# Beaumont®

William Beaumont Hospital
Royal Oak

Medical Physics and
Radiation Safety Office

April 6, 1988

United States Nuclear Regulatory Commission
Region III
Materials Licensing Section
799 Roosevelt Road
Glen Ellyn, IL 60137

Re: Amendment to NRC License 21-01333-01

Gentlemen:

Please find enclosed a check for $120.00 for two amendments to our license #21-01333-01.

1. One request is for the addition of a new satellite outpatient Nuclear Medicine facility, scheduled for completion by October 1, 1988. Attached to this letter is the information regarding this new facility.

2. The second request is for the addition of a second remote afterloading device which will contain a 10 Curie IR-192 source. The NRC Enclosure 2, Information Required for Licensing Remote Afterloading Devices, was followed in preparing the attached information.

Please do not hesitate to contact the Radiation Safety Officer if you have any further questions.

Sincerely,

Darlene Fink-Bennett, M.D.
Chairperson, Radiation Safety Committee

Joseph J. Dylag
Administration

Ann L. Forsaith, M.P.H.
Radiation Safety Officer

Enclosure: Additional Nuclear Medicine Facility
NRC Required Information for Remote Afterloading Devices

cc: H. Dworkin, M.D., Chief, Nuclear Medicine
A. Martinez, M.D., Chief, Radiation Oncology

ALF\jlh

Log Apr-17-88
Remitter
Check No. 264815
Amount $120
Fee Category 1B 3E
Type of Fee Rmnd
Date Completed 4/20/88
By: Premier

CONTROL NO 8524 8

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REGION III

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REG3 LIC30
21-01333-01 PNU

3601 West Thirteen Mile Road Royal Oak, Michigan 48072-2793 (313) 288-8373

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## ADDITIONAL NUCLEAR MEDICINE FACILITY

Please amend our NRC license to add a new satellite outpatient nuclear medicine facility, scheduled for completion on October 1, 1988. The address is:

Beaumont Medical Office Building
West Bloomfield, Michigan 48033

1. The following byproduct material and amounts are requested for medical use at the West Bloomfield facility:

| Byproduct | | Amount |
|---|---|---|
| 5.a. | Material in 10CFR35.100 | As needed |
| 5.b. | Material in 10CFR35.200 | As needed |
| 5.c. | Material in 10CFR35.300 | 100 mCi |

2. The authorized users shall be:

Howard J. Dworkin, M.D.
Darlene Fink-Bennett, M.D.
John E. Freitas, M.D.
Conrad E. Nagle, M.D.
Richard A. Wetzel, M.D.
Jack E. Juni, M.D.
William Beierwaltes, M.D.

All are board certified nuclear medicine physicians currently authorized by our Radiation Safety Committee.

3. Instrumentation Data

a. Survey Meters

Bicron Surveyor 2000 GM meter
Range: 0 - 2000 mR/hr
Thin End Window Probe

Panoramic Survey Meter - Victoreen 470A
Ionization Survey meter
Range: 0 - 1000 R/hr

Deluxe Wipe Test Counter - Nuclear Associates
GM survey meter with LED display and check source calibration

"Vamp" Area Monitor - Victoreen 808E-100
Range: 0 - 100 mR/hr

b. Dose Calibrator

Capintec Dose Calibrator CRC-12

Continued...

3. Instrumentation data (continued)

   c. Gamma Scintillation Camera

      Seimens Orbitor 370

4. Ordering and receiving of radioactive material

   a. For routine studies, all radioactive materials used at the West Bloomfield facility will be ordered on an individual patient dose basis from William Beaumont Hospital - Royal Oak or an NRC-licensed commercial nuclear pharmacy. For emergency studies up to 300 millicuries of Tc-99m sodium pertechnetate and 80 millicuries of Tc-99m sulfur colloid will be supplied to the West Bloomfield facility on a daily basis Monday through Friday. Also, up to a 1500 mCi Mo-99/Tc-99m generator is supplied on a weekly basis and is used when additional Tc-99m pertechnetate is required. The Tc-99m pertechnetate may be used to prepare emergency radiopharmaceuticals from approved kits.

   b. No xenon-133 gas will be ordered or delivered to the West Bloomfield facility.

   c. The radiopharmacy of the Nuclear Medicine Department of Royal Oak will verify that therapy doses of I-131 do not exceed the possession limit of 100 millicuries. The person who recieves the I-131 therapy dose will check the physician's written request to confirm that the material received is what was ordered.

   d. All deliveries are made directly to a technologist in the West Bloomfield Nuclear Medicine Department. Deliveries are only made during times when a technologist is on duty.

5. Waste disposal

   a. All used and unused doses and kits are returned in original shielding to William Beaumont Hospital - Royal Oak or NRC licensed commercial nuclear pharmacy for disposal on the following work day. Generators are returned in the original shielding and shipped container to William Beaumont Hospital - Royal Oak or NRC licensed commercial nuclear pharmacy the week following receipt.

Continued...

5. Waste Disposal (continued)

   b. Other solid waste will be held for decay in lead storage until radiation levels as measured with a low-level survey meter have reached background levels. All radiation labels will be removed or obliterated and the waste will be disposed of in normal trash.

6. Personnel monitoring devices

   a. R.S. Landauer Jr. & Co. Monthly Whole Body Film Badges
      Monthly Finger TLD Badges

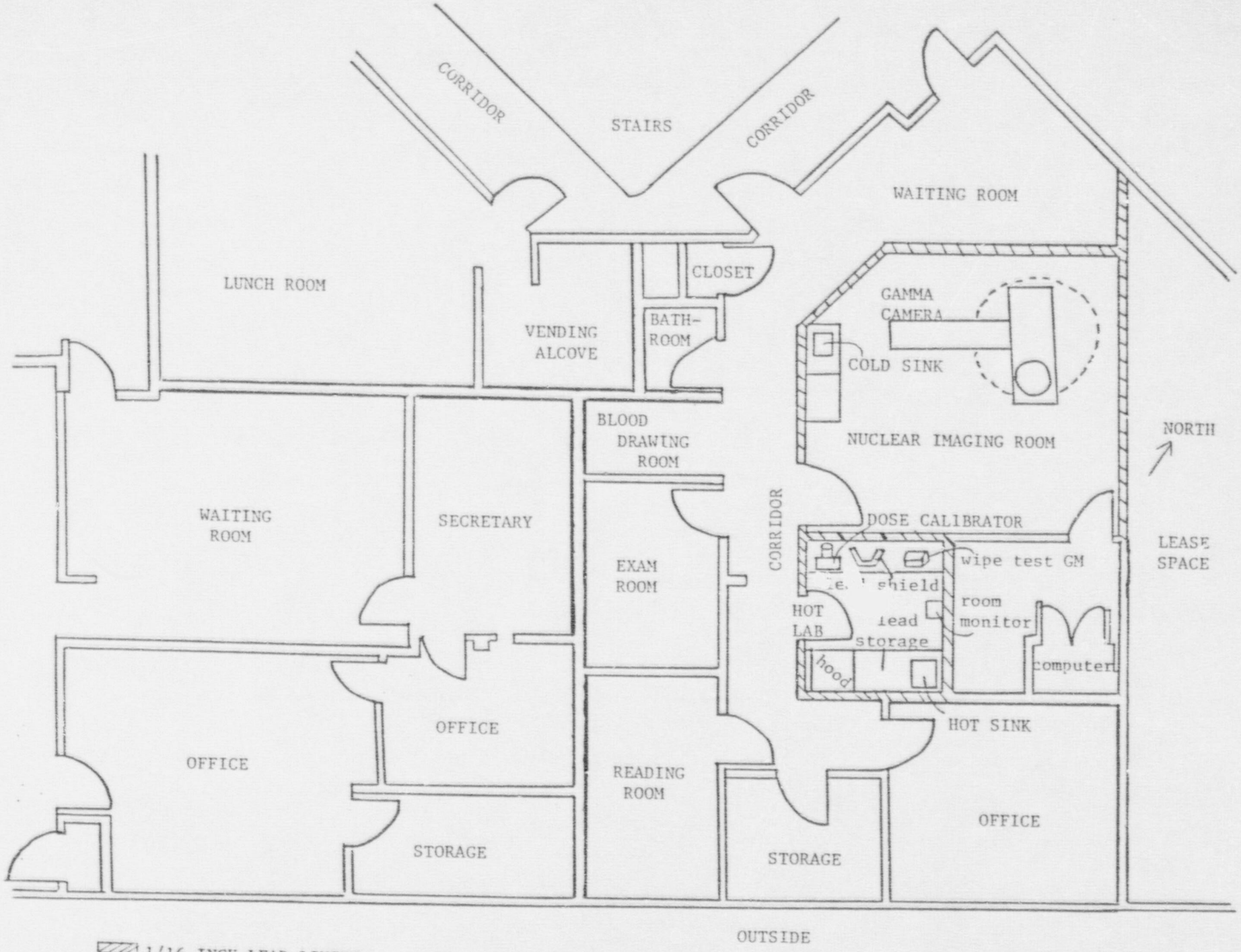
   b. Bioassay by measurement of thyroid uptake shall be performed when individuals handle millicurie amounts of I-131 in compliance with Regulatory Guide 8.20.

7. All other pertinent policies and procedures contained in our recently approved NRC renewal application and amendments shall be followed in the West Bloomfield facility.

CC/cf
(CC11/388.nrc)

see attachment

FACILITY DIAGRAM: Beaumont Medical Office Building
West Bloomfield, Michigan 48033



# NRC Required Information for Remote Afterloading Devices

## I. Description of the source and device

A. Source Description:

1. Radionuclide: *$^{192}Ir$*

2. Manufacturer name and model number:
*BYK Mallinckrodt, Model CI L BV*

3. Maximum activity (in Curies):
*10 Ci +/-20%*

4. Number of sources:
*1 in machine, 1 in shipping container for exchange*
*(total maximum 20 Ci +/-20%)*

B. Device Description:

1. Manufacturer's name:
*Nucletron*

2. Model name/number
*Microselectron-HDR (080.000)*
*NRC S & D review no. MD-497-D-104-D*

## II. Intended Use

*The Microselectron-HDR is intended to be used for intraluminal, intracavitary and interstitial treatment of cancer.*

## III. Proposed Users

*All physician users will be approved by the Radiation Safety Committee, AND possess certification from one of the following:*

*1. ABR in Therapeutic Radiology or Radiology*

*2. AOBR in Radiation Oncology*

*3. Canadian Royal College of Physicians and Surgeons (RCPS) in Therapeutic Radiology*

William Beaumont Hospital

License # 21-01333-01

April 6, 1988

## IV. Training for individuals

A. Provide outline of training given to device operators.

*1. Manufacturer's installation engineer provides on-site training to Beaumont Physics staff in programming and operating the device, to include:*

*-Programming the console.*
*-Normal patient setup.*
*-Connection of machine to patient.*
*-Description of safety features, location and use of emergency-stop buttons*
*-Initiation/interruption/termination of treatment.*
*-Routine diagnosis of fault conditions.*
*-Emergency procedures, including "dry runs" of emergency removal (using "dummy" source).*
*-Location of emergency phone list.*
*-Securing unit when not in use.*
*-Procedures for loading/unloading souces from machine.*

*2. Beaumont Hospital physics staff will train and supervise dosimetrists/technologists in operation of the machine. Items covered are identical to above, with the exception of source exchanges.*

B. Describe additional training provided to individuals who will conduct source exchanges.

*The procedures for loading and unloading sources from the transport container are part of the on-site training covered in "A" above.*

C. Provide name and affiliation of instructor conducting training in A and B above.

*Installation and instruction of William Beaumont Hospital individuals will be provided by one of the following individuals, employed by Nucletron*

| *Person* | *Years Experience* | *Experience and Training* |
|---|---|---|
| *L. Van Zwol* | *11* | *Technical Director of Nucletron, responsible for design of Selectron equipment and quality control. Training in handling radiation sources given by Amersham International in Europe. Also, "Ionizing Radiation" Level B (handling of Encapsulated Radioacitve Sources - IVBS Rotterdam).* |
| *R. Hermanus* | *6* | *International Service Manager of Nucletron responsible for worldwide warranty and service of the 200 Selectron systems. He has installed over 50 systems. Training, "Ionizing Radiation" Level B (handling of Encapsulated Radioacitve Sources - IVBS Rotterdam).* |

| | | |
|---|---|---|
| *M. Cragg* | *4* | *Service Manager, Nucletron. 30 installations of Selectron equipment and servicing in USA, United Kingdom, and Canada.* |
| *C. Mellink* | *2* | *Trained by Nucletron (L. Van Zwol and R. Hermanus). Has carried out installations in USA, Canada, China, Europe.* |
| *A.M. Mount* | *9* | *Nucletron Corp., Columbie, Maryland. Physicist with 5 years background in handling radiation sources for medical and industrial use while working for Amersham in England, plus 2 years experience with Nucletron in England where there are 30 Selectron systems, and 2 years in North America where there are 35 Selectron systems.* |
| *M. Gribble* | *11* | *Joined Nucletron September 1985. Medical Physicist who was advisor for the 11 Selectron systems used by the Ontario Cancer Foundation in Canada. Training by R. Hermanus and A.M. Mount. Previous radiation physics experience in United Kingdom, USA and Canada.* |
| *R. Geisendaffer* | *1* | *Joined Nucletron September 1986. Trained by M. Gribble and A.M. Mount. Attended 4 weeks certified training in Holland on operation, service and safety of the machines and sources.* |
| *J. Conti* | *1* | *Trained by R Geisendaffer. Attended 4 weeks certified training in Holland on operation, service and safety of the machines and sources.* |

*The Beaumont Hospital employees responsible for training and supervision will be:*

| *Person* | *Years Experience* | *Experience and Training* |
|---|---|---|
| *Greg Edmundson* | *7* | *Technical Director of Radiation Oncology Beaumont Hospital 1985-. RT(T) Stanford University Hospital, 1981, with special emphasis on brachytherapy and dosimetry. Overall charge of physics support for brachytherapy, Mayo Clinic, 1981-1985.* |
| *Morris Bank, Ph.D.* | *14* | *Brachytherapy physicist, Beaumont Hospital, 1988-. Certified in Radiological Physics by ABR, 1977. Complete charge of medical physics services, RSO, Hurley Hospital, Flint, MI 1973-88.* |
| *V.K.P. Kumar, Ph.D* | *15* | *Director of Clinical Physics, Beaumont Hospital, 1986-. Assistant Professor of Radiation Physics in Radiation Therapy, 1982-1986.* |

| | | |
|---|---|---|
| *P.D. Sharma, M.Sc.* | *16* | *Medical Physicist, Beaumont Hopsital,1988-. Head of Medical Physics Department, Ontario Cancer Foundation, Thunder Bay Centre, 1972-1988.* |
| *Farhad Kader, M.S.* | *2* | *Medical Physicist, Beaumont Hospital, 1987-. Radiologic Physicist, Deputy RSO, Morristown Memorial Hospital, Morristown, NJ, 1986-87.* |

D. Confirm that individuals who are trained in the use of the device and have practiced the emergency procedures will be on-site while the device is in use.

*Duration of the treatments is very short (5-30 minutes). The console will be attended at all times during treatment by trained individuals (normally technologists) who have practiced emergency procedures. Responsible physics personnel will be available on-site as well.*

E. Outline topics covered in retraining and state the frequency of such retraining. Confirm that the retraining will include "dry-runs" of emergency procedures.

*Topics covered in retraining are identical to initial training in A above, including "dry runs" of emergency procedures. Retraining will be at yearly intervals. Retraining will be conducted by Beaumont Hospital physics staff.*

## V. Facilities

A. Submit annotated drawings (plan and elevation) indicating the following:

1. Scale

   *Marked on each drawing.*

2. Direction of North

   *Marked on each drawing.*

3. Identification of room (ie room number)

   *Marked on each drawing.*

4. Type, density and thickness of all shielding materials, walls, floor, ceiling.

   *High density concrete. Thicknesses marked on drawings. Please note that this room was previously used as a Cobalt-60 teletherapy room, and currently houses a 4 MV linear accelerator.*

5. Location of entrance, windows, conduits, etc.

   *Marked on each drawing.*

6. Nature of and distance to adjacent areas

*Minimum distances as marked on drawings. Two sides of room are unexcavated (this is basement level). Contiguous areas include controlled hallway, office, and an adjacent linear accelerator treatment room. The level above is a public area of the hospital. There is nothing below the room.*

7. Use of adjacent areas (ie restricted or unrestricted, ref 10CFR 20.3(14) and (17)

*For purpose of this application, all adjacent areas are to be considered uncontrolled areas.*

B. Describe continuous viewing system:

1. Primary

*Primary viewing system is via closed-circuit television*

2. Backup if primary system fails or commit to halting treatments.

*A mirror system, with a viewing port in the door, is used as a backup system.*

C. Describe area security:

1. Interlocks on entry, etc.

*The doorswitch is interlocked to the MicroSelectron computer (initiates "STOP" sequence). One emergency stop button is mounted on the MicroSelectron-HDR in the room and another at the control station outside the room.*

2. Restricted area controls (ie signs, locks, alarms, lights, etc)

*a. Accelerator treatment room entryway has "Caution--High Radiation Area" and "Caution--Radioactive Materials" signs.*

*b. Treatment room door is locked after normal treatment hours. When in use, door is interlocked to the MicroSelectron-HDR computer, initiating "STOP" sequence upon entry. The remote control unit of the MicroSelectron-HDR is locked with a keyswitch when not in operation.*

*c. An independent radiation monitor is installed in the room, with flashing red indicators both inside and outside of the treatment room when radiation is present.*

*d. The remote control console of the MicroSelectron-HDR indicates source position.*

3. If other radiation producing devices in the room, a means of assuring only one device in operation at a time

*Both MicroSelectron-HDR and accelerator are controlled by key switches. Keys are always removed from machines when not in use. Key to MicroSelectron-HDR and accelerator are permanently fastened to the same ring, preventing their simultaneous use.*

4. Means of verifying source "safe" condition (ie permanently installed monitor)

*Although the remote control console indicates whether the source is in the "treatment" or "safe" position, a permanently installed room monitor will be used.*

5. Confirm that once tripped, the entry interlock must be reset before activation of device.

*Yes.*

D. Shielding evaluations/Calculations:

*Only the patient will be in the treatment room during the use of the MicroSelectron-HDR. Attempted entry into the room during treatment time will cause the sources to be withdrawn from the patient, to the MicroSelectron-HDR's safe.*

1. Estimate of maximum "on-time" per hour, per week

*20 minutes per hour,120 minutes per week.*

2. Calculation of exposure rate in each adjacent area with most adverse source orientation.

*Treatment will utilize currently installed patient support assembly of linear accelerator. Assumption of source position:*

*-10' from head wall*
*-centered in room (8' from each side wall)*
*-36" above floor*

*Calculations below ignore attenuation in patient's body. All points of calculation are considered to be in unrestricted areas.*

3. For unrestricted areas, must meet the following conditions:
(1) With "on" time considered and occupancy = 1, ≤2 mR in any 1 hour, ≤ 100 mR in any 7 days

*For purposes of this application, take worst-case conditions (i.e. "on-time" not considered). Maximum instantaneous exposure rate in adjacent areas not to exceed 2 mR/hr.*

*4 points are considered: (see drawings)*

*A) Wall in adjacent accelerator room,*
*B) At Control Station*
*C) On the floor above, and*
*D) In adjacent office*

*Assume:*
*Γ for $^{192}Ir$ = 0.46 mR $M^2$ $Ci^{-1}$ $Hr^{-1}$*
*Source Activity = 10 Ci*
*Tenth Value Layer of $^{192}Ir$ for concrete = 7.5"*

| | Distance | Shielding | |
|---|---|---|---|
| *Point A* | *11'(3.3M)* | *36" concrete* | *(4.8 TVL)* |
| *Point B* | *12'(3.6M)* | *36" concrete* | *(4.8 TVL)* |
| *Point C* | *12'4"(3.7M)* | *36" concrete* | *(4.8 TVL)* |
| *Point D* | *21'(6.3M)* | *18" concrete* | *(2.4 TVL)* |

*Instantaneous Exposure rates:*

*Point A: $0.46 \times 10 \times 3.3^{-2} \times 10^{-4.8} = 6.7 \times 10^{-6}$ mR/Hr*
*Point B: $0.46 \times 10 \times 3.6^{-2} \times 10^{-4.8} = 5.6 \times 10^{-6}$ mR/Hr*
*Point C: $0.46 \times 10 \times 3.7^{-2} \times 10^{-4.8} = 5.3 \times 10^{-6}$ mR/Hr*
*Point D: $0.46 \times 10 \times 6.3^{-2} \times 10^{-2.4} = 4.6 \times 10^{-4}$ mR/Hr*

*As expected, exposure rates are far below requirements, in this room which was originally designed for Cobalt-60 teletherapy.*

4. For restricted areas, the following should be described:
   (a) Physical/administrative control of access
   (b) Signs: location, number, wording
   (c) Personnel monitoring
   (d) Training (ref 10 CFR 19.12)
   (e) Surveys (ref. 10 CFR 20.20(b))

*Treatment room is restricted.*

*(a)* Physical/administrative control of access

*Remote control console is located immediately outside the treatment room door. Console is always attended during treatments.*

*(b)* Signs: location, number, wording

*Accelerator treatment room entryway has "Caution--High Radiation Area" and "Caution--Radioactive Materials" signs.*

*(c)* Personnel monitoring:

*All personnel working in the area are monitored with permanently assigned G-1 film badges. Finger ring dosimeters will be kept available at the console for emergency handling of the source.*

*(d)* Training (ref 10 CFR 19.12)

*All personnel working in the area are given yearly in-service training in accordance with 10 CFR 19.12*

*(e)* Surveys (ref. 10 CFR 20.20(b))

*Wipe tests will be performed quarterly, and just prior to and after the source exchange.*

*Area surveys will be conducted in the treatment room and adjacent areas quarterly.*

## VI. Operating Procedures

A. You need not provide copy of procedures but should confirm the following minimum commitments:

*All of the following provisions are incorporated into written procedures available in the department.*

1. Have implemented written operating procedures

2. Copies given to appropriate staff

3. Procedures:

   - o Require securing unit, console, room when unattended
   - o Require that only patient be in room with device activated

4. Daily (or each day of use) checks will be performed and will include checks of:

   - o Interlocks
   - o Reproducibility of source positioning within catheter within +/- 1 mm
   - o Verification of source position indicators (e.g. lights, alarms, room monitor)
   - o Inspection of guide tubes for kinks and other imperfections

5. Confirm that treatment time calculations will be independently verified.

B. Calibration of Source in Device:

1. Describe procedures, frequencies and equipment used to determine:

o Dose accuracy within 5%

*Dose accuracy will be determined by measuring integrated exposure and exposure rate in air at a standardized distance from the source, utilizing a specially constructed calibration jig which holds a standard Farmer-type ionization chamber a fixed distance from the source, under conditions of low and reproducible scatter. The dosimetry system has calibration traceable to the NBS. Re-calibration is performed biannually. These measurements will be conducted monthly, and whenever a source change is made.*

o Travel time error

*This system has dual timers. The primary timer is activated only when the source is in treatment position, and is stopped during source motion. The backup timer is activated when the source leaves the safe, and is stopped when it arrives back into the safe. This arrangement explicitly measures both travel time and dwell time for every treatment. The ratio of travel time to treatment time will be checked monthly on a typical mock setup.*

o Accuracy of timing device

*The timing device will be checked with a stopwatch on a quarterly basis*

2. Describe qualifications of individual(s) performing calibration if they do <u>not</u> meet criteria in 10 CFR 35.24(a) or 35.24(b)

*Individuals meet criteria in 10 CFR 35.961*

C. If the device with installed sources(s) will be moved from one treatment room to another, dexcribe checks that will be conducted after each move and before use to ensure proper operation of both the device and associated safety systems (e.g. interlocks, lights)

*N/A*

## VII. <u>Emergency Procedures</u>

Submit a copy of emergency procedures and specify that these procedures will be posted near each place of use. As a minimum your procedures should include:

o When the procedures are to be followed,

o Step-by-step actions and by whom these actions are to be taken,

o Giving first consideration to minimizing exposure to the patient,

- Requiring securing area; posting warning notice, and
- Providing names and on-duty/off duty telephone number of at least 2 people to be notified

*See enclosed emergency procedures. These will be prominently posted near the control console.*

## VIII. Waste Disposal

*Sources will be returned to manufacturer for disposal*

# Micro-HDR EMERGENCY PROCEDURES

**To be followed by person operating the console**

## IF THE SOURCE FAILS TO RETURN TO THE UNIT

(Area radiation monitor flashing, or "treat" light remains on)

1. Depress the emergency stop button on the wall. The source will retract and the radiation emergency is ended. Take the printout which records the set treatment time and also records the estimated treatment time. Notify the physicians and physicists.

## IF THE SOURCE HAS NOT RETRACTED

2. Quickly and calmly enter the room, and open the panel on top of the unit, by pushing it down to release the catch.

3. Turn the GOLD colored crank in the direction of the arrows. This will pull the source back into the safe and end the radiation emergency. Record the estimated treatment time, and notify the physicians and physicists.

## IF THE CRANK SHOULD BE JAMMED

4. Disconnect the applicator from the unit, and pull the unit away from the patient, which will pull the source cable out of the applicator.

5. Quickly slide the source into the lead storage cask. Use the forceps to guide the source cable into the funnel.

6. Assist the patient from the room. Close the door, mark it "NO ENTRY", and notify the physicians and physicists.

7. Record the estimated treatment time.

*Remember...The first priority of the emergency procedure is to*

REDUCE EXPOSURE TO THE PATIENT.

Emergency Numbers...

Physicist: _____

Doctor: _____

Nucletron: _____

William Beaumont Hospital

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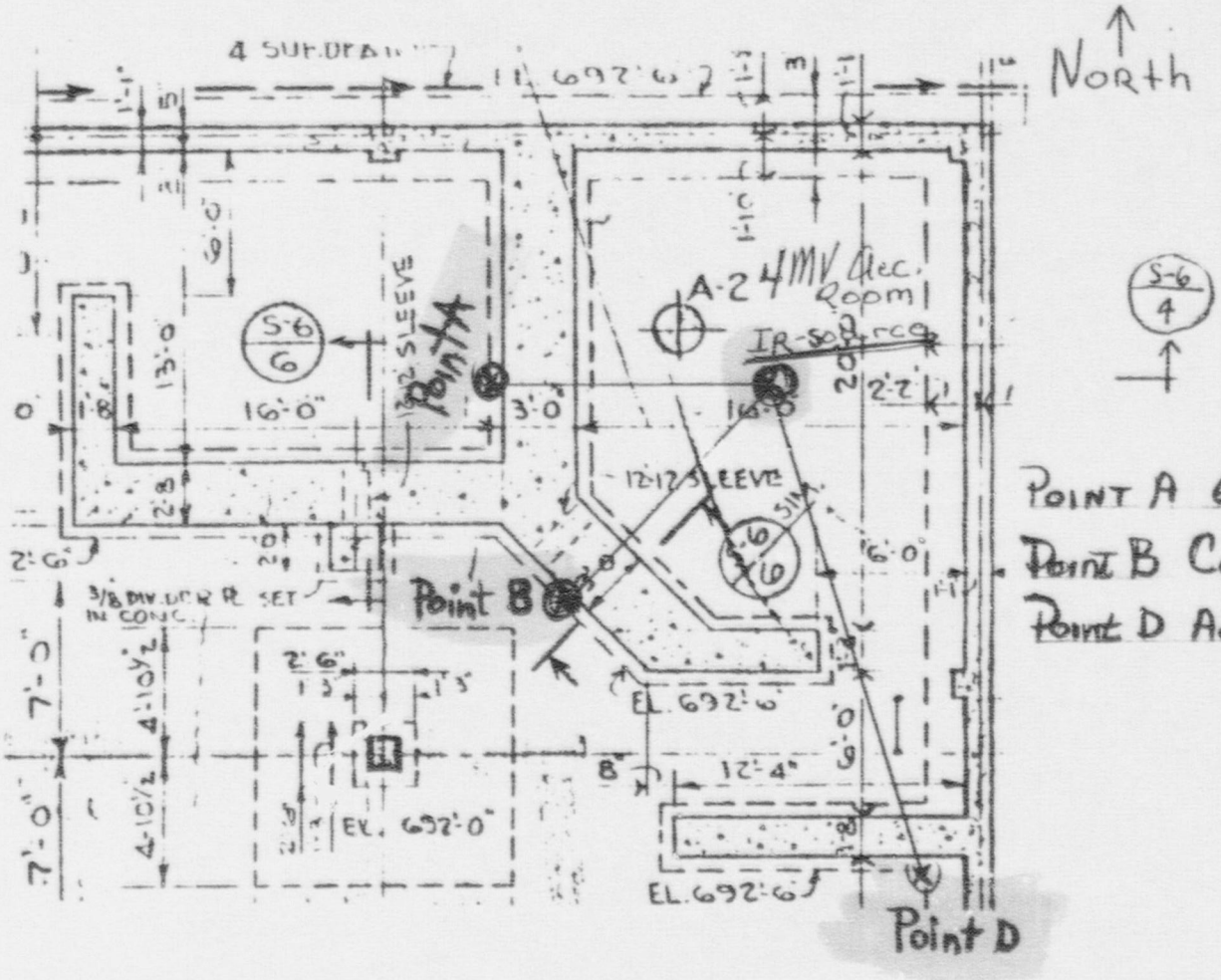
April 6, 1988




Point A 6MV Accelerator Room
Point B Control Area 4MV Acc
Point D Adjacent Office

Area where Remote Afterloader will be used
Basement of South Tower of Hosp.

Scale: ⅛" = 1 foot

William Beaumont Hospital
License # 21-01333-01
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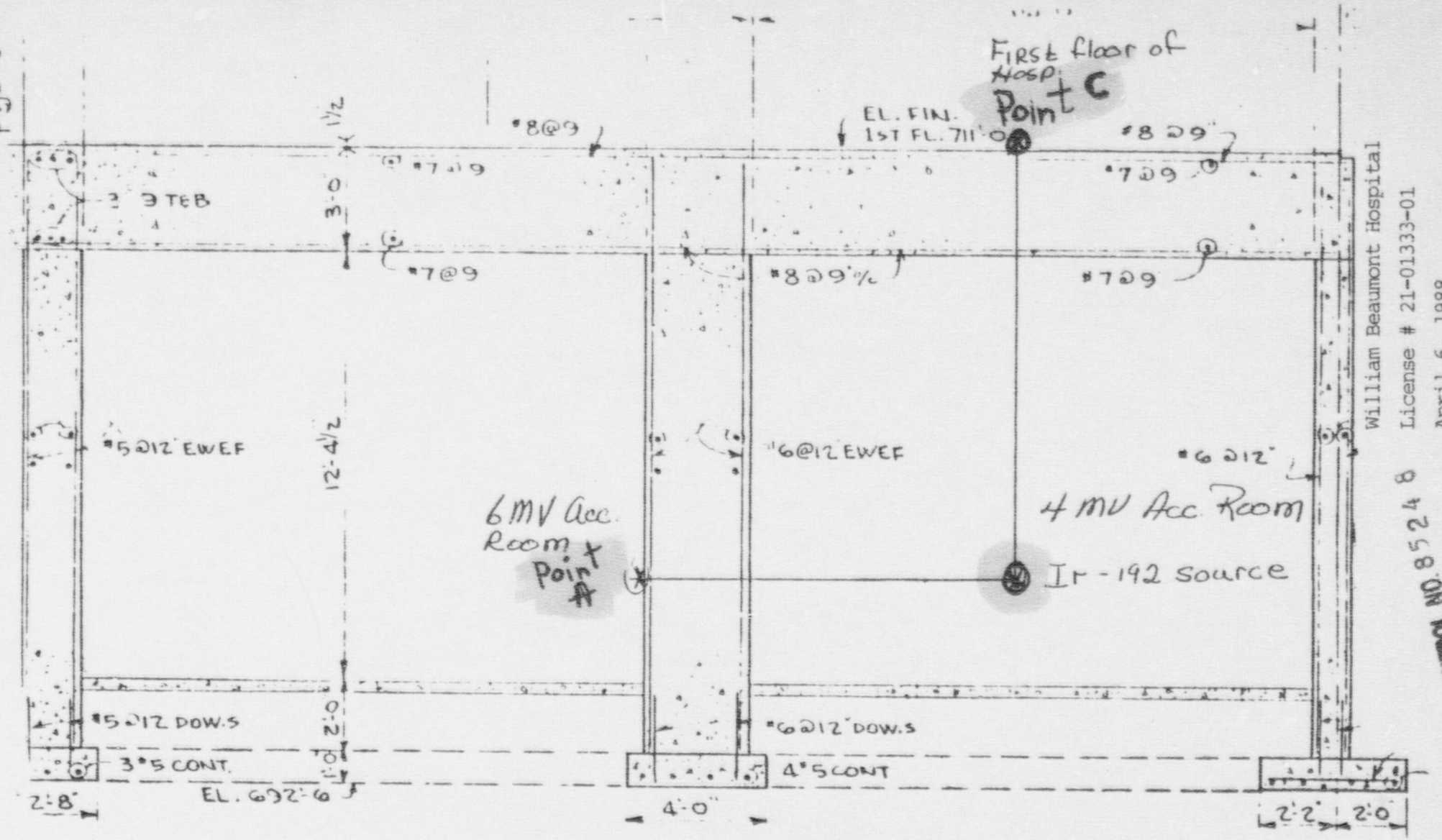
CONTROL NO 8524




Elevated Drawing of Area

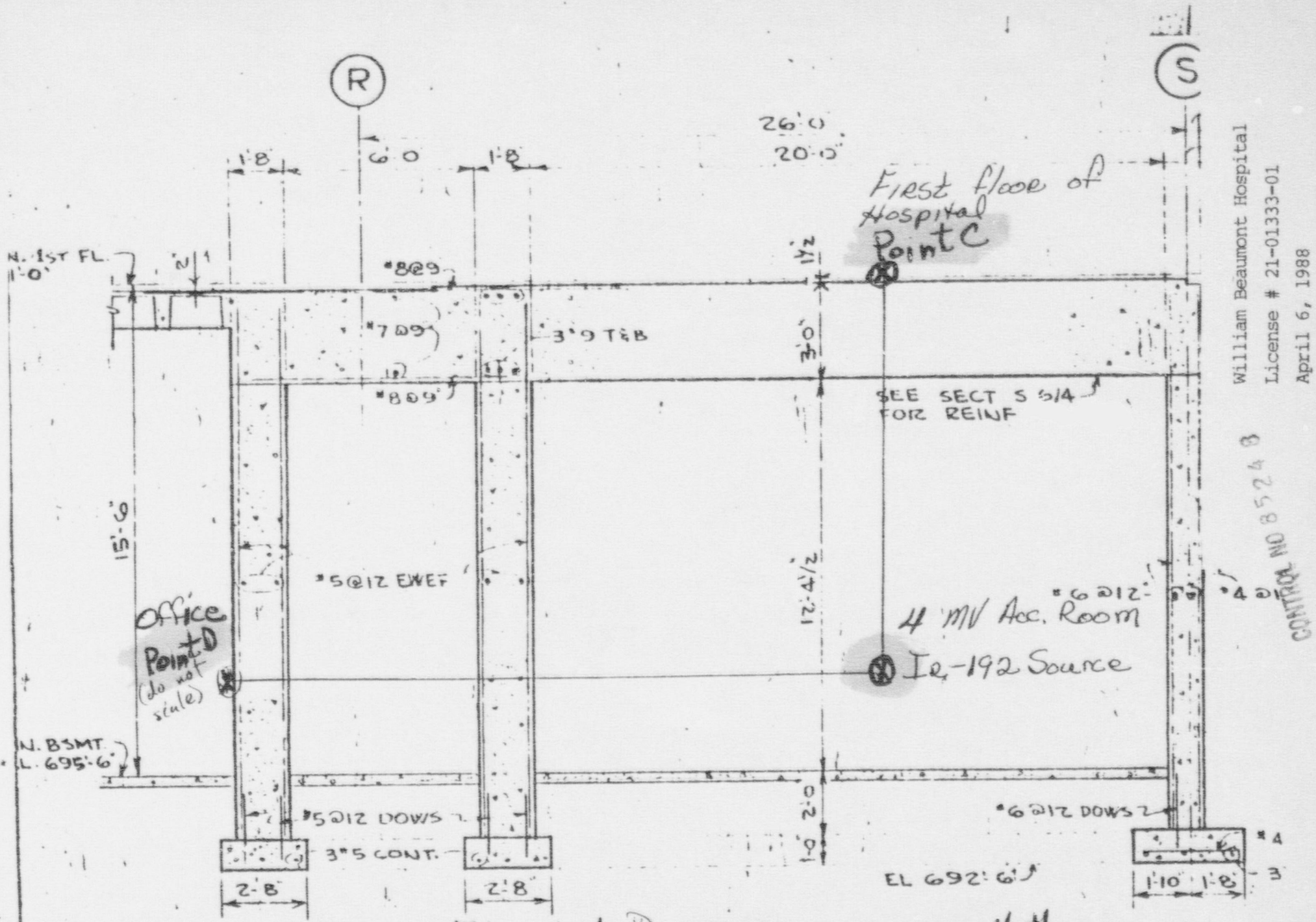
East

ION (S-6/4)
=1'-0"

Scale = ¼" = 1 foot

William Beaumont Hospital License # 21-01333-01 April 6, 1988

CONTROL NO. 8524 8




Elevated Drawing

SECTION (5/6 5)

SCALE 1/4"=1'-0"

William Beaumont Hospital
License # 21-01333-01
April 6, 1988

CONTROL NO 852483