

**BAY**  
**REGIONAL MEDICAL CENTER**  

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**A McLAREN HEALTH SERVICE**

September 9, 2004

Colleen C. Casey  
Materials Licensing Branch  
U.S. Nuclear Regulatory Commission  
Region III  
2443 Warrenville Rd.  
Lisle, Illinois 50532-4352

**Control No.: 313471**

**License No.: 21-18585-01**

Dear Ms. Casey,

Please review the following in response to your request for additional information regarding the licensee, Bay Regional Medical Center, Bay City, Michigan dated July 20, 2004. We understand that our request for amendment to add the Novoste BetaCath system has been combined into the license renewal application, under the above control number: 313471.

The responses are listed below with the same item numbering as each additional information request:

1. The SSDR numbers for the I-125 sources which we will use were verified on line in the SSDR and are listed below:

<u>SSDR#</u>	<u>Model</u>	<u>Manufacturer/Distributor</u>
MA-1078-S-102-S	3500	Implant Sciences Corp.
IL-136-S-338-S	6711 (OncoSeed™)	Medi-Physics, Inc. / Amersham
NR-1081-S-101-S	I-125SL, I-125SH	Mills Biopharmaceutical / Mentor

2. We confirm that the only material we wish to possess under 10 CFR 35.400 are the above listed I-125 sources.

3. The Radiation Safety Officer for the licensee will be Rajinder Singh Md., PhD.

4. No response required.
5. Records of the final closeout survey of the areas where the materials covered under 10 CFR 31.11 were used, is attached.
6. Responses appropriate to the licensing of the Novoste BetaCath IVB System are attached as a separate document: " Requested Information item 6: Novoste BetaCath IVB System".
7. Information regarding facility diagram scale, identification of restricted and unrestricted areas, the direction of North and the location of lockable doors is attached.

If there are further questions regarding item numbers 3, 5 or 7, please contact Mr. Steve Gerhardt, Bay Regional Medical Center, Nuclear Medicine department at 989-894-6469.  
If there are further questions regarding item numbers 1, 2 or 6, please contact Mr. Larry Langrill, medical physicist, at 989-839-3452.

Sincerely,

A handwritten signature in cursive script that reads "Alice Gerard RN".

Alice Gerard, Vice President Patient Care Services

## Decommissioning Survey

All areas of use for materials covered under part 10 CFR 31.11 were wiped and surveyed for final closeout as requested. The results are listed below:

Survey meter used: Ludlum model # 14C serial # 139499 with end window probe

Well counter used: Ludlum model # 2200 serial # 162864

Date: 13 August 2004

Surveyor: Steven M. Gerhardt BS CNMT RT(N)

All area's were surveyed with the indicated survey meter with no area greater than the background of 0.01 mr/hr.

Wipes were performed as indicated on the attached maps with the results listed below:

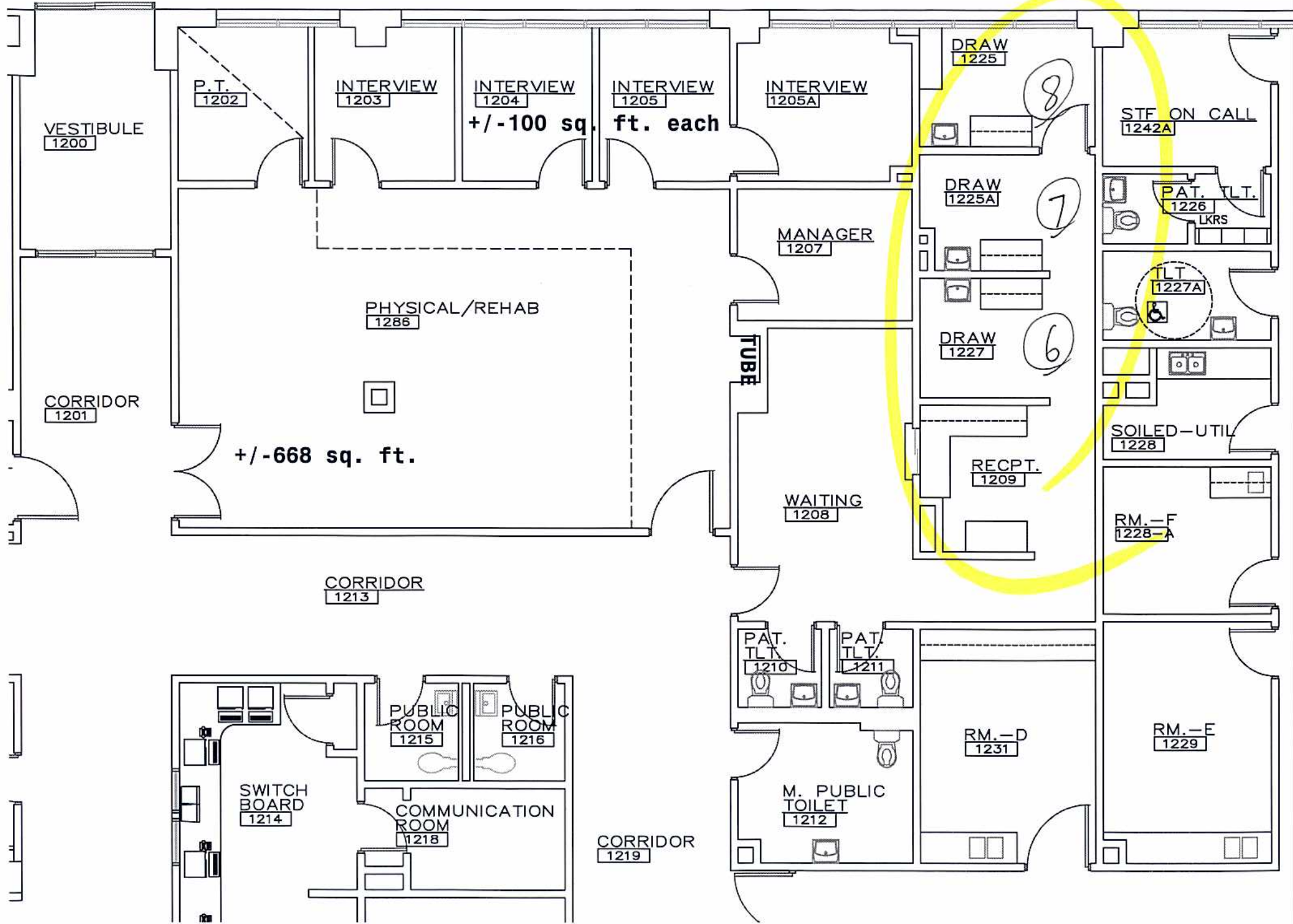
<u>Area</u>	<u>DPM</u>
1	< Minimum detectable
2	< Minimum detectable
3	9
4	< Minimum detectable
5	< Minimum detectable
6	14
7	< Minimum detectable
8	< Minimum detectable



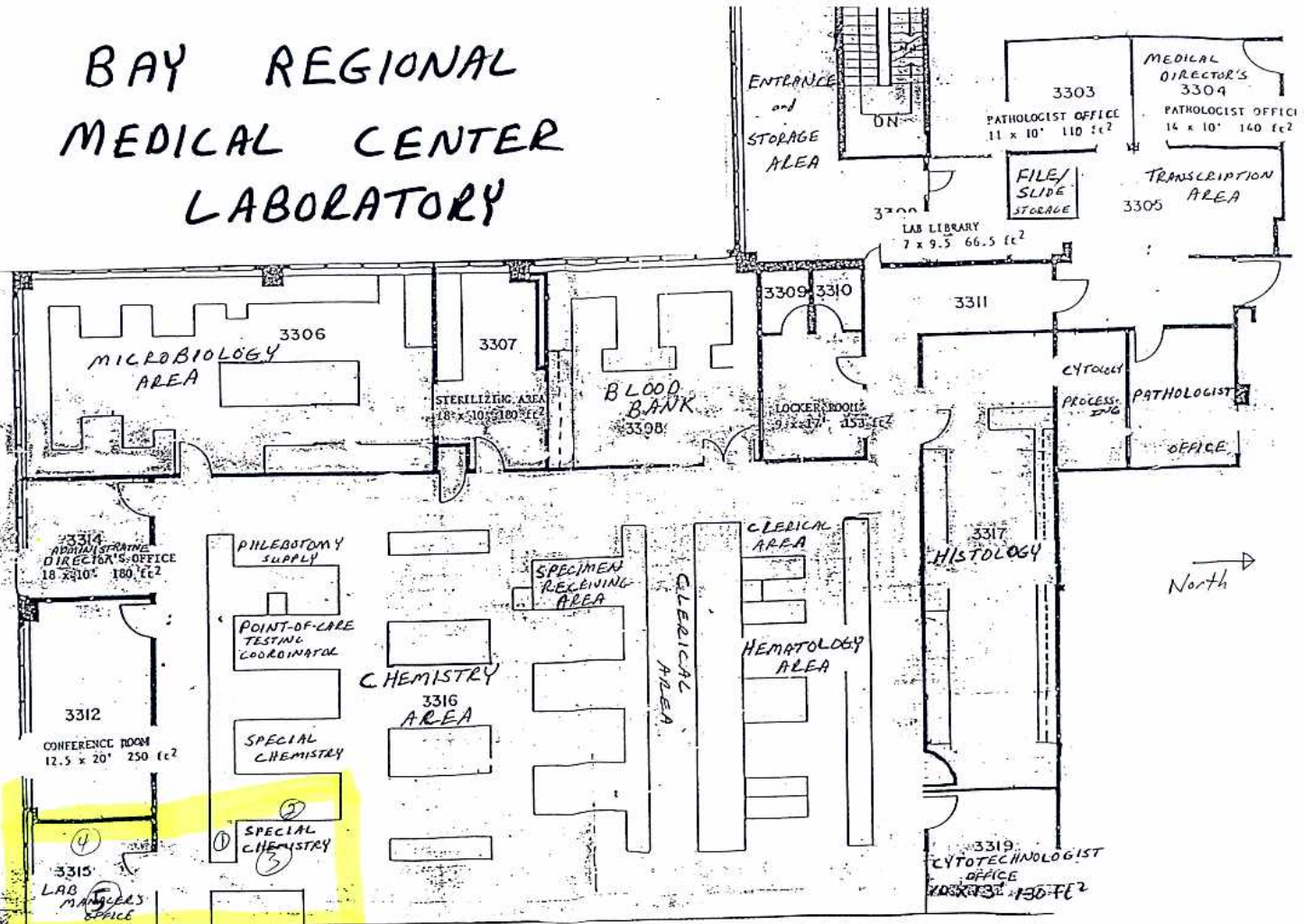
BS CNMT RT(N)

1/8" = 1' ↑ North

#8



# BAY REGIONAL MEDICAL CENTER LABORATORY



**Requested Information item 6: Novoste BetaCath IVB System**  
**Bay Regional Medical Center, Control # 313471, August 23, 2004**

This information is supplied concerning amendment of license number 21-18585-01 to add Sr-90 in sealed sources (Bebig Model Sr0.S03 and AEAT SICW Series) up to 5 mCi per source, up to 800 mCi total, in Novoste A1000 Series Transfer Devices for intravascular brachytherapy use.

Authorized users will meet the training and experience requirements in either 10 CFR 35.690\*, "Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units" or until October 25, 2004, 10 CFR 35.940, "Training for use of brachytherapy sources."

The authorized user, interventional cardiologist/physician, and authorized medical physicist will receive the vendor training for use of the device.

Procedures will be conducted under the supervision of the authorized user, who will consult with the interventional cardiologist/physician and authorized medical physicist prior to initiating treatment. The procedures will be conducted in the physical presence of the authorized user or the authorized medical physicist.

The written directive will, prior to treatment, specify treatment site, the radionuclide, and dose.

The authorized medical physicist will perform independent measurement of source output, prior to the first patient treatment, using a dosimetry system that meets the requirements of 10 CFR 35.630(a)\*.

We will develop, implement, and maintain written emergency procedures for both stuck and detached sources, including the provision of appropriate emergency response equipment and any appropriate surgical procedures.

We will survey the patient and IVB treatment catheter immediately following source retraction or removal to confirm complete retraction of the source(s) as specified in 10 CFR 35.404\*.

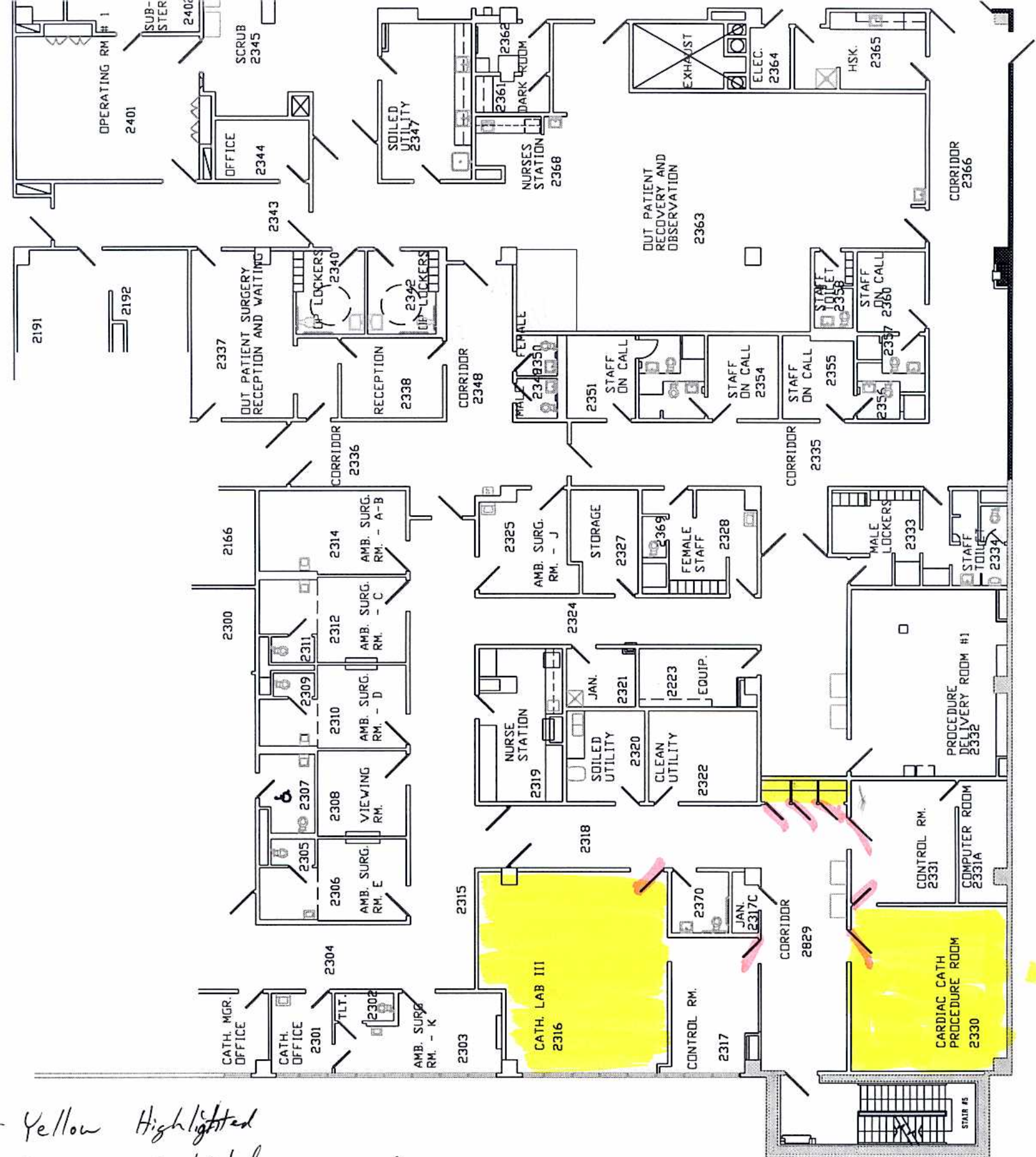
In order to protect the radiation safety of patients and to reduce the risk of a medical event, an introducer sheath will be used unless such use is contraindicated for an individual patient.

In order to protect the radiation safety of patients and to reduce the risk of a medical event, a dual syringe system will be used unless such use is contraindicated for an individual patient.

We will establish procedures in writing for treatment steps that are not covered by the manufacturers' instructions.

We will lock the storage container in a secure location when not in use. The storage and use locations are shown in the attached annotated diagram.

The device will be inspected and serviced at intervals recommended by the manufacturer, and maintenance and repair shall be performed only by the manufacturer or persons specifically licensed by NRC or an Agreement State to perform such services.



Yellow Highlighted  
 areas are restricted  
 Pink Highlighted  
 doors are lockable

North

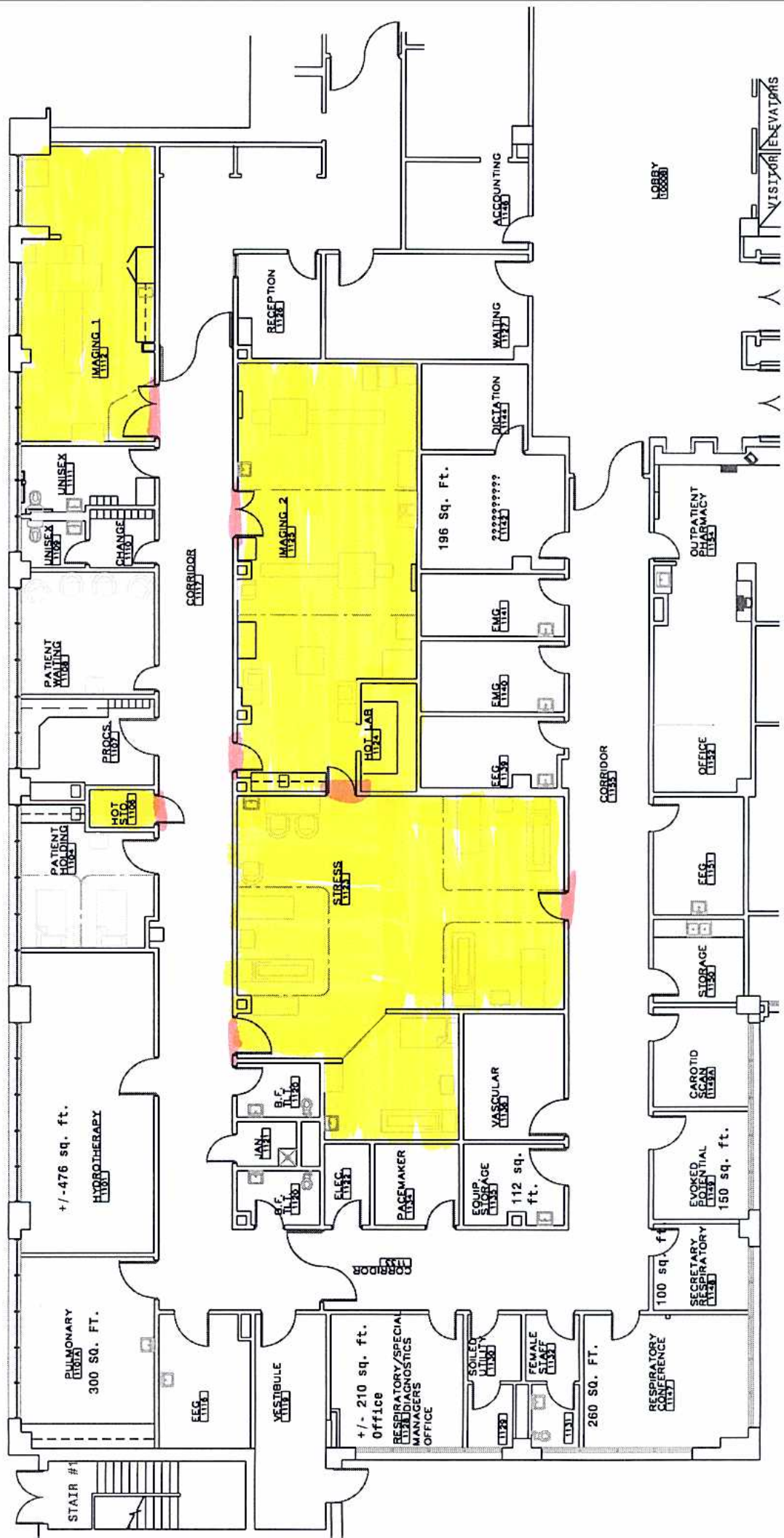
$\frac{1}{16}'' = 1''$



$$\frac{1}{16} \text{th}'' = 1'$$

- Yellow highlighted areas are Restricted

- Pink highlighted doors are lockable





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