NRC FORM 313M (9-81) 10 CFR 35	U.S. NUCLEAR REGULATORY COMMISSION **APPLICATION FOR MATERIALS LICENSE – MEDICAL**	Approved by OMB 3150-0041

INSTRUCTIONS – *Complete Items 1 through 26 if this is an initial application or an application for renewal of a license. Use supplemental sheets where necessary. Item 26 must be completed on all applications and signed. Retain one copy. Submit original and one copy of entire application to: Director, Office of Nuclear Materials Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. Upon approval of this application, the applicant will receive a Materials License. An NRC Materials License is issued in accordance with the general requirements contained in Title 10, Code of Federal Regulations, Part 30, and the Licensee is subject to Title 10, Code of Federal Regulations, Parts 19, 20 and 35 and the license fee provision of Title 10, Code of Federal Regulations, Part 170. The license fee category should be stated in Item 26 and the appropriate fee enclosed.*

1.a. NAME AND MAILING ADDRESS OF APPLICANT *(institution, firm, clinic, physician, etc.)* INCLUDE ZIP CODE

St. Luke's Hospital
11311 Shaker Blvd.
Cleveland, Ohio 44104

TELEPHONE NO.: AREA CODE(216) 368 - 7474

1.b. STREET ADDRESS(ES) AT WHICH RADIOACTIVE MATERIAL WILL BE USED *(If different from 1.a.)* INCLUDE ZIP CODE

Same

2. PERSON TO CONTACT REGARDING THIS APPLICATION

Paul J. Early, Director, HPS
Nuclear Medicine Associates

TELEPHONE NO.: AREA CODE(216) 641 - 5799

3. THIS IS AN APPLICATION FOR: *(Check appropriate item)*

a. ☐ NEW LICENSE
b. ☒ AMENDMENT TO LICENSE NO. 34-00398-08
c. ☐ RENEWAL OF LICENSE NO. _____

4. INDIVIDUAL USERS *(Name individuals who will use or directly supervise use of radioactive material. Complete Supplements A and B for each individual.)*

Ronald Thompson, M.D. et al

5. RADIATION SAFETY OFFICER (RSO) *(Name of person designated as radiation safety officer. If other than individual user, complete resume of training and experience as in Supplement A.)*

Bennett Levine, M.D. with consultation from Nuclear Medicine Associates
Cleveland, Ohio 44125

6.a. RADIOACTIVE MATERIAL FOR MEDICAL USE

RADIOACTIVE MATERIAL LISTED IN:	ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS *(In millicuries)*
10 CFR 31.11 FOR IN VITRO STUDIES		
10 CFR 35.100, SCHEDULE A, GROUP I		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP II		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP III		
10 CFR 35.100, SCHEDULE A, GROUP IV		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP V		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP VI		

ADDITIONAL ITEMS:	MARK ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS *(In millicuries)*
IODINE-131 AS IODIDE FOR TREATMENT OF HYPERTHYROIDISM		
PHOSPHORUS-32 AS SOLUBLE PHOSPHATE FOR TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA AND BONE METASTASES		
PHOSPHORUS-32 AS COLLOIDAL CHROMIC PHOSPHATE FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.		
GOLD-198 AS COLLOID FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.		
IODINE-131 AS IODIDE FOR TREATMENT OF THYROID CARCINOMA		
XENON-133 AS GAS OR GAS IN SALINE FOR BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES	X	1200

6.b. RADIOACTIVE MATERIAL FOR USES NOT LISTED IN ITEM 6.a. *(Sealed sources up to 3 mCi used for calibration and reference standards are authorized under Section 35.14(d), 10 CFR Part 35, and NEED NOT BE LISTED.)*

ELEMENT AND MASS NUMBER	CHEMICAL AND/OR PHYSICAL FORM	MAXIMUM NUMBER OF MILLICURIES OF EACH FORM	DESCRIBE PURPOSE OF USE
The purpose of this NRC license amendment application is to add Xenon-133 to the license. The addition of Dr. Ronald Thompson is the subject of a separate application already on file with the NRC, Region III.			

NRC FORM 313M

CONTROL NO. 7 9540

INFORMATION REQUIRED FOR ITEMS 7 THROUGH 23

For Items 7 through 23, check the appropriate box(es) and submit a detailed description of all the requested information. Begin each item on a separate sheet. Identify the item number and the date of the application in the lower right corner of each page. If you indicate that an appendix to the medical licensing guide will be followed, do not submit the pages, but specify the revision number and date of the referenced guide: Regulatory Guide 10.8 , Rev. 1 Date: Oct., 1980

7. MEDICAL ISOTOPES COMMITTEE	15. GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL *(Check One)*
☐ Names and Specialties Attached; and	☐ Appendix G Rules Followed; or
☐ Duties as in Appendix B; or *(Check One)*	☐ Equivalent Rules Attached
☐ Equivalent Duties Attached	16. EMERGENCY PROCEDURES *(Check One)*
8. TRAINING AND EXPERIENCE	☐ Appendix H Procedures Followed; or
☐ Supplements A & B Attached for Each Individual User; and	☐ Equivalent Procedures Attached
☐ Supplement A Attached for RSO.	17. AREA SURVEY PROCEDURES *(Check One)*
9. INSTRUMENTATION *(Check One)*	☐ Appendix I Procedures Followed; or
☐ Appendix C Form Attached; or	☐ Equivalent Procedures Attached
☐ List by Name and Model Number	18. WASTE DISPOSAL *(Check One)*
10. CALIBRATION OF INSTRUMENTS	☐ Appendix J Form Attached; or
☐ Appendix D Procedures Followed for Survey Instruments; or *(Check One)*	☐ Equivalent Information Attached
☐ Equivalent Procedures Attached; and	19. THERAPEUTIC USE OF RADIOPHARMACEUTICALS *(Check One)*
☐ Appendix D Procedures Followed for Dose Calibrator; or *(Check One)*	☐ Appendix K Procedures Followed; or
☐ Equivalent Procedures Attached	☐ Equivalent Procedures Attached
11. FACILITIES AND EQUIPMENT	20. THERAPEUTIC USE OF SEALED SOURCES
☐ Description and Diagram Attached	☐ Detailed Information Attached; and
12. PERSONNEL TRAINING PROGRAM	☐ Appendix L Procedures Followed; or *(Check One)*
☐ Description of Training Attached	☐ Equivalent Procedures Attached
13. PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL	21. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE GASES (e.g., Xenon – 133)
☐ Detailed Information Attached	X Detailed Information Attached
14. PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIALS *(Check One)*	22. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL IN ANIMALS
	☐ Detailed Information Attached
☐ Appendix F Procedures Followed; or	23. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL SPECIFIED IN ITEM 6.b
☐ Equivalent Procedures Attached	☐ Detailed Information Attached

24. PERSONNEL MONITORING DEVICES

TYPE (Check appropriate box)			SUPPLIER	EXCHANGE FREQUENC
a. WHOLE BODY		FILM	Refer to previous applications	
		TLD		
		OTHER (Specify)		
b. FINGER		FILM		
		TLD	Refer to previous applications	
		OTHER (Specify)		
c. WRIST		FILM		
		TLD		
		OTHER (Specify)		

d. OTHER (Specify)

25. FOR PRIVATE PRACTICE APPLICANTS ONLY

a. HOSPITAL AGREEING TO ACCEPT PATIENTS CONTAINING RADIOACTIVE MATERIAL

NAME OF HOSPITAL

MAILING ADDRESS

CITY | STATE | ZIP CODE

b. ATTACH A COPY OF THE AGREEMENT LETTER SIGNED BY THE HOSPITAL ADMINISTRATOR

c. WHEN REQUESTING THERAPY PROCEDURES, ATTACH A COPY OF RADIATION SAFETY PRECAUTIONS TO BE TAKEN AND LIST AVAILABLE RADIATION DETECTION INSTRUMENTS.

26. CERTIFICATE

(This item must be completed by applicant)

The applicant and any official executing this certificate on behalf of the applicant named in Item 1a certify that this application is prepared in conformity with Title 10, Code of Federal Regulations, Parts 30 and 35, and that all information contained herein, including any supplements attached hereto, is true and correct to the best of our knowledge and belief.

a. LICENSE FEE REQUIRED *(See Section 170.31, 10 CFR 170)*

(1) LICENSE FEE CATEGORY: 7C

(2) LICENSE FEE ENCLOSED: $ 120.00

b. APPLICANT OR CERTIFYING OFFICIAL *(Signature)*: X P. David Youngdahl

(1) NAME *(Type or Print)*: X P. DAVID YOUNGDAHL

(2) TITLE: X PRESIDENT

c. DATE: X 8885

NRC FORM 313M (9-81)

CONTROL NO. 7 9540

PRIVACY ACT STATEMENT

Pursuant to 5 U.S.C. 552a(e)(3), enacted into law by section 3 of the Privacy Act of 1974 (Public Law 93-579), the following statement is furnished to individuals who supply information to the Nuclear Regulatory Commission on NRC Form 313M. This information is maintained in a system of records designated as NRC-3 and described at 40 Federal Register 45334 (October 1, 1975).

1. **AUTHORITY** Sections 81 and 161(b) of the Atomic Energy Act of 1954, as amended (42 U.S.C. 2111 and 2201(b)).

2. **PRINCIPAL PURPOSE(S)** The information is evaluated by the NRC staff pursuant to the criteria set forth in 10 CFR Parts 30-36 to determine whether the application meets the requirements of the Atomic Energy Act of 1954, as amended, and the Commission's regulations, for the issuance of a radioactive material license or amendment thereof.

3. **ROUTINE USES** The information may be used: (a) to provide records to State health departments for their information and use; and (b) to provide information to Federal, State, and local health officials and other persons in the event of incident or exposure, for their information, investigation, and protection of the public health and safety. The information may also be disclosed to appropriate Federal, State, and local agencies in the event that the information indicates a violation or potential violation of law and in the course of an administrative or judicial proceeding. In addition, this information may be transferred to an appropriate Federal, State, or local agency to the extent relevant and necessary for a NRC decision or to an appropriate Federal agency to the extent relevant and necessary for that agency's decision about you. A copy of the license issued will routinely be placed in the NRC's Public Document Room, 1717 H Street, N.W., Washington, D.C.

4. **WHETHER DISCLOSURE IS MANDATORY OR VOLUNTARY AND EFFECT ON INDIVIDUAL OF NOT PROVIDING INFORMATION** Disclosure of the requested information is voluntary. If the requested information is not furnished, however, the application for radioactive material license, or amendment thereof, will not be processed.

5. **SYSTEM MANAGER(S) AND ADDRESS** Director, Division of Fuel Cycle and Material Safety, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

ITEM #21

PROCEDURES AND PRECAUTIONS FOR USE WITH XENON GASES

A. Quantities to be Used:

1. Patient information

a. 10 studies per week
b. 10 mCi per patient

2. A 1200 mCi possession limit is requested.

B. Use and Storage Areas:

1. Xenon will be stored in a lockable wall mounted cabinet (approximately 24" tall x 24" wide x 12" deep) as indicated in the attached diagram. The original lead shipping container will be used to ensure radiation levels at the surface of the cabinet are well below 2.0 mR/hr. Accessory lead shielding will be used (i.e., 1/8" - 1/4" lead vials or sheet) as necessary if levels exceed 2.0 mR/hr. The camera room shown will be used for all patient administrations and imaging procedures.

2. The wall cabinet is vented with an exhaust duct leading directly to a central lavatory ventilation system terminating on the roof. This is a dedicated system with the exhaust fan mounted on the roof to ensure negative pressure throughout the duct work. All air for the storage room is supplied from the adjacent camera room and drawn out by the roof exhaust system. The nearest point of re-entry into the building is at least 30 feet away. An air flow of 70 cfm is being drawn through the wall cabinet at all times. This 70 cfm is diluted by air from other branch inlets and discharged at rooftop at a rate of 10,000 cfm. The camera room is supplied by 250 cfm of fresh air. Return is via the 70 cfm vented through the adjacent storage room cabinet and the balance via the hallways. All other exhaust vents in the imaging room are closed permanently. An emergency vent located in the window of the camera room discharges no less than 500 cfm to the outside.

3. Negative pressure is maintained in the storage cabinet at all times. The camera room is at negative pressure with the hall doors closed and the emergency exhaust fan operating. Make up air comes from the fresh air supply and through cracks around doors, etc. Measurements of air flow will be made two times per year using an air flow meter.

C. Procedure for Routine Use:

1. The camera room emergency fan will be turned on to the 500 cfm exhaust rate for approximately 18 minutes. The door will be adjusted so a sensible draft is felt at opening. The patient will be fitted with the rebreathing apparatus and instructed as to the procedure. A trial run will be conducted when possible. The valving and tubing will be examined for continuity. The dose will be prepared and assayed in the dose calibrator, if possible. The Xenon will be administered to the patient (intravenously or into the tubing airway) and three to four views obtained. The gas will be collected on the charcoal trap and in the overflow bag of the trap system until practically no Xenon remains in the patient as evidenced by the camera persistence scope (approximately 15 minutes). The face mask will be removed from the patient and carried to the vented wall cabinet. The charcoal trap pump will be allowed to run until the overflow bag is collapsed and the tubing airways are purged.

2. A Xenon-133 dispensing system and charcoal trap will be used. Face masks that cover both mouth and nose or nose clamps for use with the mouthpiece delivery systems will be employed to reduce leakage of the Xenon into the camera room.

D. Emergency Procedures:

In the event there is an accidental patient-associated loss of Xenon into the camera room, the emergency fan blower will clear the room to levels of 1×10^{-5} uCi/ml in a time described below. During this time period, the camera room will be evacuated, provided patient safety and comfort can be assured. All unnecessary personnel will evacuate the room. The camera room door will be guarded against inadvertant entry during this time period.

In order to implement the ALARA philosophy directed in 10 CFR 20.1 (c), the accidental release of Xenon into the camera room will result in evacuation of the room for a time period of 30 minutes if the patient's condition permits. During this time, the concentration will be reduced as follows:

1. Xenon, an inert gas, will rapidly equilibriate with the air in the camera room.

2. The emergency vent will reduce the concentration exponentially with time given:

   Room size = 18' x 15' x 9' = 2430 ft^3 = 6.56 x 10^7 ml

   Blower capacity = 500 cfm

   Dose released = 10,000 uCi

   Initial concentration (C_o) = 1.52 x 10^{-4} uCi/ml

   Clearance rate (λ) = 20.6% per minute

   Final concentration = C

   Then:

   $$C = C_o e^{-\lambda t}$$

   $$C = 1.52 \times 10^{-4} \times e^{-0.206 \times 30}$$

   $$= 3 \times 10^{-7} \text{ uCi/ml}$$

   which is the concentration for unrestricted areas permitted in 10 CFR 20.

E. Air Concentrations of Xe-133 in Restricted Areas:

1. It is estimated that 100 mCi will be used per week. (A)

2. 25% of the Xenon used will be vented (f). 75% of the Xenon used will be trapped.

3. The camera room exhaust will operate at 500 cfm when Xenon is being used. If 10 patients are studied per week, the blower "on" time will be approximately 18 minutes* x 10 patients = 180 minutes/week. It will be assumed that as much as 25% of the activity used will be lost accidentally.

*Time period required for average Xenon study.

4. The average concentration (C) will be:

$$C = \frac{A \times f}{V}$$

$$C = \frac{100 \text{ mCi} \times 1 \times 10^3 \text{ uCi/mCi} \times .25}{500 \text{ cfm} \times 180 \text{ min/wk} \times 2.8 \times 10^4}$$

$$C = \frac{100 \times 1 \times 10^3 \times .25}{500 \times 180 \times 2.8 \times 10^4}$$

$$C = 9.9 \times 10^{-6} \text{ uCi/ml}$$

This level is less than that permitted in restricted areas. In addition, the storage room is vented continuously at 70 cfm with no recirculation of air. This also exceeds the minimum required ventilation.

F. Methods of Xenon-133 Disposal:

1. Dulution through exhaust system -

Xenon used and retained will be disposed by decay in storage on the charcoal column and/or in the vented cabinet. Containers and apparatus used will be surveyed unshielded with the low level survey meter held on contact with the source containing device. If levels are the same as background, the containers will be disposed after defacing the labels.

All other Xenon will be vented through the exhaust system to the roof which is secured against access except for routine maintenance needs, or for that which is accidentally lost during patient studies out the second floor emergency vent.

a. It is anticpated that 5.2 Ci of Xenon will be used per year, 25% of which will be vented to the atmosphere per year (A). This is all of the Xenon used annually which is liberated as accidental losses or leakage and exhausted from patient studies.

b. An air flow rate of 78.9 cfm will be used in the calculation. This value is the average flow from the vented cabinet plus emergency camera room ventilation with "on" times considered.

c. Air flow per year is: (V)

$$V = 78.9 \text{ cfm} \times \frac{1.484 \times 10^{10} \text{ ml/year}}{\text{cfm}} = 1.17 \times 10^{12} \text{ ml/yr}$$

d. The average concentration of air to the environment is: (C)

$$C = \frac{A}{V}$$

$$= \frac{5.2 \times 10^{6} \times .25}{1.17 \times 10^{12}} = \frac{1.3 \times 10^{6}}{1.7 \times 10^{12}}$$

$$= 7.6 \times 10^{-7} \text{ uCi/ml}$$

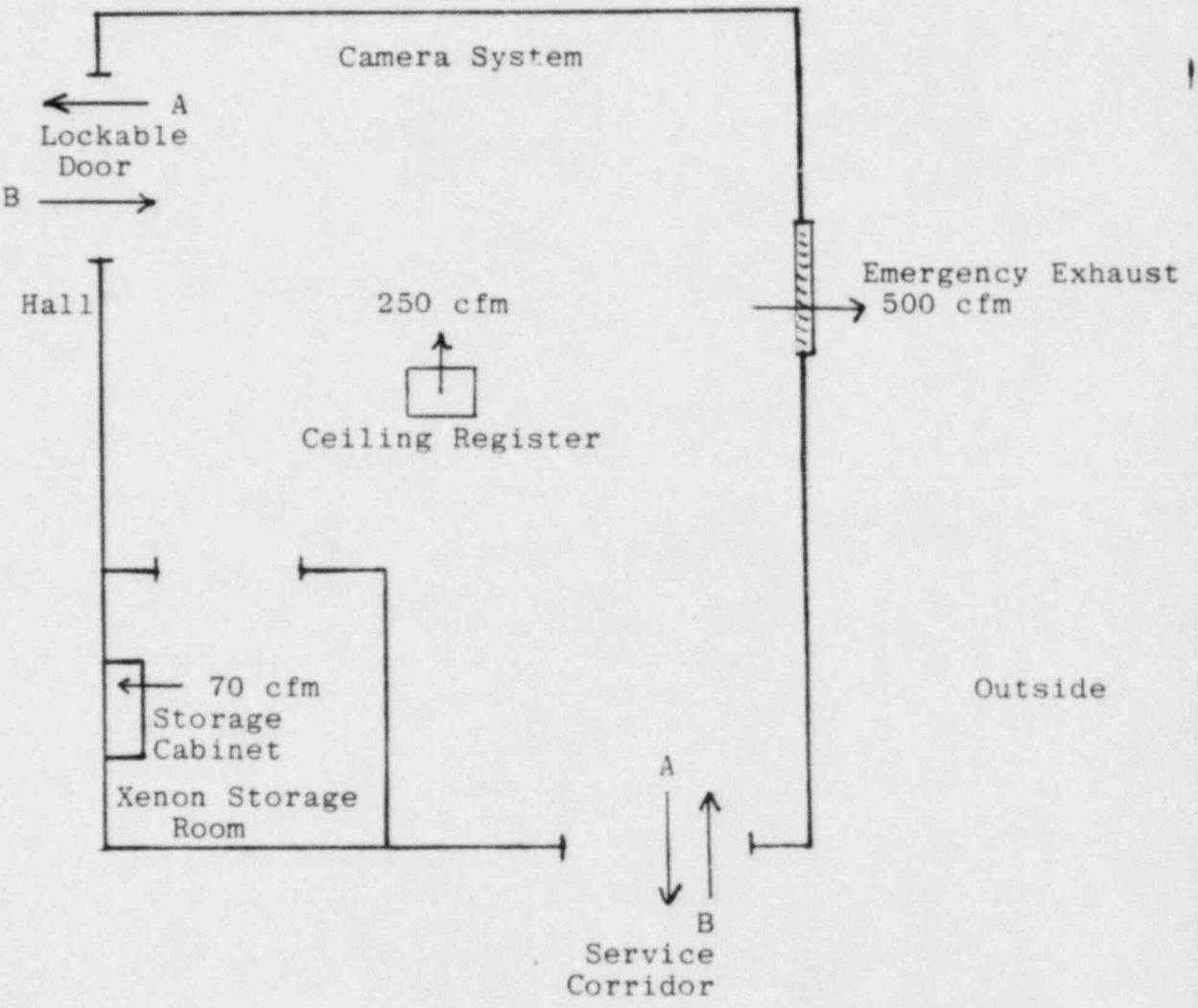
This value is less than the quantity 3×10^{-7} uCi/ml permitted in 10 CFR 20.106 for unrestricted areas.

2. Absorption into charcoal traps:

a. In order to detect a saturated trap, a G-M survey meter probe will be held on contact with the inlet hose to achieve a maximum reading during the washout phase of a patient study. The probe will then be placed on the outlet port of the charcoal trap and a measurement made. If exhaust levels reach 10% of inlet levels, the trap will be assumed saturated. The charcoal column will then be replaced. This test will be performed on completion of the last Xenon study scheduled each week.

b. Saturated filters will be stored for decay in the cabinet such that levels do not exceed 2.0 mR/hr at the exterior. A survey will be conducted without the benefit of shielding and if levels are those of background, the filter may be discarded.

St. Luke's Hospital
Amendment to License #34-00398-08
Diagram of one of the Nuclear Medicine Department Rooms
to be Used for Xe-133 Ventilation Studies



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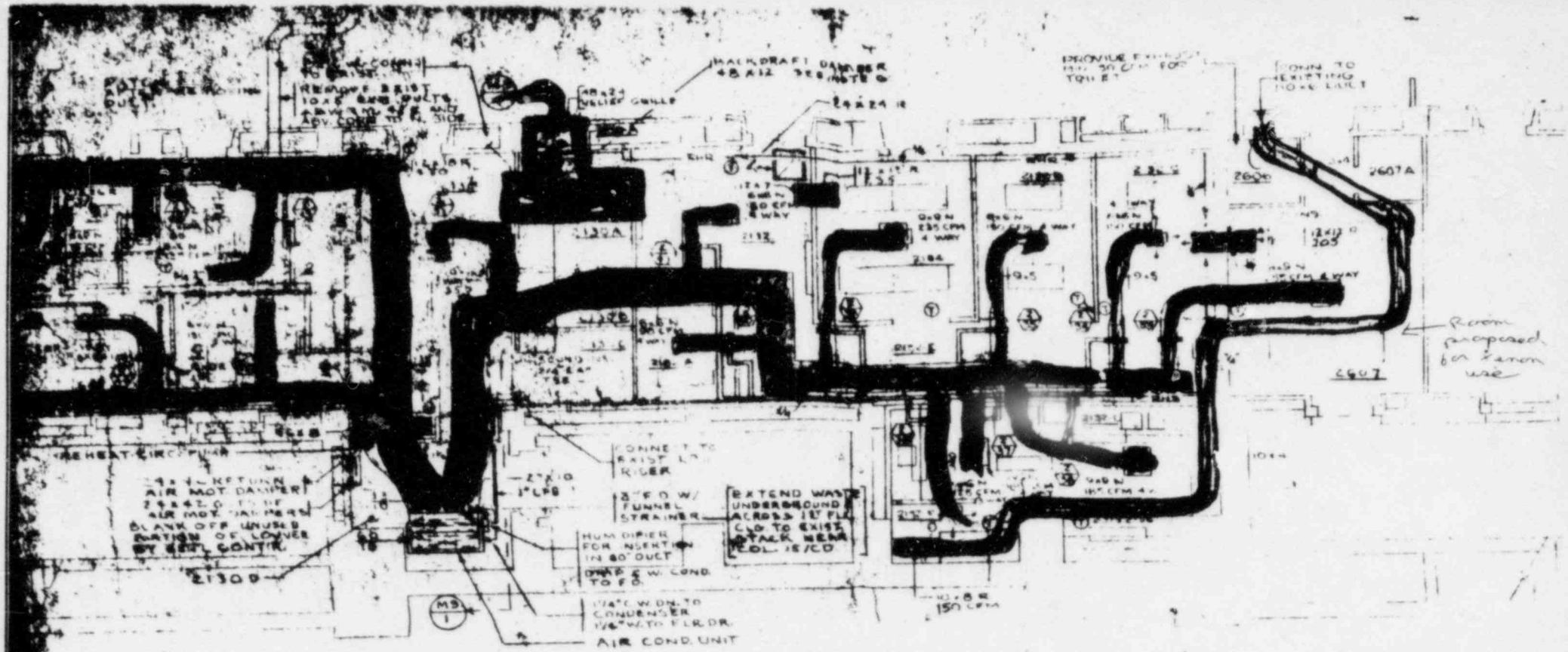

SECOND FLOOR PLAN, CENTRAL PAVILION

SCALE: 1/8" = 1'-0"

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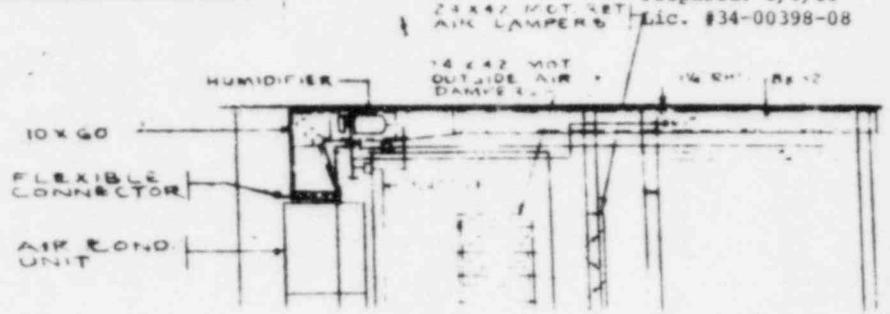

RED - AIR RETURN

BLACK - AIR SUPPLY

19

20

CONNECT TO
EXIST. SERVICE