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P01

SENT BY: 01:tt FX 2106 3-14-90 1:04PM : OCCUP SAFE HLTH 312 790 5665 # 1



# The University of Michigan

RADIATION CONTROL SERVICE  
1101 NORTH UNIVERSITY BUILDING

1205 NORTH UNIVERSITY AVENUE  
ANN ARBOR, MICHIGAN 48109

(313) 764-4420  
(313) 764-4421

30-1988

## TELECOPY TRANSMITTAL SHEET

DATE: March 14, 1990

TO: Pat Vachon/NAC FAX NO.: (708) 790-5665

FROM: Mark L. Driscoll/CS FAX NO.: (313) 763-1185

RE: Attachment for amendment to  
License 21-002K5-04  
Sorry for the delay

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Notify us immediately by telephone if material is not received properly.

*ALZ*

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P02

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Application for:

Radiation Safety Evaluation of a  
Custom Made Device Containing  
Licensed Radioactive Material

Submitted to:

Nuclear Regulatory Commission Region III

Applicant:

Regents, The University of Michigan  
Occupational Safety & Environmental Health  
Radiation Safety Service  
1101 North University Building  
1205 North University Avenue  
Ann Arbor, Michigan 48109-1057

For additional information regarding this application contact  
Mark L. Driscoll, Interim Director  
Radiation Safety Service  
764-4420

### 1. Identification

A. The radioactive cesium-137 sources are mini tubes and Heyman capsules manufactured by the 3M company and are NRC-approved. Ten capsules and 9 mini tubes fit into a source tray described in Appendix A.

B. (1) Manufacturer: Douglas Heidorn, Ph.D.  
Department of Radiation Oncology  
1500 E. Medical Center Drive  
The University of Michigan Medical Center  
Ann Arbor, MI 48108

(2) Device: Cesium-137 low dose rate irradiator

### 2. Proposed use

A. The device is intended to be used for only research purposes. Cancer cells grown in petri dishes will be irradiated in order to test their response to different dose rates and total doses. The irradiator will be permanently housed inside a structurally reinforced NuAire Model Nu 1500 incubator regulating temperature, humidity and air flow. The incubator will permanently reside in a limited-access, heavily shielded room which also houses a cobalt-60 research machine. This room is restricted to trained radiation personnel only. Users of the irradiator will be instructed in its use and safe operation.

B. In the unlikely event of a fire, the cerrobend irradiator would melt, but both the cerrobend and the sources would be contained inside the steel-lined incubator. The cerrobend would cool around the sources thereby providing shielding.

### 3. Design and construction

A. The shielding is constructed from interlocking Cerrobend pieces weighing approximately 70 pounds each. Cerrobend is a cadmium/bismuth/lead/tin composite with a density of .83 times that of lead. The source tray is made from machined plexiglas and sits in a cerrobend wagon which slides on 4 ball bearing wheels with a center guide to insure proper positioning. The 100 pound cerrobend door slides on a custom-made, linear ball bearing track and is supported on the track by an aluminum plate with aluminum side supports. The incubator is reinforced with 1/4 inch steel plate supported by four 2-inch steel channel beams. The structural reinforcement enables the incubator to support the 550 pound irradiator. Engineering drawings are attached.

B. The irradiator is specially designed with unique safety features and passive mechanical interlocks. These include:

#### Front and back shielded housings

The irradiator consists of 2 separate but connected shielded housings. The front housing contains sliding trays for petri dishes and can accommodate the sliding source tray for purposes of irradiating cells in the petri dishes ("on" position). The source tray must be slid into the back housing ("safe" position) before the user can open the door to the front housing in order to access the petri dishes.

#### Source tray

The 19 sealed Cs-137 sources are sandwiched between two plexiglas plates and is called the source tray. One plate has machined grooves for each of the cesium sources in a pre-calculated position. The other plexiglas plate fits over the first plate and screws down so that each source remains fixed. Thus, the sources will be accountable as a single entity, namely, the source tray.

The source tray rests in a sliding cerrobend wagon in the bottom of the irradiator. Neither the source tray nor the wagon can be removed during normal use. It is possible, however, for qualified personnel to access the sources for leak testing by removing the safety bracket on the front door.

#### Door interlock

The irradiator door can be opened only when the source tray has been completely pushed into the back housing in the "safe" position. With the door opened, the largest measured dose rate in the front of the irradiator is 30 mR/hr at a distance of one foot from the front of the irradiator. When the door is fully closed, a hole in the door lines up with a brass pushrod connected to the source wagon. The brass rod can be pulled through the hole such that the source tray is in the "on" position. The source tray is prevented from being moved to the "on" position by a safety bracket when the door is open.

The interlock is completely passive and does not rely on any electronic device. The interlock is fail-safe and cannot be overridden during ordinary use.

#### 4. Human access

Users of the irradiator will have no direct access to the sources.

5. Radiation Profiles

	<u>Door open<sup>1</sup></u>			<u>Door closed<sup>2</sup></u>	
	<u>Front</u>	<u>Body dose</u>	<u>Side</u>	<u>Front</u>	<u>Side</u>
	<u>Hand dose</u>		<u>1 meter</u>	<u>1 meter</u>	<u>1 meter</u>
Estimated max. occupancy time	100 mR/h	30 mR/h	< 2 mR/h	< 2 mR/h	< 2 mR/h
	1 h/wk, 2 h/mo, 24 h/yr <sup>3</sup>			48 h/yr <sup>4</sup>	
Total max. yearly dose	2.4 R/yr	.6R/yr <sup>5</sup>		< .1 R/yr	

<sup>1</sup>The door is open only during the time when cells in the petri dishes are being accessed. During this time, the user is closest to the shielded sources and is exposed to the maximum radiation.

<sup>2</sup>The door will remain closed when petri dishes are not being accessed. Users of the cobalt machine will work typically 3-4 meters from the irradiator and will receive an insignificant dose from the shielded cesium sources.

<sup>3</sup>It is estimated that an individual will spend no more than 24 hr/yr in front of the irradiator accessing petri dishes. A log book will be kept at the incubator for the purpose of recording users' exposure times.

<sup>4</sup>It is estimated that an individual will be spending no more than 48 hr/yr in the cobalt room.

<sup>5</sup>Total body dose will be much less than .6 R/yr. This number represents a maximum dose to only a small portion of the body. Averaged over the entire torso, the yearly dose is less than .1 R/yr. Please see attached sheet for a pictorial explanation of the dose profiles.

The measured exposure rates are extrapolated from measurements made using a single 43 mCi source. Complete radiation profiles will be submitted when all the sources are in place. Dose rates from the cobalt machine have been measured at various points in the room. The measured dose rate near the irradiator is negligible.

6. Labeling and instructions for use

An SOP (Standard Operating Procedure) will be posted on the incubator as well as a list of authorized users. Standard radiation postings and warnings are posted on the entrance to the room. These same signs with the words "CAUTION RADIOACTIVE

MATERIAL" will be fixed to the incubator and irradiator.

#### 7. Availability of services

A) The University of Michigan Radiation Safety Service (RSS) will perform transfer the sources from their current storage location in the Radiation Oncology Department to their permanent place of residence in the irradiator in the cobalt room. At that time, all shielding will be in place and the irradiator will be ready for use.

B) Independent radiation surveys will be performed by both the RSS and the applicant, Dr. Heidorn. Films will be used to check the leakage of the irradiator. Personnel dosimeters, TLDS and calibrated survey meters will be used to measure the ambient exposure rates.

C) The 19 sources were leak tested in November, 1989 by the RSS. Once the sources are placed in the source tray, the top exposed surface of the source tray will be leak tested twice per year by the RSS.

D) Repairs and periodic maintenance will be performed by the applicant, Dr. Heidorn, or by Dr. Ted Lawrence.

E) Source exchange will not be necessary since Cs-137 has a half-life of 30 years.

F) If the irradiator is no longer needed, the sources can be removed from the source tray and returned to their current storage location in the active supply of the Radiation Oncology Department. The cerrobend housing can be melted and re-used.

#### 8. Tests to be performed on the irradiator

A) Radiation profiles - Dose rates will be measured at 5, 30 and 100 cm from the irradiator surfaces with the source tray in the "on" and "off" positions. (In the "off" position with the door open).

B) QA to test for cracks where possible radiation leaks may exist - The irradiator will be wrapped in "ready-pak" X-ray sensitive film for several hours. Any leaks will show up when the film is developed.

C) "ON" - "OFF" control operation has been thoroughly tested and the interlock passes all tests. Routine, semi-annual checks will be conducted by an authorized user to verify interlock system integrity. This will be done at the same time as the semi-annual leak test by the RSS.

D) The RSS has performed leak tests on individual sources.

E) Activities of individual sources were measured using a calibrated gamma well counter. The measured activities can be found in Appendix A.

#### ADDENDUM

The drawings indicate that the cerrobend shielding in the front housing is 4 cm thick and the text claims a 6 cm thickness. A 2 cm slab will be screwed to the side of the front housing to compensate for this. Because the irradiator sits in a corner of

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a heavily shielded former cobalt-60 teletherapy room, 3 sides do not require full (6 cm thickness) shielding (bottom, back and far side).

Dosimetry All lab personnel will be required to wear dosimetry badges (whole body film badge and finger ring).

Semi-annual gaulity assurance check The interlock operation will be tested and the source tray will be leak tested twice yearly by an authorized user and the RSS. Results of these tests will be permanently recorded in the log book.

Alarmed survey meter An audible alarmed survey meter capable of detecting ambient dose rates greater than xx mR/hr is permanently mounted on the wall approximately 20 feet from the irradiator. This meter is tested weekly.

The RSS will be notified of any structural or procedural changes associated with the irradiator.

## APPENDIX A

CUSTOM MADE RADIATION SOURCE HOLDERB. Identification

Source tray - Cs-137, 480 mCi

C. Radioactive Material

- (1) Cesium 137  
 (2) Sources ID and activities  
 Manufacturer: 3M  
 Model Number: Ten miniature tubes - # 6B6G  
 Nine heyman capsules- # 6H6E

Source ID	Quantity	Measured activities	Total activity
Mini tube 10	3	20.3, 20.5, 20.7 mCi	61.5 mCi
Mini tube 15	3	30.3, 30.4, 30.7 mCi	91.4 mCi
Mini tube 20	3	43.0, 43.3, 43.4 mCi	129.7 mCi
Heyman capsule	10	19.1 - 19.5 mCi	193.5 mCi

Total Activity - 476.1 mCi measured 1/17/1990

D. Construction See attached sheet for drawings of the source holder.

E. Labeling The following information is etched on the source tray:

DANGER  
 High Radioactivity  
 Radioactive Material  
 Cs-137  
 480 mCi 1/1990

F. Source Assay The individual cesium sources were assayed using a calibrated RADX ASSAYER1 dose calibrator. The individual activities were summed to give the total activity of the source tray.

G. Quality Control Inspections of the Finished Source

(1) The source tray will be visually inspected to make sure that the 4 bolts are fully screwed in to tightly seal the two plates of the source tray. The sealed tray has been loaded with dummy sources and dropped from a height of 4 feet onto a hard surface and the source plates stay attached and do not break or crack.

(2) A wipe test will be done on the two flat surfaces of the tray and on the 4 edges prior to installation.

(3) Personnel TLDs and a calibrated Keithley survey meter

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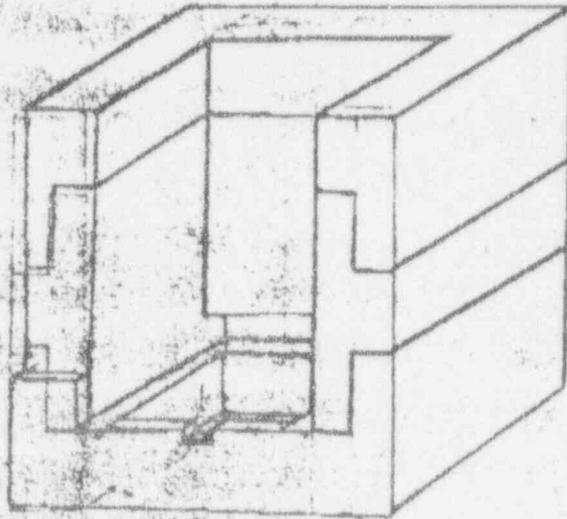
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will be used to measure the radiation levels at various locations around the irradiator.

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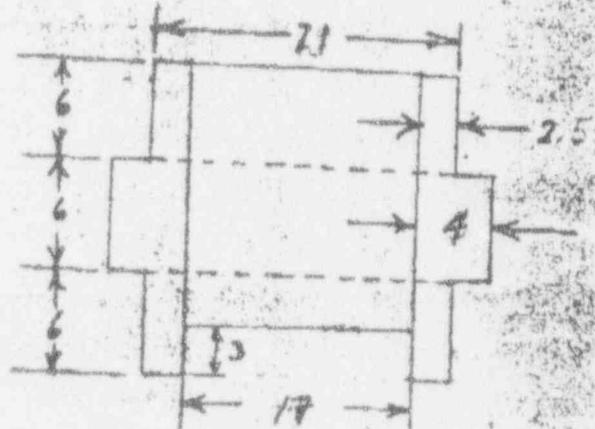
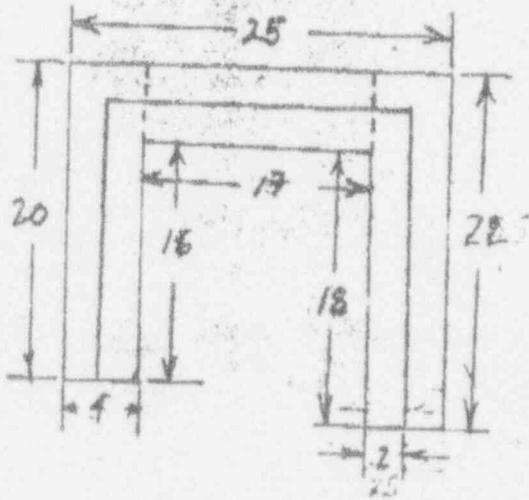
CERROBEND PIG

(ALL DIMENSIONS IN CENTIMETERS)

SIDE

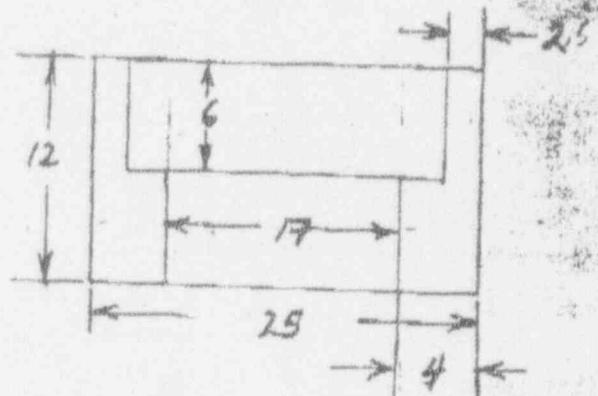
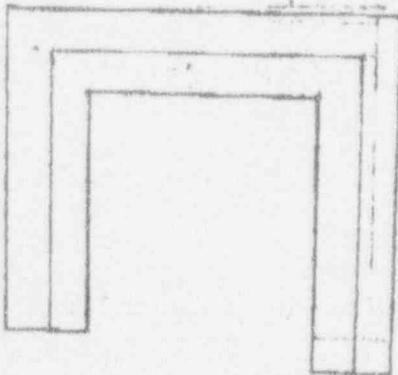
FRONT

MIDDLE  
PIECE



SAME DIMS. AS ABOVE

TOP  
PIECE



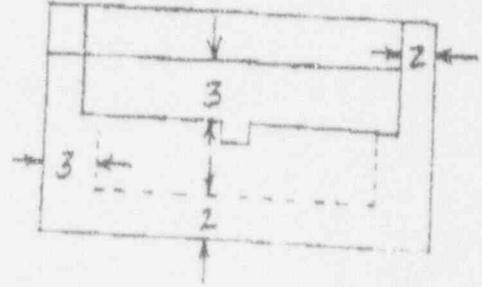
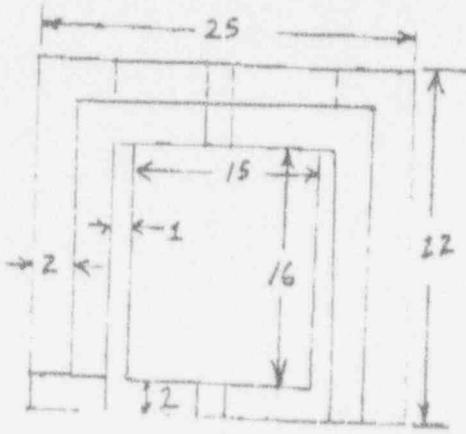
Each cerrobend piece will weigh ~ 50 lbs.

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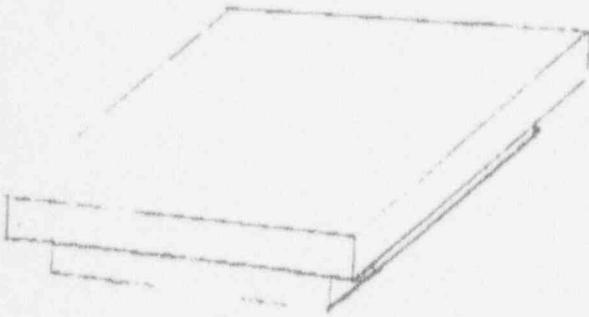
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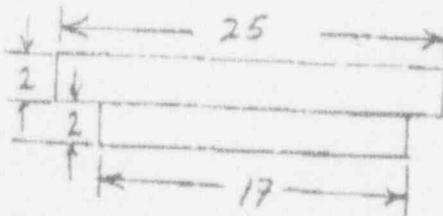
BOTTOM  
PIECE



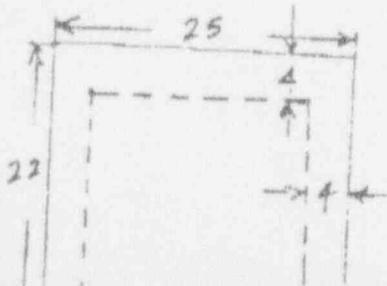
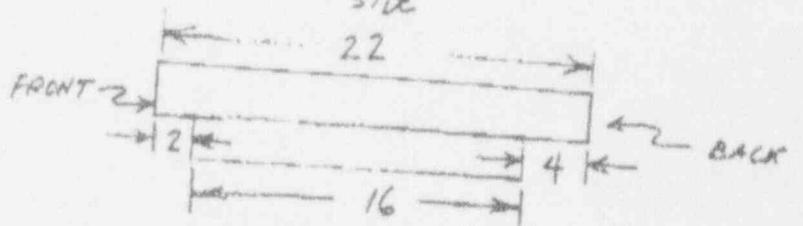
TOP



FRONT



SIDE

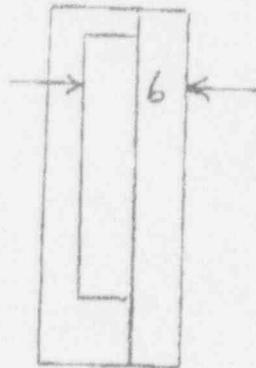
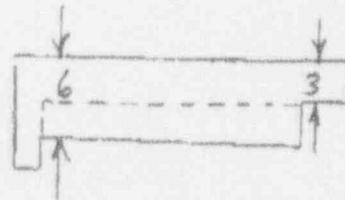
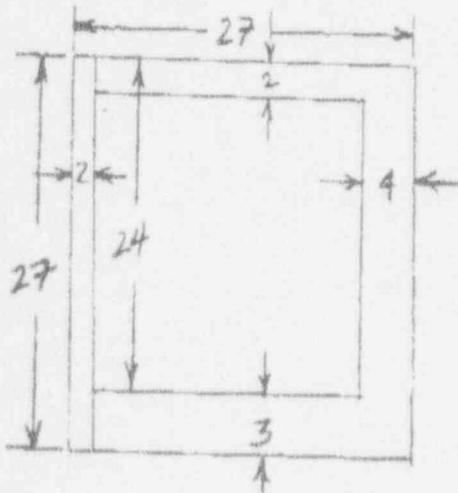
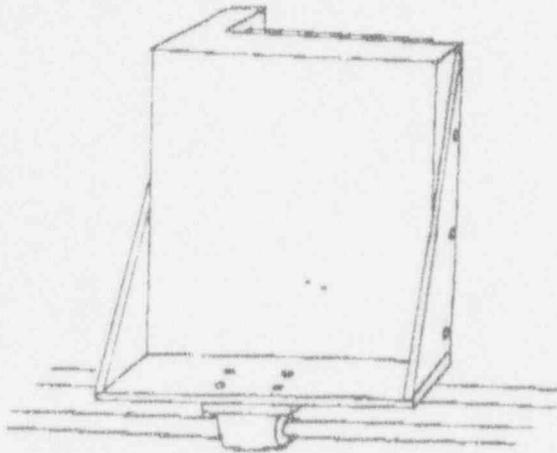


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FRONT DOOR

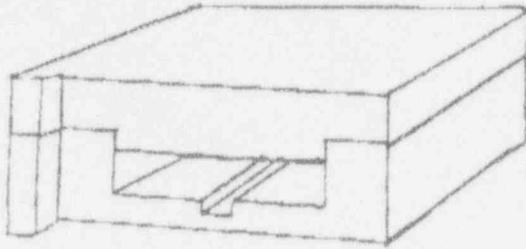


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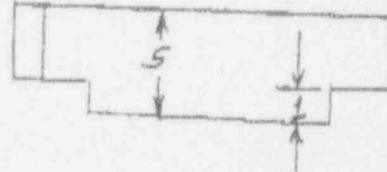
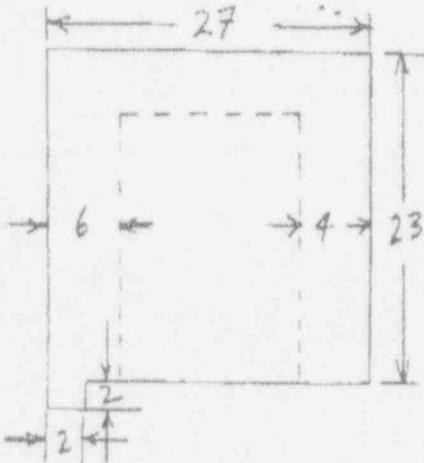
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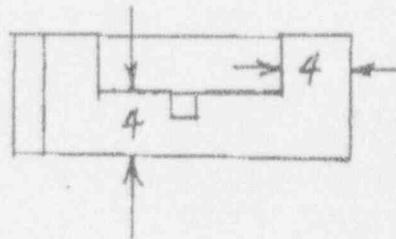
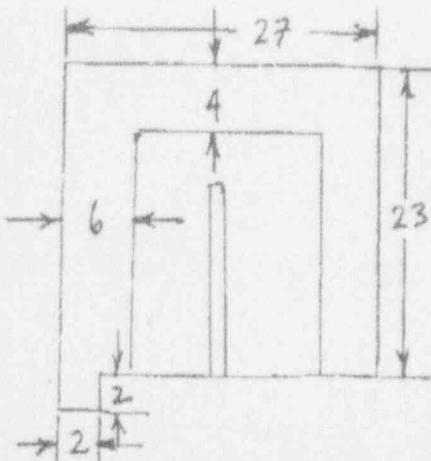
BACK HOUSING



TOP



BOTTOM



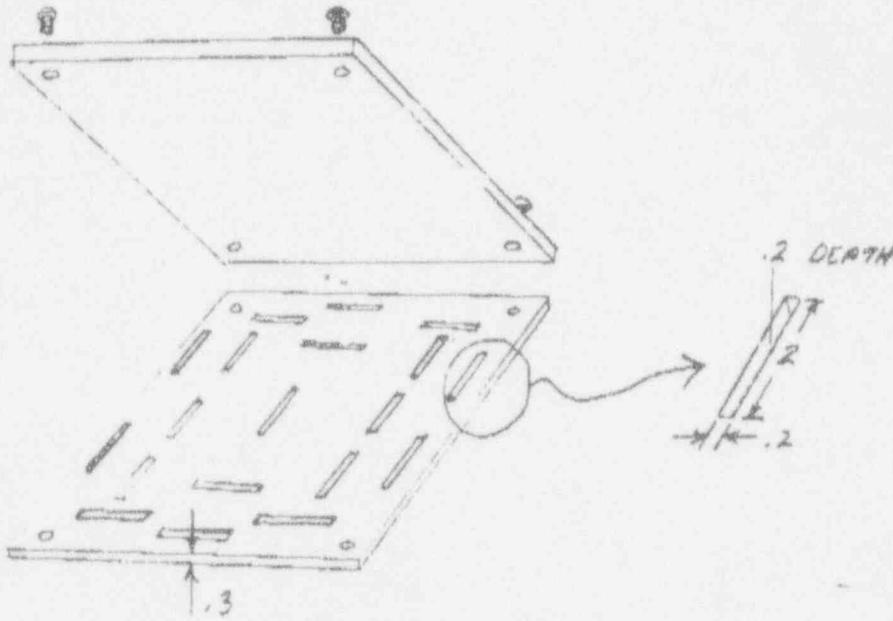
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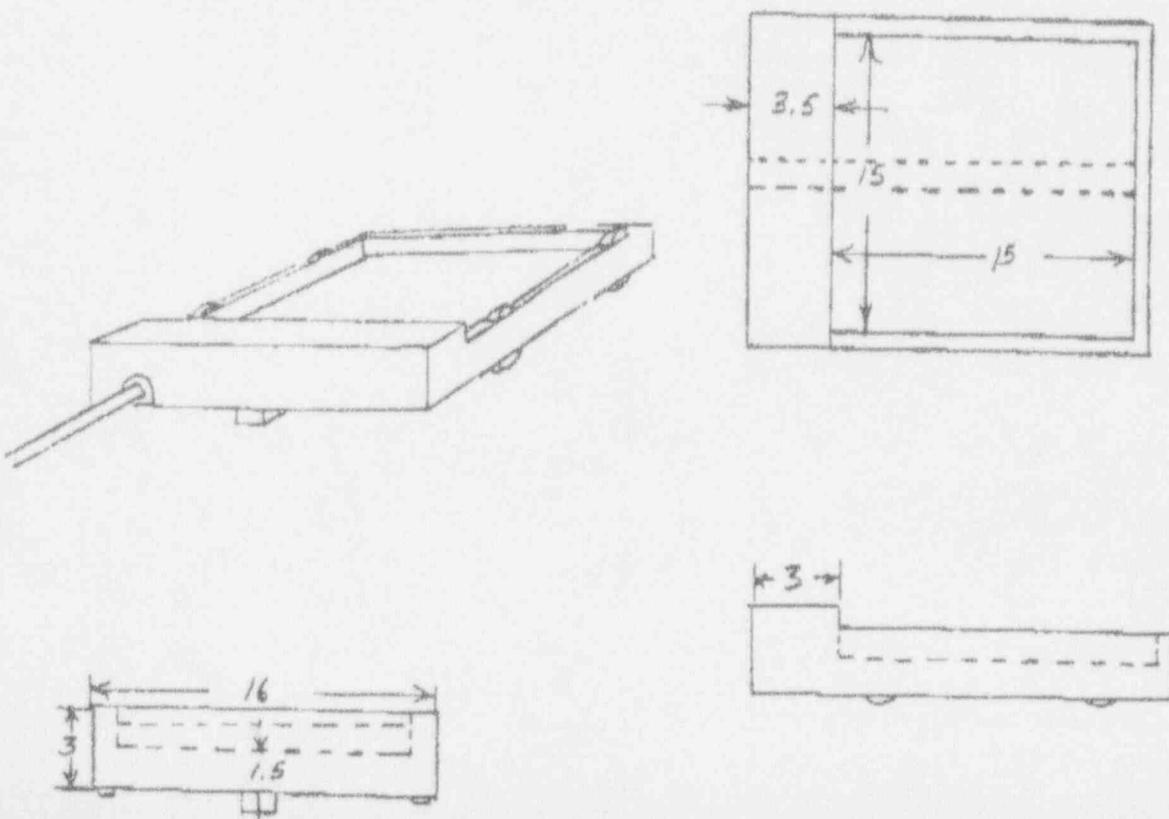
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SOURCE TRAY



CERROBEND SOURCE HOLDER



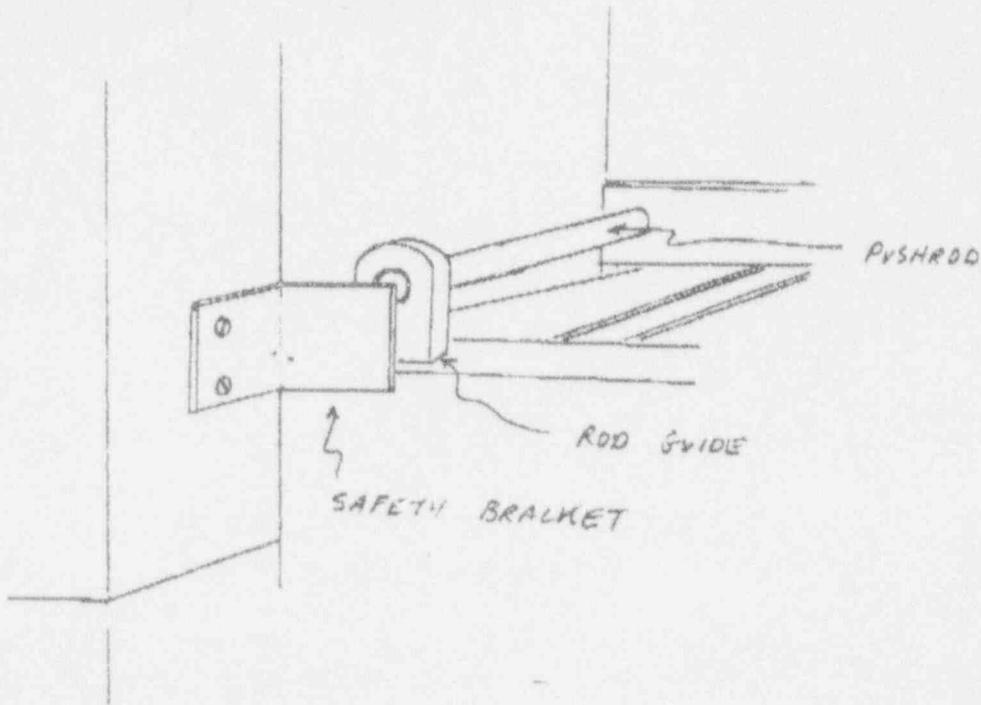
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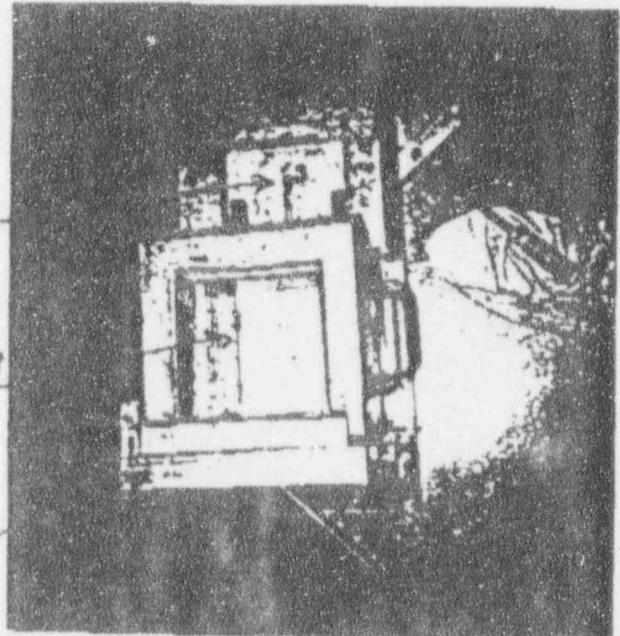
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SAFETY BRACKET ASSEMBLY



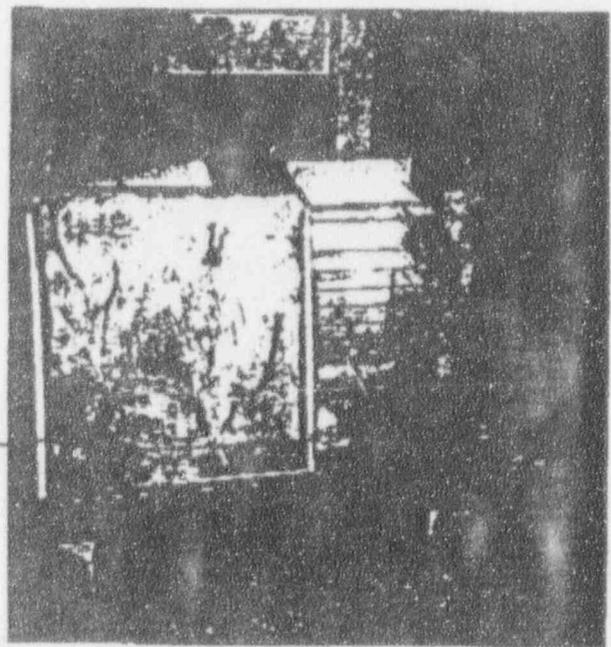
Top with Lids removed

Back compartment for source tray in "off" position  
Front compartment for source tray in "ON" position + trays for petri dishes of cells  
sliding door (closed)



pushing for source tray

Pushrod access hole in door

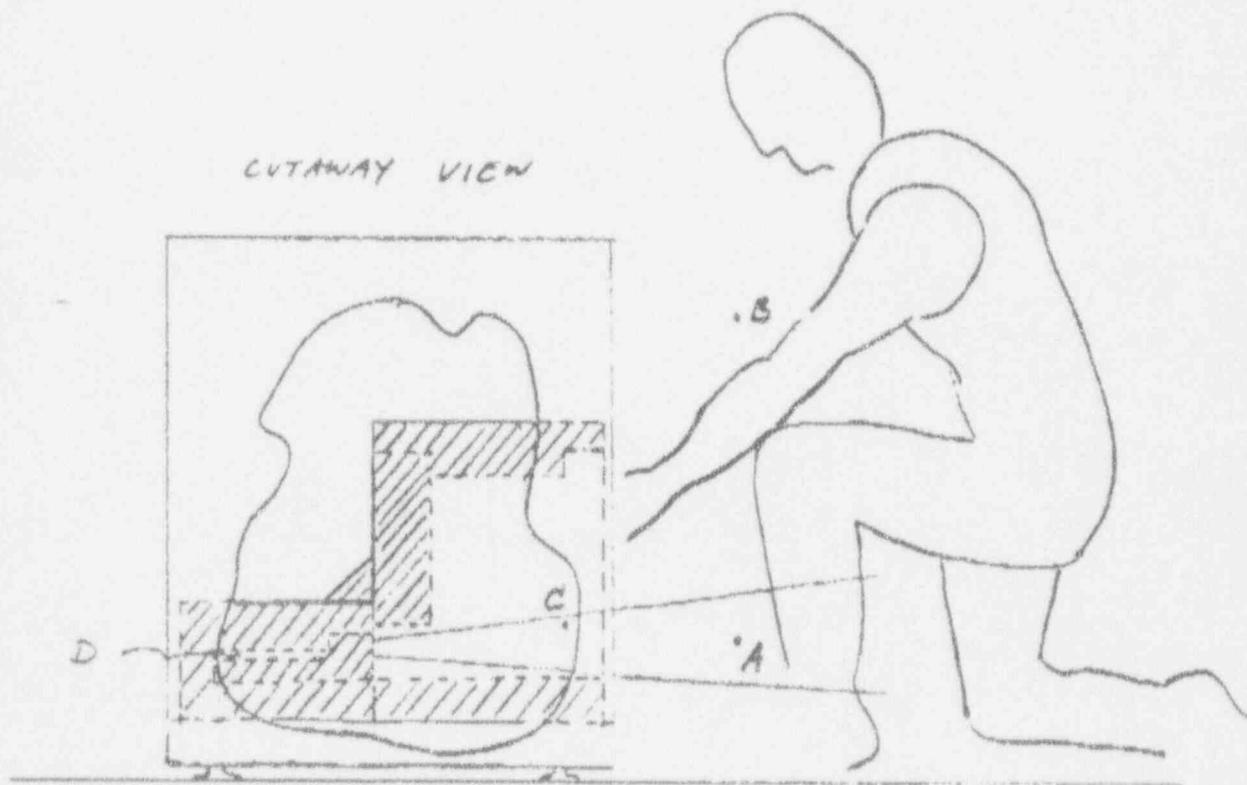


Trays for Petri dishes

Linear ball bearing Track for sliding door

front - door open - lid removed

# DOSE PROFILES FOR LOW DOSE IRRADIATOR



• A - 30 mR/hr

• B - 5 mR/hr

• C - 100 mR/hr

D - SOURCES IN CERROBEND WAGON

### KEY

 - CERROBEND SHIELDING

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SCANDIPLAN: BRACHY

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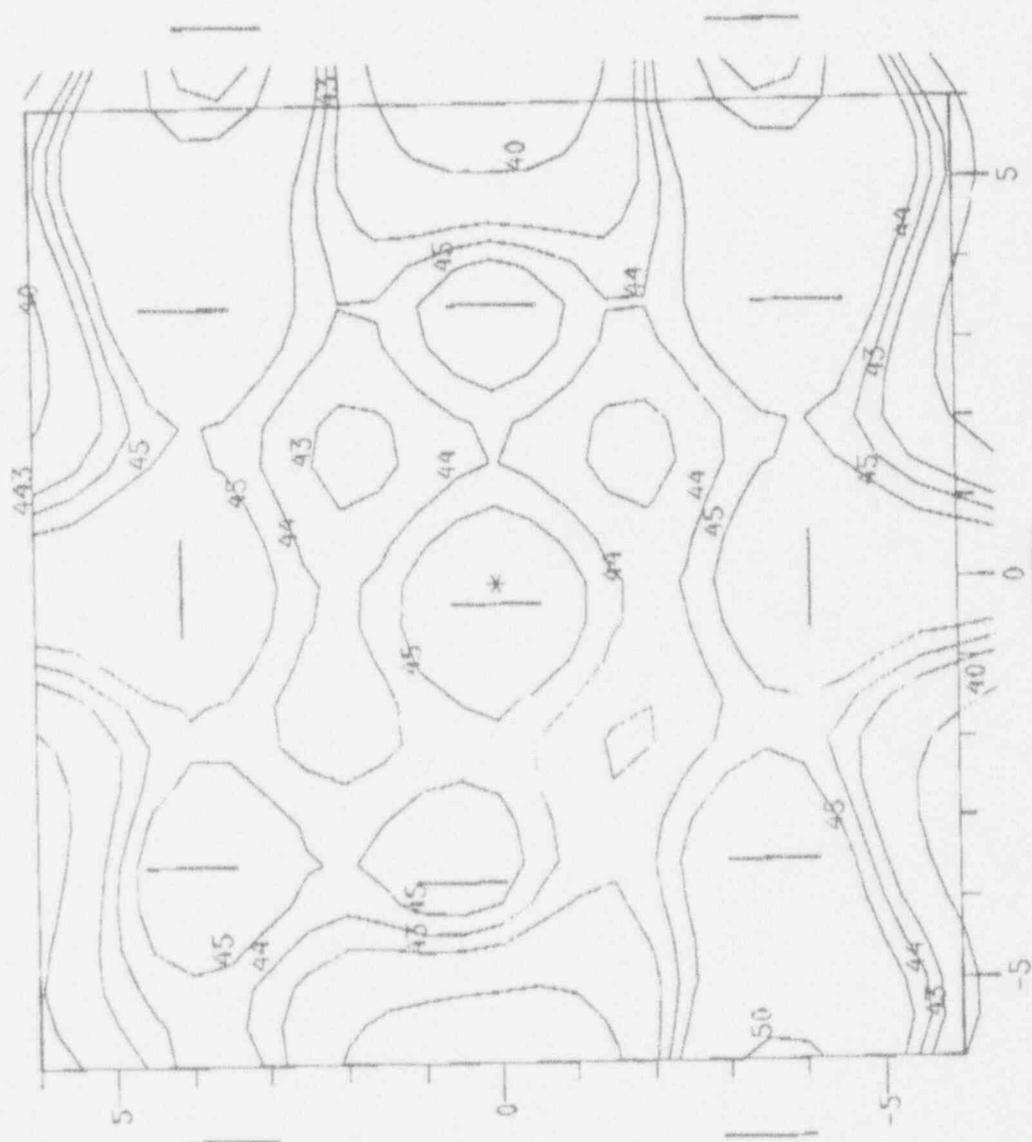
FILE: CEA PLAN #: 1 DESC: PP  
PLOT DATE: 8-FEB-90 14:19:58

SOURCE ARRANGEMENT

The isodose rate curves are in red /hr  
for a plane 2 cm from source tray.

CUT # = 8 REF\_AXIAL @ 2.0

CUT CENTER: X= 0. Y= 0.5 Z= 2.0



ISO-DOSE: 52.0 50.0 45.0 44.0 43.0 40.0

UNIVERSITY OF MICHIGAN DEPARTMENT OF RADIATION THERAPY

RADIATION SAFETY ORIENTATION PROGRAM OUTLINE

I. BASIC TERMINOLOGY AND DEFINITIONS

1. Radiation Units and Quantities
  - A. Roentgen
  - B. Rad & Gray
  - C. Rem
2. Radiation Control
  - A. Degrees of control
  - B. Controlled areas
  - C. Access to control areas
  - D. Areas immediately adjacent to a controlled area
3. Categories of Individuals Controlled
  - A. Individuals occupationally exposed
  - B. Individuals who may be exposed occasionally
  - C. General public

II. RADIATION PROTECTION STANDARDS

1. Personnel Monitoring
  - A. External radiation exposures
  - B. Internal radiation exposures
  - C. Records and reports
2. Personnel Exposure Limits
  - A. Maximum permissible doses
  - B. ALARA concept
3. Prenatal Radiation Exposure
  - A. Personnel
  - B. Patients
  - C. General Public
4. Surveys and Area Monitoring
5. Radioisotope Receipt, Storage, and Disposal
6. Personnel Rights and Statutory Protection
  - A. USNRC Rules and Regulations
  - B. State of Michigan, Ionizing Radiation Rules
  - C. UM Radiation Control Service
7. Reporting and Notification Requirements
  - A. UM Radiation Control Service
  - B. US Nuclear Regulatory Commission

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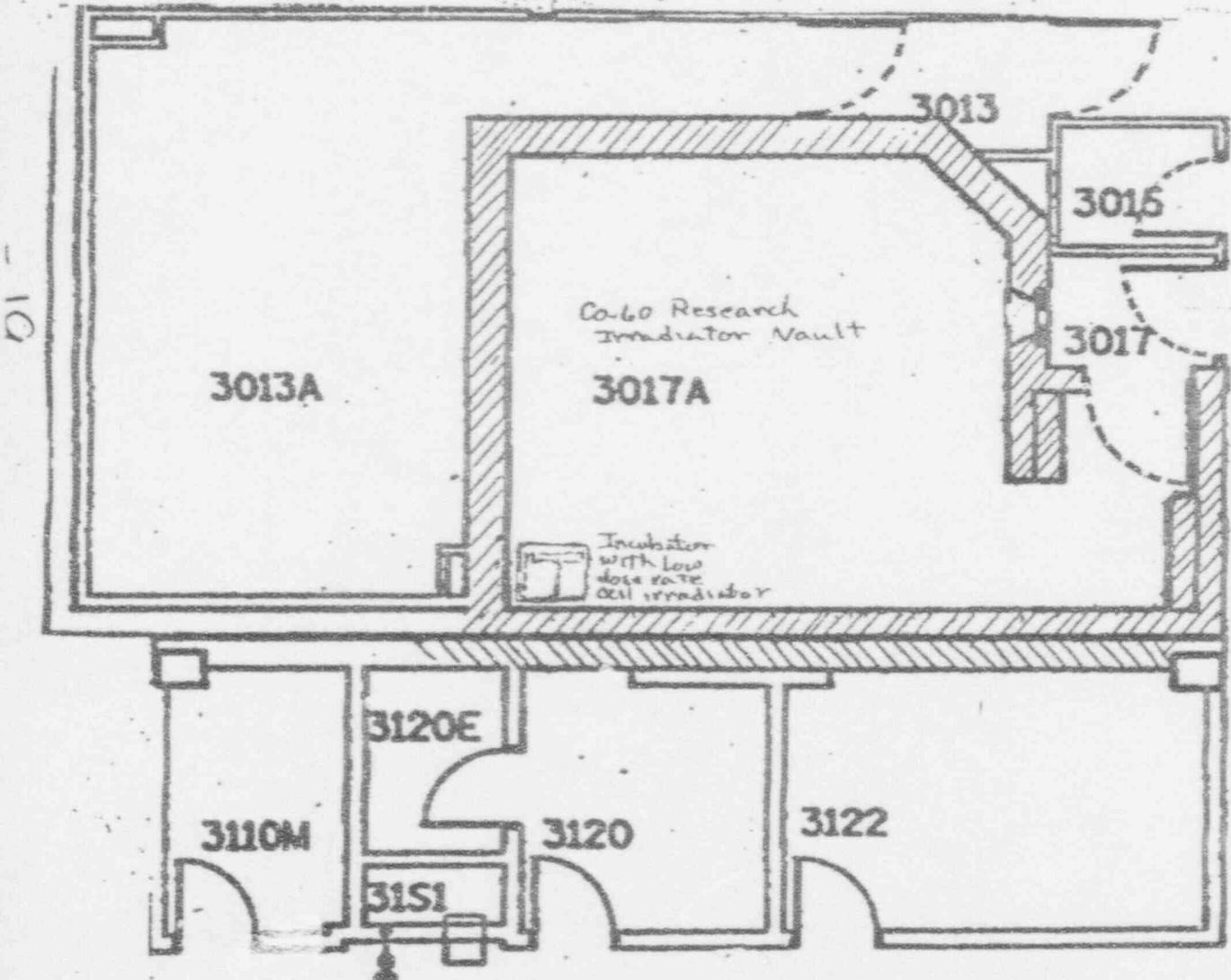
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Page 2

REFERENCES:

- NCRP REPORT NO. 39 -- "BASIC RADIATION PROTECTION CRITERIA"
- NCRP REPORT NO. 40 -- "PROTECTION AGAINST RADIATION FROM BRACHYTHERAPY SOURCES"
- NCRP REPORT NO. 37 -- "PRECAUTIONS IN THE MANAGEMENT OF PATIENTS WHO HAVE RECEIVED THERAPEUTIC AMOUNTS OF RADIONUCLIDES"
- NCRP REPORT NO. 48 -- "RADIATION PROTECTION FOR MEDICAL AND ALLIED HEALTH PERSONNEL"
- 10 CFR 19 ----- "NOTICE, INSTRUCTIONS, AND REPORTS TO WORKERS; INSPECTIONS"
- 10 CFR 20 ----- "STANDARDS FOR PROTECTION AGAINST RADIATION"
- 10 CFR 21 ----- "REPORTING OF DEFECTS AND NONCOMPLIANCE"
- 10 CFR 35 ----- "HUMAN USES OF BYPRODUCT MATERIAL"
- U OF M RCS ----- "RADIATION SAFETY MANUAL"

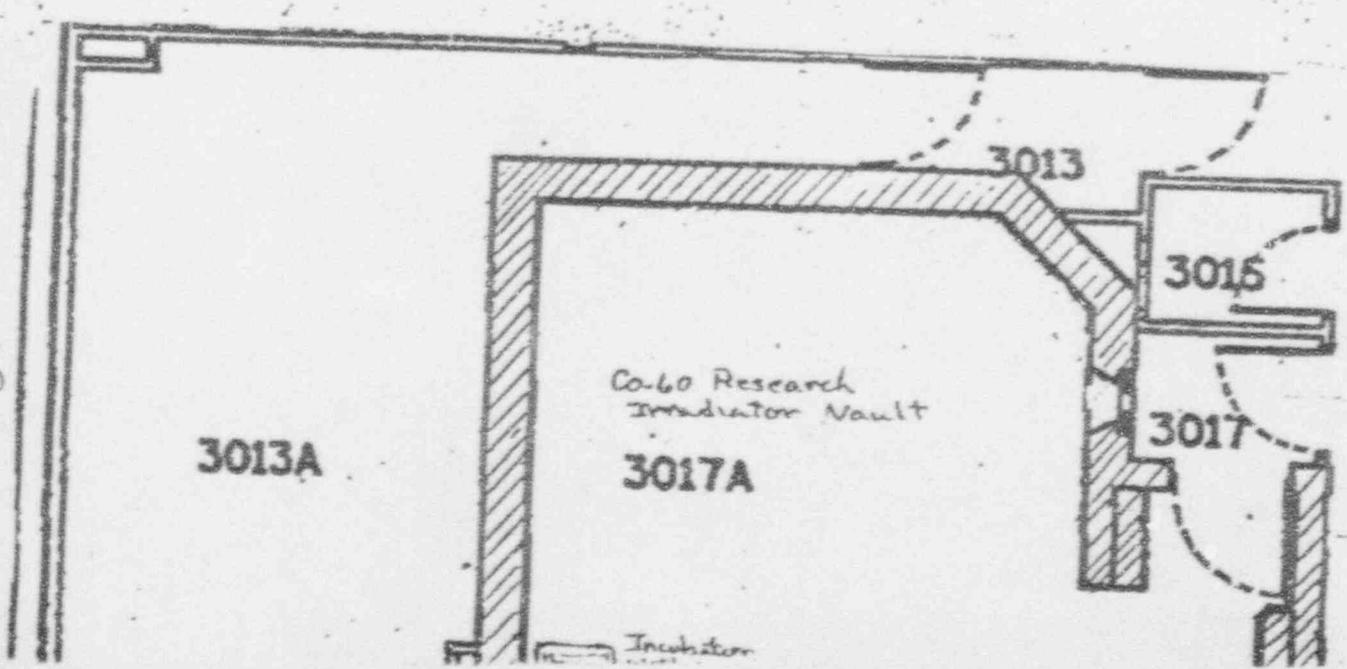
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312 790 5885 : #21



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1331 EAST ANN ST. BLDG.

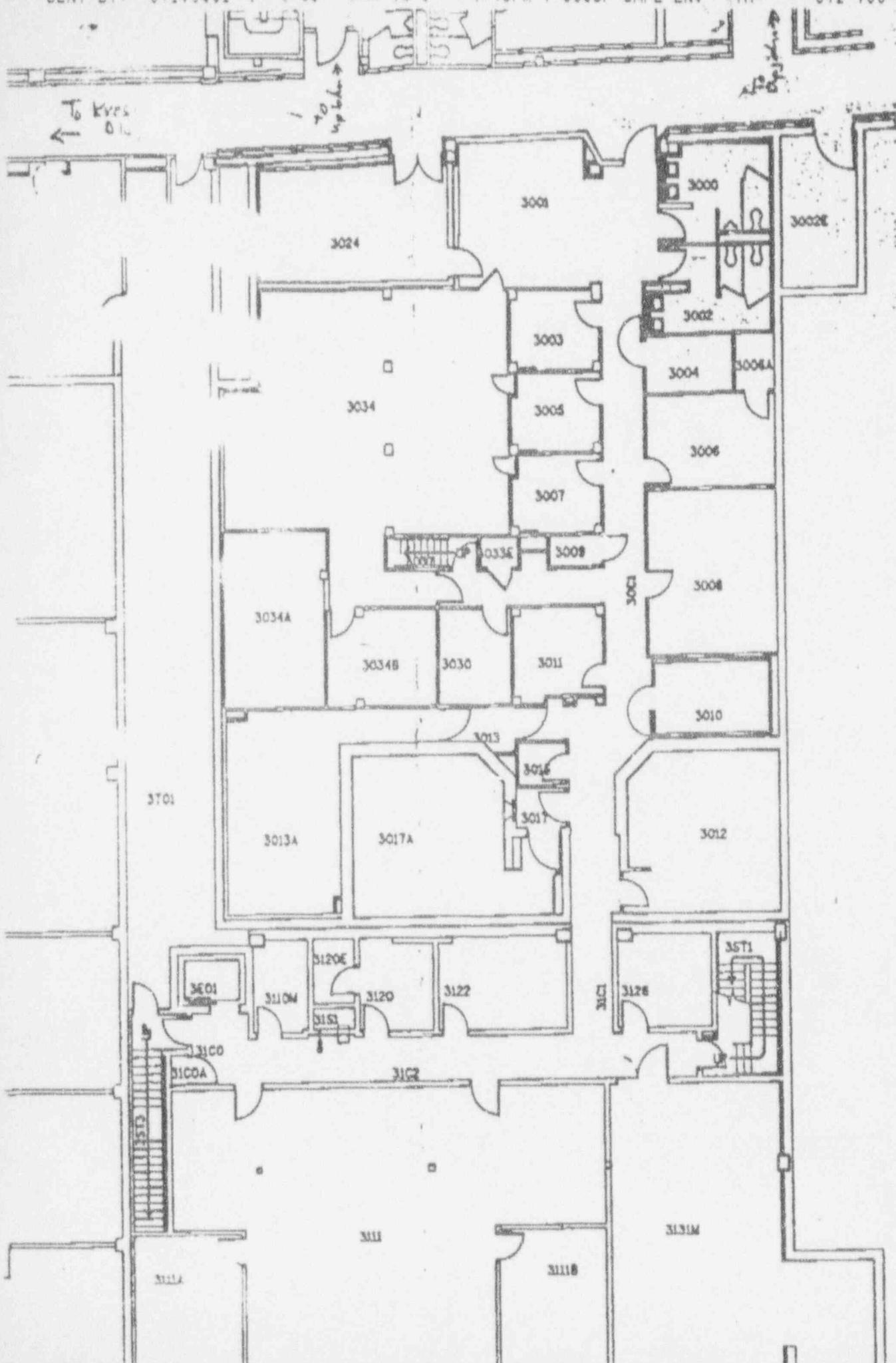
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1331 EAST ANN ST. BLDG.

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