted areas. A report of this survey will be maintained on file or forwarded to the NRC, if required.

A diagram of the new Nuclear Medicine facility is enclosed. Radiation safety procedures will be the same as those approved under our current license, with appropriate modifications made to relfect the new space. The one modification that requires further description is the ventilation system, since this must be specifically approved to permit continued utilization of Xenon-133 for lung ventilation studies. The following information is provided in accordance with the format recommended in Appendix M of Regulatory Guide 10.8:

1. Based on prior experience, the anticipated number of Xenon-133 studies is approximately 4 per week with a usual administered activity of 10-20 mCi. Thus, our current possession limit of 500 mCi remains sufficient to provide for shipments whose calibration dates are several days after receipt.

2. The location of supply and exhaust vents are shown on the enclosed facility diagram. The airflow rates shown are based on engineering design specifications. The actual airflow rates will be measured when construction is completed and the exhaust rates will then be checked semi-annually by our consulting physicist.

   Both the hot lab and imaging room will be continuously maintained under negative pressure:

hot lab	supply	- 240 CFM
	exhaust	- 250 CFM
imaging room.	supply	- 600 CFM
	exhaust	- 620 CFM

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CONTROL NO. 79029
MAY 28 1985

The 250 CFM exhaust in the hot lab is through the hood directly to the roof of the hospital (no recirculation). The exhaust vent in the imaging room is located 4 inches above the floor on the wall nearest the gamma camera where the Xe-133 will be utilized. Normally, 90% of this 620 CFM exhaust will be recirculated within the nuclear medicine area and 10% will be exhausted directly to the outside at roof level. During Xe-133 studies, the recirculation unit will be turned off and the exhaust will be 100% to the outside. The recirculation unit will be turned back on only when the nuclear medicine technologist has ascertained (using a survey meter and/or the gamma camera) that no detectable Xe-133 is present in the room after completion of the patient study. The written protocol for the Xe-133 study will include this information.

3. The Xe-133 will be administered to the patient in the imaging room using an Atomic Products Corporation Model 130-330 Xenon Delivery Unit. The rebreathing system and the patient will be washed out through an Atomic Products Model 127-313 Xenon Gas Trap. The effluent from the trap will be continuously monitored with an Atomic Products Model 136-100 Gas Trap Efficiency Monitor. Nose clamps will be utilized to minimize the escape of Xe-133 into the room during the procedure.

4. In the event that there is an accidental release of a full patient dose of Xenon-133 into the imaging room, the patient and staff will vacate the imaging room for approximately 15 minutes. Based on the 620 CFM exhaust rate, this allows for approximately 5 air changes. The room will be surveyed upon reentry in order to verify that no detectable Xe-133 is remaining.

   In the event that there is an accidental release of a full patient dose in the hot lab, the hot lab will be vacated for approximately 25 minutes. Based on the 250 CFM exhaust, this allows for approximately 5 air changes. The room will be surveyed upon reentry in order to verify that no detectable Xe-133 is remaining.

5. AIR CONCENTRATIONS IN RESTRICTED AREAS

   assumptions: 4 studies/week or 80 millicuries/week = A
   20% lost during use and storage = f

$$\frac{A \times f}{1 \times 10^{-5}\ \mu Ci/ml} = 1.6 \times 10^{9}\ ml/week$$

$$\frac{1.6 \times 10^{9}\ ml/week}{40\ hr/week} = 4 \times 10^{7}\ ml/hour$$

$$\frac{4 \times 10^{7}\ ml/hour}{1.7 \times 10^{6}\ ml/hr/CFM} = 24\ CFM$$

Thus, in order to meet the requirements of 10 CFR Part 20.103, the imaging room and hot lab must have ventilation rates of at least 24 CFM with no recirculation. The anticipated ventilation rates of 250 CFM and 620 CFM in the hot lab and imaging rooms, respectively, are far in excess of the required minimum ventilation rate calculated above.

6. DISPOSAL OF XENON-133

As described earlier, the Xenon-133 will be disposed of by absorption onto a charcoal trap.

Assuming 20% leakage:

$A = 4 \text{ studies/week} \times 52 \text{ weeks/yr} \times 20 \text{ mCi/study} \times 0.2 = 832 \text{ mCi released/year}$

$V = 850 \text{ CMF} \times 1.484 \times 10^{10} \text{ ml/year/CFM} = 1.3 \times 10^{13} \text{ ml/year}$

$$C = \frac{8.32 \times 10^{5} \text{ uCi/year}}{1.3 \times 10^{13} \text{ ml/year}} = 6.4 \times 10^{-8} \text{ uCi/ml}$$

Thus, the maximum anticipated air concentration, averaged over one year, does not exceed 3×10^{-7} uCi/ml, as required.

As described earlier, the performance of the trap will be monitored continuously using the Atomic Products Gas Trap Efficiency Monitor. Saturated filters will be stored behind lead bricks in the hot lab until the filter reads background when surveyed with a GM survey meter.

Thank you for your prompt attention to this amendment request. We would appreciate approval of the new space for Xenon-133 studies even if a survey report must be submitted to your office for approval before releasing the current nuclear medicine rooms for unrestricted use.

Sincerely,

Lee Jaeger,
Assistant Administrator

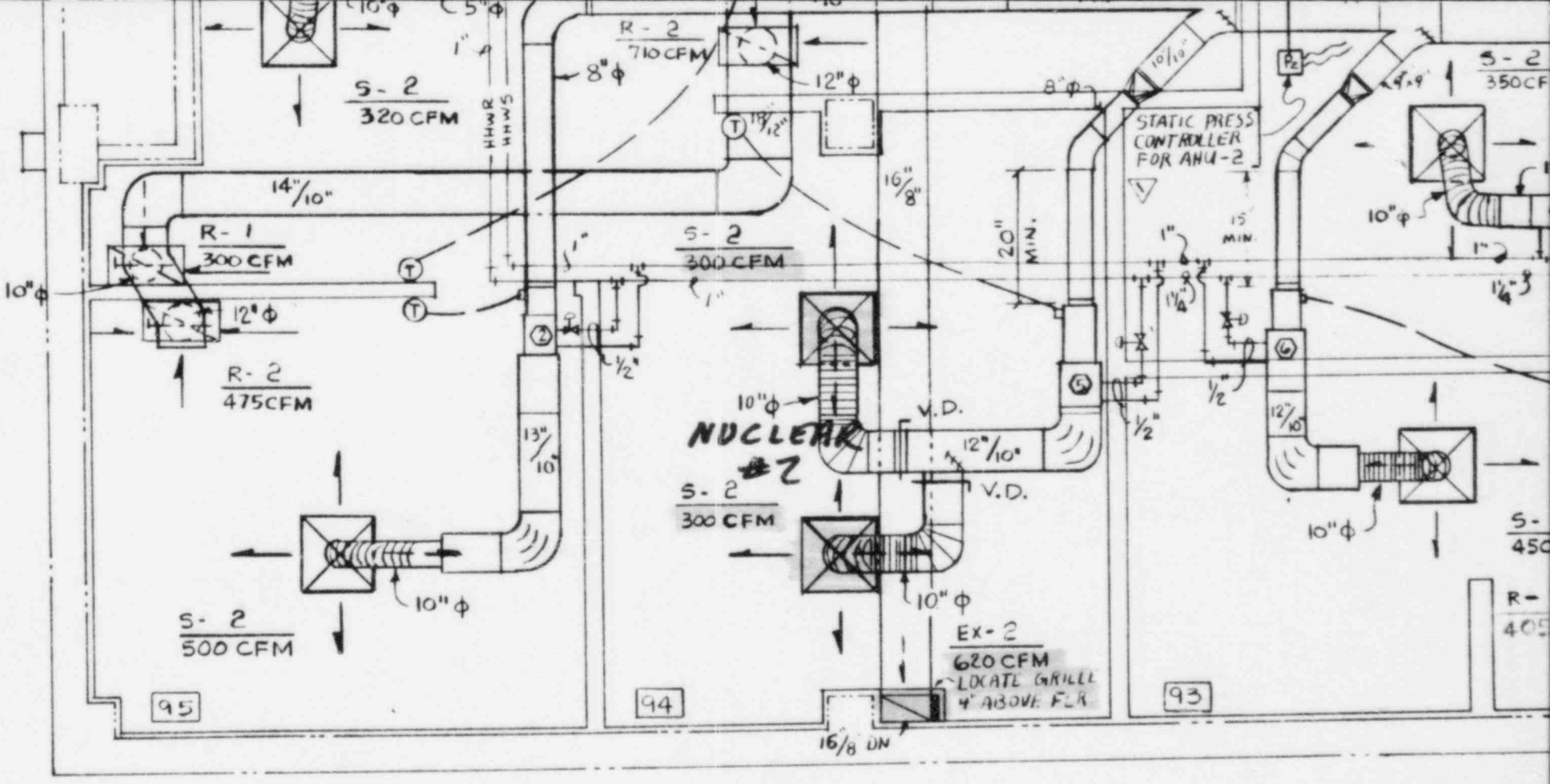
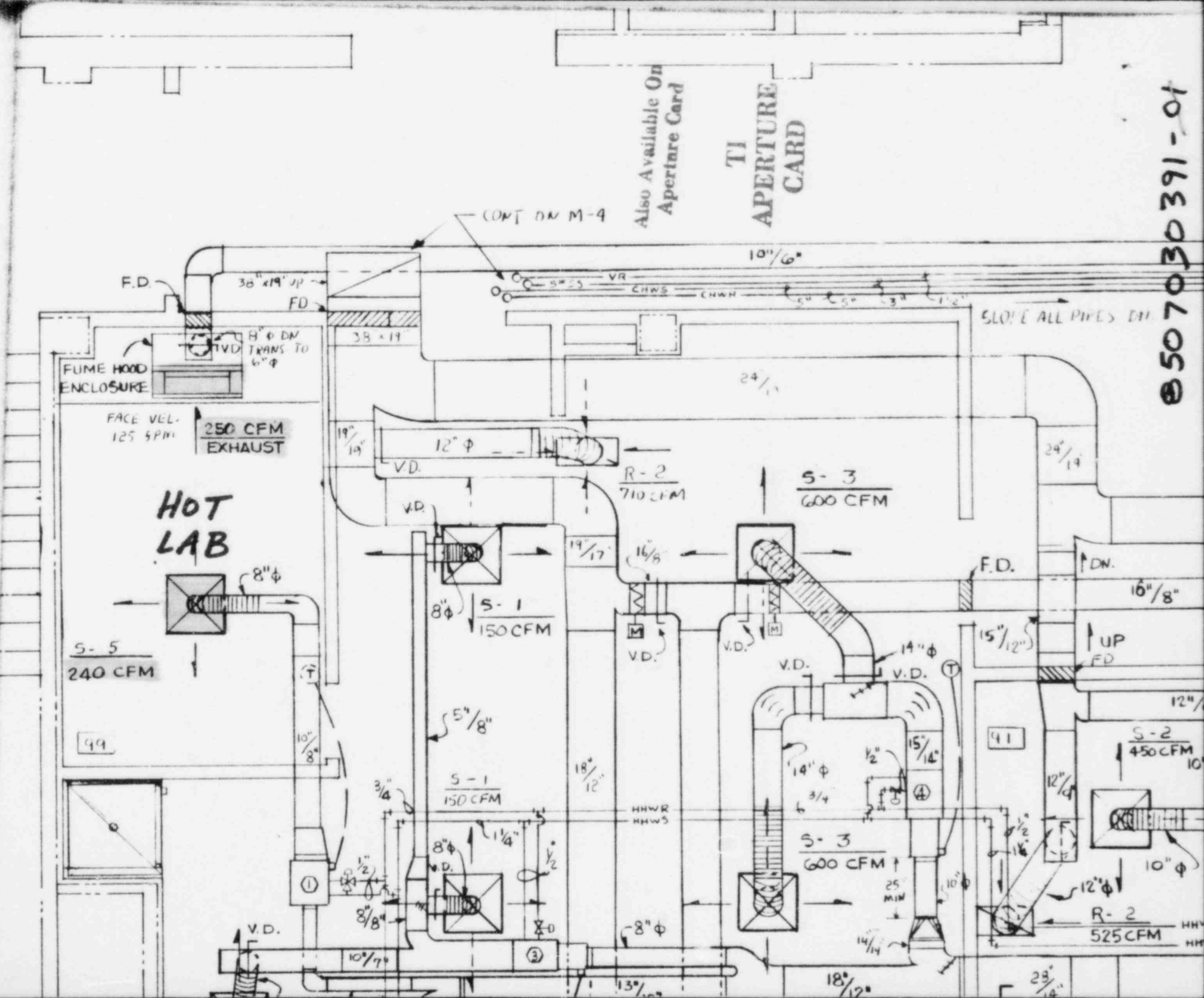
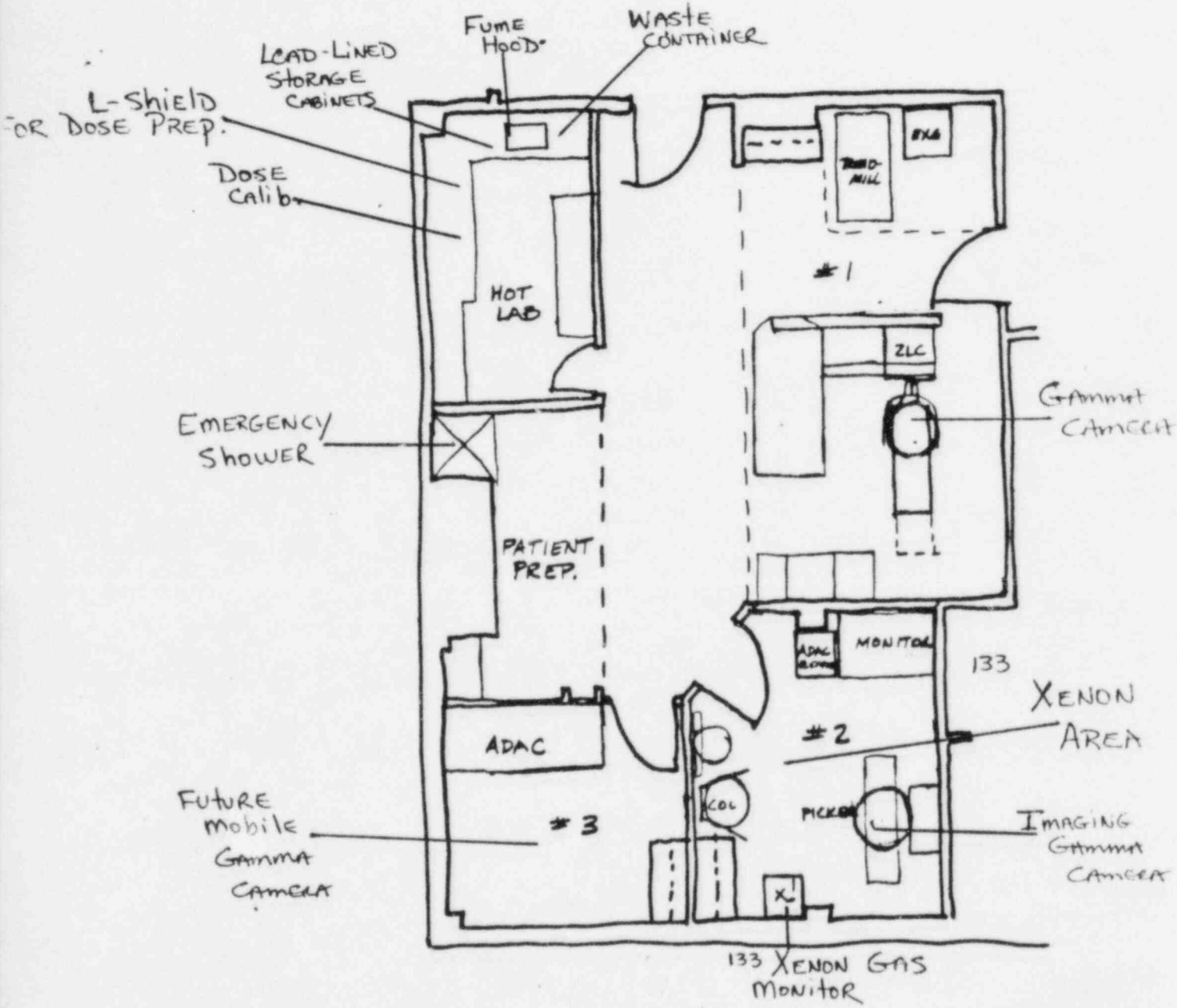


ILLUSTRATION
#2

CONTROL NO.





Nuclear Department
Radiology Renovation
Phase II

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Illustration
#1

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