NRC FORM 313 (1-84) 10 CFR 30, 32, 33, 34, 35 and 40

EXHIBIT A

APPLICATION FOR MATERIAL LICENSE

U.S. NUCLEAR REGULATORY COMMISSION
APPROVED BY OMB 3150-0120 Expires: 5-31-87

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.

FEDERAL AGENCIES FILE APPLICATIONS WITH:

U.S. NUCLEAR REGULATORY COMMISSION
DIVISION OF FUEL CYCLE AND MATERIAL SAFETY, NMSS
WASHINGTON, DC 20555

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS, IF YOU ARE LOCATED IN:

CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, MAINE, MARYLAND, MASSACHUSETTS, NEW JERSEY, NEW YORK, PENNSYLVANIA, RHODE ISLAND, OR VERMONT, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION I
NUCLEAR MATERIAL SECTION B
631 PARK AVENUE
KING OF PRUSSIA, PA 19406

ALABAMA, FLORIDA, GEORGIA, KENTUCKY, MISSISSIPPI, NORTH CAROLINA, PUERTO RICO, SOUTH CAROLINA, TENNESSEE, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION II
MATERIAL RADIATION PROTECTION SECTION
101 MARIETTA STREET, SUITE 2900
ATLANTA, GA 30323

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION III
MATERIALS LICENSING SECTION
799 ROOSEVELT ROAD
GLEN ELLYN, IL 60137

ARKANSAS, COLORADO, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, SOUTH DAKOTA, TEXAS, UTAH, OR WYOMING, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
MATERIAL RADIATION PROTECTION SECTION
611 RYAN PLAZA DRIVE, SUITE 1000
ARLINGTON, TX 76011

ALASKA, ARIZONA, CALIFORNIA, HAWAII, NEVADA, OREGON, WASHINGTON, AND U.S. TERRITORIES AND POSSESSIONS IN THE PACIFIC, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION V
MATERIAL RADIATION PROTECTION SECTION
1450 MARIA LANE, SUITE 210
WALNUT CREEK, CA 94596

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTION.

1. THIS IS AN APPLICATION FOR (Check appropriate item)
- [X] A. NEW LICENSE
- [ ] B. AMENDMENT TO LICENSE NUMBER ____________
- [ ] C. RENEWAL OF LICENSE NUMBER ____________

2. NAME AND MAILING ADDRESS OF APPLICANT (Include Zip Code)
Cancer Treatment Center Partners
c/o William F. Demas, M.D.
320 N. Hametown Road
Akron, Ohio 44313

3. ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED
2375 Benden
Wooster, Ohio

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION
Dale E. Starchman, Ph.D.

TELEPHONE NUMBER
216-494-7353

SUBMIT ITEMS 5 THROUGH 11 ON 8½ x 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL
a. Element and mass number, b. chemical and/or physical form, and c. maximum amount which will be possessed at any one time.

6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE.

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.

9. FACILITIES AND EQUIPMENT.

10. RADIATION SAFETY PROGRAM.

11. WASTE MANAGEMENT.

12. LICENSEE FEES (See 10 CFR 170 and Section 170.31)
FEE CATEGORY
AMOUNT ENCLOSED $ previously submitted

13. CERTIFICATION. (Must be completed by applicant) THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, AND 40 AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948, 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

SIGNATURE—CERTIFYING OFFICER	TYPED/PRINTED NAME	TITLE	DATE
(signature) W F Demas	William F. Demas, M.D.	Authorized Agent	7/6/89

14. VOLUNTARY ECONOMIC DATA

a. ANNUAL RECEIPTS

[ ] <$250K	[ ] $1M–3.5M
[ ] $250K–500K	[ ] $3.5M–7M
[ ] $500K–750K	[ ] $7M–10M
[ ] $750K–1M	[ ] >$10M

b. NUMBER OF EMPLOYEES (Total for entire facility excluding outside contractors)

c. NUMBER OF BEDS

d. WOULD YOU BE WILLING TO FURNISH COST INFORMATION (Dollar and/or staff hours) ON THE ECONOMIC IMPACT OF CURRENT NRC REGULATIONS OR ANY FUTURE PROPOSED NRC REGULATIONS THAT MAY AFFECT YOU? (NRC regulations permit it to protect confidential commercial or financial—proprietary—information furnished to the agency in confidence)

[ ] YES [ ] NO

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	COMMENTS	APPROVED BY
app	July 8	7A	see 86218 for fee info	CP
AMOUNT RECEIVED	CHECK NUMBER		fee Paid	DATE
$3880			CONTROL NO. 87594	7/18/89

PRIVACY ACT STATEMENT ON THE REVERSE

Dale E. Starchman, Ph.D.
b. April 16, 1941, Wallace Idaho, m. Jane 1969, ch: Ann, Cindy, Julie, Mark

EDUCATION:
1963, B.S. (Physics), Pittsburg State University, Kansas
1965, M.S. (Radiation Biophysics), University of Kansas
1968, Ph.D. (Radiation Biophysics), University of Kansas

BOARD CERTIFICATIONS:
1973, American Board of Health Physics, Health Physics (comprehensive)
1978, American Board of Radiology, Radiological Physics (all sections)

ACADEMIC APPOINTMENTS (CURRENT):
Professor, Clinical Radiation Biophysics, Northeastern Ohio Universities College of Medicine (NEOUCOM)
Chairman, Clinical Radiation Biophysics Section (NEOUCOM)
Professor (Adjunct), Radiology, The University of Akron

HONORS AND AWARDS:
Outstanding Young Alumnus Award, Pittsburg State University, 1978
U.S.P.H.S. Radiological Health Trainee, 1966-68
Kappa Mu Epsilon, Honorary Mathematics Society
Sigma Xi, Honorary Scientific Society
Listed, Marquis Who's Who

ELECTED OFFICES:
Board Member at Large (National), AAPM Board of Directors, 1984-86
President, Penn-Ohio Chapter of AAPM, 1975-76
Recording Secretary, Midwest Chapter of AAPM, Centered in Chicago, 1970

CURRENT MEMBERSHIPS:
American Association of Physicists in Medicine (AAPM), Health Physics Society (HPS), American College of Radiology (ACR), Radiological Society of North America (RSNA), Sigma Xi, Kappa Mu Epsilon.

NATIONAL SOCIETY COMMITTEES:
Director, First Annual Summer School of Health Physics Society, 1978
Chairman, Summer School Sub-Committee of HPS, 1977-78
Member, HPS Education and Training Committee, 1975-78
Board Member, Mideast Region Radiological Physics Center Bd. of Advisors
Council Member, AAPM Education Council, 1980-83
Chairman, AAPM-American Assoc. Med. Dosimetrists Task Group, 1976-78
Liaison Member, Program Committee to Education Council, AAPM, 1980-83
Member, AAPM Diagnostic Radiology Task Group on Quality Control, 1975-
Chairman, Task Force for Syllabus and Review Text on Radiobiology for Residents in Diagnostic Radiology, RSNA, 1983-86. Member 1975-86.
Member, RSNA Associated Sciences Committee, 1978-86
Member, AAPM Committees: Technologists Liaison (1975-78), Insurance (1975-78), Program (1980-83), Continuing Education (1983-85), Ethics (1983-present), Finance (1987-present)

PAPERS:
More than 40 in research areas including selection, quality assurance and acceptance testing of diagnostic x-ray units; design of radiology facilities; effects of tissue inhomogeneities on electron therapy; radiation atrophy in bone; large field therapy swing technique; polymer dosimetry; photon spectra through thick shields; fetal effects, etc.

BOOKS AND MONOGRAPHS:
Co-author of ACR Planning Guide for Radiation Therapy Installations; 2 AAPM Diagnostic QA Monographs; RSNA Radiobiology Syllabus and Review Text (1st & 2nd editions, Editor of 3rd edition - published October 1986); and 2 chapters in Organ System Radiology, edited by Howland & Milier published by Thomas in 1984. Textbook: Ultrasound Physics and Instrumentation by Hykes, Hedrick, and Starchman, published N.Y., 1985 by Churchill Livingstone, Inc.

PAST POSITIONS:
Chief Health Physicist at IIT Research Institute (IITRI) and Radiological Physicist for Institute of Radiation Therapy at Mercy Hospital and Medical Center, Chicago,1968-71. Health Physics Division, Atomic Energy Commission Savannah River Plant and Lab, Aiken, South Carolina, Summers 1965 and 1966.

PRESENT POSITION (Since 1971):
President, Medical Physics Services, Inc. (7 person group of consultants to N.E. Ohio hospitals). Teaches residents, medical students & technologists.

Item 5 --- Radioactive Material

5.1 Sealed Sources to be Used in Teletherapy Unit

1. Radionuclide: Co-60

2. Manufacturer's name and model number: Neutron Products, NPTT-Series or Nordion International, Inc. (AECL) Model C-146 or C-151 or GE Model 106D3912 or similar standard series models manufactured by Neutron Products, GE, or AECL which are compatible with the Theratron 80 and have been approved for licensing purposes by the NRC.

3. Maximum Activity: 18,000 Curies (2 sources of not more than 9000 Curies each).

4. Maximum output from one source in unit: 9000 RHM

5.2 Teletherapy Unit

The unit will be an AECL Theratron Model 80 with an integral beam stop.

5.3 Depleted Uranium

The unit will incorporate and have associated with it depleted uranium used as shielding material.

April 1989
D.E.S.

Item 6 -- Purposes for which License Material will be Used

The teletherapy unit will be used for treatment of patients only.

Item 7 -- Persons Responsible -- Training and Experience

7.1 Proposed Authorized Users -- Human Use

1. William F. Demas, M.D.
   Certified by the American Board of Radiology in Therapeutic Radiology

2. Michael J. Seider, M.D.
   Certified by the American Board of Radiology in Therapeutic Radiology

7.2 Proposed Authorized Users -- Non-human Use -- n.a.

7.3 Proposed Radiation Safety Officer (RSO)
The RSO will be William F. Demas, M.D. (authorized user shown above)

7.4 Proposed Qualified Experts as described in 10CFR35.

The following teletherapy physicists (employed by Medical Physics Services, Inc.) meeting the qualifications of 10CFR35.961(a) will act as Qualified Experts for this installation:

1. Dale E. Starchman, Ph.D., Certified by the American Board of Radiology in Radiological Physics (all areas) and Certified by the American Board of Health Physics (comprehensive).

2. David L. Hykes, M.S., Certified by the American Board of Radiology in Radiological Physics (all areas).

3. Paul N. Shaheen, M.S., Certified by the American Board of Radiology in Therapeutic Radiological Physics.

4. Louis R. Milavickas, Ph.D., Certified by the American Board of Radiology in Therapeutic Radiological Physics and in Medical Nuclear Physics.

It is the intention of the applicant (subject to review and changes as the requirements of the facility evolve during operation) that radiological physics support by Medical Physics Services, Inc. include not just those tasks required to meet NRC requirements, but include on-site consultation at the level of 1 full day per week devoted to radiological physics and radiation protection.

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D.E.S.

Item 8 -- Training for individuals working in or frequenting restricted areas.

We have developed the training program described in attachment 8.

Item 9 -- Facilities and Equipment

An annotated drawing of the teletherapy area and a full shielding analysis report prepared by Dr. Starchman are appended as ATT 9. This includes a description of the facility and equipment, uses, safety system, etc.

Item 10 -- Radiation Safety Program

10.1 **Personnel Monitoring Program**

We have developed a Personnel External Exposure Monitoring Program which is appended as ATT 10.1.

10.2 **Instrumentation**

We have agreed to utilize instrumentation as described in Attachment 10.2.

10.3 **Calibration of Survey Instruments**

We will have all survey instruments calibrated by commercial services which have established and implemented the model procedure for calibrating survey instruments that was published in Appendix B to Regulatory Guide 10.8, Revision 2 (or equivalent as demonstrated by their having had their procedures approved by the NRC). The survey meter calibration service we plan to utilize is Health Physics Associates of Highland Park, Illinois.

10.4 **Leak Test Program**

We will perform leak tests as described in attachment 10.4.

10.5 **Operating Procedures**

We have developed operating procedures which are appended in attachment 10.5.

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D.E.S.

Personnel Training Program

Training will be provided for all employees operating the teletherapy unit or working routinely in the area of the teletherapy area before assuming these duties, annually as a refresher training, and whenever a significant change occurs in duties, regulations, or the terms of the NRC license.

Description of the Training Program
Training will be sufficient to ensure that:

A. Individuals who work in or frequent restricted areas are instructed in the items specified in 19.12 of 10 CFR Part 19, and

B. Individuals whose duties may require work in the immediate vicinity of radioactive materials are informed about radiation hazards and appropriate precautions.

Content of the Training Program

A. The program of instruction for teletherapy operators will include:

a. Pertinent terms and conditions of the NRC license, including procedures developed as a prerequisite for obtaining the license and commitments incorporated into the license by condition.

b. Appropriate response to emergencies or unsafe conditions, including participation by appropriate staff in "dry runs" of emergency procedures conducted as a part of the initial and annual refresher training.

c. Areas where radioactive material is used or stored.

d. Potential hazards associated with radioactive material.

e. Radiological safety procedures appropriate to the duties of the employee.

f. Pertinent NRC regulations.

g. The obligation of all personnel to report unsafe conditions to the radiation safety officer.

h. The right of all personnel to be informed of radiation exposure and bioassay results.

i. The locations where the licensee has posted or made available notices, copies of regulations, and copies of pertinent licenses and license conditions (including applications and applicable correspondence) as required by 10 CFR 19.

B. The program of instruction for non-operators (e.g. housekeeping personnel, etc.) will consist of items in A appropriate for duties each person is involved in.

Records That Document Training

Records of initial and refresher training will be maintained until the NRC terminates the teletherapy license and will include:

a. The name of the individual who conducted the training,

b. The names of the individuals who received the training,

c. The dates and duration of the training session, and

d. A list of the topics covered.

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April 1989
D.E.S.

Co-60 Shielding Analysis for Cobalt Room
in Office Facility to be constructed at
2375 Benden in Wooster, Ohio

The shielding analysis was made by Dale E. Starchman, Ph.D., Certified Radiological Physicist (all areas), American Board of Radiology and Certified Health Physicist (comprehensive), American Board of Health Physics, for cobalt-60 use. The materials below were prepared by Dr. Starchman so as to show only that information relevant to this application for license amendment.

All areas outside treatment room have been analyzed so as to permit unrestricted occupancy.

Note that the room shielding is sufficiently thick to permit the entire analysis to be made on the basis of worst case analysis and unrestricted occupancy outside the therapy room itself. This lends itself to a rather straight forward proof that with a cobalt-60 unit the room will meet all NRC shielding requirements. This very conservative approach also will result in operators, etc. receiving exposures well below permissible limits for occupationally exposed personnel in line with the ALARA program.

Figure I (floor plan), Figure II (vertical section plan), and Figure III (detail of measurement access ports) are enclosed. Worst case analysis with maximum field size and orientation for all patients for each barrier yielded less than 2 mR in any 1 hour in all cases with 100% occupancy. Electrical beam stops will be set so as to assure that the beam will be intercepted by the integral beam stop in such a manner that the beam is centered to the beam stop within ±3 degrees except when the beam is directed down within ±15 degrees of vertical at the floor. All concrete specifications are based on 147 lbs/cubic foot dried density. Leakage radiation with source on with the Theratron 80 is very small compared to scatter, especially since scatter is based on worst case analysis in terms of orientation and maximum field size so that shielding requirements are not materially affected by the leakage.

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D.E.S.

Co-60 Shielding Analysis for Cobalt Room
in Office Facility to be constructed at
2375 Benden in Wooster, Ohio
(continued)

Wall D-E:

Normal thickness of wall 24" concrete

45 degree scatter (calculated to point D")

WUT = 1000 R in any 1 hr at 1 meter
TVL = 7.8" concrete
a = ratio of scatter to incident primary radiation
= 0.0036 for 20 X 20 cm field or 0.0036 $(44/20)^2$
= 0.017 for 44 X 44 cm field at 100 cm corresponding to same solid angle as 35 X 35 cm field at 80 cm
d = 16 ft

$$\text{Rate} = \frac{(1{,}000\ \text{R/hr})(1000\ \text{mR/R})(0.017)(3.28/16)^2}{10^{24/7.8}}$$

= 714/1194 = 0.6 mR in any 1 hr

Actual rate will be much less than this because oblique thickness of wall to 45 degree scatter is 24"/sin 45 degrees = 33.9" concrete vs 24" used in above calculations.

90 Degree Scatter (calculated to point D')

TVL = 6.05"
a = 0.0009 for 20 X 20 cm field X $(44/20)^2$
= 0.0044 for 35 X 35 cm field at 80 cm
d = 12 ft

$$\text{Rate} = \frac{(1000\ \text{R/hr})(1000\ \text{mR/R})(0.0044)(3.28/12)^2}{10^{24/6.05}}$$

= 328/9267 = 0.04 mR in any 1 hour

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For purposes of this particular analysis, units of R, rad, and rem are assumed to be interchangeable (where 1 R = 1 rad = 1 rem = 1 cGy = 1 cSv).

Maximum field size 35 X 35 cm at 80 cm which corresponds to 44 X 44 cm at 100 cm. The ratio, a, of scattered to incident exposure available from Table B-2 of NCRP 49 is therefore corrected from 20 X 20 to 44 X 44 based on the ratio of $(44/20)^2$ at 100 cm to account for the difference in solid angle subtended by the scatterer.

Workload:

Assume an average of 4 patients/hr X 400R/patient at 80 cm which implies 1600 R/hr at 80 cm, or 1000 R/hr at 1 meter which is in agreement with NCRP 34 and NCRP 49 assumptions of W = 40,000 R/week at a meter for an 80 cm SSD unit and a caseload of 32 patients per day. Additional workload during periods involving more than 32 patients per day would be accomplished by extending the number of hours during which treatments would be performed to 10 hours in each of 5 days a week, which at up to 2 mR/hr would result in less than 100 mR/ week. Because all calculations are based on hourly rates, such added hours would not affect the conclusions of this analysis.

Use Factor:

Assume worst case (maximum field size and all patients in each hour treated using the critical orientation that produces highest radiation in an adjacent area).

Occupancy Factor:

Assume all areas to be "unrestricted areas".

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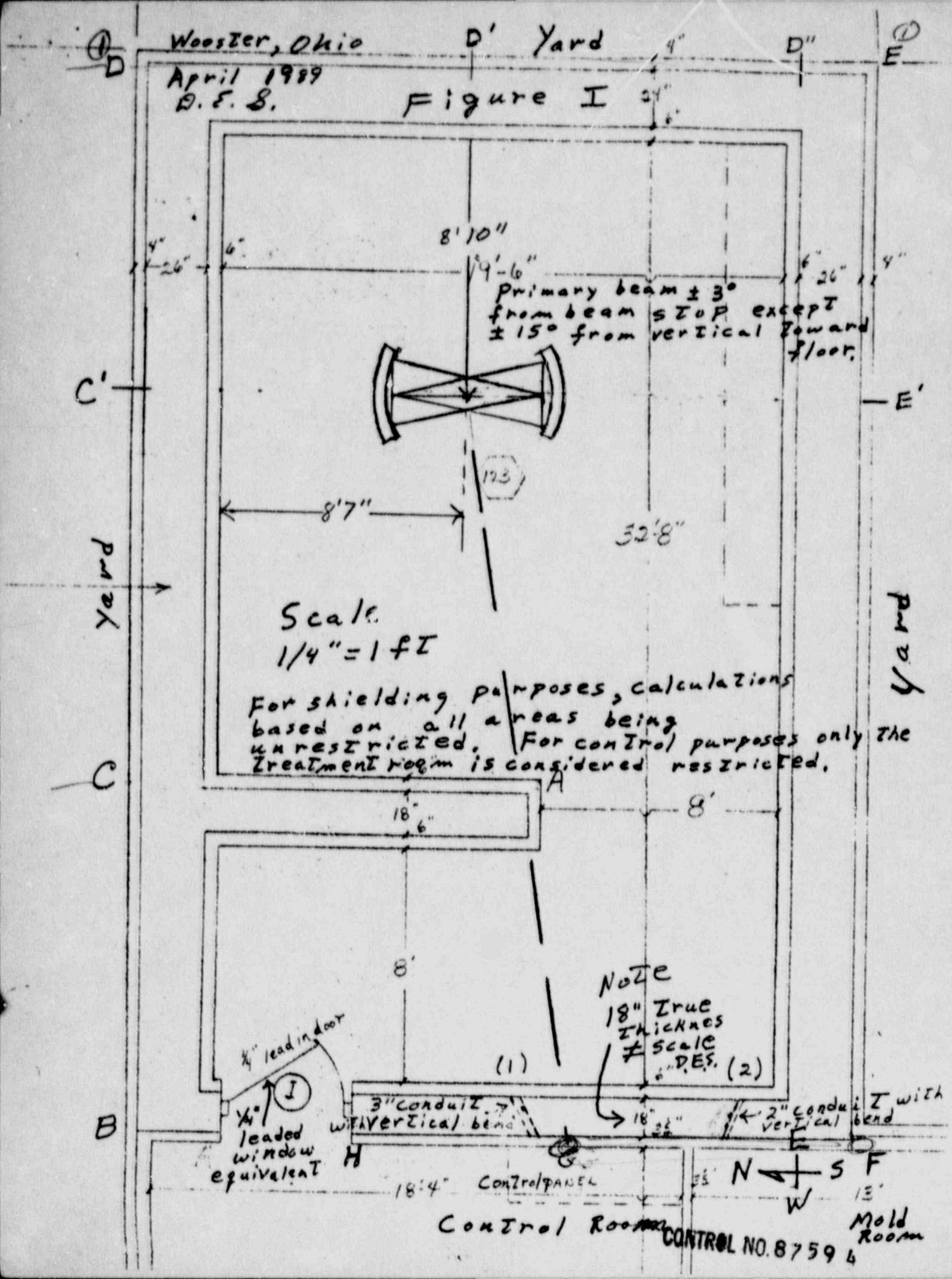

Wooster, Ohio
April 1989
D.E.S.
Figure I
D' Yard
D"
D
E
C'
E'
C
A
B
8'10"
9'-6"
26"
4"
6"
Primary beam ± 3° from beam stop except ± 15° from vertical toward floor.
123
8'7"
32'8"
Scale
1/4" = 1 ft
For shielding purposes, calculations based on all areas being unrestricted. For control purposes only the treatment room is considered restricted.
18"
8'
Note
18" True Thickness ≠ Scale
(1)
(2)
¼" lead in door
I
¼" leaded window equivalent
3" conduit with vertical bend
2" conduit with vertical bend
18'4"
Control Panel
Control Room
Mold Room
N
S
W
E
CONTROL NO. 87594

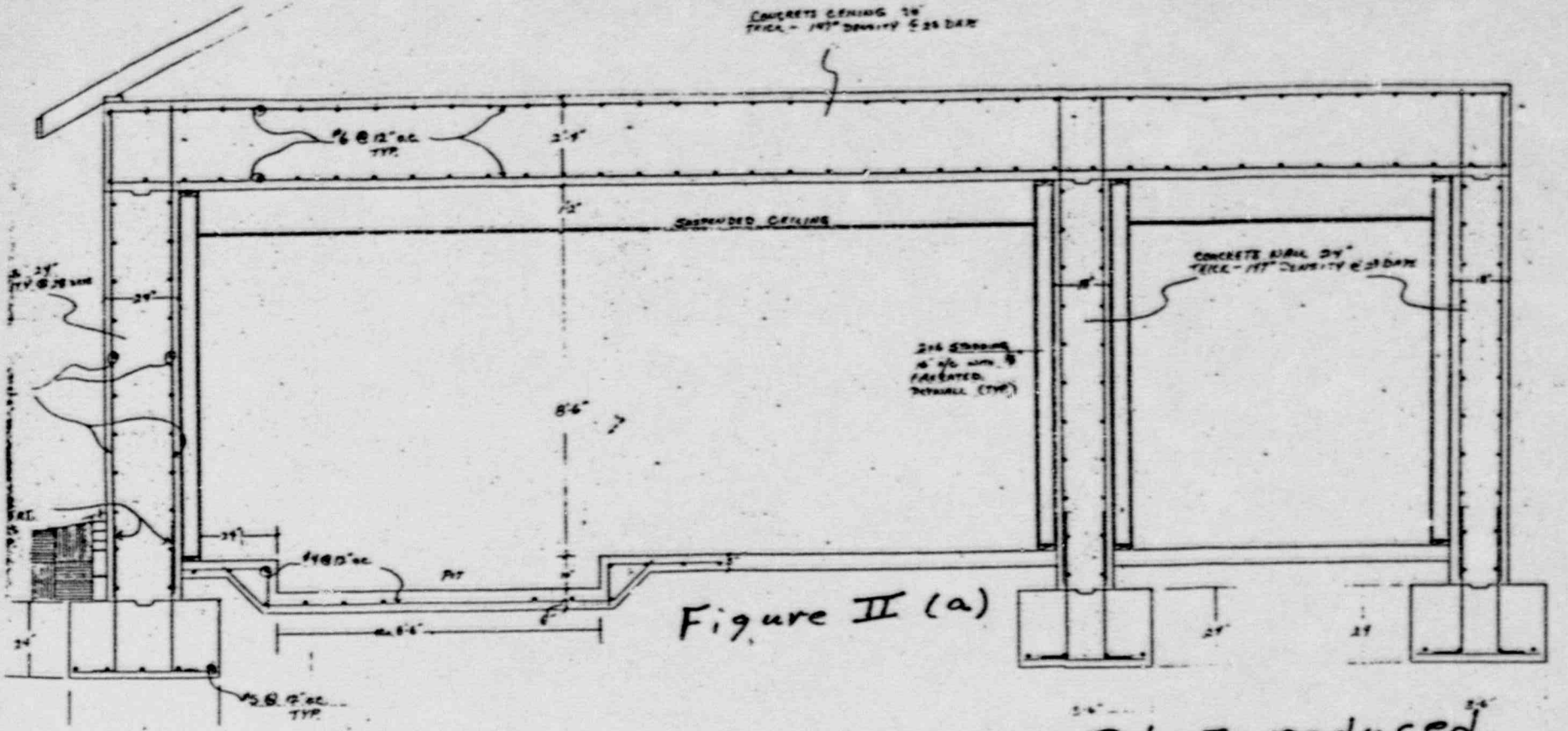


Figure II (a)

Photoreduced
— Not to scale

E ——— W

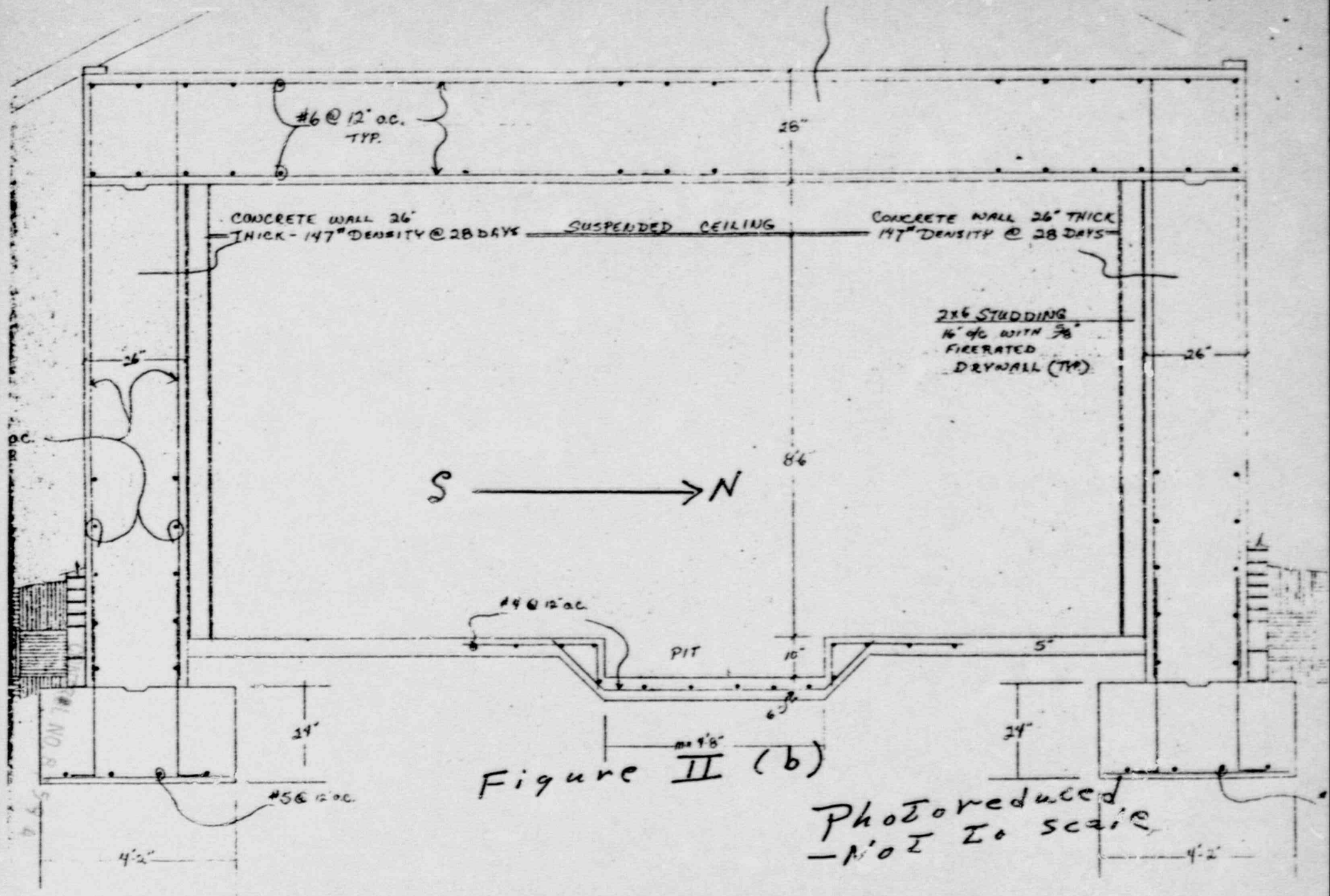


Figure II (b)

Photoreduced
— Not to scale

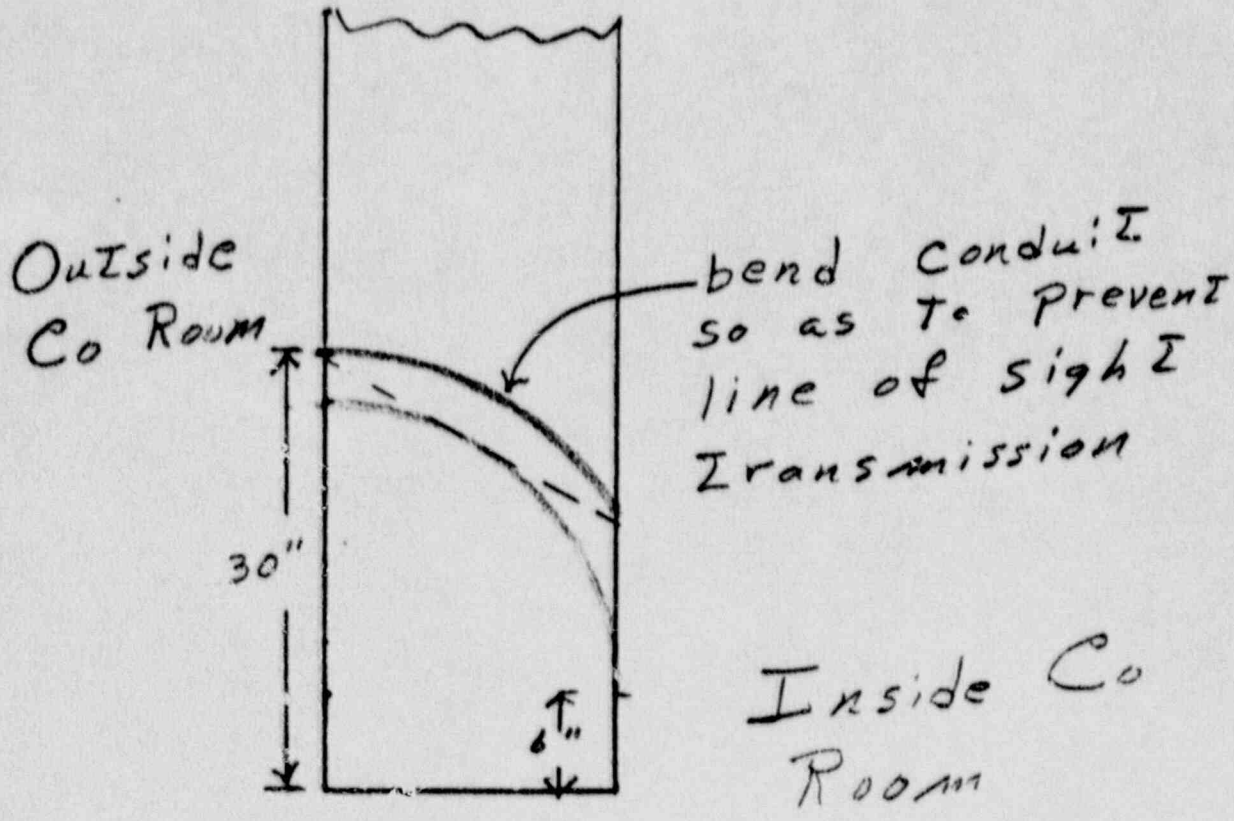
Figure III

Access for Measurements etc.

See floor plan

Conduit (1) — 3" diameter

Conduit (2) — 2" diameter



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April 1989

Co-60 Shielding Analysis for Cobalt Room
in Office Facility to be constructed at
2375 Benden in Wooster, Ohio
(continued)

Wall F-G:
Normal thickness of wall true 18" (≠ scale) concrete
60 degree scatter (calculated to point F)

WUT = 1000 R in any 1 hr at 1 meter
TVL = 7.6" concrete
a = 0.0023 for 20 X 20 cm field X $(44/20)^2$
= 0.011 for 35 X 35 cm field at 80 cm
d = 28 ft

$$\text{Rate} = \frac{(1{,}000\ \text{R/hr})(1000\ \text{mR/R})(0.011)(3.28/28)^2}{10^{18/7.6}}$$

= 151/234 = 0.6 mR in any 1 hr

Actual rate will be less than this because oblique thickness of wall to 60 degree scatter is 18"/sin 60 degrees = 21" concrete vs 18" used in above calculations.

Wall C-D (calculated to point C')
Primary beam TVL is 8.15" concrete vs 30 degree scatter TVL is 8.0" concrete. Transmission through beamstop is 0.1% vs 30 degree scatter to incident ratio is shown to be 2.9% below. Therefore primary beam transmission is negligible compared to 30 degree scatter consideration.

Worst case is represented by beam directed 30 degrees above or below horizontal so that 30 degree scatter impinges on wall with normal incidence at closest distance of 11.5 ft.

WUT = 1000 R in any 1 hr at 1 meter
TVL = 8" concrete
d = 11.5 ft
x = 26" concrete
a = scatter to incident ratio of 0.006 for 20 X 20 cm field or $0.006\ (44/20)^2 = 0.0290$ for 44 X 44 cm field at 100 cm corresponding to same solid angle as 35 X 35 cm at 80 cm.

$$\text{Rate} = \frac{(1000\ \text{R/hr})(1000\ \text{mR/hr})(0.0290)(3.28/11.5)^2}{10^{26/8}}$$

= 2359/1778 = 1.3 mR in any 1 hour

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Co-60 Shielding Analysis for Cobalt Room
in Office Facility to be constructed at
2375 Benden in Wooster, Ohio
(continued)

Wall E-F

See analysis for C-D. Wall is same thickness (26") and distance is greater for E-F.

Wall A-C

See analysis for F-G. Wall is same thickness (18") and distance to occupied areas is same for areas G-H-B if they were shielded by A-C alone from once scattered radiation only.

Wall G-H-B

In shadow of wall A-C. Not subjected to single scattered radiation. Subjected to twice scattered radiation only. Total thickness 18" concrete in wall with 1/4" leaded door and 1/4" leaded frame.

Ceiling

Ceiling is 2'4" = 28" thick (covers to outside of all concrete walls, including outer maze wall). Total distance is 12 ft from floor to top of roof. This corresponds to a distance of approximately 9' from isocenter to top of roof.

Primary beam TVL is 8.15" concrete vs 30 degree scatter TVL is 8.0" concrete. Transmission through beamstop is 0.1% vs 30 degree scatter to incident ratio is shown to be 2.9% below. Therefore primary beam transmission is negligible compared to 30 degree scatter consideration.

Worst case is represented by beam directed 30 degrees to North or South of vertical up so that 30 degree scatter impinges on ceiling with normal incidence at closest distance of 9 ft.

WUT = 1000 R/hr in any 1 hr at 1 meter
TVL = 8" concrete
d = 9 ft
x = 28" concrete
a = scatter to incident ratio of 0.006 for 20 X 20 cm field or $0.006\ (44/20)^2 = 0.0290$ for 44 X 44 cm field at 100 cm.

$$\text{Rate} = \frac{(1000\ \text{R/hr})(1000\ \text{mR/hr})(0.0290)(3.28/9)^2}{10^{28/8}}$$

$$= 3852/3162 = 1.2\ \text{mR in any 1 hour}$$

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Floor

Floor is slab on grade with no occupancy or crawl space below the floor or at a level adjacent to and below the finished floor.

Voids

All services will enter the room above door (in shadow of maze wa?l) at a height of greater than 7 ft above the finished floor. The only voids planned other than conduits in the floor are the 3" diameter measurement access port labeled (1) and the 2" diameter measurement access port labeled (2) in Figure I as detailed in Figure III. Any necessary recesses in walls will be backed with equivalent lead.

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Office Facility at 2375 Benden
Wooster, Ohio

D.E.S.
April 1989

Radiation Warning and Control

1. Room will be provided with an electrical interlock on door which prevents treatment starting with door open and which stops treatment when door is opened. When treatment is stopped by opening door, unit must be reset at control panel to re-start treatment when door is closed.

2. Room will be provided with a radiation warning light outside the teletherapy room which indicates when the beam is on and emitting a useful beam of radiation and indicating when the beam is off.

3. This room will be provided with a proper radiation warning sign on the door indicating the presence of a high radiation area within the room. The room will be locked and the console key will be turned to the off position and removed when not attended by radiation oncology personnel.

4. This room will be provided with an emergency button within the room which may be used to completely turn off the unit in case of an emergency. In order to resume treatments with the unit, it will require resetting and re-initiating all treatment procedures.

5. Patient viewing in this room will be provided with a closed circuit television. A mirror system and leaded glass window will be installed so as to provide a backup system if the TV system malfunctions.

6. An intercom system will be provided to maintain voice contact with the patient during the treatment.

7. The teletherapy room will be equipped with a radiation monitoring device which continuously monitors the teletherapy beam condition and is equipped with a back-up battery power for emergency operation. This device will energize a visible signal to make the operator continuously aware of teletherapy beam condition in order that appropriate emergency procedures may be instituted to prevent unnecessary radiation exposure. Operating procedures will require daily operational testing of the installed radiation monitor.

8. Whenever the continuous radiation monitoring device is not operational, any person entering the teletherapy room following an irradiation will enter with an operable, calibrated radiation survey survey meter and shall determine the beam condition.

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Radiation Warning and Control
(continued)

9. Prior to initiation of the treatment program, the teletherapy unit will be equipped with electrical or mechanical stops limiting use of the primary beam of radiation so as to ensure compliance with Section 20.105(b), Title 10, Part 20, Code of Federal Regulations, Chapter 1, "Standards for Protection Against Radiation," as evidenced by a radiation survey. Necessary use restrictions shall be fully described in radiation survey reports submitted to the NRC. It is assumed that these stops will be set so as to assure that the beam will be intercepted by the integral beam stop in such a manner that the beam is centered to the beam stop within ±3 degrees except when the beam is directed down within ±15 degrees at the floor.

10. Prior to initiation of the treatment program, radiation surveys and tests shall be performed in accordance with the following:

A. An initial radiation survey shall be made by the person responsible for design analysis of structural shielding, D.E. Starchman, Ph.D., Certified Health Physicist and Certified Radiological Physicist, or if he is not available by one of the teletherapy physicists listed in the application (all of whom are certified by the ABR in areas including therapeutic radiological physics).

(i) The teletherapy source housing, with he teletherapy source in the "off" position. The maximum and average radiation levels at one meter from the teletherapy source in the "off" position shall not exceed 10 milliroentgens per hour and 2 milliroentgens per hour, respectively.

(ii) All areas adjacent to the treatment room with the teletherapy source in the "on" position. The survey, except Item (c), shall be performed with a phantom in the primary beam of radiation and shall clearly establish:

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Radiation Warning and Control
(continued)

(a) That radiation levels in restricted areas are not likely to cause personnel exposure in excess of the limits specified in Section 20.101, Title 10, Part 20, Code of Federal Regulations, Chapter 1, "Standards for Protection Against Radiation" (10 CFR 20).

(b) That quantities of radiation in unrestricted areas do not exceed the limits specified in Section 20.105(b), 10 CFR 20.

(c) The intensity of the primary beam of radiation at a specified distance from the teletherapy source.

B. Tests shall be made to determine proper operation of:

(i) Electrical interlocks on entrance doors to the teletherapy treatment room.

(ii) The teletherapy source "on-off" indicators, both at the source housing and on the teletherapy machine control panel.

(iii) Electrical or mechanical stops installed for the purpose of limiting use of the primary beam of radiation (restriction of source housing angulation or elevation, carriage or stand travel and operation of the beam "on-off" mechanism).

(iv) The teletherapy treatment timing device.

C. A report of the results of the above surveys and tests shall be sent to the Material Licensing Section, U.S. Nuclear Regulatory Commission Region III, 799 Roosevelt Road, Glen Ellyn, Illinois 60137, not later than thirty (30) days following each installation of a teletherapy source. A copy of such report shall be sent to the U. S. Nuclear Regulatory Commission Region III, 799 Roosevelt Road, Glen Ellyn, Illinois 60137.

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Personnel External Exposure Monitoring Program

1. The RSO will promptly review all exposure reports to look for workers or groups of workers whose exposure is unexpectedly high or low. This procedure does not apply to backup monitor records, for example, pocket ionization chambers, when the monitor of record is a film or thermoluminescence dosimeter (TLD).

2. All individuals who are occupationally exposed to ionizing photon radiation on a regular basis (radiation oncologists, medical physicists, and radiation therapy technologists) will be issued a film or TLD whole body monitor as deemed appropriate by the RSO. The monitoring devices will be processed by a contract service on a monthly basis by a qualified commercial service such as R.S. Landauer, Jr., Inc.

3. Other individuals who are exposed to radiation on an occasional basis (such as security personnel, secretarial personnel, housekeeping personnel, and nurses) who may work in the building but who spend a small fraction of their time in the console area or treatment room will not normally be issued exposure monitors.

ATT 10.1
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D.E.S.

Instrumentation

We agree to have the following radiation instruments in our possession and available for use:

1. Survey meter capable of detecting 0.1 mR/hr to 100 mR/hr.

2. A beam-on radiation monitor permanently mounted in the teletherapy room that is equipped with an emergency power supply separate from the power supply for the teletherapy unit. The beam-on monitor will be capable of providing a visible indication (e.g., flashing light) of an exposed or partially exposed source, and the visible indicator will be observable by a person entering the teletherapy room.

3. A dosimetry system for making full calibration and spot-check measurements (or have access to it).

4. An instrument of sufficient sensitivity to count leak test samples, e.g., a NaI(Tl) well crystal connected to a single or multichannel analyzer (or have access to it).

ATT 10.2
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D.E.S.

Leak Test Procedures

One of the teletherapy physicists listed in ATT 7.4 acting as qualified experts for this installation will perform leak tests as follows:

A moistened Q-tip or filter paper, etc will be used to wipe the nearest accessible surfaces to the source (e.g. collimator blades). The wipe test will then be removed to a low background area where it will be checked with a low level GM survey meter to assure that no activity above background is present on it. If there is no detectable radioactivity on the leak test, it will be treated as non-radioactive material and will be counted on a NaI crystal connected to an analyzer.

Counting efficiency will be determined using a Co-60 or Cs-137 check source of 1 uCi or less. Calculations will be performed to demonstrate that leak test is less than 0.05 uCi in a statistically valid manner.

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D.E.S.

Operating Procedures

1. The teletherapy room shall be locked when the area is unattended. The console shall be turned off and the key removed when the area is unattended.

2. Before the source is moved to the on position, the room shall be visually checked to assure that no one except the patient is in the room. If the operator leaves the area or it would otherwise be possible for someone else to enter the room without the operator's knowledge between the time the patient is set-up and the time the source is moved to the on position, the room must be checked again before moving the source to the on position.

3. Daily checks shall be made of the room radiation monitor by using a dedicated check source. A record of the checks shall be maintained for 2 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. If the radiation monitor is inoperable, any individual entering the teletherapy room must 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. This must be added to the above described records. The radiation monitor shall be promptly repaired or replaced if it is inoperable.

4. Prior to ordering a teletherapy source the RSO and a teletherapy physicist will review the NRC license conditions to assure that the source conforms to that authorized. Radioactive materials contained in teletherapy sources or as part of the teletherapy unit (e.g. depleted uranium used as shielding material) will be disposed of through transfer to an authorized recipient (e.g. source manufacturer). The NRC must be notified in writing when it is decided that all activities involving radioactive materials authorized by NRC will be discontinued.

5. The teletherapy unit is to be operated by or under the supervision of an authorized user (Dr. Demas and/or Dr. Seider). Such operation for treatment of patients will be by a person with appropriate training (e.g. radiation therapy technologist). Operation by a teletherapy physicist or by an authorized repair person will be performed as required by their functions. The primary beam is to be directed within ±3 degrees of the center of the beam stop except that it may be directed vertically toward the floor (±15 degrees).

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6. The door to the cobalt room is **never** to be closed when anyone other than the patient is in the teletherapy room.

7. After assuring that no one other than the patient is in the teletherapy room, the operator will set the timer and turn the beam on. The operator shall stay in the area so as to be able to observe the patient, console, indicator lights outside the cobalt room, and the entrance to the room while the treatment proceeds. When the treatment is completed the operator will note the indicator lights at the console, above the door, and on the room monitor prior to entering the room.

8. For mechanical safety of the unit and of the patient, the unit is not to be rotated from outside the room except for rotational therapy and associated measurements. If such rotational mode is to be performed, following each final setup every day, just prior to treatment, the unit is to be carefully rotated by the technologist using the hand control in the teletherapy room with the beam off. Care shall be exercised to assure that no collision between the gantry and the couch or patient is possible.

9. Full calibration measurements shall be performed by a teletherapy physicist as authorized by the NRC license. The instrument calibration requirements and the extent and frequency of the measuremnts shall be as specified in 10CFR35.632.

10. Periodic spot checks shall be made as described in 10CFR 35.634(a). This description currently includes monthly checks of timer constancy, timer linearity, on-off error, coincidence of radiation field and light field, accuracy of all distance measuring and localization devices used for medical use, and standard measured output vs expected output. These procedures will be performed in accordance with procedures established by a teletherapy physicist who will review the results within 15 days and promptly notify the licensee in writing, of the results of each spot-check. Once each month the safety spot-checks described in 10CFR 35.634(d) will be performed. This description currently includes electrical interlocks on door, stops on angulation of primary beam, beam condition lights, viewing systems, and treatment room doors. Arrangements will be made for prompt repair of any system in 35.634(d) which is not operating properly. Following door interlock malfunction, the teletherapy unit will not be used until repairs are made. Records of all periodic spot checks will be maintained using the schedule of and containing the information described in 10CFR 35.634.

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11. Film badges will be worn by all persons to whom they have been assigned by the RSO at all times when they are in the teletherapy and simulator areas. They are not to be left in radiation areas. They are to be exchanged and processed promptly each month. If a person receives or suspects he or she has received a high exposure, the RSO and teletherapy physicist is to be notified immediately.

12. The survey meter is to be checked each day of use. The survey meter is to be calibrated once a year by an authorized facility.

13. The teletherapy unit shall be fully inspected and serviced during source replacement or at intervals not to exceed 5 years, whichever comes first.

14. Condition 21 of the teletherapy license requires that only persons or firms specifically authorized by NRC or an Agreement State can: install, relocate, or remove teletherapy units containing sources; perform source exchanges; perform any maintenance or repair of the teletherapy unit that involves work on the source drawer, the shutter, or other mechanism that could expose the source, reduce the shielding around the source, or compromise the safety of the unit and result in increased radiation levels. Note that on the Theratron 80 the light bulb in the field size indicator is related to the source drawer assembly and is to be replaced only by a person or firm so authorized by the NRC.

15. Records shall be maintained by and be readily available at the console and/or from the office of the RSO including copies of NRC license application, correspondence with the NRC in support of a license request, record of results of safety device checks, personnel dosimetry records, records of survey instrument calibration, records of daily checks of beam-on monitor, records of calibration of the dosimetry system used for full calibration measurements, records of calibration or intercomparison of the dosimetry system used for spot check measurements, results of full calibration measurements, results of spot check measurements, record of evaluation of the training and experience of the "qualified expert" as defined in 10CFR 35.24, records of leak test results, records of training of new personnel and annual refresher training of personnel, records of full inspection and servicing of the teletherapy unit, copies of reports of surveys conducted in accordance with Conditions 18 and 19 of the teletherapy license, and records of receipt and disposal of radioactive material.

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CONTROL NO. 8759 4

16. In the event of an accident or unusual occurence such as teletherapy unit malfunction or misadministration, immediately notify the RSO, teletherapy physicist, and authorized user as appropriate using telephone numbers listed on Emergency Procedures posted at console.

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D.E.S.

Item 10.6 --- Emergency Procedures

We have developed emergency procedures which are appended in ATT 10.6.

Emergency Procedures for Beam Control Failure or Malfunction

If the light signals or beam-on monitor indicate that the beam control mechanism has failed to terminate the exposure at the end of the preset time (e.g. if the red light stays on and the green light is off, or if both the red and the green lights stay on for more than a few seconds), the source may still be in the on position. The operator shall **not attempt to manually close the source drawer** because normally the time and exposure required to remove the patient and secure the area will be less than that required to attempt to close the drawer. The following steps are to be carried out promptly and in a calm manner by the Radiation Therapy Technologist:

1. Open the door to the treatment room.

2. If the patient is ambulatory, tell him or her to get off the table and leave the room.

3. If the patient is not ambulatory, enter the treatment room but avoid exposure to the direct beam. Pull the treatment table as far away from the direct beam as possible. Transfer the patient to a stretcher and remove the patient from the room.

4. Close the door and secure the area by locking the door to the treatment room.

5. Turn off the main switch at the control panel.

6. Notify the radiation therapist, radiation safety officer, and teletherapy physicist at once.

7. Conspicuosly post a sign in the area to warn others of the problem.

8. In addition to the above, unless there is some other **critical** factor such as a serious hazard to the patient, **the operator should personally guard the door until the RSO, teletherapy physicist, or manufacturer's representative is physically present.**

ATT 10.6
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D.E.S.

Emergency Procedures for Beam Control Failure or Malfunction
(continued)

Radiation Therapist _____

Phone No.: On Duty _____ Off Duty _____

Radiation Safety Officer _____

Phone No.: On Duty _____ Off Duty _____

Teletherapy Physicists: Call any teletherapy physicist whose location is known **and** call Dale E. Starchman, Ph.D. at 216-494-7353 day or night. Messages may be left but continue calling all teletherapy physicists until one is personally made aware of the situation.

10.7 ALARA Program

We have developed an ALARA program which is appended as ATT 10.7.

Program for Maintaining Occupational Radiation Exposures at Medical Institutions ALARA

1. Management Commitment

a. We, the management of this private practice are committed to the program described in this document for keeping exposures (individual and collective) as low as is reasonably achievable (ALARA). In accord with this commitment, we hereby describe an administrative organization for radiation safety and will develop the necessary written policy, procedures, and instructions to foster the ALARA concept within our institution.

b. We will perform a formal annual review of the radiation safety program including ALARA considerations. This will include reviews of operating procedures and past exposure records, inspections, and consultations with the radiation staff or outside consultants.

c. Modifications to operating and maintenance procedures and to equipment and facilities will be made if they will reduce exposures unless the cost, in our judgment, is considered to be unjustified. We will be able to demonstrate, if necessary, that improvements have been sought, that modifications have been considered, and that they have been implemented where reasonable. We will be prepared to describe the reasons for not implementing them.

d. In addition to maintaining doses to individuals as far below the limits as is reasonably achievable, the sum of the doses received by all exposed individuals will also be maintained at the lowest practical level. It would not be desirable, for example, to hold the highest doses to individuals to some fraction of the applicable limit if this involved exposing additional people and significantly increasing the sum of radiation doses received by all involved individuals.

2. Radiation Safety Officer

a. Review of Proposed Users and Uses.

(1) The RSO will thoroughly review the qualifications of each applicant with respect to the types and quantities of materials and uses for which that person has applied to ensure that the applicant will be able to take appropriate measures to maintain exposure ALARA.

(2) When considering a new use of byproduct material, the RSO will review the efforts of the applicant to maintain exposure ALARA. The user should have systematized procedures to ensure ALARA and should have incorporated the use of special equipment.

(3) The RSO will ensure that the user justifies his procedures and that doses will be ALARA (individual and collective).

b. Review of ALARA Program

(1) The RSO will encourage all users to review current procedures and to develop new procedures as appropriate to implement the ALARA concept.

(2) The RSO will perform a quarterly review of occupational radiation exposure with particular attention to instances in which Investigational Levels in Table J-I are exceeded. The principal purpose of this review is to assess trends in occupational exposure as an index of the ALARA program quality and to decide if action is warranted when Investigational Levels are exceeded.

(3) The RSO will evaluate the institution's overall efforts for maintaining exposures ALARA on an annual basis. This review will include the efforts of the RSO, authorized users, and workers as well as those of management.

Education Reponsibilities for an ALARA Program

(1) The RSO will schedule briefings and educational sessions to inform workers of ALARA program efforts.

(2) The RSO will ensure that authorized users, workers and ancillary personnel who may be exposed to radiation will be instructed in the ALARA philosophy and informed that management and the RSO are committed to implementing the ALARA concept.

d. Cooperative Efforts for Development of ALARA Procedures

Workers will be given opportunities to participate in formulation of the procedures that they will be required to follow.

(1) The RSO will be in close contact with all authorized users and workers in order to develop ALARA procedures for working with radioactive materials.

(2) The RSO will establish procedures for receiving and evaluating the suggestions of individual workers for improving health physics practices and will encourage the use of those procedures.

e. Reviewing Instance of Deviation from Good ALARA Practices

The RSO will investigate all known instance of deviation from good ALARA practices, and if possible, determine the causes. When the cause is known, the RSO will require changes in the program to maintain exposures ALARA.

3. Authorized Users

a. New Procedures Involving Potential Radiation Exposures

(1) The authorized user will consult with and receive the approval of the RSO during the planning stage before using radioactive materials for a new procedure.

(2) The authorized user will evaluate all procedures before using radioactive materials to ensure that exposures will be kept ALARA. This may be enhanced through the application of trial runs.

b. Responsibility of the Authorized User to Those Supervised

(1) The authorized user will explain the ALARA concept and the commitment to maintain exposures ALARA to all of those supervised.

(2) The authorized user will ensure that workers under his or her supervision are trained and educated in good health physics practices and in maintaining exposures ALARA.

4. Workers

a. Workers will be instructed in the ALARA concept and its relationship to their working procedures and working conditions.

b. Workers will know what resources are available if they believe that ALARA is not being promoted on the job.

5. Establishment of Investigational Levels to Monitor Individual Occupational External Radiation Exposures

This private practice facility hereby establishes Investigational Levels for occupational external radiation exposure that, when exceeded, will initiate review or investigation by the RSO. The Investigational Levels apply to the exposure of individual workers.

Table J-I

	Investigational Levels (mrem per calendar quarter)	
	Level I	Level II
Whole body, head and trunk, active blood-forming organs, lens of eyes, or gonads	125	375
Hands and forearms, feet and ankles	1875	5625
Skin of whole body*	750	2250

*Not normally applicable to nuclear medicine or teletherapy operations.

The RSO will review and record on Form NRC-5, "Current Occupational External Radiation Exposures," or an equivalent form (e.g., dosimeter processor's report) the results of personnel monitoring at least once in any calendar quarter. The exposures will be compared with the Investigational Levels in Table J-I and the following actions will be taken:

a. Quarterly exposure of individuals less than Investigational Level 1

Except when deemed appropriate by the RSO, no further action will be taken in those cases in which an individual's exposure is less than Table J-I values for Investigational Level I.

b. Quarterly personnel exposure equal to or greater than Investigational Level I, but less than Investigational Level II

The RSO will review the exposure of each individual whose quarterly exposure equals or exceeds Investigational Level I. If the exposure does not equal or exceed Investigational Level II, no action related specifically to the exposure is required unless deemed appropriate by the RSO. The RSO, will however, consider each such exposure in comparison with those of others performing similar tasks as an index of ALARA program quality and will record the review.

c. Quarterly personnel exposure equal to or greater than Investigational Level II

The RSO will investigate in a timely manner the causes of all personnel exposures equaling or exceeding Investigational Level II and, if warranted, take action. A report of the investigation, actions taken, if any, and a copy of the individual's Form NRC-5 or its equivalent will be recorded following completion of he investigation. The RSO's minutes will be sent to the management of the institution for review. The minutes, containing details of the investigation, will be made available to NRC inspectors for review at the time of the next inspection.

d. Establishment of an individual worker's Investigational Level II above that listed in Table J-I

If a worker or a group of workers needs to exceed Investigational Level II, a new, higher Investigational Level II may be established on the basis that it is consistent with good ALARA practices for that individual or group. Justification for a new Investigational Level II will be documented.

The RSO will review the justification for, and will approve, all revisions of Investigational Level II. In such cases, when the exposure equals or exceeds the newly established Investigational Level II, those actions listed in paragraph c will be followed.

ATT 10.7
April 1989
D.E.S.

10.8 **Radiation Safety Committee**

Not applicable to private practice physicians.

Item 11 --- **Waste Management**

Radioactive materials contained in teletherapy sources or as part of the teletherapy unit (e.g. depleted uranium used as shielding material) will be disposed of through transfer to an authorized recipient (e.g. source manufacturer).

Item 12 --- **License Fees**

The fee of $580 for human use of byproduct material, source material, or special nuclear material contained in teletherapy devices (10CFR170 category 7A application - new license) has already been paid. Refer to control number 86218.

Medical Physics Services, Inc.

5942 EASY PACE CIRCLE, N.W.
CANTON, OHIO 44718
216-494-7353

Wayne R. Hedrick, Ph.D.
Certified Diagnostic Radiological and Medical Nuclear Physicist, ABR

Clinical Radiation Biophysicists
Ronald G. Johnson, Ph.D.
Susy Isaac Alunkal, M.S.

Northeastern Ohio Universities College of Medicine
216-438-6200 (Aultman Hospital)

Dale E. Starchman, Ph.D., President
Certified Radiological Physicist, ABR
Certified Health Physicist, ABHP

David L. Hykes, M.S.
Certified Radiological Physicist, ABR

Louis R. Milavickas, Ph.D.
Certified Therapeutic Radiological and Medical Nuclear Physicist, ABR

Paul N. Shaheen, M.S.
Certified Therapeutic Radiological Physicist, ABR

April 30, 1989

William F. Demas, M.D. / Michael J. Seider, Ph.D., M.D.

Attn: Radiation Oncologists of Akron, Inc.
Akron City Hospital
525 East Market St.
Akron, Ohio 44304

Gentlemen:

Enclosed is an application for an NRC license which should be reviewed by each of the parties involved in this project in order to assure that all are in agreement that conditions are achievable and acceptable and that assumptions are accurate. The cover letter to the NRC should then be re-typed on the letterhead of the responsible organization and signed by the Chief Executive Officer or his designee with "contractual authority" in the organization legally responsible for owning and operating the cobalt unit. A check in the amount of $580.00 must normally accompany an application for a teletherapy license. This fee was already submitted to the NRC by Dr. Demas in October 1988 (see copy of NRC response enclosed including control number by Ms. Kathy Graden, who specifically reviews teletherapy license applications).

I have prepared responses to all the items addressed by the 110 page NRC licensing guide and by the actual NRC regulations contained in Chapter 10 of the Code of Federal Regulations Parts 19, 20 and 35. This application, responses to any additional questions the NRC might request clarifying details, and the resulting license are considered in essence to form a contract between the licensee and the NRC. The NRC will send inspectors to the facility who will issue citations for even the slightest variation on a single day or lack of a record for any item. For major items fines can be levied. The program submitted to the NRC must be adhered to in detail. Any questions should be referred to me for analysis and preparation of responses. Sometimes responses and questions requiring simple clarification can be expedited by my discussing them by phone with the reviewer.

The unit specified here is the one described by you and possible use of any of several possible sources suggested by Neutron Products and Teletherapy Services, Inc. is applied for. The NRC license resulting from this application will incorporate the application itself as a legally binding condition of operation of the facility through a "tie-down" clause. It is imperative that before submission of the application to the NRC all decisions regarding the system including unit manufacture and model, source model and activity, room configuration, etc. be consistent with the application. Any erroneous information or reversals of decisions resulting in later changes will require prior approval by the NRC via an amendment application which will delay the project and require added expense.

When purchasing items relating to this application (dosimeters, etc.) I would suggest that you discuss the items with me in advance to assure that they are appropriate for the facility needs and for use in fulfilling NRC requirements.

I should continue to be copied on all architectural prints and changes from this point on. In the interest of facilitating this project **all** correspondence from the NRC should be referred to me.

Note the location of the conduit access drawn in Figure I permitting a 3" diameter for the one located in the shadow of the maze wall.

The detail on the 2" and 3" diameter conduit accesses should be curved in the horizontal plane to eliminate line of sight transmission. For any given wall thickness, curvature should not allow any straight line to be drawn unobstructed from one side of wall to the other. Enclosed in the application is a detail I drew showing such a configuration (Figure III).

Consultation with concrete mix design specialists may be required to design a mix corresponding to 147 lbs/ft^3. Multiple test samples should be evaluated. At least one sample should be obtained at every pour.

Two copies of the application and analysis are enclosed to be included in the final application which is to be submitted to the NRC in duplicate. Another copy is enclosed for circulation to the builder and other principals in this venture. <u>All</u> parties should review this application so as to be familiar with the committments being made to the NRC

Please contact me if you find any discrepancies, if you have any questions or if I can be of further service.

Sincerely yours,

Dale E. Starchman, Ph.D.

Dale E. Starchman, Ph.D.
Certified by the American Board of Radiology (all areas)
and by the American Board of Health Physics (comprehensive)

cc: Mary Alice Streeter
Certified Public Accountant
1638 Sunset Lane
Wooster, Ohio 44691

Notes:

1) Scale of 18" wall at console (F-G-H-B) does not appear to have been properly scaled on the floor layout blueprint used here. The wall is properly scaled on the other prints sent to me.

2) The leaded window in the cobalt room may require some thought in terms of size and location depth in the opening so as to permit viewing of the mirror. The mirror should be slightly curved and adjustable so as to permit convenient viewing of the patient at the relatively large distance involved. You might choose to look at the mirror in the Akron City Clinac 4 room and then scale accordingly. Depending on the TV camera flexibility, the mirror may also be used to view beam on/off indicator lights on the front of the cobalt unit itself during required tests. The independent beam monitor should be directly visible through the window for required tests of operation.

3) I would suggest that you consider the possible desirability of placing a door between the cobalt console area and the [illegible] room for the convenience and efficiency of personnel.

4) The tentative use of 1/16" lead to a height of 7 ft in the **simulator room** on the walls as shown on your print may not be necessary for all walls, but I believe this is prudent planning at this time in view of the possibility of using different simulators and/or orientations. If definite information on the simulator and its orientation becomes available prior to purchasing the lead, I would be happy to review the possibility of certain portions of the brick walls being adequate without lead. The window and frame must be leaded with careful overlap of all leaded components. In view of their locations, I believe it appropriate to use 18 gauge hollow steel doors and frames in both locations. Simulators are regulated by Ohio Code, not the NRC and must be registered 30 days prior to receipt (subject to $1000/day fines). Enclosed is a registration form.

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
799 ROOSEVELT ROAD
GLEN ELLYN, ILLINOIS 60137

OCT 27 1988

William F. Demas, M.D.
320 N. Hametown Road
Akron, OH 44313

Dear Dr. Demas:

We have received your application for a teletherapy license dated October 6, 1988.

We are unable to conduct a review of your license application at this time due to lack of sufficient information. Enclosed you will find Regulatory Guide FC 414-4 which you must utilize to apply for your license. This guide instructs you on each item to be submitted for our review. It is necessary for you to answer every item addressed in this guide completely. If you do not respond to each item adequately, each deficiency will only delay your license approval further.

Please resubmit your license application in accordance with the enclosed guide with all items fully addressed.

If you have any questions or require clarification on any of the information stated above, you may contact us at (312) 790-5625.

We will continue our review of your application upon receipt of this information. Please reply in duplicate, within 10 days, and refer to Control Number 86218.

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.

Sincerely,

Kathy J. Graden

Kathy J. Graden
Materials Licensing Section

Enclosure: Regulatory
Guide FC 414-4

Discussed on 11/3/88 WD
30 days to Dec 3rd.
Amanda Frazier 312-790-5704

CONTROL NO. 87594

U.S. Nuclear Regulatory Commission
Region III
Materials Licensing Section
799 Roosevelt Road
Glen Ellyn, Illinois 60137

Control No: 86218
Attn: Ms. Kathy Graden

Gentlemen:

An application form was submitted by Dr. Demas with a fee of $580.00 on October 6, 1988. The NRC assigned the file Control Number 86218 and stated in a letter dated October 27, 1988 that it could not be acted on without the information required by the licensing guide being fully addressed.

This constitutes an application (to be treated as a totally separate entity from the previous application form except for the fee) for an NRC Materials License to permit possession and operation of an AECL Theratron Model 80 Cobalt-60 teletherapy unit in a new room described as "cobalt room" to be located in a building being constructed at 2375 Benden in Wooster, Ohio. Ownership of the unit, source model, unit model, activity, authorized users, authorized use, radiation safety officer, leak test procedures, all radiation safety and operating programs and procedures, instruction and monitoring program, emergency procedures, calibration procedures, safety equipment, and responsibility for operation of the unit, etc. will be as described in the enclosed application.

This application was prepared by Dale E. Starchman, Ph.D., Certified Radiological Physicist (all areas), American Board of Radiology and Certified Health Physicist (comprehensive), American Board of Health Physics. This shielding analysis was made by Dr. Starchman (1 page c.v. enclosed).

The room shielding is sufficiently thick to permit the entire analysis to be made on the basis of worst case analysis and unrestricted occupancy outside the therapy room itself. This lends itself to a rather straight forward proof that the room will meet all NRC shielding requirements for this cobalt-60 unit. This very conservative approach also will result in operators, etc. receiving exposures well below permissible limits for occupationally exposed personnel in line with the ALARA program.

This project has a high priority and will involve all new construction of the structural shielding which is to commense as soon as possible.

We would therefore appreciate your phoning Dr. Starchman at 216-494-7353 if there appears to be any area of concern regarding structural shielding or if any further materials should be submitted.

Sincerely yours,

W. J. Dircks

Chief Executive Officer of responsible organization
or for another person with contractual authority

12/13/88 Lewis

R3

R1301020 LICENSING TRACKING SYSTEM DATE: 10/11/88
PAGE: 1

LTS WORKSHEET

R3

DOCKET NO : 03030843 LICENSE NO : _____ STATUS: 3

MAIL CONTROL: 386218 RECEIPT DATE : 881011 ACTION TYPE: 2

FED. GOVT : N INST. CODE : 25978 LICENSE REGION: 3

ISSUE DATE: _____ ORIGINAL DATE: _____ EXPIRATION DATE: _____

NAME : DEMAS,M.D.,WILLIAM F.

DEPT/BUREAU: _____

BUILDING : _____

STREET : 320 N. HANITOWN ROAD

CITY : AKRON STATE: OH ZIP: 44313

CONTACT PERSON: William F. Demas, M.D. PHONE: (716) 375-3557

PRIMARY PGM CODE : 2300 SECONDARY PGM CODES: _____

INSPECTION REGION: 3 PRIORITY CODE: _ INSPECTION CATEGORY: ___

RADIATION SAFETY OFFICER: _____

STATES WHERE USE IS AUTHORIZED: _

0 - ALL LISTED STATES
1 - SAME AS STATE IN ADDRESS
2 - ALL STATES
3 - NON-AGREEMENT STATES

AUTHORIZED STATES: _____ (USE ONLY IF ABOVE IS ZERO)

REPORTING IDENTIFICATION SYMBOL: _____

APPROVAL FOR: REDISTRIBUTION: STORAGE ONLY:
TEMPORARY JOB SITES: INCINERATION:
BURIAL:

EXEMPTIONS: (1)_____ (2)_____

MATERIAL TYPE : ---------- FORM CODE: --- AGGREGATE CODE: ---
MODEL NUMBER : ---
DESCRIPTION : ---
TOTAL QUANTITY : ---------------- UNIT: ---
OTHER : - # SOURCES: ---

MATERIAL TYPE : ---------- FORM CODE: --- AGGREGATE CODE: ---
MODEL NUMBER : ---
DESCRIPTION : ---
TOTAL QUANTITY : ---------------- UNIT: ---
OTHER : - # SOURCES: ---

MATERIAL TYPE : ---------- FORM CODE: --- AGGREGATE CODE: ---
MODEL NUMBER : ---
DESCRIPTION : ---
TOTAL QUANTITY : ---------------- UNIT: ---
OTHER : - # SOURCES: ---

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DESCRIPTION : ---
TOTAL QUANTITY : ---------------- UNIT: ---
OTHER : - # SOURCES: ---

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MODEL NUMBER : ---
DESCRIPTION : ---
TOTAL QUANTITY : ---------------- UNIT: ---
OTHER : - # SOURCES: ---

MATERIAL TYPE : ---------- FORM CODE: --- AGGREGATE CODE: ---
MODEL NUMBER : ---
DESCRIPTION : ---
TOTAL QUANTITY : ---------------- UNIT: ---
OTHER : - # SOURCES: ---

MATERIAL TYPE : ---------- FORM CODE: --- AGGREGATE CODE: ---
MODEL NUMBER : ---
DESCRIPTION : ---
TOTAL QUANTITY : ---------------- UNIT: ---
OTHER : - # SOURCES: ---

NAME AUTHORIZATION

ADDRESS WHERE MATERIAL IS USED OR POSSESSED

BUILDING:
ROOM:
STREET:
CITY:
STATE:

BUILDING:
ROOM:
STREET:
CITY:
STATE:

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ROOM:
STREET:
CITY:
STATE:

CONVERSATION RECORD

TIME	DATE
10:30am	12/13/88

TYPE

☐ VISIT ☐ CONFERENCE ☒ TELEPHONE

12/13 ☐ INCOMING ☒ OUTGOING

Location of Visit/Conference:

NAME OF PERSON(S) CONTACTED OR IN CONTACT WITH YOU	ORGANIZATION (Office, dept., bureau, etc.)	TELEPHONE NO:
William Demas M.D.		(314) 375-3557

ROUTING

NAME/SYMBOL	INT

SUBJECT

Info ONLY

Co. No. 860218

SUMMARY

Talked to Dr. Demas and discussed response. Dr. Demas indicated that he was still waiting for facility calculations.

I indicated that we would VOID (response was due 12-3-88) and when he was ready to submit response, to reference VOID CO NO. 860218 for reactivation.

Dr. Demas agreed.

ACTION REQUIRED

VOID. Hold in VOID Drawer!

NAME OF PERSON DOCUMENTING CONVERSATION	SIGNATURE	DATE
Spray	[illegible]	12/13/88

ACTION TAKEN

SIGNATURE	TITLE	DATE

CONVERSATION RECORD

TIME 9:35 | DATE 11/3/88

TYPE
☐ VISIT ☐ CONFERENCE ☒ TELEPHONE
☒ INCOMING ☐ OUTGOING

Location of Visit/Conference:

ROUTING	
NAME/SYMBOL	INT

NAME OF PERSON(S) CONTACTED OR IN CONTACT WITH YOU: William Demas, M.D.

ORGANIZATION (Office, dept., bureau, etc.):

TELEPHONE NO.: (216) 375 3557

SUBJECT: Control No. 86218

SUMMARY

Dr. Demas called to ask for an extension to the 10 day response time on deficiency letter sent.

He needs 30 days in order to get all info together, therefore, an extension for response granted until December 3rd, 1988.

ACTION REQUIRED

NAME OF PERSON DOCUMENTING CONVERSATION | SIGNATURE: Kathy J. Gruber | DATE: 11/3/88

ACTION TAKEN

SIGNATURE | TITLE | DATE

OCT 27 1988

William F. Demas, M.D.
320 N. Hametown Road
Akron, OH 44313

Dear Dr. Demas:

We have received your application for a teletherapy license dated October 6, 1988.

We are unable to conduct a review of your license application at this time due to lack of sufficient information. Enclosed you will find Regulatory Guide FC 414-4 which you must utilize to apply for your license. This guide instructs you on each item to be submitted for our review. It is necessary for you to answer every item addressed in this guide completely. If you do not respond to each item adequately, each deficiency will only delay your license approval further.

Please resubmit your license application in accordance with the enclosed guide with all items fully addressed.

If you have any questions or require clarification on any of the information stated above, you may contact us at (312) 790-5625.

We will continue our review of your application upon receipt of this information. Please reply in duplicate, within 10 days, and refer to Control Number 86218.

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.

Sincerely,

Original Signed By
Kathy J. Graden
Materials Licensing Section

Enclosure: Regulatory
Guide FC 414-4

RIII
KJG
Graden/jl
10/26/88

NRC FORM 313
(7-87)
10 CFR 30, 32, 33, 34, 35 and 40

U.S. NUCLEAR REGULATORY COMMISSION
APPROVED BY OMB
3150-0120
Expires: 6-30-90

APPLICATION FOR MATERIAL LICENSE

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.

APPLICATIONS FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

U.S. NUCLEAR REGULATORY COMMISSION
DIVISION OF FUEL CYCLE AND MATERIAL SAFETY, NMSS
WASHINGTON, DC 20555

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS. IF YOU ARE LOCATED IN:

CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, PENNSYLVANIA, RHODE ISLAND, OR VERMONT, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION I
NUCLEAR MATERIALS SAFETY SECTION B
631 PARK AVENUE
KING OF PRUSSIA, PA 19406

ALABAMA, FLORIDA, GEORGIA, KENTUCKY, MISSISSIPPI, NORTH CAROLINA, PUERTO RICO, SOUTH CAROLINA, TENNESSEE, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION II
NUCLEAR MATERIALS SAFETY SECTION
101 MARIETTA STREET, SUITE 2900
ATLANTA, GA 30323

030-30843

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION III
MATERIALS LICENSING SECTION
799 ROOSEVELT ROAD
GLEN ELLYN, IL 60137

ARKANSAS, COLORADO, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, SOUTH DAKOTA, TEXAS, UTAH, OR WYOMING, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
MATERIAL RADIATION PROTECTION SECTION
611 RYAN PLAZA DRIVE, SUITE 1000
ARLINGTON, TX 76011

ALASKA, ARIZONA, CALIFORNIA, HAWAII, NEVADA, OREGON, WASHINGTON, AND U.S. TERRITORIES AND POSSESSIONS IN THE PACIFIC, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION V
NUCLEAR MATERIALS SAFETY SECTION
1450 MARIA LANE, SUITE 210
WALNUT CREEK, CA 94596

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTION.

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

- [X] A. NEW LICENSE 34-25978-01
- [ ] B. AMENDMENT TO LICENSE NUMBER _____
- [ ] C. RENEWAL OF LICENSE NUMBER _____

2. NAME AND MAILING ADDRESS OF APPLICANT *(Include Zip Code)*

William F. Demas, M.D.
320 N. Hametown Road
Akron, Ohio 44313

N
7.11
88

3. ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

Benden Drive
Wooster, Ohio 44169

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION	TELEPHONE NUMBER
William F. Demas, M.D.	216-375-3557

SUBMIT ITEMS 5 THROUGH 11 ON 8½ x 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL a. Element and mass number, b. chemical and/or physical form, and c. maximum amount which will be possessed at any one time.	6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.
Cobalt 60	Radiation Therapy of cancer patients.
7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE William F. Demas, M.D. M. Seider, M.D. Paul Shaheen, M.S.	8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS. Yes.
9. FACILITIES AND EQUIPMENT. Cobalt 60 Theratron 80	10. RADIATION SAFETY PROGRAM. Yes.
11. WASTE MANAGEMENT.	12. LICENSEE FEES *(See 10 CFR 170 and Section 170.31)* FEE CATEGORY / AMOUNT ENCLOSED $

13. CERTIFICATION. *(Must be completed by applicant)* THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, AND 40 AND THAT ALL INFORMATION CONTAINED HEREIN, IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948, 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

SIGNATURE-CERTIFYING OFFICER	TYPED/PRINTED NAME	TITLE	DATE
W H Demas	William F. Demas, M.D.	President	10/6/88

RECEIVED
OCT 11 1988
REGION III

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	COMMENTS	APPROVED BY
AMOUNT RECEIVED	CHECK NUMBER		CONTROL NO 8621 8	DATE