VOID SHEET

TO: License Fee Management Branch

FROM: CASSANDRA FRAZIER

SUBJECT: VOIDED APPLICATION

Control Number: 90311

Applicant: Milwaukee City Med. Corp.

Date Voided: 12/24/90

Reason for Void:

Licensee submitted ltr. 12-14-90 requesting additional time to complete response. I told licensee that I would void action + that would give them the time to do a complete response. Licensee requested. Action will be reactivated

12-24-90

Signature Date

Attachment:
Official Record Copy of
Voided Action

FOR LFMB USE ONLY

Final Review of VOID Completed:

- ☐ Refund Authorized and processed
- ☑ No Refund Due
- ☐ Fee Exempt or Fee Not Required

Comments:

Log completed ☐

Processed by:

1/1

RECEIVED
90 DEC 31 A10:41

9101220281 901224
REG3 LIC30
MATLSLICENSING PDR

ML30

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

(FOR LFMS USE)
INFORMATION FROM LTS

PROGRAM CODE: 02110
STATUS CODE: 0
FEE CATEGORY: 8X 7B
EXP. DATE: 19920331
FEE COMMENTS: 170.11(A)(9) CODE

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED
APPLICANT/LICENSEE: MILWAUKEE COUNTY MEDICAL COMPLEX
RECEIVED DATE: 901010
DOCKET NO: 3003444
CONTROL NO.: 390311
LICENSE NO.: 48-04193-01
ACTION TYPE: AMENDMENT

2. FEE ATTACHED
AMOUNT: ~~---0---~~
CHECK NO.: ~~---0---~~

3. COMMENTS

SIGNED ~~Douglas Bell~~
DATE 10-11-90

B. LICENSE FEE MANAGEMENT BRANCH (CHECK WHEN MILESTONE 03 IS ENTERED (__)

1. FEE CATEGORY AND AMOUNT: ---

2. CORRECT FEE PAID APPLICATION MAY BE PROCESSED FOR: 170.11(A)(9)
AMENDMENT ~~---~~
RENEWAL ---
LICENSE ---

3. OTHER ---

SIGNED ---
DATE 10/

MILWAUKEE COUNTY
medical complex

8700 West Wisconsin Avenue Milwaukee, WI 53226 414-257-7900, TTY 257-5774

December 14, 1990

Cassandra F. Frazier
Materials Licensing Section
U.S. Nuclear Regulatory Commission
Region III
799 Roosevelt Road
Glen Ellyn, IL 60137

Re: Control Number 90311

Dear Ms. Franzier:

We are working on the additional information you requested in your letter dated November 16, 1990. It is our intention to answer your questions within the next several weeks. We will, however, not be able to submit the necessary information by December 16th and therefore request that this amendment request b kept open for an additional 30 days.

Sincerely,

Charles R. Wilson

Charles R. Wilson, Ph.D.
Radiation Safety Officer

CRW:mb
cc: Mike Gillin, Ph.D.
Janice Lato

F

NOV 16 1990

Milwaukee County Medical Complex
ATTN: Charles R. Wilson, Ph.D.
Radiation Safety Officer
8700 West Wisconsin Avenue
Milwaukee, WI 53226

Gentlemen:

We have reviewed your letter dated October 1, 1990, requesting an amendment to License Number 48-04193-01 and find that we will need additional information as follows:

1. Material

Please note that the maximum activity approved for the Micro Selectron LDR Afterloading Device is 3 curies. Please clarify your request.

2. Proposed Users

a. In regards to your proposed users, Section III, please confirm that these individuals will be physicians as defined in Section 35.2 of 10 CFR Part 35, and will hold one of the medical specialty certifications listed in 10 CFR 35.940.

b. Confirm that your Radiation Safety Committee will approve users for this device who meet the qualification as stated above.

3. Training

In reference to Section IV, "Training for Individuals", please submit a more detailed description of the training requirement for individuals using the afterloader device. The description should include the following:

a. Provide an outline of the training and experience you will require for all afterloader device operators. This might include technicians, authorized users, and supervised users or anyone else who may operate the afterloader device. Training should include the following:

(1) Radiation protection and instrumentation;
(2) Operating and emergency procedures;
(3) Design, use, and junction of the unit, including safety systems;
(4) On-the-job training in actual operation of the afterloader device (including "dry-runs"); and
(5) Method of determining each trainee's competency to use the device.

b. Provide a description of the training and qualifications of your instructor, Michael T. Gillin, Ph.D.

c. Section IV.D. states that no other individual is on-site during treatment time, but support staff is available for telephone consultations. Due to emergency situations (i.e., source disconnect, etc.) that could arise during the use of the device, you will need to make provisions for having on-site individuals, (i.e., nursing staff, etc.) trained in the use of the afterloader device and emergency procedures. Please clarify how you will ensure that trained individuals are available on-site at all times that the device is in operation.

d. Provide an outline of the topics covered in retraining of your individuals (i.e., oncology, personnel, nurses, etc.) having responsibility for the afterloader device. State the frequency of retraining. Confirm that the retraining will include "dry-runs" of emergency procedures.

4. Facilities

a. Submit detailed calculations of maximum radiation levels that will exist in each area (restricted and unrestricted) adjacent to and above the room that houses the afterloader device. The calculations should include the following:

(1) Provide calculations for each area adjacent to the afterloader device room with the most adverse source or orientations and source combinations considered. The calculations must demonstrate that your unrestricted areas adjacent to the treatment room will have radiation levels less than 2 milliroentgen (mr) in any 1 hour and less than or equal to 100 mr in any 7 days (reference 10 CFR 20.105[b][1] and [2]).

(2) Specify all parameters used in your calculations. These parameters include such factors as distance to area of concern, type and thickness of material(s) used in barrier, and transmission factor of barrier. (Calculations must be provided for "worst case" situations.)

(3) Indicate the maximum anticipated workload data (e.g., maximum "on time" per hour and per week).

(4) Calculations for unrestricted areas must consider continuous occupancy (i.e., occupancy factor of unity).

(5) Results of calculations are to be expressed in terms of millirems in any 1 hour and millirems in any 1 week.

b. Should calculations indicate that the limits specified in 20.105 can not be met in adjoining unrestricted areas, it will be necessary to outline steps taken to prevent overexposures to radiation. Options you may consider are:

(1) Add shielding to the barrier in question, i.e., modifying the facility description.

(2) You may request an exemption and demonstrate that the requirements of paragraph 20.105(a) of 10 CFR Part 20 are met. In this case, the applicant must include information on average radiation levels and anticipated occupancy times for each unrestricted area. The applicant must also maintain records to support the assumptions used in justifying the request for an exemption.

c. You may designate and maintain your areas as restricted. It appears from your application, Section V.D.2., that you will have areas that will exceed the limits in Part 20.105(b) for unrestricted areas and therefore must be considered restricted (i.e., room 4C98, Hallway, Intestitial spaces, and stairwell). Please submit a more detailed description for each restricted area. The description must include:

(1) The physical and administrative controls used to restrict access to the restricted area,

(2) The number, wording, size, and location of warning signs to be placed in the vicinity of the restricted area.

(3) The program for ensuring that personnel entering the restricted area receive proper instruction in accordance with Section 19.12.

(4) The program for ensuring that personnel entering the restricted area are monitored in accordance with Section 20.202.

(5) The surveys that will be performed in accordance with Section 20.201.

d. In reference to your request to use the afterloader device in locations other than the normal treatment room, please note that any request for an alternate treatment room must be submitted to the NRC for review and approval. Therefore, if you wish to have other rooms designated for use of the afterloader device, you must submit specified information for each location, as described in the Enclosure, "Information Required for Licensing Remote Afterloading Devices." In addition, please describe the 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).

e. This is in reference to your indication that the afterloader device may be used in the radiation oncology treatment room. Please provide your procedures for assuring that only one device is in operation at a time.

f. Regarding Section V.C.6., please indicate what separate action must be taken before the afterloader device can be reactivated after entry interlock has been tripped.

g. Please confirm that the room housing the afterloader device will have a permanent radiation monitor capable of continuously monitoring source status. Please also confirm that:

(1) The radiation monitor must provide visible notice of an afterloader device malfunction that results in an exposed or partially exposed source, and must be observable by an individual entering the treatment room.

(2) The radiation monitor must be equipped with a backup power supply separate from the power supply to the afterloader device (may be a battery system).

(3) The radiation monitor must be checked with a dedicated check source for proper operation each day before the afterloader device is used for treatment of patients.

(4) You must maintain a record of the monitor check described above for three years. The record must include the date of the check, notation that the monitor indicates when its detector is and is not exposed, and the initials of the individual who performed the check.

(5) If a radiation monitor is inoperable, you must require any individual entering the afterloader device treatment room to use a survey instrument or audible alarm personal dosimeter to monitor for any malfunction of the source exposure mechanism that may result in an exposed or partially exposed source. The instrument or dosimeter must be checked with a dedicated check source for proper operation at the beginning of each day of use and a record of the check must be maintained as described in (4) above.

(6) You must promptly repair or replace the radiation monitor if it is inoperable.

Please note that in lieu of having a permanent radiation monitor, you may commit to providing personnel with an audible alarm personal dosimeter or performing a survey with a calibrated and operable radiation survey instrument after each exposure or use of the afterloader device to determine that the sealed source has been returned to its shielded position. This survey should include connectors and applicator apparatus, such as catheters, tubes, and needles. A record of these surveys must be maintained for three years and should contain the date of survey, a description of survey instrument used (model and serial numbers), background reading, survey reading, and the initials of surveyor. Please confirm that if a survey indicates source exposure you will immediately implement your emergency procedures.

5. Operating Procedures

a. Please confirm that whenever the afterloader device is either unattended or not in use that the keys will be stored in an area inaccessible to unauthorized individuals.

b. Please confirm that checks made to ensure the proper function of the afterloader device are performed on the day of its use.

c. Please confirm that you will perform and maintain records of all checks including tests of the interlocks; reproducibility of source positioning with n the catheter to within ± 1 millimeter; verification of source position indicators (e.g., lights, alarms, room monitor); and inspection of guide tubes for kinks and other imperfections.

d. Please confirm that treatment time calculations will be independently verified before treatment is begun.

e. Please provide us with the name and qualifications of the Oncology Physicist who will perform calibrations of the afterloader device.

f. Please provide us with a copy of your calibration procedures, as supplied by the manufacturer. Please confirm that your calibration procedures will include dose accuracy to within ± 5 percent, travel time error, and accuracy of timing device.

g. Please commit to performing calibrations at a specific frequency. We recommend that calibrations be performed after each installation of a new source and monthly thereafter.

h. Please confirm that all personnel involved with treating patients on the afterloading device will be monitored in accordance with 20 CFR 20.202, including whole body badges to be worn by persons entering the restricted area.

6. Emergency Procedures

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:

a. When the procedures are to be followed;

b. Step-by-step actions and by whom these actions are to be taken;

c. Give first consideration to minimizing exposure to patient;

d. Require securing area, posting warning notice; and

e. Provide names and on-duty/off-duty telephone numbers of at least two people to be notified.

7. Source Exchange

Section IV.B. indicates that sources are exchanged with every use; please provide a description of the procedures used by the individuals who will conduct the source exchanges. In addition, describe additional training (i.e., safety precautions to be observed) provided to individuals conducting source exchanges.

We will continue our review of your application upon receipt of this information. Please reply in duplicate, within 30 days, and refer to Control Number 90311.

Upon failure to file an answer within the specified time, we will consider that you have abandoned your request and will void this action. This is without prejudice to resubmission of the application.

If you have any questions or require clarification on any of the information stated above, you may contact us at (708) 790-5625.

Sincerely,

Cassandra F. Frazier
Materials Licensing Section

Enclosure: Information
Required for Licensing
Remote Afterloading Devices

RIII
Frazier/rr
11/14/90

MEDICAL COLLEGE OF WISCONSIN

October 1, 1990

Department of Radiology
Section of Diagnostic Radiology

William J. Adam, Ph.D.
Acting Chief of Licensing
U.S. Nuclear Regulatory Commission
Region III
799 Roosevelt Road
Glen Ellyn, IL 60137

Dear Bill:

I appreciate your prompt response iu sending me the information required for licensing a remote afterloading device. Attached is the information requested. As I indicated in our telephone conversation of Sept. 28th, there is a patient who is tentatively scheduled for therapy with this device on October 10th and if our amendment request can be processed in time for this therapy, I would appreciate it. If additional information or clarifications are needed, please call me at (414) 257-5381 or Michael Gillin, Ph.D., Chief of Medical Physics, Radiation Oncology (414) 257-5636.

No license fee is required as the Milwaukee County Medical Complex is a branch of the Milwaukee County Government.

Sincerely,

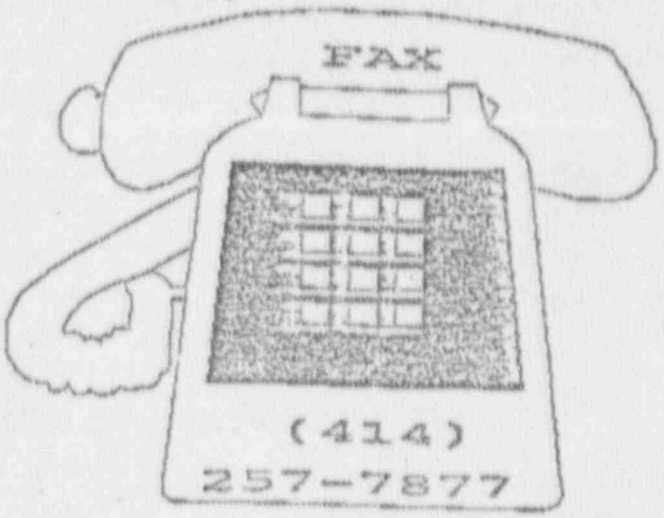
Charles R. Wilson, Ph.D.
Associate Professor of Radiology
Radiation Safety Officer

CRW:mb
Encl.

Oct 10 '90

10.11(a)(4) EXEMPT

Milwaukee County Medical Complex
8700 West Wisconsin Avenue
Milwaukee, Wisconsin 53226



TO: Wm Adams
Acting Chief of Licensing
N. R. C.
Glen Ellyn, Ill.

FROM: Charles J. Wilson, Ph.D.
Rad. Safety Officer
Medical College of Wisconsin

PAGES 8
(INCLUDES COVER)

MEDICAL COLLEGE OF WISCONSIN
DEPARTMENT OF RADIOLOGY
MILWAUKEE, WISCONSIN
U-S-A.

FAX # (414) 257-7877

Low Dose Rate Remote Afterloading System
At MCMC and FMLH

I. Description of Sources

A. Source Description

1. Ir-192
2. Ir-192 seeds in ribbon form from Best Industries or Nuclear Products, Inc. or Ir-192 wire from Amersham or CISUS
3. Maximum activity is 185 GBq (5 Ci)
4. Maximum number of sources is 15

B. Device Description

1. Manufacturer: Nucletron
2. Model name: Microselectron LDR

II. Intended Use:

To be used for interstitial and intracavitary treatment of cancer to augment the existi-g program in brachytherapy. This is the low dose rate unit and does not represent a significant change in the normal practice of brachytherapy.

III. Proposed Users:

Radiation Oncology _linical faculty, who are all board certified physicians in Radiation Oncology or the equivalent. These physicians will be supported by the Physics and Dosimetry staff of the Department of Radiation Oncology.

IV. Training for Individuals

A. Devices operators are the physician and physics staff of the Department of Radiation Oncology.

B. The sources are exchanged with each use. Sources are prepared and tested by the Physics and Dosimetry staff of the department. Since the sources are the normal strength for radiation brachytherapy, no special skills are required.

C. Michael T. Gillin, Ph.D.
Associate Professor
Radiation Oncology
Medical College of Wisconsin

D. This device is used for 24 hours per day for the duration of the implant which may last up to one week. No other individual is on-site during this entire time. Support staff is available for telephone consultations.

E. The device is tested prior to each use to insure proper source transfer, proper time measurement, and proper unit functioning. There are no emergency procedures required for this low dose rate unit. No documentation of this is made.

V. Facilities

A. Attached is a floor plan of the room 4C96 and adjacent areas (Fig. 1). The room above 5C96 and below 3C96 are of identical layout. The distance from functional floor to functional floor is 18 feet (4.6 m) and the floors are composed of 6" of concrete. There is ar interstitial space containing heating and cooling ducts and other utilities located between the functional floor. This space is occupied only during inspections and maintenance work. The distance between the functional floor and the floor of the interstitial walk platform is 10 feet (3 m). This walk platform is concrete 2.5" thick. (See attached diagrammatic section (Fig. 2) of interior partition and ceiling)

The following is a summary of the main materials in the walls, floor and ceiling:

South wall: No shielding required, outside area is above grade.

East wall: Gypsum wall board, 1 1/4" total thickness on metal studs and lead shielding 1/4" (6.3 mm) to a height of 7 feet (2.1 m). Adjacent area is a patient room and is unrestricted.

North wall: Lead shield, 1/4" (6.3 mm) to a height of 7 feet (2.1 m). Adjacent area is hospital hallway and is unrestricted.

West wall: Gypsum wall board, 2 1/2" total thickness on metal studs and lead shielding 1/4" (6.3 mm) to a height of 4.5 feet (1.37 m). Adjacent area is emergency stairwell and is unrestricted.

Floor: 6" concrete in floor plus 2 1/2" concrete in interstitial walk platform, adjacent area below is a patient room, distance between floors is 18 feet.

Ceiling: Same as floor.

Distance from center of bed, room 4C96 to following areas:

Room 3C96 and 5C96	: 18 feet (5.5 m)
Fourth floor interstitial space:	10 feet (3.0 m)
Third floor interstitial space :	8 feet (2.4 m)
Room 4C98	: 10 feet (3.0 m)
Hallway	: 12 feet (3.7 m)
Stairwell	: 6 feet (1.8 m)

B. 1. The primary treatment room has closed circuit TV and a separate audio system. Since this is a low dose rate unit, failure of any component of the visual or audio system will not prevent the system from being used, as there are no special patient monitoring requirements for normal brachytherapy.

C. 1. The normal treatment room has a door interlock. The institution reserves the right to use this device in locations other than the normal treatment room if it is decided that there is a compelling reason to do so.

2. All rooms containing patients who are undergoing a brachytherapy treatment are appropriately labeled.

3. There might be a possibility of using this device in one of the Radiation Oncology treatment rooms. Thinking is the means of assuring that other devices are not turned on to make radiation while using the remote afterloader.

4. A radiation measuring device is present for each brachytherapy patient, independent of the use of the afterloading system.

5. To the best of our understanding of this device, once the sources have been withdrawn, a separate action must be taken to redrive the sources out to the treatment position.

D. Shielding Evaluation

1. The maximum "on-time" is on the order of 1 week treatment.

2. The activities of implants to be performed in Room 4C96 will vary but adjacent unrestricted areas on the fourth floor will be surveyed to insure compliance with Section 20.105(b). If exposures in any area exceeds the limits in Section 20.105(b), the rooms 5C96 and 3C96 will be surveyed. If exposures in the following areas exceeds the limits in Section 20.105(b), the actions indicated will be taken.

a. Room 4C98, distance, 12 feet (3.7 m)
Access to this room will be restricted. No patient will be housed in this room while the implant is in progress.

b. Hallway
An ISO exposure line representing 2 mR/hr will be marked on the floor of the hallway and signs will be placed restricting access to the area behind this line to only radiation workers. Portable bedside shields (2 available) will be used to minimize the area of the hallways so restricted.

c. Interstitial Spaces (above and below room 4C96)
These spaces are normally locked and access is limited to engineering personnel. When exposure rate exceeds limits in Section 20.105(b), engineering personnel will only be allowed access to these areas when accompanied by a member of the Radiation Safety staff. Engineering will be notified of each implant for which this restriction applies.

d. Stairwell

Because of its location, this stairwell is infrequently used and occupancy is essentially nil. In the event exposure levels exceed limits, signs will be placed in the stairwell on the fifth floor and third floors stating that the area between the fifth and third floor is a restricted area, and directing anyone to exit the stairwell on the fifth or third floor except in case of an emergency. It is unlikely even in the event an individual ignores the warning signs that the individual will be exposed to a significant fraction of the recommended maximum annual dose of 0.5 rem for a member of the general public because of the limited time it would take to go between floors (estimated time less than 15 seconds).

3. For restricted areas, the normal controls will be used.

VI. Operating Procedures

1. Written standard operating procedures have been developed.

2. Copies have been distributed to the Physics and Dosimetry staff.

3. When not in use, the remote afterloading system is kept in the Brachytherapy Room within the Department of Radiation Oncology, Milwaukee County Medical Complex. The treatment room is a normal hospital room and is used for normal patient care when the unit is not in this room.

4. When the device is used, the patient who is to be treated with it is the only patient in the room.

5. Since the device is used very infrequently, daily checks are not made.

B. Calibration of Device

It is not necessary to calibrate this device nor is it possible to do so. All sources used in brachytherapy are calibrated following the recommendations in AAPM Report 13.

VII. Emergency Procedures

Emergency procedures are not required for this device.

VIII. Waste Disposal

Sources are disposed of by returning them to their manufacturer.

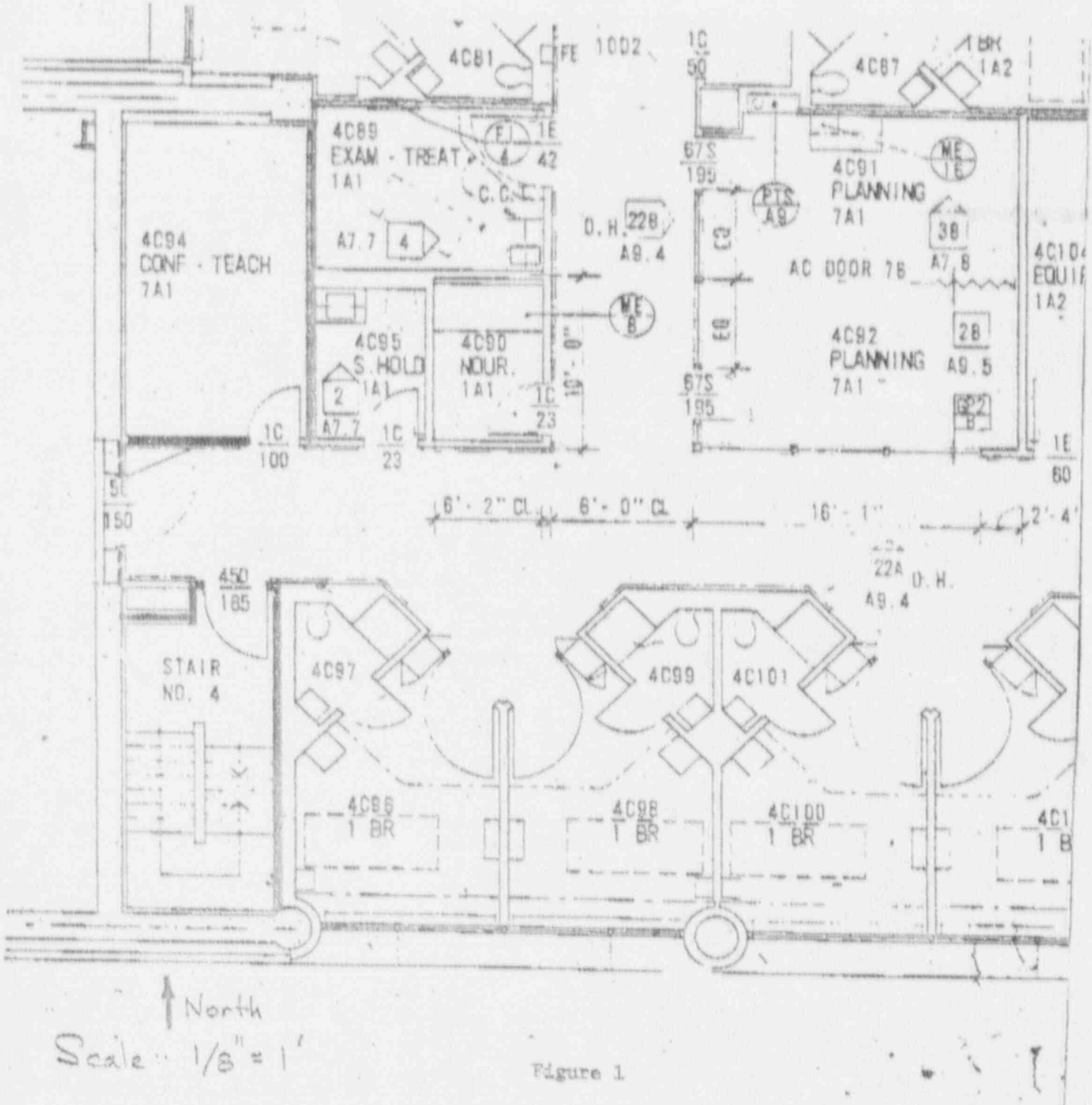


Figure 1

Froedtert Memorial Lutheran Hospital
9200 W. Wisconsin Ave., Milw., WI 53226
Southwest corner of the building showing
the room in which the Selectron is used, 4C96.

CONTROL NO. 90311

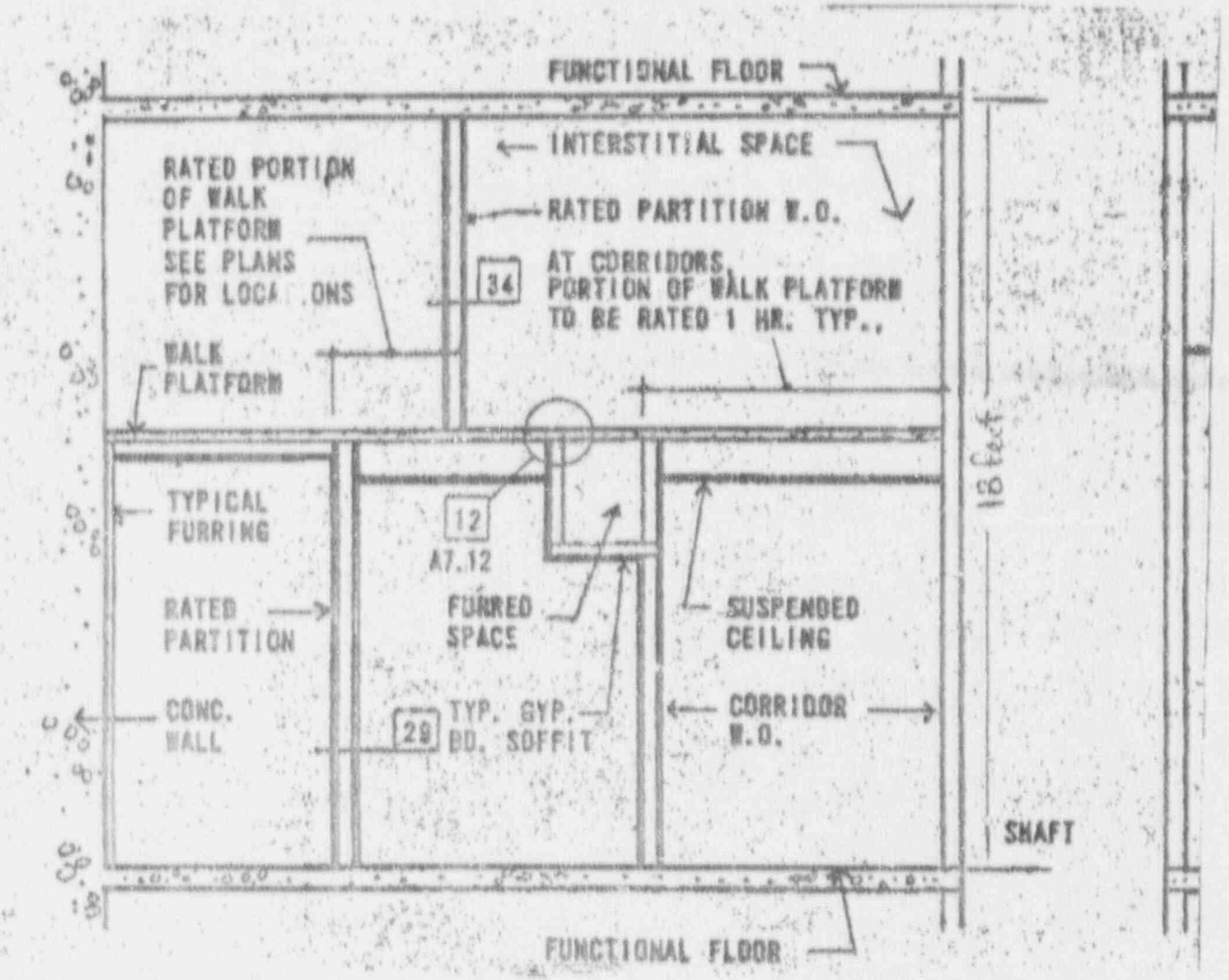


Figure 2

Diagrammatic section of interior partition and ceiling illustrating functional floors and interstitial space between floors.

Scale: 1/8" = 1'