STATE OF OKLAHOMA TEACHING HOSPITALS
Post Office Box 26307
Oklahoma City, Oklahoma 73126

September 26, 1988

Nuclear Material Licensing Section
U. S. Nuclear Regulatory Commission
Region IV,
611 Ryan Plaza Drive, Suite 1000
Arlington, Texas 76011

Dear Sir:

With reference to our NRC license no.:35-21035-01, we would like to add the use of Irrieium-192 sealed source for high dose brachytherapy under category 35.400. This is in addition to the existing limits of radionuclides in this category.

Pertinent details are provided in the attached. This license is for the State of Oklahoma Institution and is in fee exempt category.

Please let me know if any other information is required.

Sincerely yours,

B. Wally Ahluwalia

B. Wally Ahluwalia, Ph.D.
Director,
Office of Radiation Safety

BA/db
Attachments
cc: Carl R. Bogardus, M.D.
Director
Radiation Therapy

5. RADIOACTIVE MATERIAL

Sealed sources under category 35.400 are requested.

The therapeutic use of radionuclides will involve the following type of sealed source:

Iridium-192

The source description and possession limits are described below:

Source Description: Iridium-192

i. Radionuclide: 192-Ir
ii. Manufacturer name and model number 1:
BYK Mallinckrodt, Model CI L BV
iii. Maximum possession activity (in curies):
15 Ci
iv. Number of sources 2:
1 at all times and 2 at the time of replacement

Device Description:

i. Manufacturer's name:
Nucletron
ii. Model name/number
MicroSlectron-HDAR (080.000)

6. PURPOSE FOR WHICH LICENSED MATERIAL WILL BE USED

The MicroSelectron-HDR system is intended to be used for intraluminal, intracavitary, interstitial and intraoperative treatment of cancer.

The devices will be used only the following:

Carl R. Bogardus, M.D., F.A.C.R.
Certified American Board of Radiology (Therapy) 1964
Certified Board of Nuclear Medicine 1972

William J. Graham, M.D.
Certified American Board of Radiology (Therapy) 1976

Nergesh Surti, M.D.
Certified American Board of Radiology (Therapy) 1982

The training and experience of Drs. Bogardus and Graham are already on file with NRC under NRC License No. 35-21035-01 and No. 35-21035-02.

Training and experience of Dr. Surti is provided in attachment A.

7. INDIVIDUALS RESPONSIBLE FOR RADIATION SAFETY PROGRAM TRAINING AND EXPERIENCE

Dr. B. Wally Ahluwalia will be responsible for the radiation safety program.

1. His training and experience is already on NRC records related to NRC license no. 35-21035-02 and license no. 35-21035-01.

2. He is certified by the following boards.

   (i) American Board of Radiology 1983
   Therapeutic Radiological Physics
   (ii) American Board of Radiology 1986
   Medical Nuclear Physics
   (iii) American Board of Science in Nuclear Medicine 1980

8. TRAINING OF PERSONNEL

Dr. B. Waliy Ahluwalia, Ph.D. will provide the training to personnel. The training will be provided to all new employees and employees will be informed if changes in the operating procedures occur.

For training of personnel, we will follow the NRC model program of Appendix A of 1987 Regulatory Guide 10.8 Revision 2. The training will be given to all personnel, such as physicians, radiation therapy technicians, nurses involved in patient care, and general office staff. The training will be given through lecture followed by question and answer session. For all employees, the training will be conducted on annual basis and new employees will be briefed prior to starting work. Record of attendance, speaker and topics covered will be kept on file.

A training session related to application of high dose Ir-192 brachytherapy was arranged on October 7, 1987. The topics covered and by the specific speakers are detailed below:

(i) Mr. Miles Mount, President Nucletron Corporation, Columbia, M.D. Description of Micro Selectron-HDR Iridium-192, health safety procedures, patient management, and emergency procedures.

(ii) Dr. Larry Spaudling, M.D., Pulmonary Physician, Phoenix, AZ. Application of Selectron in lung cancer, patient management.

(iii) Dr. William Powers, M.D., Radiation Therapist, Wayne State University, Detroit, Michigan. Experiences with remote after loading systems.

9. FACILITY AND EQUIPMENT

A. FACILITY

The remote after loading system will be housed in the existing Van de Graff room. This room is located in the southwest corner of the radiation therapy facility of the Oklahoma Memorial Hospital. The entire radiation therapy facility is shown in Attachment B. Van de Graff room is shaded on the Attachment B. Attachment C provides the shielding details.

Room size 25' x 18' 11".
Wall thickness:
North: 2' 1" and 1' 6"
South : 2' 0"
East: 3' 7"
West: 2' 0"

The facility has sufficient shielding for a 6MV therapy unit. The accelerator room is safe for conduct of Ir-192 after loading therapy.

B. VIEWING SYSTEM

The accelerator room has a viewing window. It is also anticipated to have a T.V. monitoring system.

Monitoring system will be checked at the commencement of each treatment. In case the system is not properly functioning, no treatment will begin. If the patient has undergone extensive surgical procedure related to the placement of catheters at locations for treatment, the decision for the treatment will be made by the radiation therapist. In the interest of the patient, proper safety procedures and constant voice contact will be observed. Patient will only undergo preliminary surgical procedures if the treatment room T.V. monitoring system function is satisfactory. In case of monitoring malfunction, this system will be fixed.

C. AREA SECURITY

1. INTERLOCKS

The entry door has a switch interlocked to the Selectron computer which control the exposures. There will be two emergency stop buttons mounted in the room and another on the Micro Selectron - HDR system.

2. AREA MONITORING

Area has the following signs:

(i) Restricted Area
(ii) High Radiation Area.

The entry door has light indicator which will turn red when the Ir-192-sources will be in use.

The remote control console indicates whether the sources are in the treatament or "safe" positions.

D. SHIELDING EVALUATIONS

According to the manufacturer, the Micro Selectron-HDR, holding a maximum of 12 curies of Ir-192, 15 inches of concrete reduces the dose at 3 meters to less than 2 mR/Hr.

The accelerator room exterior dimensions are 30'-7" x 18'-6". The minimum thickness of any wall is 24 inches of concrete.

Approximate treatment time will be 10 minutes per patient and 20 patients will be treated per week. So the total machine on-time will be 200 minutes per week or 3 hours per week; so, the added exposure per week will be 6 mR/wk.

E. EQUIPMENT SHIELDING

The safe of the Micro-Selectron HDR unit is rated for a maximum of 12 curies of Ir-192. The dose rate from the surface of the treatment unit is less than 0.25 mR/hour.

A record of each treatment will be maintained..

F. ENTRY RESTRICTIONS

The entry to the treatment room is restricted to patients and the personnel of the Oklahoma Medical Center. The personnel are routinely monitored with film badges. They are all provided training. The details of the training are given in the Training section.

G. ROOM SURVEY

The facility has the following equipment for survey.

1. Victoreen Model 49 Thyac III, Sr. #2452, Range 0-200 mR/hr., or a comparable calibrated survey meter.

2. Keithly Model 36100, Serial #9870, 0.1 to 20 R/hr., or a comparable calibrated equipment.

H. OPERATIANG, EMERGENCY and OTHER PROCEDURES

1. LEAK-TESTING OF SEALED SOURCES
Sealed sources will be wipe tested according to the Appendix H procedures. Routine wipe testing of the Iridium-192 sources will be performed by the approved installers of the Nucletron Corporation.

2. ORDERING AND RECEIPT OF RADIOACTIVE MATERIAL
All radioactive materials will be ordered by Dr. B. Wally Ahluwalia, the RSO. All records will be kept by the RSO. All material will be received by RSO during working hours.

3. IRIDIUM-192 SEALED SOURCES INSTALLATION AND EXCHANGE
Installation and exchange of sources will be performed by the trained personnel of Nucletron Corporation. The function of all components and radiation levels will be checked by the Nucletron personnel and verified by RSO.

4. EMERGENCY PROCEDURES
Attachment D provides the emergency procedures. This will be posted at control panel of the machine.

5. EMERGENCY PROCEDURES "DRY RUN"
The dry run of the emergency procedures will be conducted as a part of the annual training program.

6. OPERATING PROCEDURES
Attachment E gives the operating procedures.

7. PROCEDURES FOR CALIBRATION OF SURVEY INSTRUMENTS
The survey meters will be calibrated by Dr. B. Wally Ahluwalia, in accordance with the procedures of Appendix B of the Guide 10.8. His procedures are on files of NRC license no: 35-03176-01. A sample survey meter calibration report is attached for reference.

8. PERSONNEL OCCUPATIONAL EXPOSURE MONITORING PROGRAM
All technical staff, physicians and nursing staff are monitored monthly with a film badge from R. S. Landauer, Jr. Staff who are occasionally involved with the patient care are exempt from routine monitoring. The personnel exposures are reviewed routinely.

I. SOURCE CALIBRATIONS

1. PROCEDURES AND FREQUENCY OF CALIBRATION OF SEALED SOURCE IN SELECTRON

The output of the system will be calibrated using Keithly Electrometer System. The system will be calibrated routinely at NBS approved calibration laboratory. The sealed source will be calibrated at the time of installation and every three months. The calibration equipment is described below:

Electrometer: Keithly, Model #356614, Serial No: 22495

Farmer Probe: Nuclear Enterprises Limited, Model #2571, Sr. #753

Comperable equipment is available in the department.

2. INDIVIDUAL RESPONSIBLE FOR SOURCE CALIBRATION

Dr. B. Wally Ahluwalia, will be responsible for the source calibration. His credentials are attached. His credentials meet the requirements of 10 CFR Part 35.961.

UCSD
MEDICAL CENTER
University of California, San Diego
Medical Center

225 Dickinson Street
San Diego, CA 92103-1990

ATTACHMENT A

March 7, 1988

B. Wally Ahluwalia, Ph.D.
Radiation Safety Officer
Department of Radiology
P.O. Box 26901
University of Oklahoma
Oklahoma City, OK 73190

Dear Dr. Ahluwalia:

During the period from September 1985 to March 1987 Dr. Nergesh R. Surti performed brachytherapy procedures at UCSD Medical Center. The State of California Radioactive Material License No. 1339-80 authorizes qualified physicians in Radiation Oncology at UCSD Medical Center to perform these brachytherapy procedures.

If you have further questions, please feel free to contact me at (619) 543-5303. Thank you.

Sincerely,

Stephen L. Seagren, M.D.
Associate Adjunct Professor of
Radiology and Medicine
Acting Chief,
Division of Radiation Oncology

SLS:jld

ATTACHMENT A

The American Board of Radiology

Organized through the cooperation of the
American College of Radiology, the American Roentgen Ray Society,
the American Radium Society, the Radiological Society of North America,
the Section on Radiology of the American Medical Association
and the American Society of Therapeutic Radiologists
Hereby certifies that

Nergesh Ratansha Surti, M.D.

Has pursued an accepted course of graduate study
and clinical work, has met certain standards and qualifications and
has passed the examinations conducted under the authority of
The American Board of Radiology.
On this fourth day of June, 1982
Thereby demonstrating to the satisfaction of the Board
that she is qualified to practice the specialty of

Therapeutic Radiology

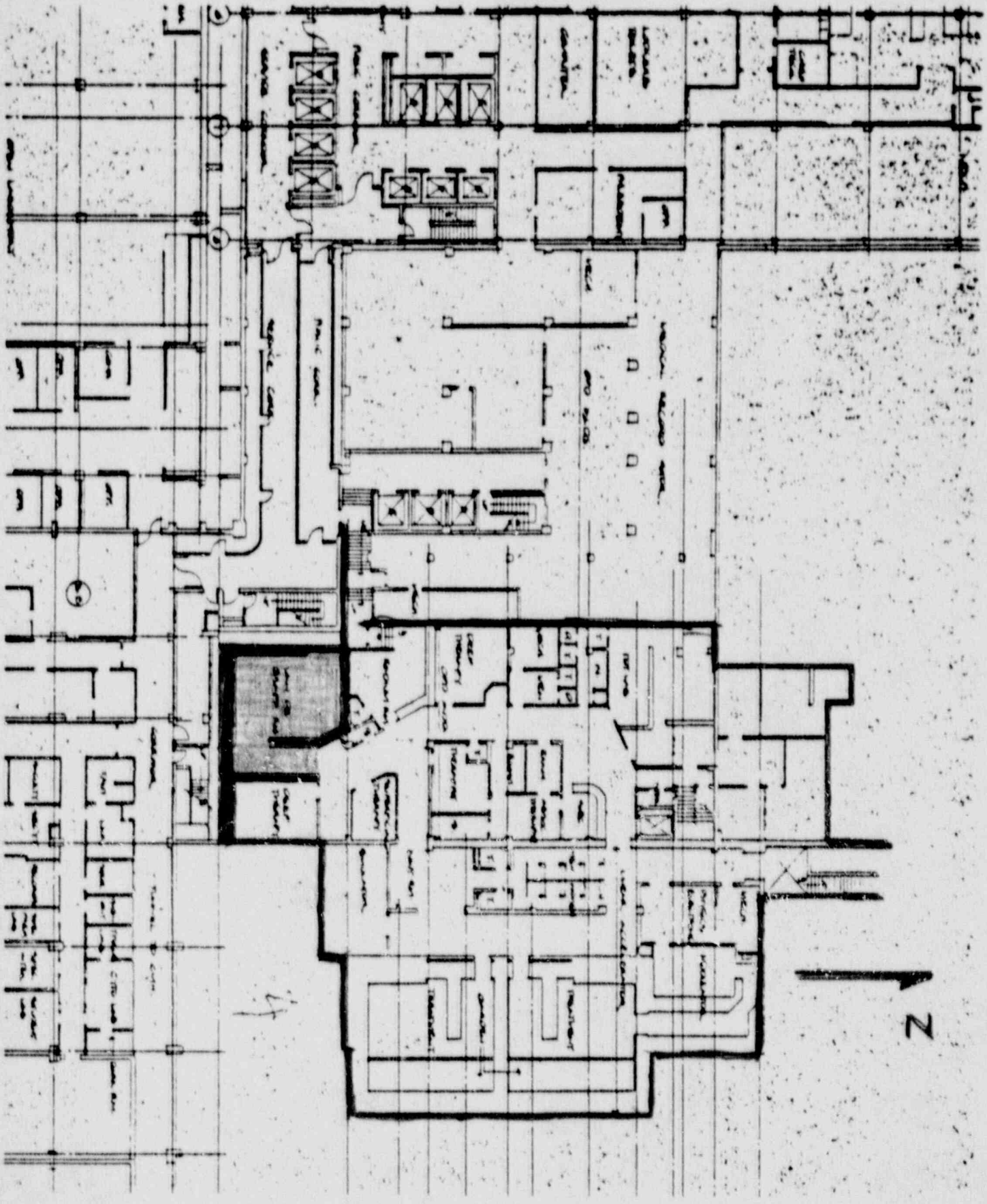
Harold B. Jacobson, M.D.
President

Secretary

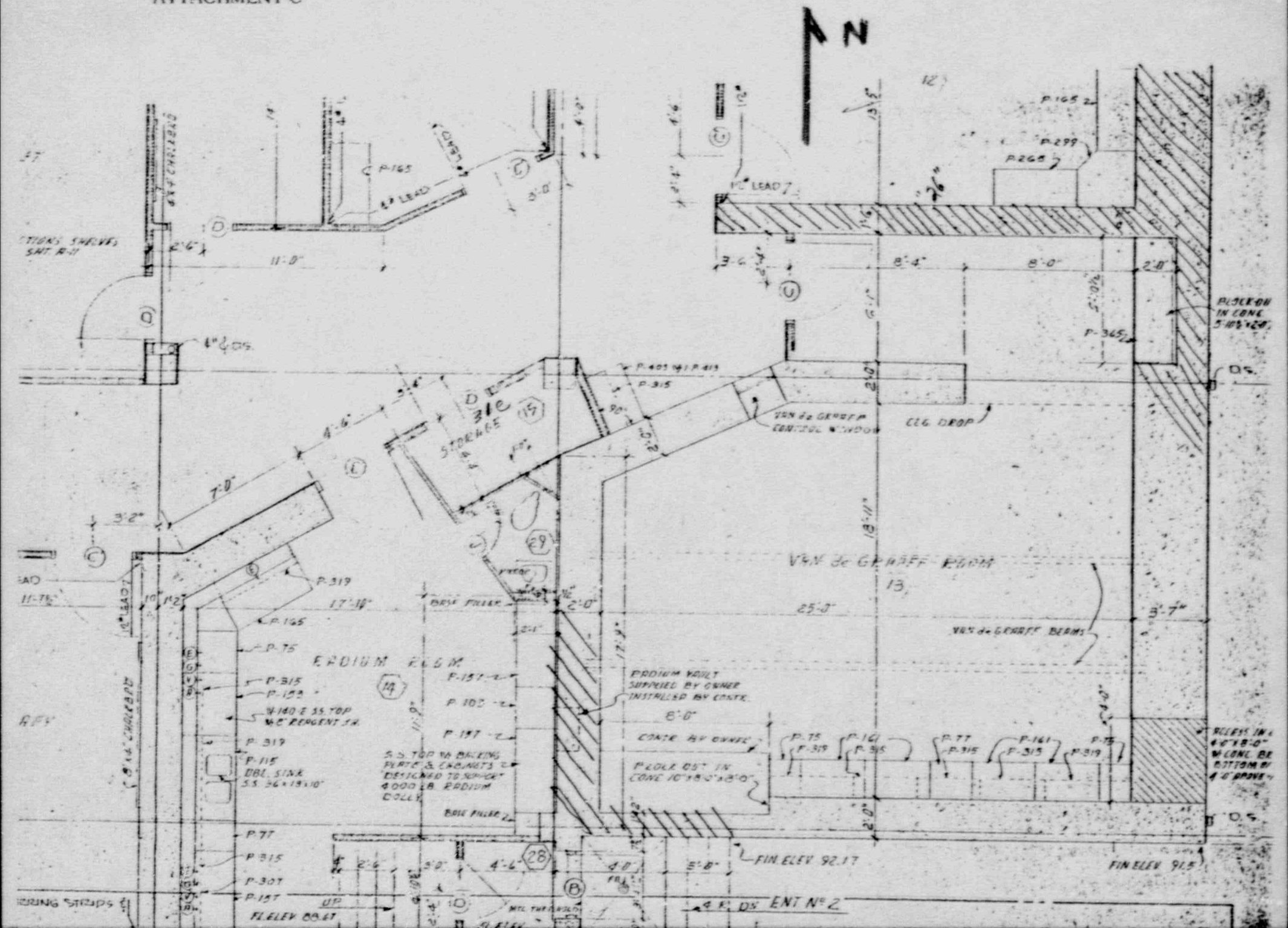
THE AMERICAN BOARD OF RADIOLOGY
INCORPORATED
IN THE
DISTRICT
OF
COLUMBIA
1934

AMERICAN BOARD
MEDICAL SPECIALTIES

ATTACHMENT B



ATTACHMENT C



ATTACHMENT D

OKLAHOMA MEDICAL CENTER
OKLAHOMA MEMORIAL HOSPITAL
OKLAHOMA CITY, OKLAHOMA

REMOTE AFTERLOADING SYSTEM

EMERGENCY PROCEDURES:

1. The patient will be viewed at all times through the viewing window and audio contact will be turned on. In case of any patient discomfort or problem, the decision for termination of the treatment will be taken by the physician. In the interest of the patient, the treatment will be completed.

2. In the event of complete failure of the system, or if the source is found to be stuck, use hand control to withdraw the source.

3. If power failure occurs, the backup battery system will enable all the sources to be returned to the shield. In case of malfuncation of the battery system, use hand control to withdraw the sources.

4. Estimate of the over exposure to personnel and patieennt will be made by the RSO and reported to NRC according to regulatory limitations.

5. Records of all system failures will be maintained.

6. All malfunctions will be immediately reported to the following persons.

   (i) Dr. B. Wally Ahluwalia, Ph.D.
   (ii) Dr. Carl R. Bogardus, M.D., F.A.C.R.
   (iii) Dr. William J. Graham, M.D.

ATTACHMENT E

OKLAHOMA MEDICAL CENTER
OKLAHOMA MEMORIAL HOSPITAL
OKLAHOMA CITY, OKLAHOMA

MICRO-SELECTRON-HDR IRIDIUM-192

REMOTE AFTERLOADING SYSTEM

OPERATING PROCEDURES:

1. The Micro Selectron-HDR is designated as a fail-safe device with the radiation source being withdrawn into the lead shield if any alarm or failure condition arises. It is impossible to send out the radiation sources unless an applicator is correctly connected and the simulator or dummy run has occurred.

2. The Micro Selectron-HDR has dual timers, one counting up and one counting down. One set of timers is started by the source leaving the safe of the unit and the other is set by the arrival of the source in its correct position in the applicator. The second gives the actual treatment time.

3. In the event of complete failure of the system, there is a hand-controlled winch which can withdraw the sources in approximately 5 seconds.

4. If a power failure occurs, the Selectron has a backup battery system to enable all the sources to be returned to the shielded safe and to maintain all treatment and patient data until the power is reconnected. When the power is reconnected, the treatment can be resumed after pressing the cancel alarm button.

5. When not in use, the control panel will be turned off and locked. The key will be kept with the technical director or his designee.

6. The console will be attended by a radiotherapy technologist at all times during the treatment.

7. A warning indicator is given for treatment in progress. If someone enters the treatment room without pressing the "interrupt" button, then the door interlock will cause a "stop treatment" and the radiation sources are automatically withdrawn into the shielded safe of the Selectron.

OPERATING PROCEDURES (continued)

8. Afterloading device will be used only when individuals who are trained in the use of the device and have practiced the emergency procedures are on-site.

9. Copies of operating end emergency procedures will be given to appropriate staff.

10. Daily Checks: On each day of use, checks consisting of the following items will be conducted.

    * Interlock
    * Reproducibility of source positions within catheter within 1 mm
    * Verification of source position indicators
    * Inspection of guide tubes for kinks and other imperfections

11. Treatment time calculations will be independently verified prior to commencement of treatment.

The American Board of Radiology

Organized through the cooperation of the
American College of Radiology, the American Roentgen Ray Society,
the American Radium Society, the Radiological Society of North America,
the Section on Radiology of the American Medical Association
and the American Society of Therapeutic Radiologists
Hereby certifies that

Bhagwat D. Ahluwalia, Ph.D.

Has pursued an accepted course of graduate study
and clinical work, has met certain standards and qualifications and
has passed the examinations conducted under the authority of
The American Board of Radiology
On this third day of June, 1983
Hereby demonstrating to the satisfaction of the Board
that he is qualified to practice the specialty of
Therapeutic Radiological Physics &
Diagnostic Radiological Physics

THE AMERICAN BOARD OF RADIOLOGY
INCORPORATED IN THE DISTRICT OF COLUMBIA
1934

AMERICAN BOARD OF SCIENCE IN NUCLEAR MEDICINE

The American Board of Science in Nuclear Medicine,
organized through the cooperation of
the American College of Nuclear Medicine,
the American College of Nuclear Physicians,
and The Society of Nuclear Medicine,

hereby certifies that

Bhagwat D. Ahluwalia, Ph.D.

has met established standards and qualifications,
and passed examinations conducted under its authority
June 23, 1980
thereby demonstrating to the satisfaction of the Board
the ability to practice Nuclear Medicine Science
in all its branches, with special competence in

Nuclear Medicine Physics and Instrumentation

President Vice President Secretary Treasurer