APPENDIX A

GUIDANCE FOR COMPLETING THE FIELD TEST RECORD

Center for Devices and Radiological Health

CDRH

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APPENDIX A

GUIDANCE FOR COMPLETING

THE FIELD TEST RECORD

The following guidance is applicable to all test procedures presently contained in the Routine Compliance Testing Manual and to the corresponding field test records:

1. When a data item is not applicable and this answer is not provided for by a "X," enter an asterisk in the first available (left justified) column for that data item, and give a very brief explanation in the REMARKS. For example, on the Mobile Field Test Record, if the mAs is completed at item 7 and the control was manufactured before May 1994, item 34 should have an asterisk in its first available column and add a comment that mAs only selection available for the control.

2. If necessary instrumentation (e.g. photometer, 100-cm^2 chamber, and so forth) either malfunctions or is not available, enter an asterisk in the first available column for each affected data item and give an explanation in the REMARKS.

3. When a numerical data item is entered, fill in all empty columns with leading and trailing zeros. For example, a 515-mR exposure reading should be coded "0515.0 mR."

4. Each item on the field test record should be completed with either data or an asterisk for the appropriate data item unless specific instructions are given in the test procedure to skip sections or subsequent guidance is provided to leave an item blank. Data items within skipped sections are left blank.

5. For data items where numerical entries require the proper units (e.g., seconds OR pulses, inches or centimeters) choose the columns with the proper units and leave the other columns blank.

6. When using one of the available Field Test Records for a special purpose system (e.g., urological system), clearly indicate in the first column in the REMARKS, the type of special purpose system and any unusual aspects of the system design that might affect Federal performance requirements for it. In addition, use an S, T, or U as the unique letter designator.

7. When testing special purpose units, if a portion of the field test record does not lend itself totally to the procedure used, enter an asterisk in the first available column for each affected data item and record the applicable data in the remarks or on an attached FD 2782.

8. When making the second set of four exposures for a linearity determination, do not alter the kVp from the setting used for the first set of four exposures. If the kVp shifts when the second mA or mAs is selected, compensate the kVp back to its original setting, if possible. If the kVp cannot be compensated, mark the first data item for the second mA setting with an asterisk and explain in the REMARKS that the kVp could not be compensated.

9. Check beam quality exposure values to see that the data is reasonable. Do not submit beam quality data for which the exposure either remains the same or increases as more filtration is added. Likewise check the exposure values for the first two sets of four exposures to see that they are reasonable. Do not submit linearity data for which the exposure increases when the mA or mAs is decreased unless the data is repeated and confirmed.

10. Enter data legibly on the field test record. Poor handwriting has caused numerous keypunching errors.

11. Always use capital letters when entering alphabetic data.

12. If a data item must be changed on the field test record, draw a line through the inappropriate data and record the appropriate value directly above the data blanks with all leading and trailing zeroes included in the corrected value, for example:

0 2 7 5 . 0
~~|0|3|0|6|.|0|~~ mR

13. The completed forms are to be distributed as follows:

    a. Original (white) to the Center for Devices and Radiological Health.

    b. White copy to the FDA Home District.

    c. Blue copy of the FD Regional Radiological Health Representative (RRHR).

    d. Yellow copy to the investigator.

TABLE OF FEDERAL AND STATE AGENCY CODES

State or other Agency	Agency code	FDA Region code (1)
Alabama	AL	SE
Alaska	AK	PA
Arizona	AZ	PA
Arkansas	AR	SW
California	CA	PA
Colorado	CO	SW
Connecticut	CT	NE
Delaware	DE	MA
District of Columbia	DC	MA
Florida	FL	SE
Georgia	GA	SE
Hawaii	HI	PA
Idaho	ID	PA
Illinois	IL	MW
Indiana	IN	MW
Iowa	IA	SW
Kansas	KS	SW
Kentucky	KY	MA
Louisiana	LA	SE
Maine	ME	NE
Maryland	MD	MA
Massachusetts	MA	NE
Michigan	MI	MW
Minnesota	MN	MW
Mississippi	MS	SE
Missouri	MO	SW
Montana	MT	PA
Nebraska	NE	SW
Nevada	NV	PA
New Hampshire	NH	NE
New Jersey	NJ	MA
New Mexico	NM	SW
New York (State)	NY	NE
North Carolina	NC	SE
North Dakota	ND	MW
Ohio	OH	MA
Oklahoma	OK	SW
Oregon	OR	PA
Pennsylvania	PA	MA
Rhode Island	RI	NE
South Carolina	SC	SE
South Dakota	SD	MW

State or other Agency	Agency code	FDA Region code
Tennessee	TN	SE
Texas	TX	SW
Utah	UT	SW
Vermont	VT	NE
Virginia	VA	MA
Washington	WA	PA
West Virginia	WV	MA
Wisconsin	WI	MW
Wyoming	WY	SW
Guam	GU	PA
Puerto Rico	PR	SE
Virgin Islands	VI	SE
Bureau of Prisons	BP	
U.S. Air Force	AF	
U.S. Army	AY	
U.S. Coast Guard	CG	
U.S. Navy	NA	
U.S. Public Health Service Hospital/Out-Patient Clinics	PH	
FDA Mid Atlantic Region	MA	CE
FDA Midwest Region	MW	CE
FDA Northeast Region	NE	
FDA Pacific Region	PA	
FDA Southeast Region	SE	
FDA Southwest Region	SW	

APPENDIX B

TRIPOD SETUP

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APPENDIX B

TRIPOD SETUP PROCEDURE

1. Adjust the tripod legs such that they are approximately equal in length.

2. Set up tripod. Fully spread the legs.

3. Mount the test stand base on the threaded stud with the two mounting bars and wing nut (See figure 1).

4. Level the stand using the bubble level. Secure the test stand in the level position by tightening the position locks on the tripod.

5. Adjust the vertical position of the test stand to the desired height with the hand crank.

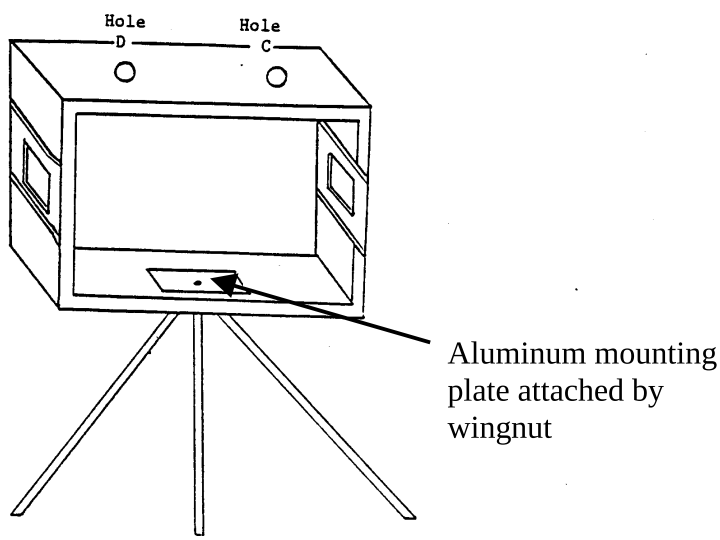

Figure 1 test stand attached to tripod

APPENDIX C

ESTIMATION OF ANNODE HEATING

CDRH
Center for Devices and Radiological Health

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APPENDIX C

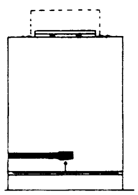
ESTIMATION OF ANODE HEATING

The following example calculations illustrate a procedure for estimating the amount of anode heating during a compliance survey. Such a determination can be made very quickly and will assure the surveyor that the tube manufacturer's specifications for anode heating will not be exceeded if additional exposures are required.

1. Assume that during a routine compliance survey of a mobile radiographic system manufactured after May 1994, the surveyor records the following data:

Test Setup

MDH (Pulse Exposure)
4.5 mm Al



Technique Factors

4. 0 9 0 kVp (22–24) over 70 kV
5. 1 0 0 mA (25–27)
6. 0 . 2 0 0 sec (28–31) OR ___ pulses (32–34)
7. ___ . ___ mAs (35–38) Capacitor discharge equipment — use maximum mAs for kV selected.

Beam Quality:

8.	0 0 2 2 . 7 mR (39–43)	@	4.5 mm Al
9.	0 0 3 5 . 2 mR (44–48)	@	3.5 mm Al
10.	0 0 5 4 . 5 mR (49–53)	@	2.5 mm Al
11.	0 0 8 1 . 0 mR (54–58)	@	1.5 mm Al

12. Warning Label Present Y (59) Y – YES N – NO

13. Exposure Terminated After Preset Time Interval Preset mAs, Or Preset Number of Pulses Y (60) Y – YES N – NO

Reproducibility (no Al in beam)

14.	0 1 0 2 . 4 mR (61–65)	15.	0 2 0 0 msec (66–69)
16.	0 1 1 0 . 0 mR (70–74)	17.	0 2 0 1 msec (75–78)
18.	0 0 9 5 . 6 mR (11–15)	19.	0 2 0 0 msec (16–19)
20.	0 1 0 1 . 0 mR (20–24)	21.	0 1 9 9 msec (25–28)

Linearity

34. 0 1 0 mAs (20–22)

If change in mA causes a kVp shift, readjust kVp (if possible) to value selected at item 4 above.

35. 0 0 5 1 . 4 mR (29–33)
36. 0 0 4 9 . 0 mR (37–41)
37. 0 0 4 3 . 7 mR (45–49)
38. 0 0 5 2 . 3 mR (50–54)

2. Sum items 8, 9, 10, 11, 14, 16, 18, 20, 35, 36, 37, and 38. For the example data, this sum is 798.8 mR. If the sum is greater than or equal to 1000 mR, the image on the direct-print paper should be adequate, and no additional exposure will be needed. If additional exposure is needed, subtract the sum from 1000 mR to determine the amount of additional exposure required. For the example data, the required additional exposure is 202 mR.

3. Using the reproducibility data (items 14, 16, 18, and 20) for the selected technique factors (items 5 and 6, or 7, as applicable), estimate the mR/mAs output of the system for the selected tube potential (item 4).

   For example, the average of items 14, 16, 18, and 20 is 102.2 mR, and the product of items 5 and 6 is 20.0 mAs. Therefore, the mR/mAs output is:

$$\frac{102.2\,\text{mR}}{20.0\,\text{mAs}} = 5.11\,\text{mR/mAs}$$

4. Estimate the total mAs (for the selected tube potential) required to obtain 1.0 R to the ion chamber.

   The total mAs used for the 12 previous exposures can be easily calculated. Therefore, simply add to this total, the mAs required for any additional exposures.

   Divide the additional exposure by the mR/mAs ration (from step 3) to determine the additional mAs required. For the example data, to get an additional 202 mR, one needs an additional mAs of at least:

$$\frac{202\,\text{mR}}{5.11\,\text{mR/mAs}} = 39.53\,\text{mAs}$$

   Since the mR/mAs ratio was calculated using item 5, reset the mA to that value. Select an exposure time to yield at least the desired additional mAs. Check the anode cooling curve to ensure this exposure time does not exceed anode limits for this kV and mA. If the exposure time exceeds the limits, make more than one exposure at shorter exposure times. For the example data, the technique factors would be 100 mA and 0.4 seconds, for an additional mAs of 40.

   The total mAs required can now be determined. For the example data, the total mAs required to obtain at least 1.0 R would be:

4 X 20 mAs	=	80 mAs	(from items 8-11)
4 X 20 mAs	=	80 mAs	(from items 14, 16, 18, and 20)
4 X 10 mAs	=	40 mAs	(from items 35, 36, 37, and 38)
1 X 40 mAs	=	40 mAs	(from additional exposure)
Total =		240 mAs	

5. Multiply the total mAs by the selected tube potential to determine the total heat unit input to the anode.

   For single-phase generators, the total number of heat units (H.U.) stored in the anode is given by the product of PKV x mAs. For three-phase systems, the total number of heat units in the anode is given by the product of PKV x mAs x 1.35. For this example, the total number of heat units input to the anode is:

$$90 \text{ kVp} \times 240 \text{ mAs} = 21{,}600 \text{ H.U.}$$

6. Check the anode cooling curve to ensure that the rated anode limits are not exceeded.

   If the total heat units calculated in step 5 do not exceed the total heat unit capacity of the anode, then the additional exposure(s) can be made immediately. If the total capacity will be exceeded, the additional exposure(s) can still be made, but the surveyor should estimate the anode cooling rate and wait for a time period sufficient to allow the anode to adequately cool.

EQUIPMENT DESCRIPTIONS
PART I

EQUIPMENT LIST

Center for Devices and Radiological Health

CDRH

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EQUIPMENT LIST FOR THE

BRH ROUTINE COMPLIANCE TEST SYSTEM

(December 1980)

NUMBER REQUIRED	ITEM
1	Carrying Case
1	BRH Routine Compliance Test Stand
1	Test Stand Slide Assembly
4	Metal Marker Strips, 0.5" x 1.5" x 1/32"
3	Copper Attenuation Blocks 8" x 8" x 0.040", 0.060", 0.080"
2	Lead Sheets, 8" x 8" x 1/8"
1	Test Stand Spacer Assembly
5	Type 1100 Aluminum Filters ($\Sigma \geq$ 6mm)
1	Beam-Defining Assembly, Lead/Lucite
1	Tripod
2	Tripod Mounting Brackets
1	Photometer
2	Plastic Cassettes
1	Linagraphic (Direct Print) Paper
1	Retractable Tape Measure, Marked in Inches and Centimeters
1	Spirit Level
1	Stop Watch
1	GM Survey Meter
1	Focal-Spot Assembly
1	MDH 1015-F
1	BENT Test Stand
1	BENT Cardboard Support Devices
1	Set of Copper Filters

EQUIPMENT DESCRIPTIONS
PART II

TEST STAND DRAWINGS

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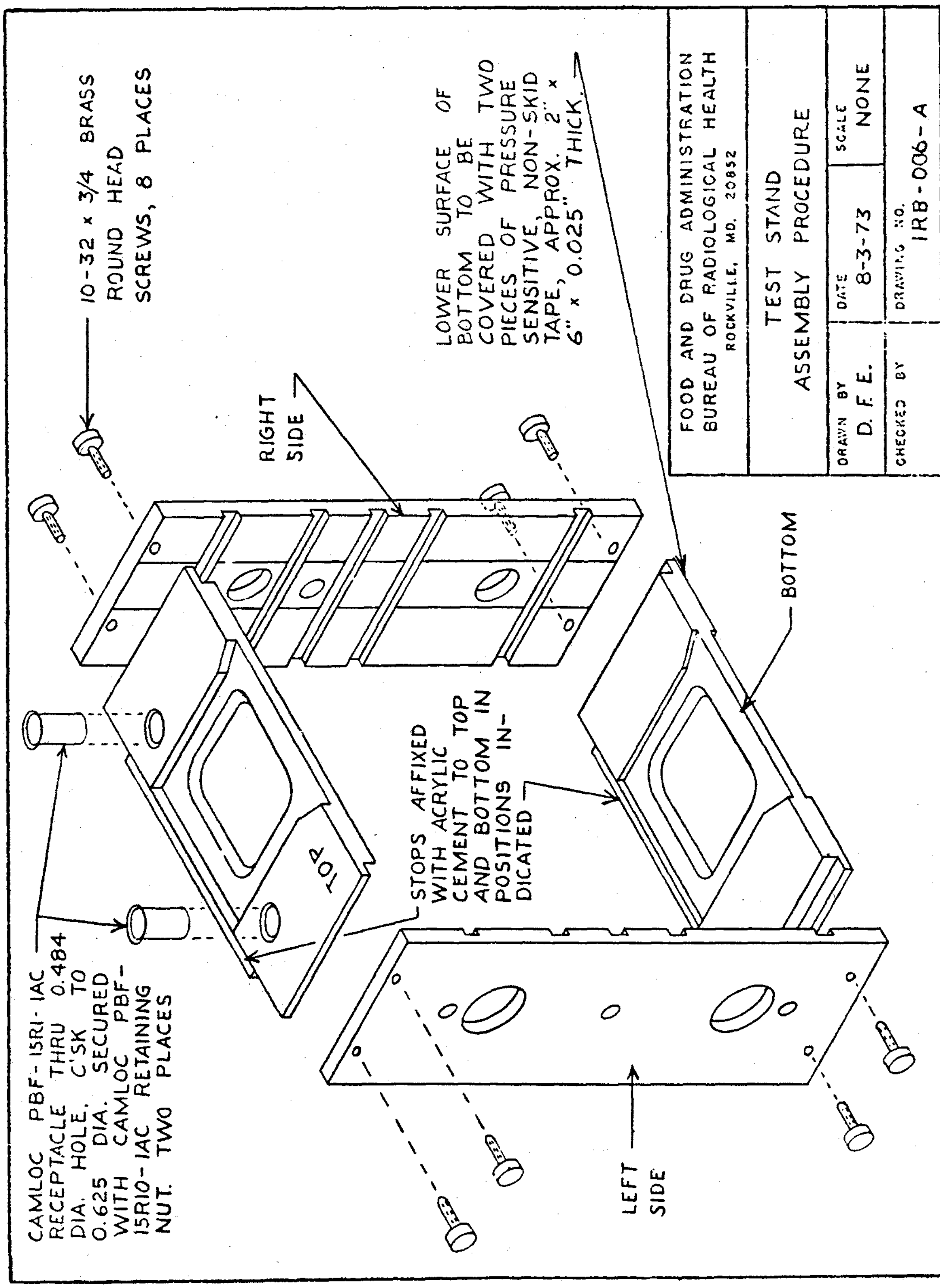
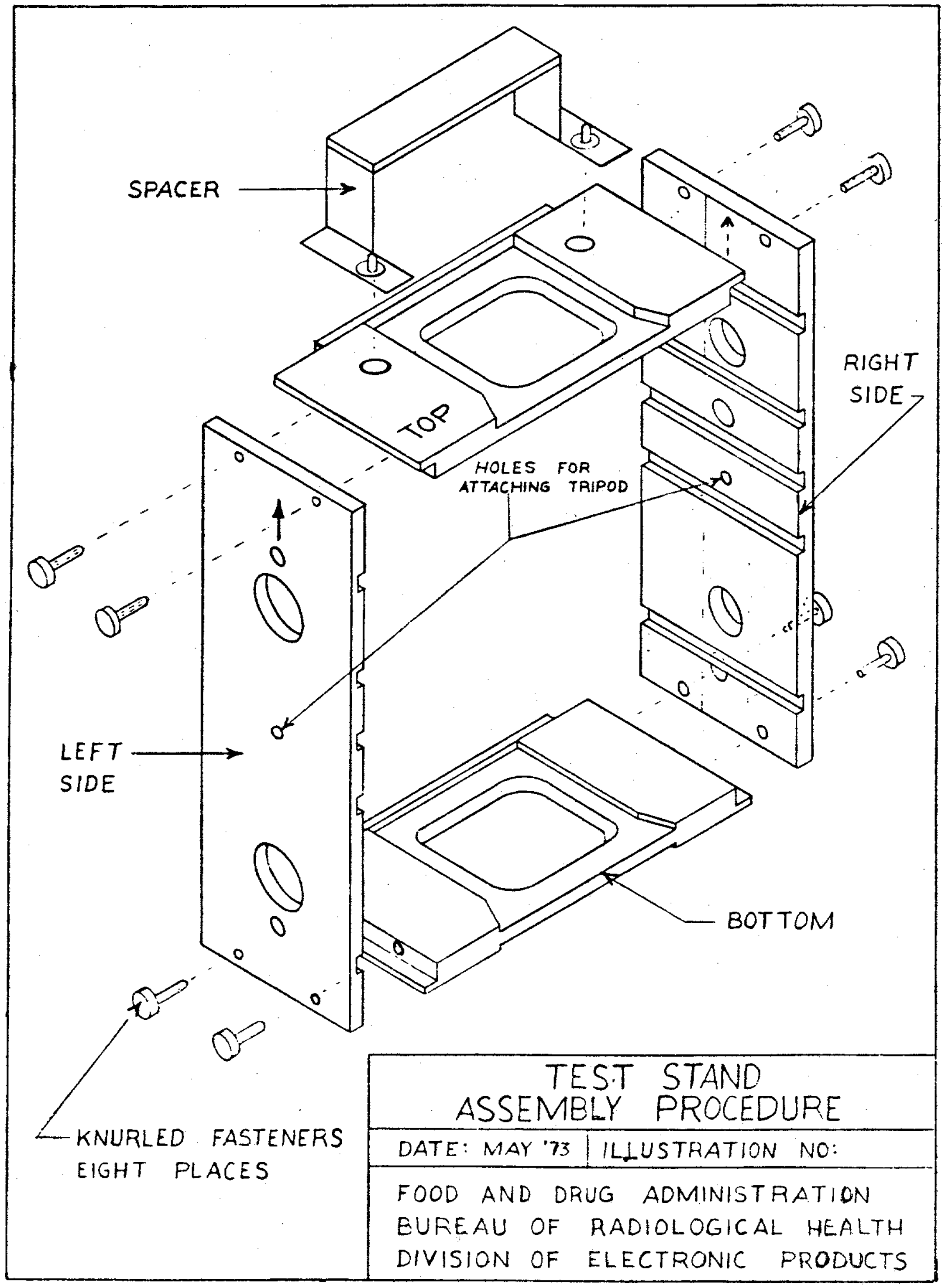
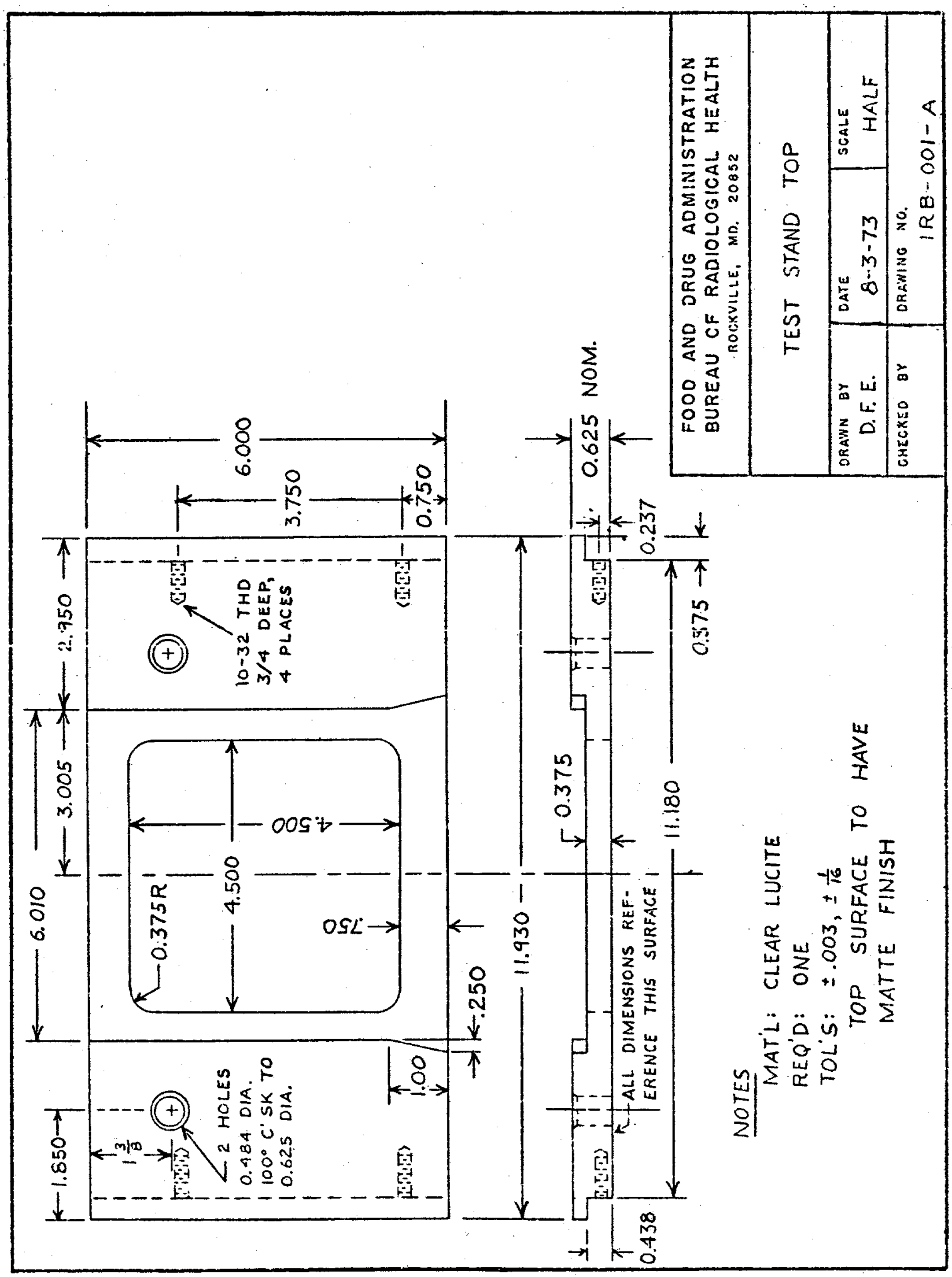

10-32 x 3/4 BRASS ROUND HEAD SCREWS, 8 PLACES
RIGHT SIDE
LOWER SURFACE OF BOTTOM TO BE COVERED WITH TWO PIECES OF PRESSURE SENSITIVE, NON-SKID TAPE, APPROX. 2" x 6" x 0.025" THICK.
CAMLOC PBF-15RI-IAC RECEPTACLE THRU 0.484 DIA. HOLE, C'SK TO 0.625 DIA. SECURED WITH CAMLOC PBF-15RIO-IAC RETAINING NUT. TWO PLACES
TOP
STOPS AFFIXED WITH ACRYLIC CEMENT TO TOP AND BOTTOM IN POSITIONS INDICATED
BOTTOM
LEFT SIDE
FOOD AND DRUG ADMINISTRATION
BUREAU OF RADIOLOGICAL HEALTH
ROCKVILLE, MD. 20852
TEST STAND
ASSEMBLY PROCEDURE
DRAWN BY D. F. E.
DATE 8-3-73
SCALE NONE
CHECKED BY
DRAWING NO. IRB-006-A

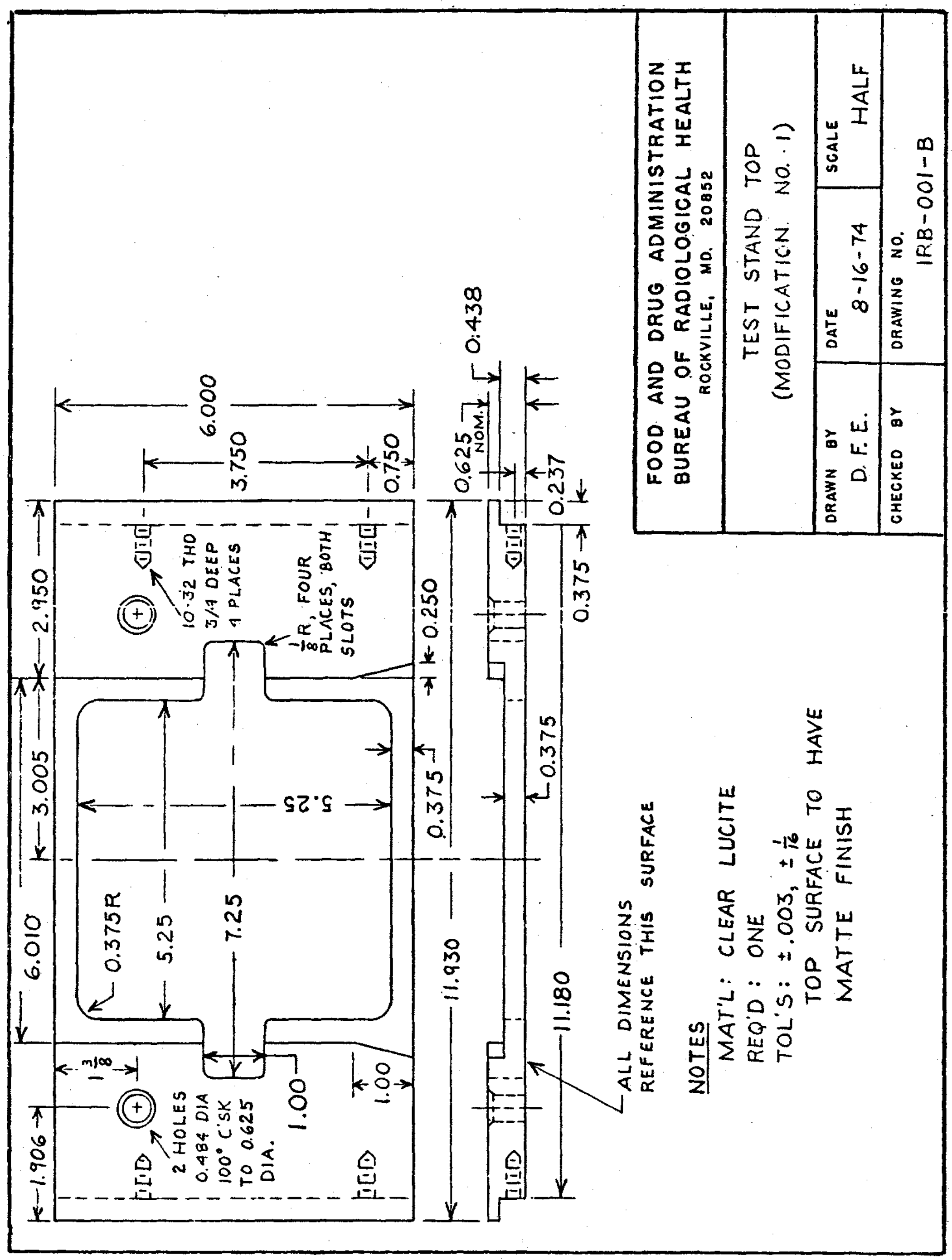


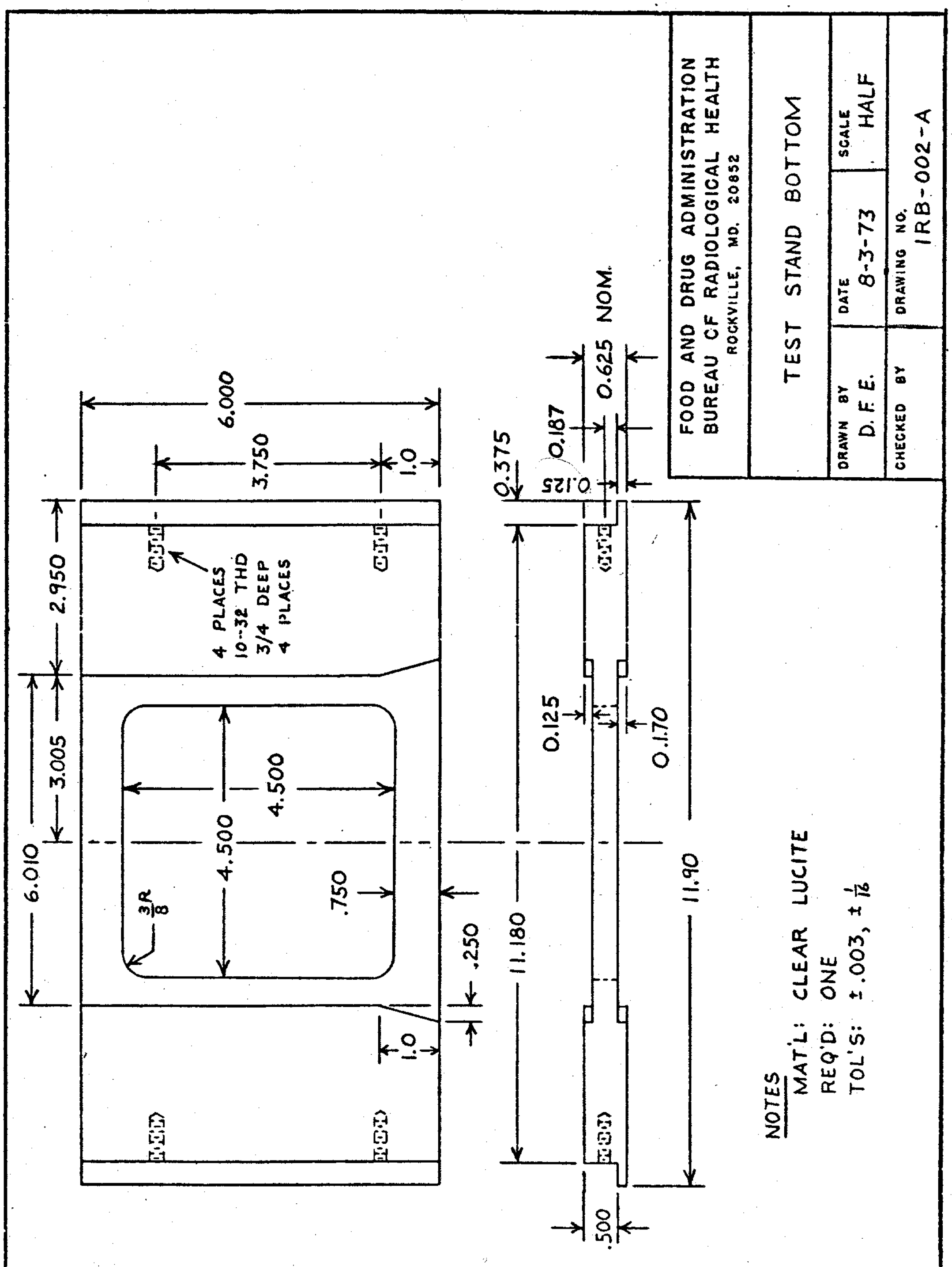
TEST STAND
ASSEMBLY PROCEDURE

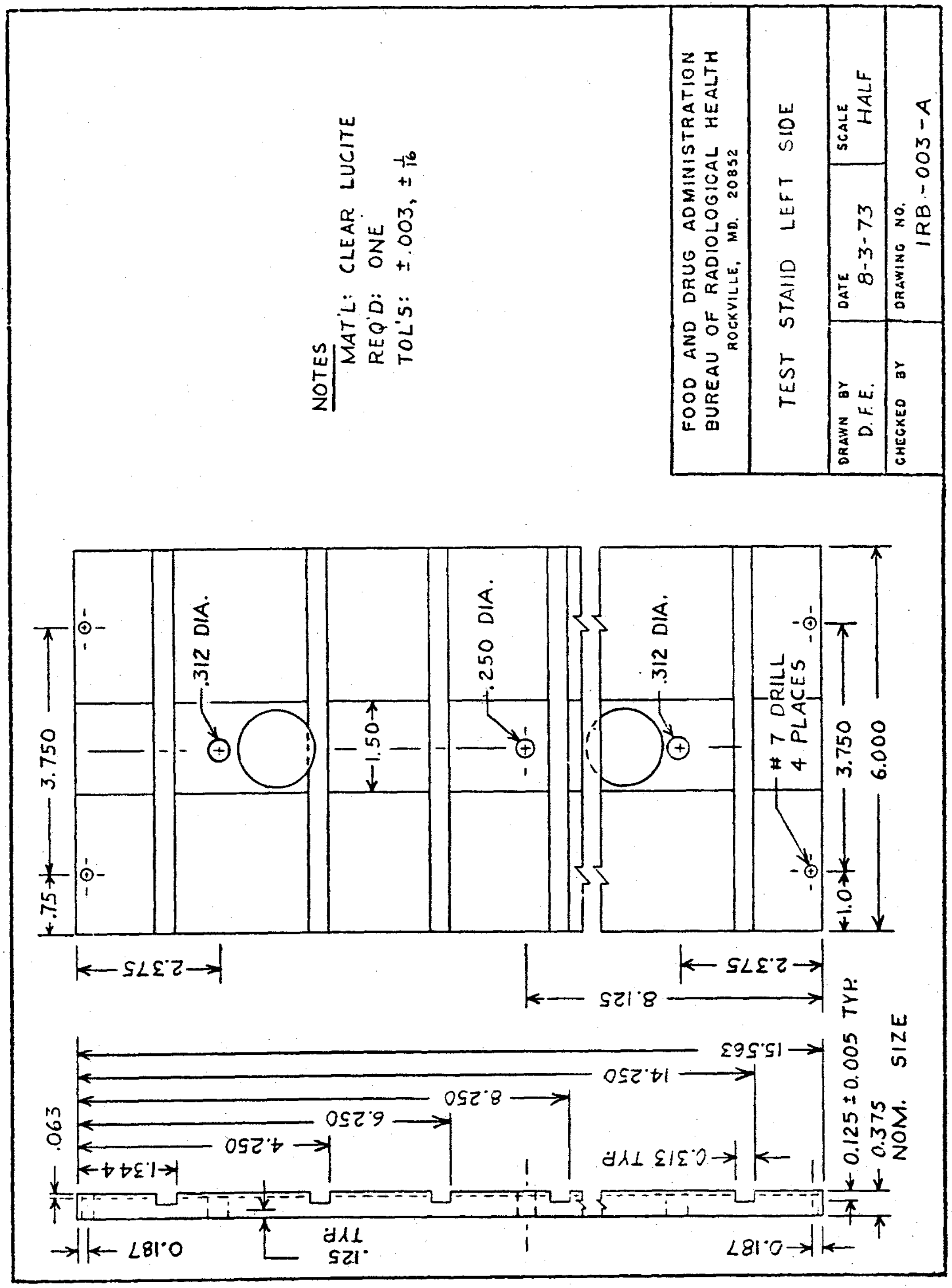
DATE: MAY '73 | ILLUSTRATION NO:

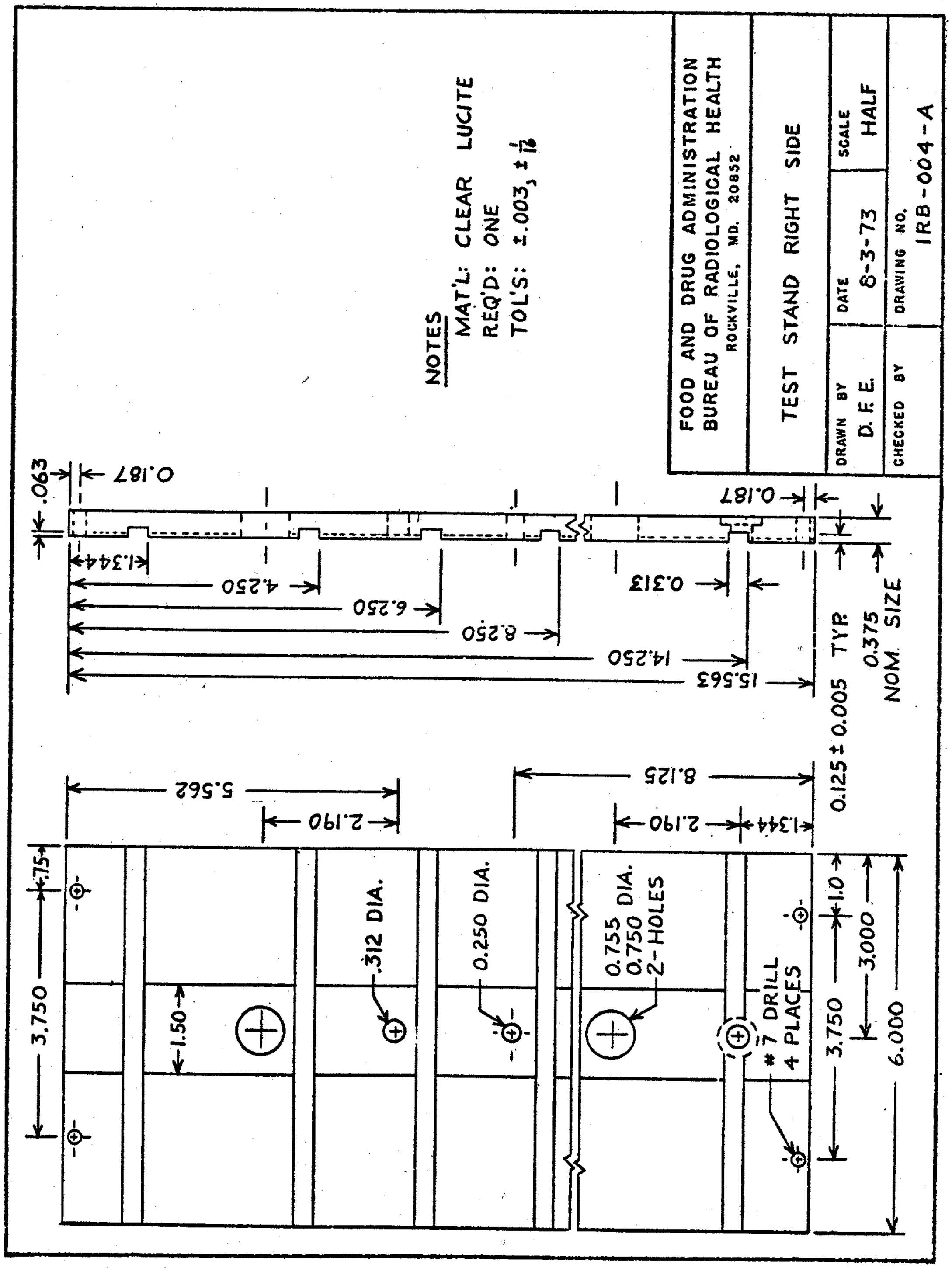
FOOD AND DRUG ADMINISTRATION
BUREAU OF RADIOLOGICAL HEALTH
DIVISION OF ELECTRONIC PRODUCTS

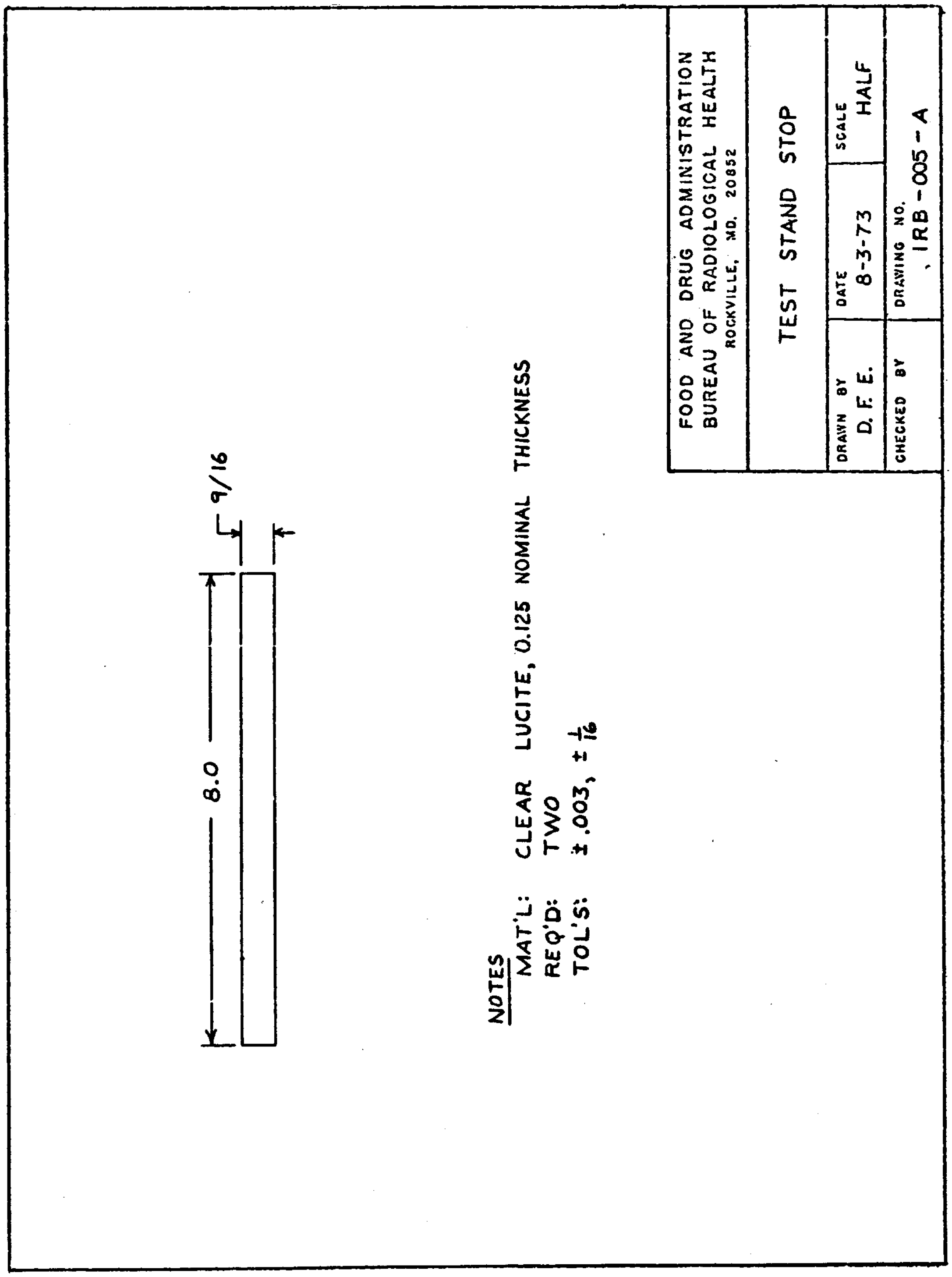

FOOD AND DRUG ADMINISTRATION
BUREAU OF RADIOLOGICAL HEALTH
ROCKVILLE, MD. 20852
TEST STAND TOP
DRAWN BY D.F.E.
DATE 8-3-73
SCALE HALF
CHECKED BY
DRAWING NO. IRB-001-A
NOTES
MAT'L: CLEAR LUCITE
REQ'D: ONE
TOL'S: ±.003, ± 1/16
TOP SURFACE TO HAVE MATTE FINISH
10-32 THD 3/4 DEEP, 4 PLACES
2 HOLES 0.484 DIA. 100° C'SK TO 0.625 DIA.
ALL DIMENSIONS REFERENCE THIS SURFACE
0.625 NOM.
6.000
3.750
0.750
0.237
0.575
2.950
3.005
6.010
1.650
1 3/8
4.500
4.500
0.375R
.750
.250
1.00
11.930
11.180
0.375
0.438

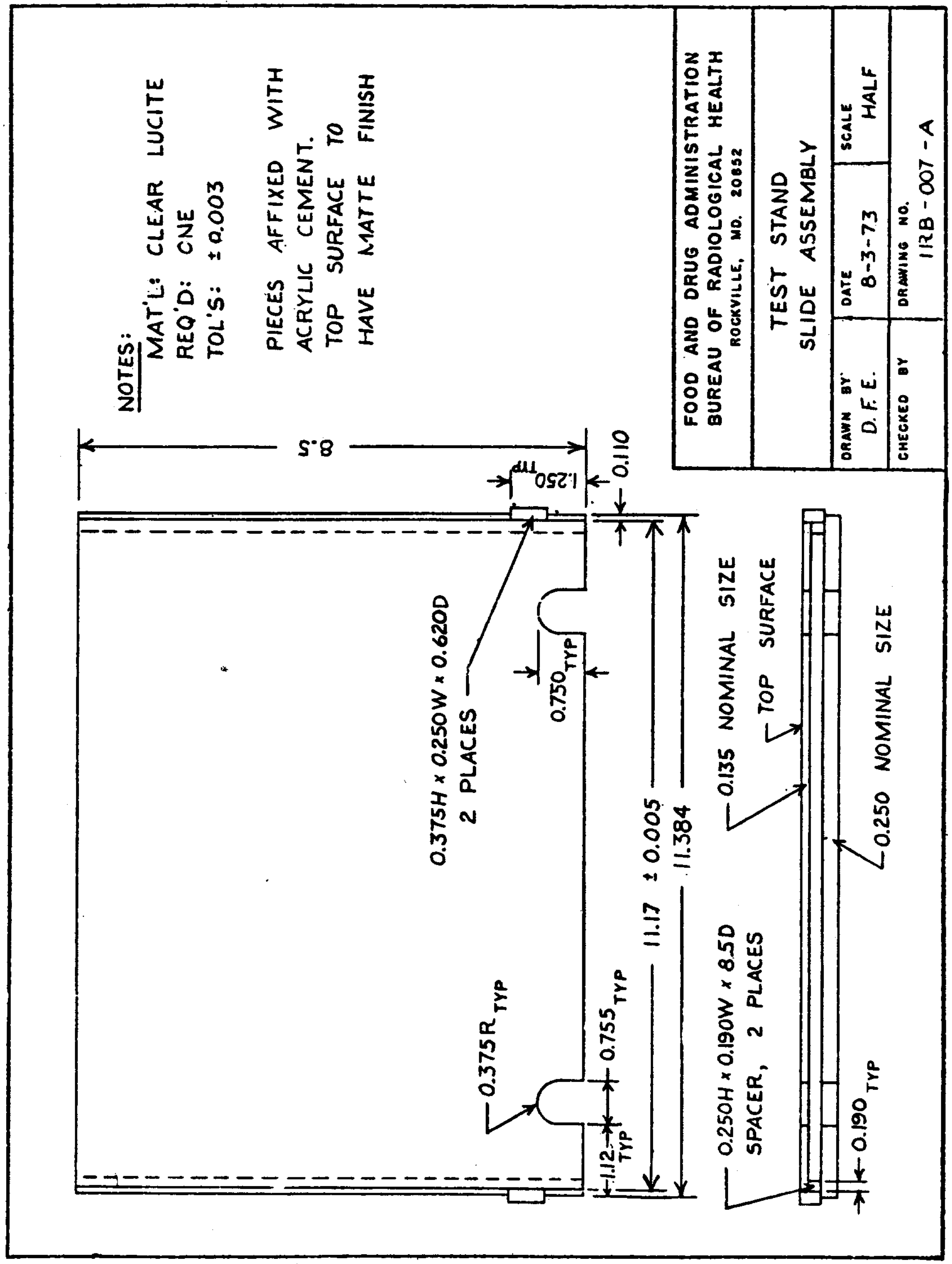

FOOD AND DRUG ADMINISTRATION
BUREAU OF RADIOLOGICAL HEALTH
ROCKVILLE, MD. 20852
TEST STAND TOP
(MODIFICATION NO. 1)
DRAWN BY
D. F. E.
DATE
8-16-74
SCALE
HALF
CHECKED BY
DRAWING NO.
IRB-001-B
NOTES
MAT'L: CLEAR LUCITE
REQ'D: ONE
TOL'S: ±.003, ±1/16
TOP SURFACE TO HAVE
MATTE FINISH
ALL DIMENSIONS
REFERENCE THIS SURFACE
6.000
3.750
0.750
0.625 NOM.
0.438
0.237
0.375
2.950
3.005
6.010
1.906
10-32 THD
3/4 DEEP
4 PLACES
1/8 R, FOUR
PLACES, BOTH
SLOTS
0.250
0.375
0.375
5.25
0.375R
5.25
7.25
11.930
11.180
1 3/8
1.00
1.00
2 HOLES
0.484 DIA
100° C'SK
TO 0.625
DIA.


FOOD AND DRUG ADMINISTRATION
BUREAU CF RADIOLOGICAL HEALTH
ROCKVILLE, MD. 20852
TEST STAND BOTTOM
DRAWN BY
D. F. E.
DATE
8-3-73
SCALE
HALF
CHECKED BY
DRAWING NO.
IRB-002-A
4 PLACES
10-32 THD
3/4 DEEP
4 PLACES
NOTES
MAT'L: CLEAR LUCITE
REQ'D: ONE
TOL'S: ±.003, ±1/16
6.000
3.750
1.0
2.950
3.005
6.010
4.500
4.500
.750
3R/8
.250
1.0
11.180
11.90
0.375
0.187
0.125
0.625 NOM.
0.125
0.170
.500


FOOD AND DRUG ADMINISTRATION
BUREAU OF RADIOLOGICAL HEALTH
ROCKVILLE, MD. 20852
TEST STAND LEFT SIDE
DRAWN BY D.F.E.
DATE 8-3-73
SCALE HALF
CHECKED BY
DRAWING NO. IRB-003-A
NOTES
MAT'L: CLEAR LUCITE
REQ'D: ONE
TOL'S: ±.003, ± 1/16
.312 DIA.
.250 DIA.
.312 DIA.
7 DRILL 4 PLACES
3.750
1.50
.75
1.0
3.750
6.000
2.375
8.125
2.375
15.563
14.250
8.250
6.250
4.250
1.344
.063
0.313 TYP.
0.125 ± 0.005 TYP.
0.375 NOM. SIZE
0.187
.125 TYP.
0.187


NOTES
MAT'L: CLEAR LUCITE
REQ'D: ONE
TOL'S: ±.003, ± 1/16
FOOD AND DRUG ADMINISTRATION
BUREAU OF RADIOLOGICAL HEALTH
ROCKVILLE, MD. 20852
TEST STAND RIGHT SIDE
DRAWN BY
D. F. E.
DATE
8-3-73
SCALE
HALF
CHECKED BY
DRAWING NO.
IRB-004-A
.063
0.187
1.344
4.250
6.250
8.250
14.250
15.563
0.313
0.187
0.125 ± 0.005 TYP.
0.375
NOM. SIZE
5.562
2.190
8.125
2.190
1.344
.75
3.750
1.50
.312 DIA.
0.250 DIA.
0.755
0.750 DIA.
2-HOLES
7 DRILL
4 PLACES
1.0
3.000
3.750
6.000


FOOD AND DRUG ADMINISTRATION
BUREAU OF RADIOLOGICAL HEALTH
ROCKVILLE, MD. 20852
TEST STAND STOP
DRAWN BY
D. F. E.
DATE
8-3-73
SCALE
HALF
CHECKED BY
DRAWING NO.
IRB-005-A
9/16
8.0
NOTES
MAT'L: CLEAR LUCITE, 0.125 NOMINAL THICKNESS
REQ'D: TWO
TOL'S: ±.003, ±1/16


NOTES:
MAT'L: CLEAR LUCITE
REQ'D: ONE
TOL'S: ± 0.003
PIECES AFFIXED WITH
ACRYLIC CEMENT.
TOP SURFACE TO
HAVE MATTE FINISH
8.5
1.250 TYP
0.110
0.375H × 0.250W × 0.620D
2 PLACES
0.750 TYP
11.17 ± 0.005
11.384
0.135 NOMINAL SIZE
TOP SURFACE
0.250 NOMINAL SIZE
0.375R TYP
0.755 TYP
1.12 TYP
0.250H × 0.190W × 8.5D
SPACER, 2 PLACES
0.190 TYP
FOOD AND DRUG ADMINISTRATION
BUREAU OF RADIOLOGICAL HEALTH
ROCKVILLE, MD. 20852
TEST STAND
SLIDE ASSEMBLY
DRAWN BY
D.F.E.
DATE
8-3-73
SCALE
HALF
CHECKED BY
DRAWING NO.
11RB-007-A

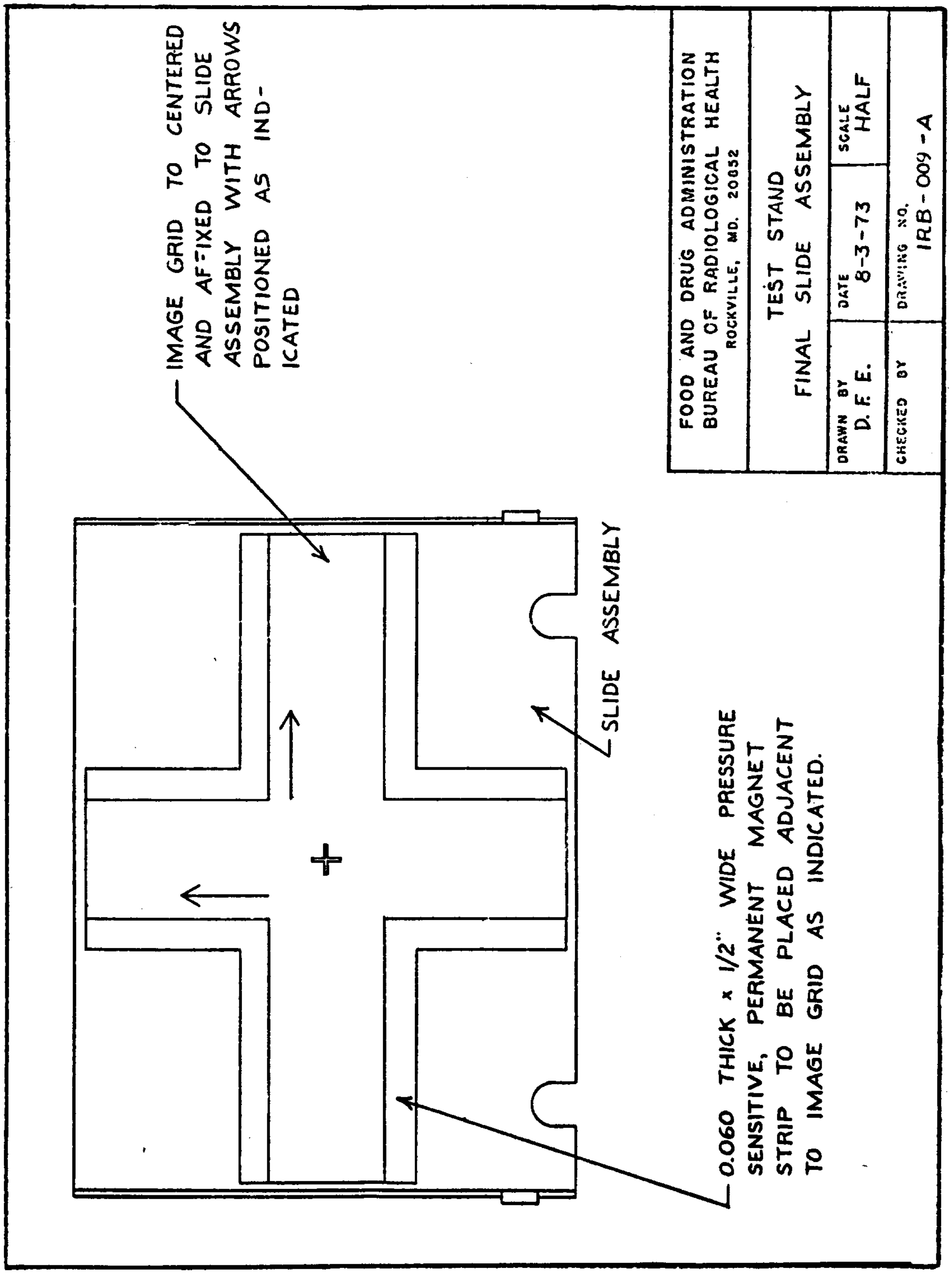
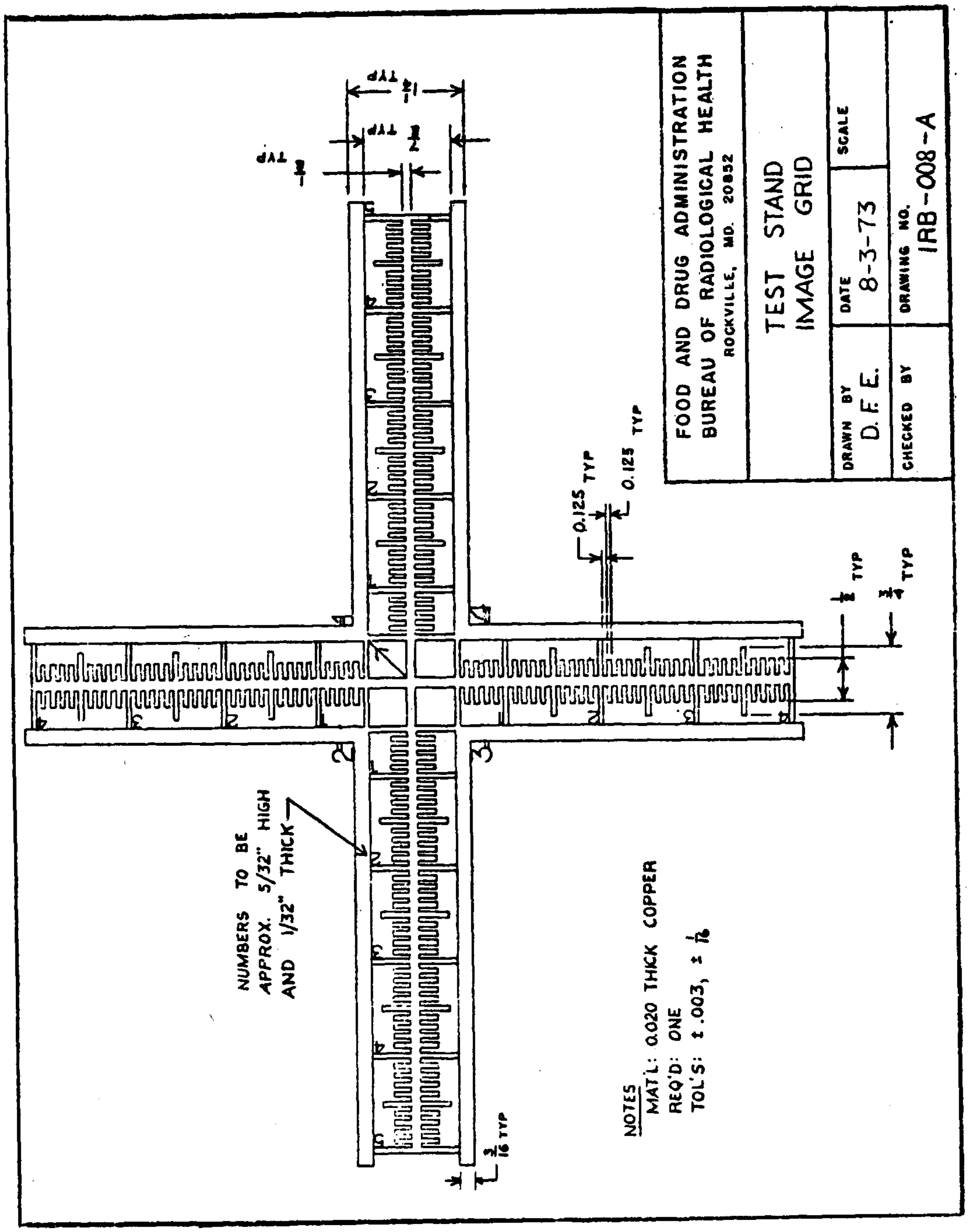
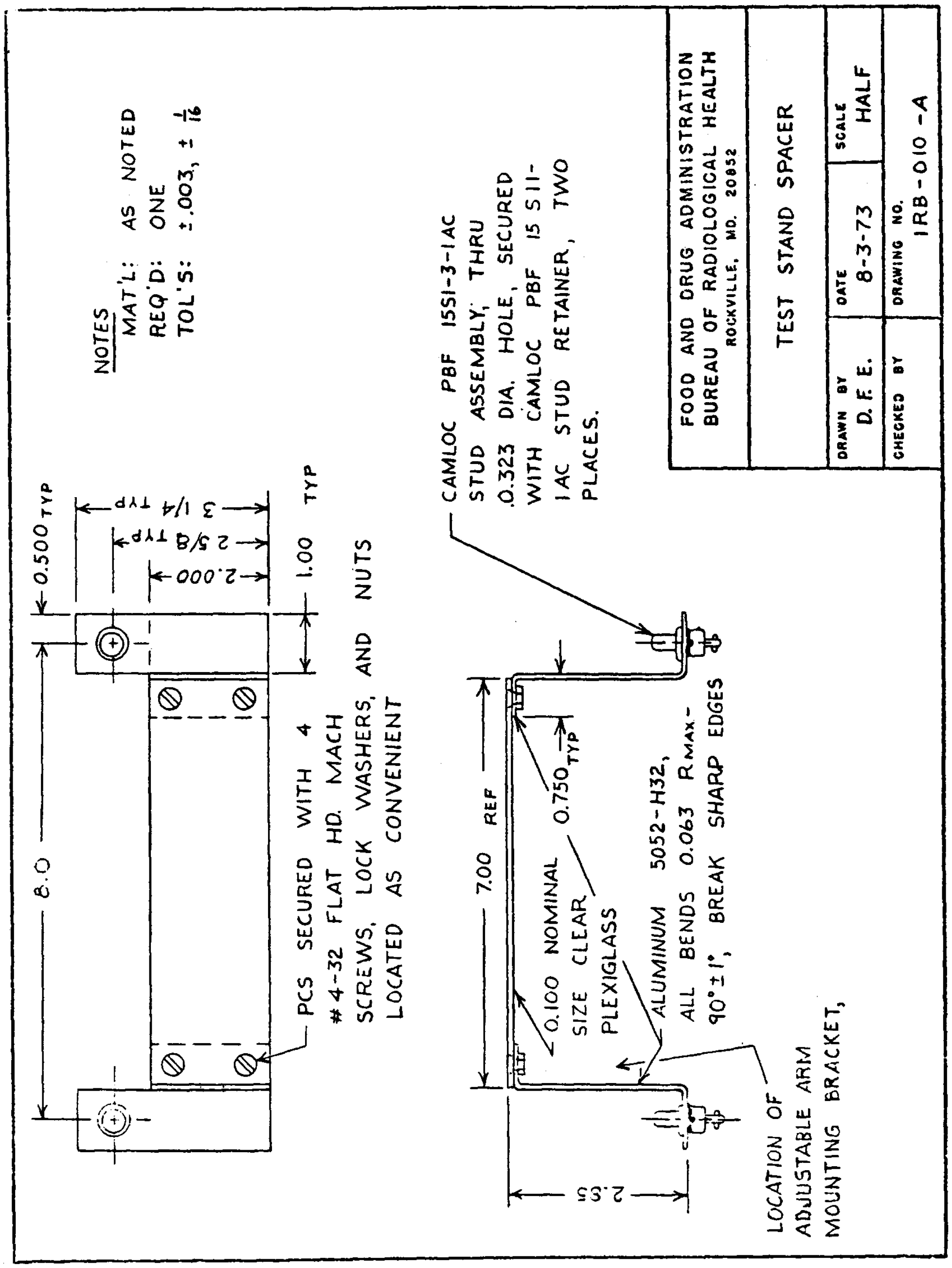
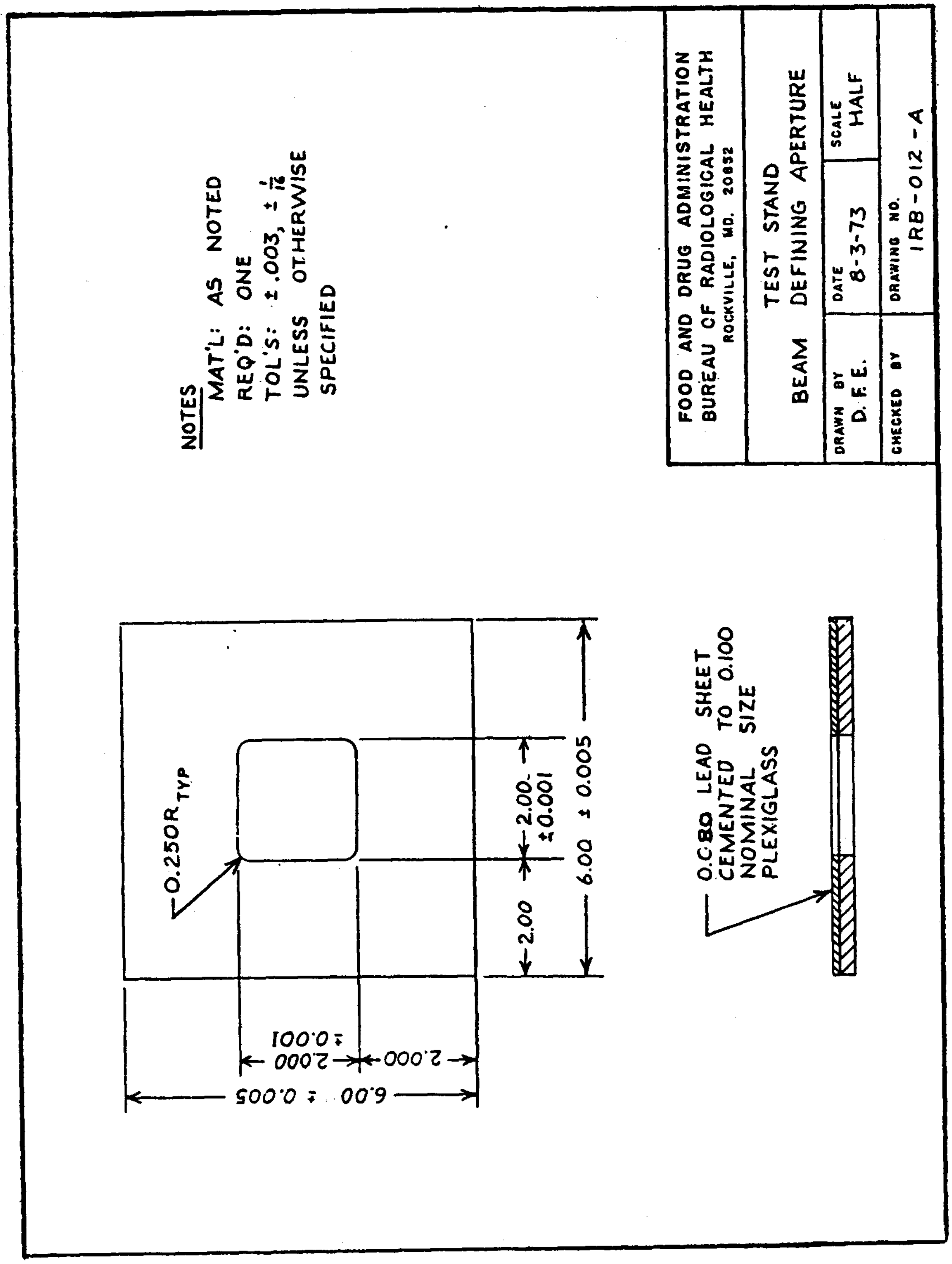


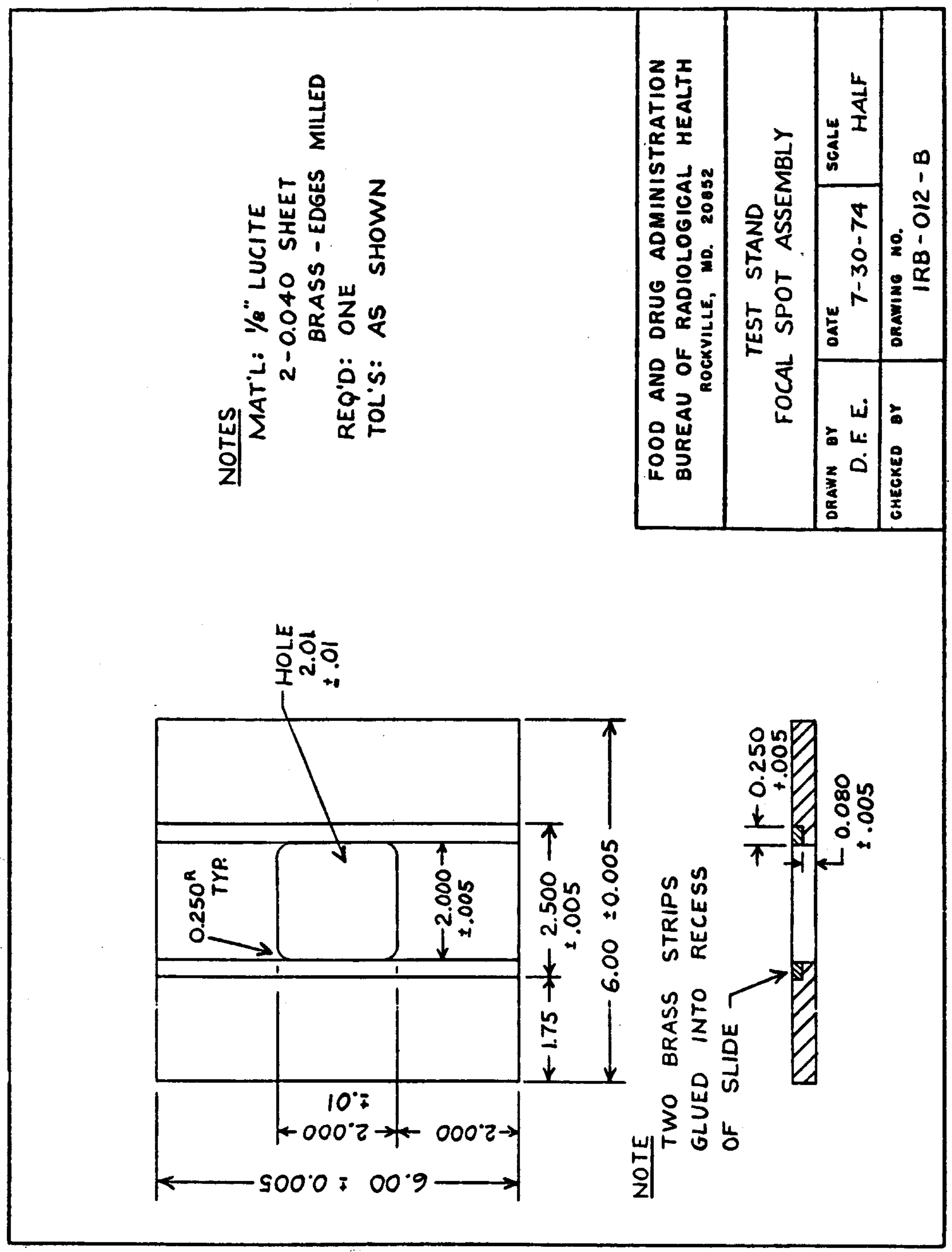
IMAGE GRID TO CENTERED AND AF?IXED TO SLIDE ASSEMBLY WITH ARROWS POSITIONED AS IND-ICATED
SLIDE ASSEMBLY
0.060 THICK x 1/2" WIDE PRESSURE SENSITIVE, PERMANENT MAGNET STRIP TO BE PLACED ADJACENT TO IMAGE GRID AS INDICATED.
FOOD AND DRUG ADMINISTRATION
BUREAU OF RADIOLOGICAL HEALTH
ROCKVILLE, MD. 20852
TEST STAND
FINAL SLIDE ASSEMBLY
DRAWN BY
D. F. E.
DATE
8-3-73
SCALE
HALF
CHECKED BY
DRAWING NO.
IRB-009-A


FOOD AND DRUG ADMINISTRATION
BUREAU OF RADIOLOGICAL HEALTH
ROCKVILLE, MD. 20852
TEST STAND
IMAGE GRID
DRAWN BY
D.F.E.
DATE
8-3-73
SCALE
CHECKED BY
DRAWING NO.
IRB-008-A
NUMBERS TO BE
APPROX. 5/32" HIGH
AND 1/32" THICK
NOTES
MAT'L: 0.020 THICK COPPER
REQ'D: ONE
0.125 TYP
0.125 TYP

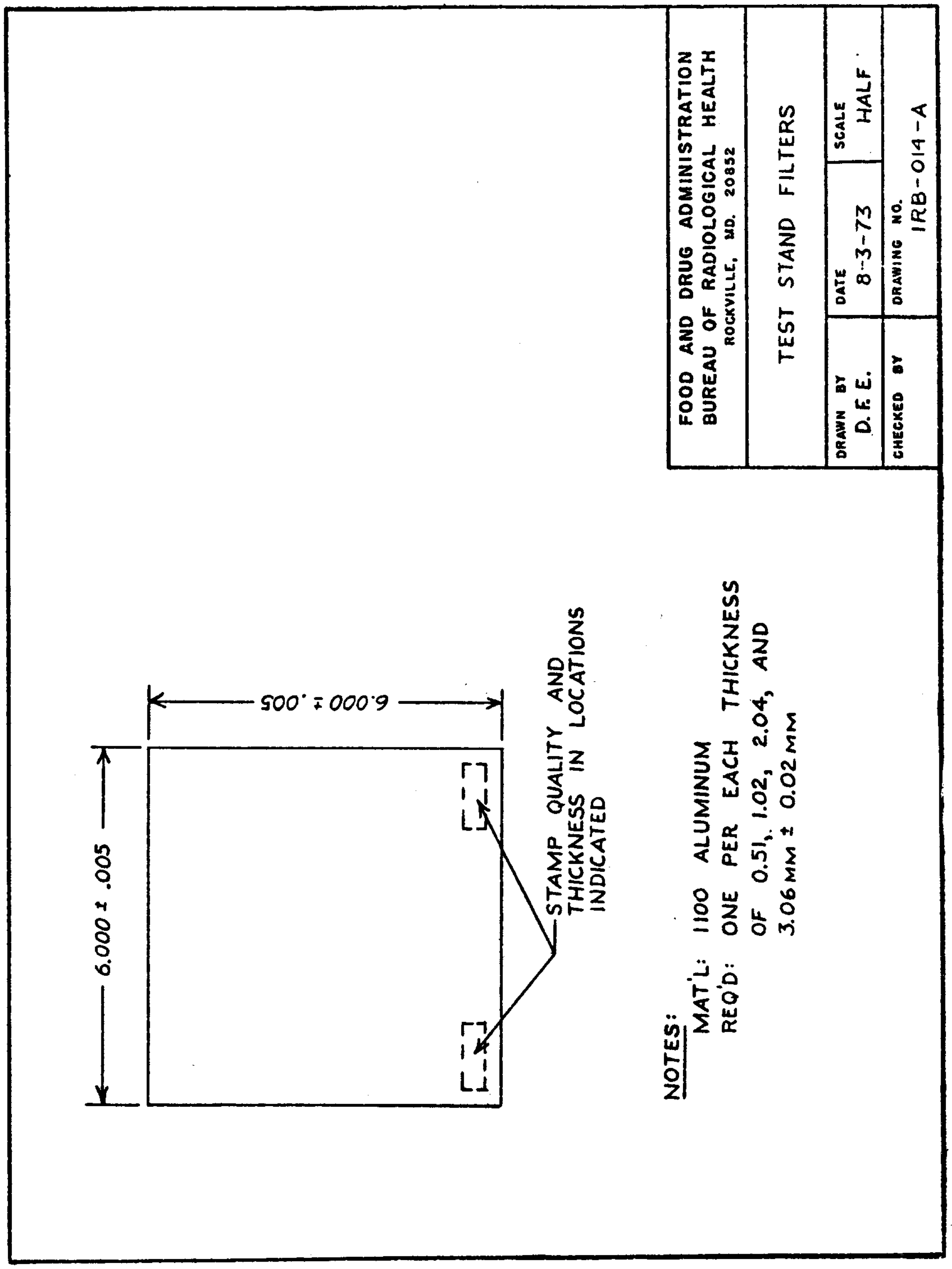

NOTES
MAT'L: AS NOTED
REQ'D: ONE
TOL'S: ±.003, ± 1/16
0.500 TYP
8.0
3 1/4 TYP
2 5/8 TYP
2.000
1.00 TYP
PCS SECURED WITH 4 #4-32 FLAT HD. MACH SCREWS, LOCK WASHERS, AND NUTS LOCATED AS CONVENIENT
CAMLOC PBF 1551-3-1AC STUD ASSEMBLY; THRU 0.323 DIA. HOLE, SECURED WITH CAMLOC PBF 15 511-1AC STUD RETAINER, TWO PLACES.
7.00 REF
0.750 TYP
0.100 NOMINAL SIZE CLEAR PLEXIGLASS
ALUMINUM 5052-H32, ALL BENDS 0.063 R MAX - 90°±1°, BREAK SHARP EDGES
LOCATION OF ADJUSTABLE ARM MOUNTING BRACKET,
2.55
FOOD AND DRUG ADMINISTRATION
BUREAU OF RADIOLOGICAL HEALTH
ROCKVILLE, MD. 20852
TEST STAND SPACER
DRAWN BY
D. F. E.
DATE
8-3-73
SCALE
HALF
CHECKED BY
DRAWING NO.
IRB-010-A

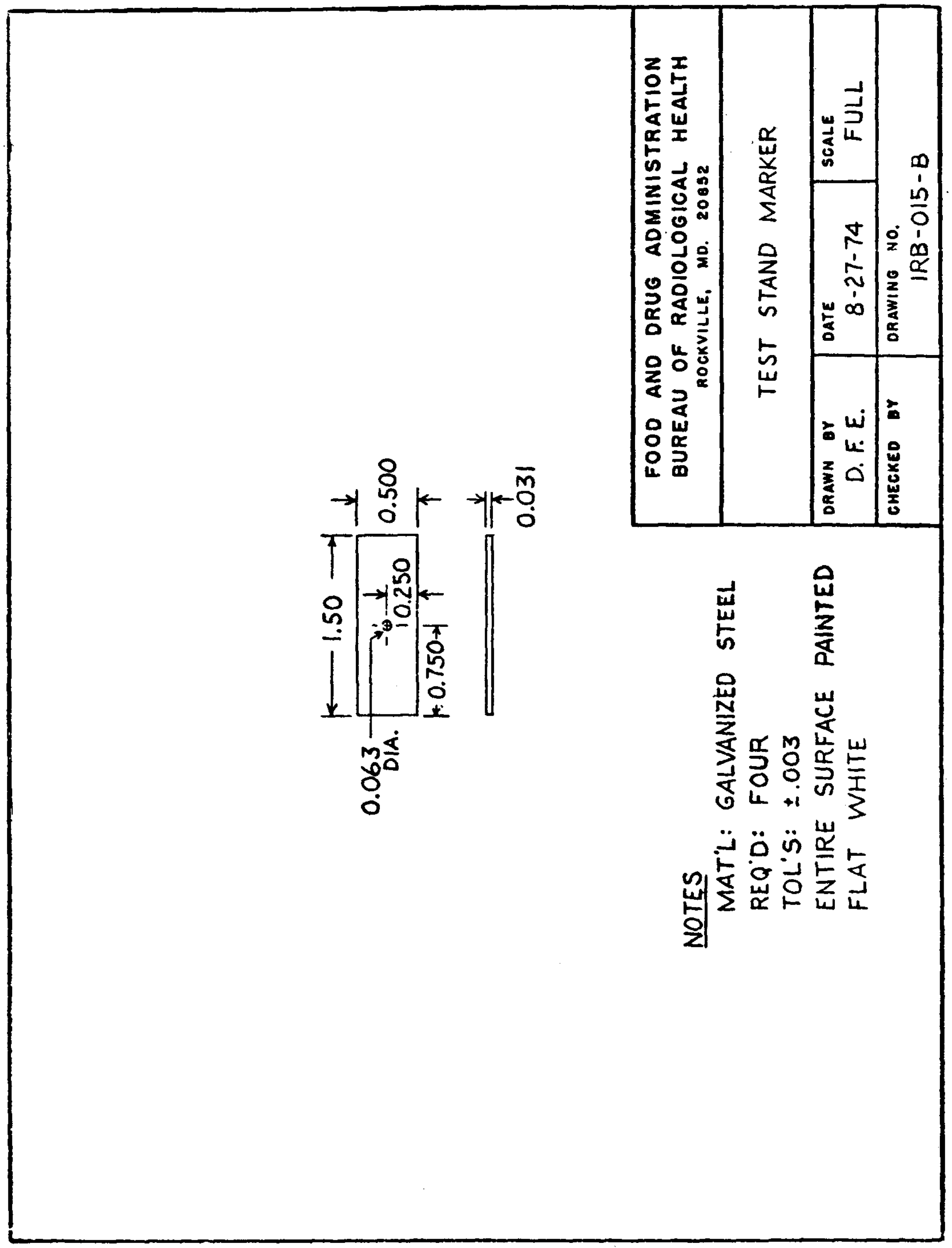


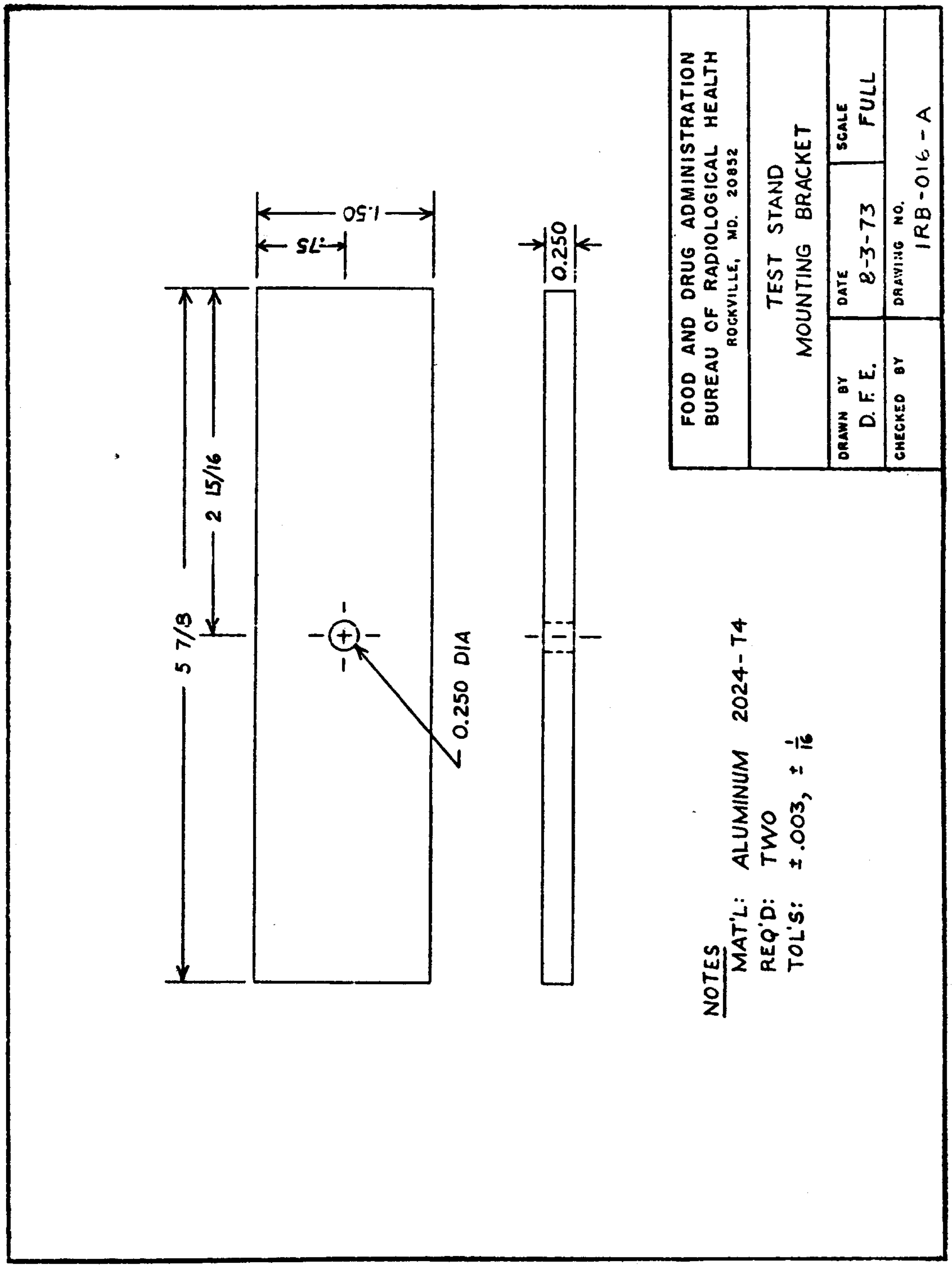
FOOD AND DRUG ADMINISTRATION
BUREAU OF RADIOLOGICAL HEALTH
ROCKVILLE, MD. 20852
TEST STAND
BEAM DEFINING APERTURE
DRAWN BY
D. F. E.
DATE
8-3-73
SCALE
HALF
CHECKED BY
DRAWING NO.
IRB-012-A
NOTES
MAT'L: AS NOTED
REQ'D: ONE
TOL'S: ±.003, ±1/16
UNLESS OTHERWISE
SPECIFIED
0.250R TYP
2.00
2.00 ±0.001
6.00 ± 0.005
2.000
2.000 ±0.001
6.00 ± 0.005
0.080 LEAD SHEET
CEMENTED TO 0.100
NOMINAL SIZE
PLEXIGLASS

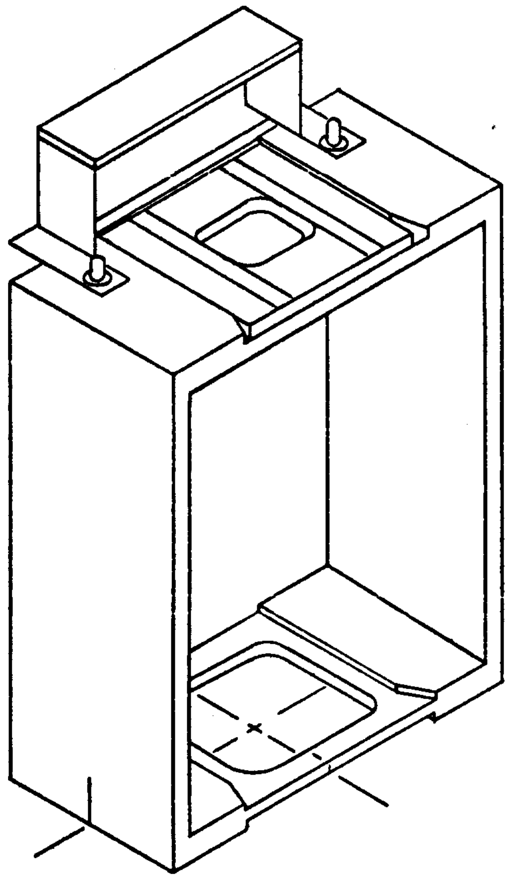


NOTES
MAT'L: 1/8" LUCITE
2-0.040 SHEET
BRASS - EDGES MILLED
REQ'D: ONE
TOL'S: AS SHOWN
FOOD AND DRUG ADMINISTRATION
BUREAU OF RADIOLOGICAL HEALTH
ROCKVILLE, MD. 20852
TEST STAND
FOCAL SPOT ASSEMBLY
DRAWN BY
D. F. E.
DATE
7-30-74
SCALE
HALF
CHECKED BY
DRAWING NO.
IRB-012-B
HOLE
2.01
±.01
0.250R
TYP.
2.000
±.005
2.500
±.005
1.75
6.00 ±0.005
2.000
2.000
±.01
6.00 ± 0.005
0.250
±.005
0.080
±.005
NOTE
TWO BRASS STRIPS
GLUED INTO RECESS
OF SLIDE

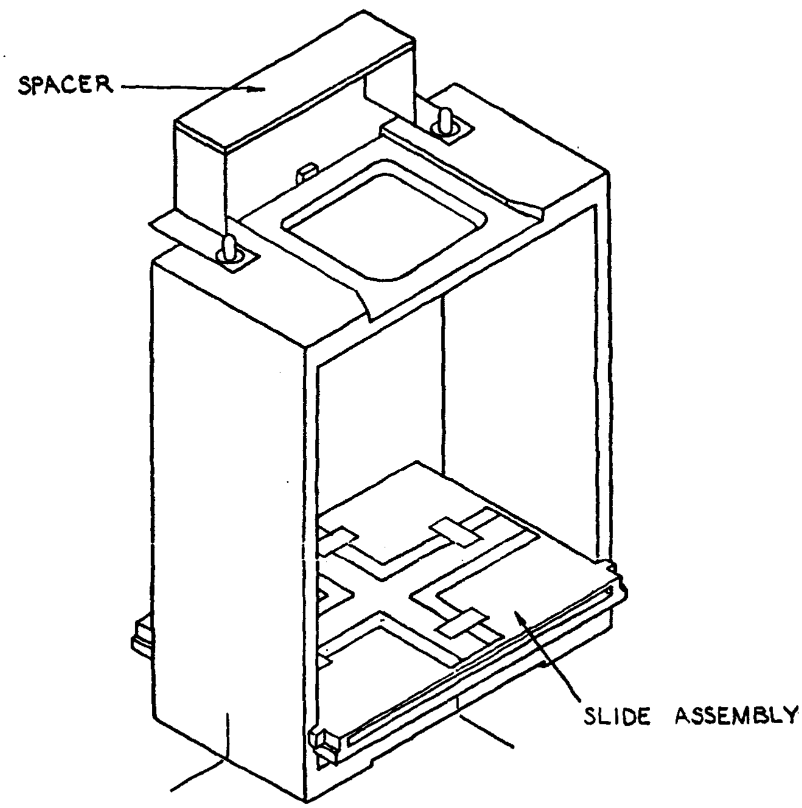

FOOD AND DRUG ADMINISTRATION
BUREAU OF RADIOLOGICAL HEALTH
ROCKVILLE, MD. 20852
TEST STAND FILTERS
DRAWN BY
D.F.E.
DATE
8-3-73
SCALE
HALF
CHECKED BY
DRAWING NO.
IRB-014-A
6.000 ± .005
6.000 ± .005
STAMP QUALITY AND
THICKNESS IN LOCATIONS
INDICATED
NOTES:
MAT'L: 1100 ALUMINUM
REQ'D: ONE PER EACH THICKNESS
OF 0.51, 1.02, 2.04, AND
3.06 MM ± 0.02 MM


FOOD AND DRUG ADMINISTRATION
BUREAU OF RADIOLOGICAL HEALTH
ROCKVILLE, MD. 20852
TEST STAND MARKER
DRAWN BY
D. F. E.
DATE
8-27-74
SCALE
FULL
CHECKED BY
DRAWING NO.
IRB-015-B
1.50
0.500
0.250
0.750
0.031
0.063 DIA.
NOTES
MAT'L: GALVANIZED STEEL
REQ'D: FOUR
TOL'S: ±.003
ENTIRE SURFACE PAINTED
FLAT WHITE

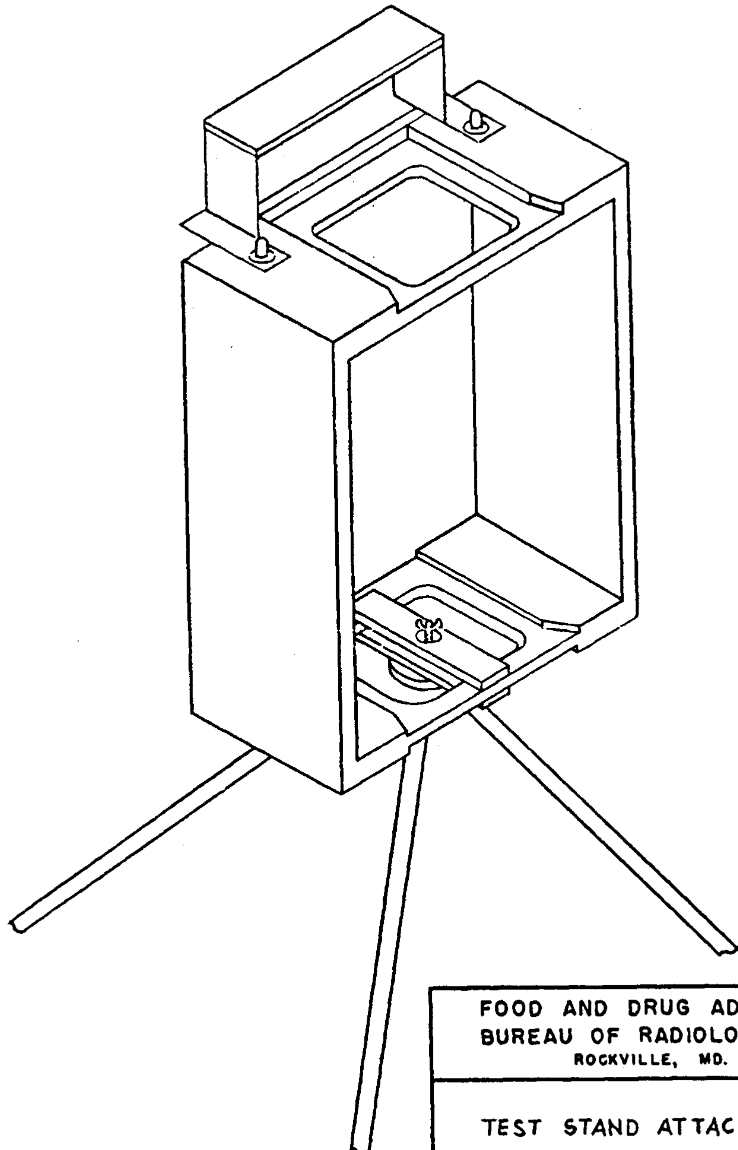

FOOD AND DRUG ADMINISTRATION
BUREAU OF RADIOLOGICAL HEALTH
ROCKVILLE, MD. 20852
TEST STAND
MOUNTING BRACKET
DRAWN BY
D. F. E.
DATE
8-3-73
SCALE
FULL
CHECKED BY
DRAWING NO.
IRB-016-A
1.50
.75
0.250
2 15/16
5 7/8
0.250 DIA
NOTES
MAT'L: ALUMINUM 2024-T4
REQ'D: TWO
TOL'S: ±.003, ± 1/16



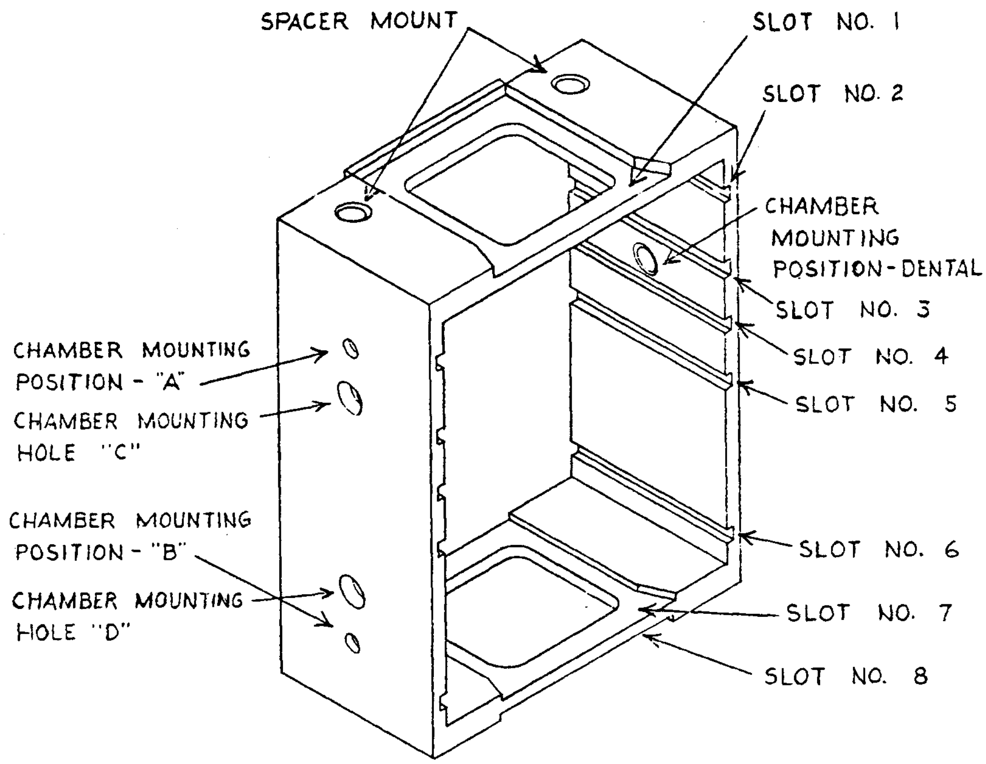
FOOD AND DRUG ADMINISTRATION BUREAU OF RADIOLOGICAL HEALTH ROCKVILLE, MD. 20852		
TEST STAND WITH FOCAL SPOT ASSEMBLY		
DRAWN BY D. F. E.	DATE 8-30-74	SCALE NONE
CHECKED BY	DRAWING NO.	



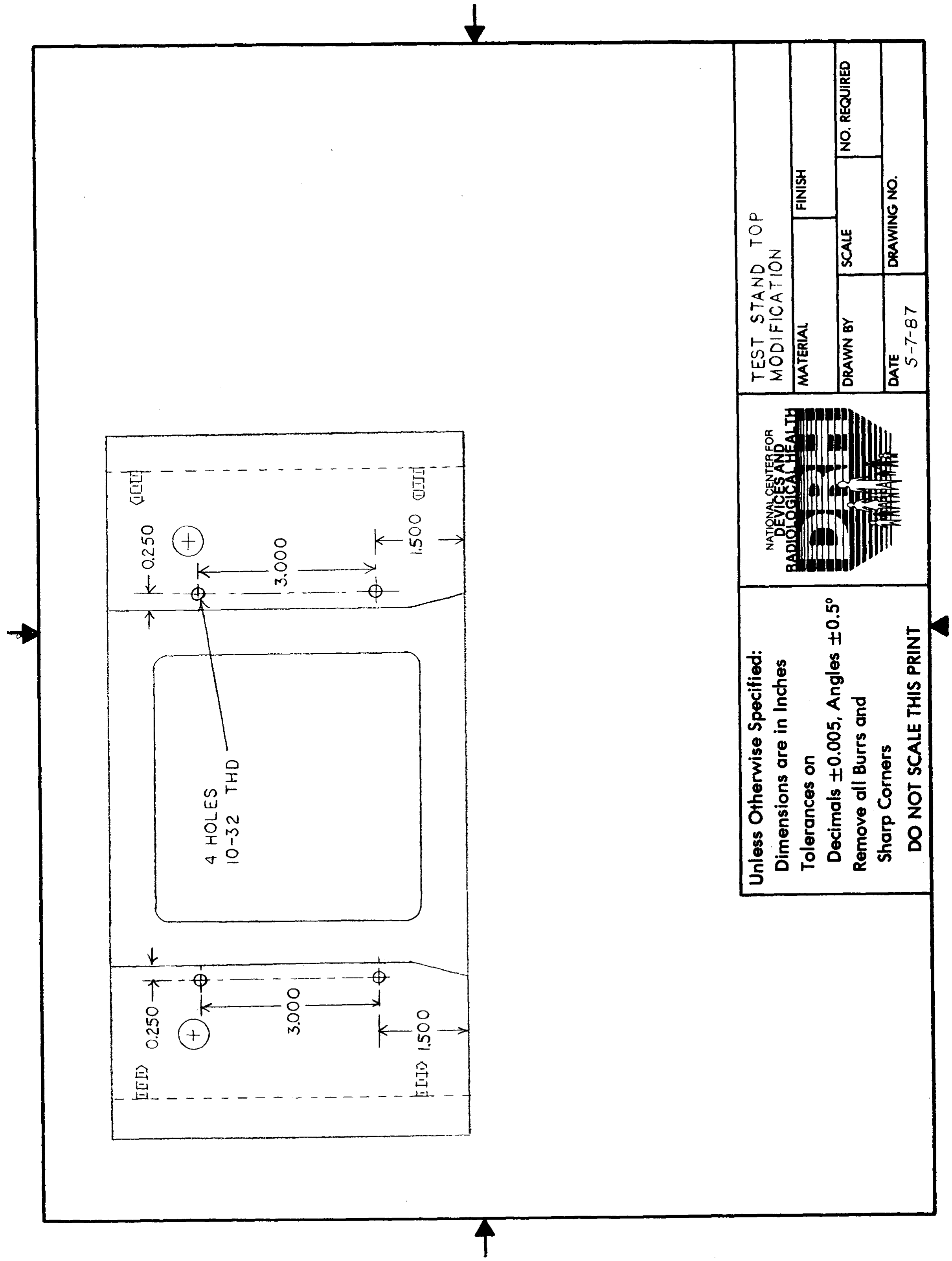
TEST STAND W/SLIDE ASSEMBLY	
DATE:	ILLUSTRATION NO:
FOOD AND DRUG ADMINISTRATION BUREAU OF RADIOLOGICAL HEALTH DIVISION OF ELECTRONIC PRODUCTS	

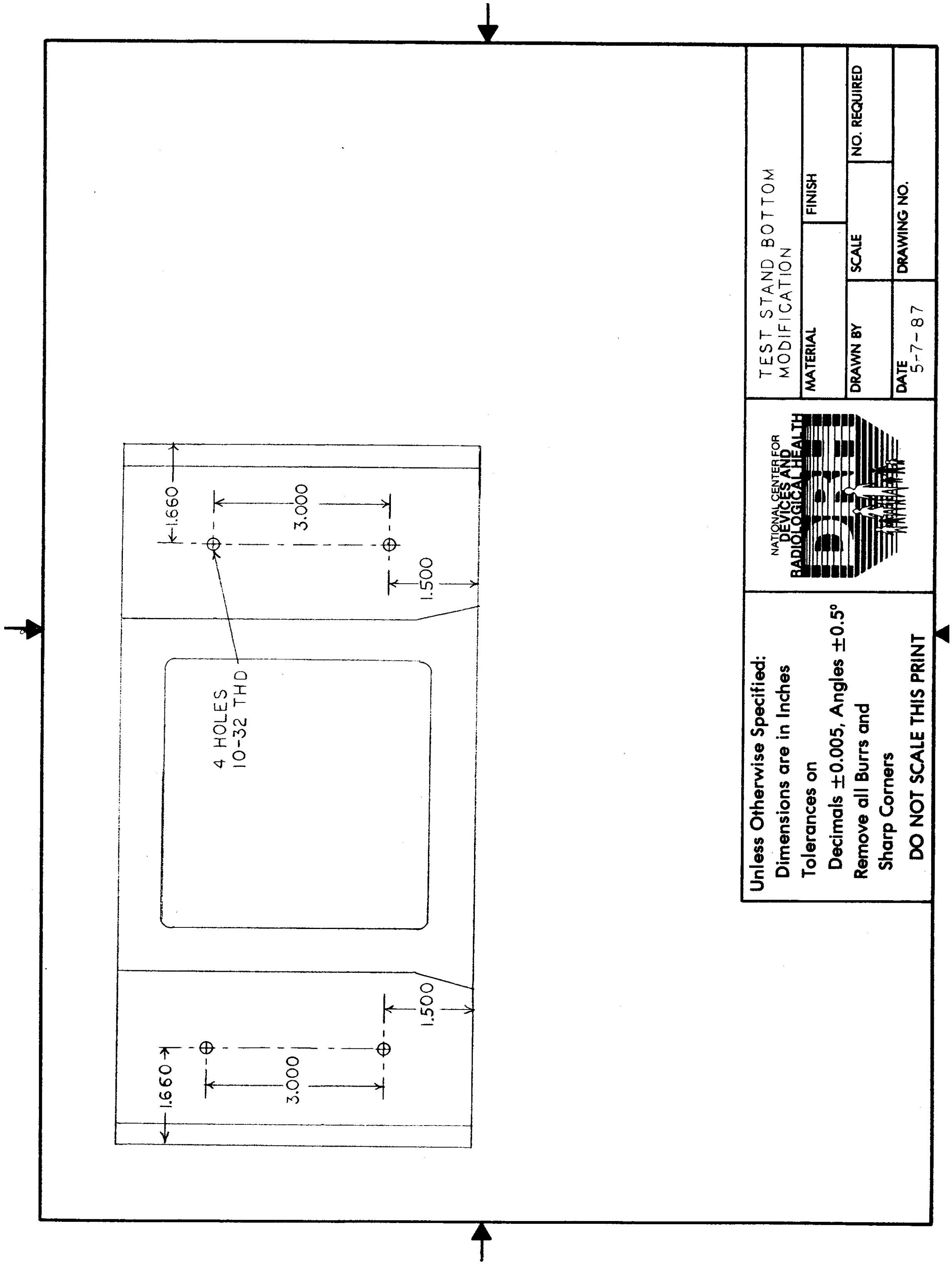


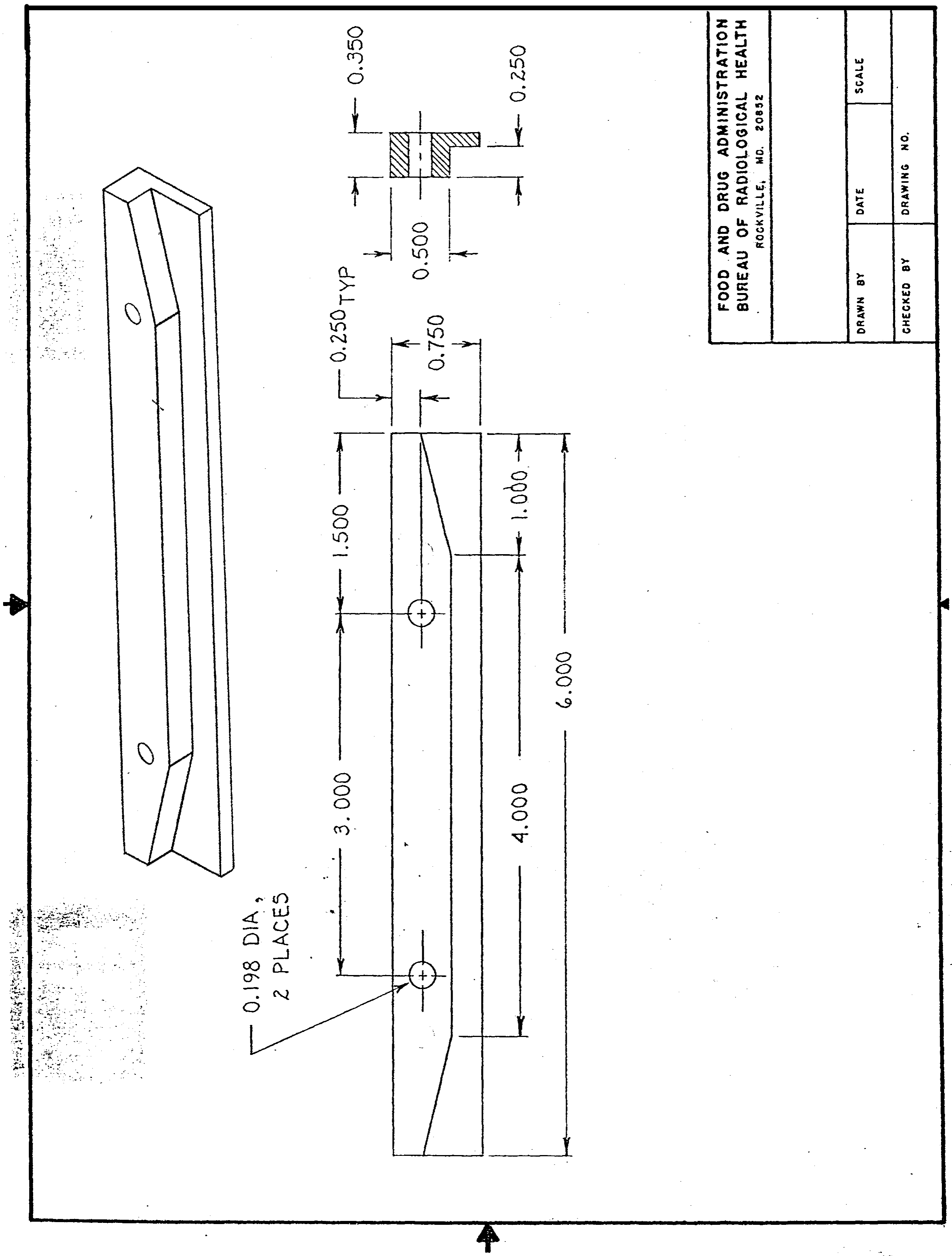
FOOD AND DRUG ADMINISTRATION BUREAU OF RADIOLOGICAL HEALTH ROCKVILLE, MD. 20852		
TEST STAND ATTACHED TO TRIPOD		
DRAWN BY D. F. E.	DATE 8-30-74	SCALE NONE
CHECKED BY	DRAWING NO.	



FOOD AND DRUG ADMINISTRATION BUREAU OF RADIOLOGICAL HEALTH ROCKVILLE, MD. 20852		
TEST STAND DETAILS		
DRAWN BY D. F. E.	DATE 9-28-74	SCALE NONE
CHECKED BY	DRAWING NO.	


TEST STAND TOP
MODIFICATION
MATERIAL
FINISH
DRAWN BY
SCALE
NO. REQUIRED
DATE
5-7-87
DRAWING NO.
NATIONAL CENTER FOR
DEVICES AND
RADIOLOGICAL HEALTH
Unless Otherwise Specified:
Dimensions are in Inches
Tolerances on
Decimals ±0.005, Angles ±0.5°
Remove all Burrs and
Sharp Corners
DO NOT SCALE THIS PRINT
4 HOLES
10-32 THD
0.250
3.000
1.500
0.250
3.000
1.500


TEST STAND BOTTOM MODIFICATION
MATERIAL
FINISH
DRAWN BY
SCALE
NO. REQUIRED
DATE 5-7-87
DRAWING NO.
NATIONAL CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
Unless Otherwise Specified:
Dimensions are in Inches
Tolerances on
Decimals ±0.005, Angles ±0.5°
Remove all Burrs and
Sharp Corners
DO NOT SCALE THIS PRINT
1.660
3.000
1.500
4 HOLES 10-32 THD
1.500
1.660
3.000


FOOD AND DRUG ADMINISTRATION
BUREAU OF RADIOLOGICAL HEALTH
ROCKVILLE, MD. 20852
DRAWN BY
DATE
SCALE
CHECKED BY
DRAWING NO.
0.350
0.250
0.500
0.250 TYP
0.750
1.500
1.000
3.000
4.000
6.000
0.198 DIA,
2 PLACES

EQUIPMENT DESCRIPTIONS

PART III

INSTRUCTION MANUAL FOR THE 1015F X-RAY MONITOR

Center for Devices and Radiological Health
CDRH

REPRINTED
APRIL 2000

INSTRUCTION MANUAL

FOR

1015F X-RAY MONITORS

1.0 DESCRIPTION

The 1015F X-ray Monitors are portable instruments designed for verifying proper operation of diagnostic X-ray machines and fluoroscopes. They use air-equivalent ion chambers with uniform energy response over a wide range in conjunction with a current-to-frequency converter and digital processing techniques to measure exposure, exposure rate, pulse exposure, and pulse width. The unit features portable operation, the instrument housing serving also as a carrying case, with battery lifetime of approximately 750 operation hours before replacement. A remote control and display unit provides operator safety and avoids cable noise problems. Optional features include interchangeable ion chambers for low exposure rate measurements and an analog output signal for observing pulse shape details of X-ray signals.

2.0 SPECIFICATIONS

(Stated specifications apply to the Model 1015F X-ray Monitor with the Model 10X5-6 6-cm^3 chamber. For specifications of the Model 1015F X-ray Monitor with different ion chambers, see Tables I and II at the end of the manual.)

2.1 Ranges

Exposure Rate:	1 mR/min to 650 R/min
Exposure:	0.02 mR to 99.9 R
Pulse Exposure:	1 mR to 13 R
Pulse Duration:	1 ms to 99.9 s

2.2 Accuracy

Energy Dependence:	10%, 20 keV to 1.33 meV
Exposure Rate Dependence:	5%, 0.4 mR/s to 80 R/s average and up to 500 R/s for 50 ms pulses
Noise Level:	0.02 mR or 1 mR/min
Resolution:	1% or 0.02 mR for exposure, 1 mR/min for exposure rate, and 0.1 ms for pulse duration
Exposure and Exposure Rate Calibration Accuracy	5% using Cobalt-60 at 1013 mb atmospheric: pressure (internally

	compensated for temperature)
Uncertainty in Pulse Amplitude Discrimination Level:	5%, rms
Pulse Duration Accuracy:	0.02% of measured pulse duration 0.5 ms for rectangular pulse of 200 mR/s measured at 50% of the peak exposure rate

2.3 OPERATING ENVIRONMENT

Temperature:	5°C to 45°C
Humidity:	Up to 95% RH, without condensation

3.0 OPERATION

This section describes the operation of the 1015 Series X-ray Monitors. Theoretical principles are described in Section 4. Where specifications are referenced, they apply to the Model 1015F X-ray Monitor with the 10X5-6 (6-cm^3) ion chamber. See Tables I and II at the end of this manual for applicable numbers for the different chambers used with the Model 1015F.

3.1 ASSEMBLY

As shown in Figure 1, the X-ray Monitor contains within its carrying case the control unit, the probe, and the 20-foot interconnecting cable. The lid of the carrying case may be removed if desired by sliding the lid to one side after opening. To remove the cover, grasp the body of the unit firmly with the fingers at the edge near the hinges and apply steady longitudinal pressure with the thumbs along the lid. Do not force the lid open beyond the normal hinge stop position. The hinge stop will become permanently sprung and the lid will slip off the hinges unexpectedly.

The X-ray probe is mounted for carrying on the battery access cover, secured in place with a clamping nut.

The X-ray probe cable is coiled up in the pocket alongside the control panel. The 20-foot cable permits the ion chamber to be placed in the beam of an X-ray machine for operation while the operator remains behind the radiation barrier. The probe may be installed in the test stand by removing the mounting nut, inserting the unit through the appropriate hole in the stand, and then fastening the probe in place from inside the fixture with the nut. Avoid hitting the ion chamber against the test stand, or stressing in any other way.

The Model 1015F X-ray Monitor is assembled, shipped and stored with the Model 10X5-6 Ion Chamber connected to the probe assembly ready for use. The Model 10X5-180 Ion Chamber is shipped and stored in the lid of the X-ray Monitor. To remove either chamber and replace it with the other, simply grasp the probe assembly firmly in one hand and the knurled connector with the two or three fingers of the other hand. DO NOT ATTEMPT TO ROTATE THE CONNECTOR. Pull steadily, but firmly, on the connector without applying stress to the ion chamber itself. To assemble, align the black dots on the two halves of the connector, find the mating position, and press closed. Forcing either connector to rotate will cause damage to the unit.

3.2 BATTERIES

The battery access cover, which also serves as the carrying support for the probe, may be removed by unlatching the nylon latches on each side of the cover. These latches require about a 5-lb pull on the knob to release. To replace the access cover, make sure that the latches are "open" and free to engage the case. If the access cover is forced down when the latches are in the "closed" position, the latches could break from the excessive stress applied to the cover.

The four D cells are held in place by spring clips in a battery case. To replace the batteries, remove the battery case through the battery access opening and insert new batteries. Any D cell will function in the circuit; however, alkaline batteries are recommended because of their long life.

CAUTION

> Observed the polarity markings when installing new batteries. Reversal of the batteries will blow the in-line fuse in the battery wire.

The 300-V battery should be changed annually as a precautionary measure. It may be removed and installed in a manner similar to the D cell removal.

3.3 CONTROLS AND DISPLAY

Refer to Figure 1 for the description.

3.3.1 DISPLAY

The display consists of a 3-digit liquid crystal display and two sets of two red light-emitting diodes that together present the value and range of the measurement. The 3 more significant digits that contain information are selected by automatic ranging circuits, and the combination of the range lights and the decimal point position on the display provides a direct readout of the measured exposure, exposure rate, or time interval.

The meaning of the displayed number depends upon both the selected mode and which of the light-emitting diodes is flashing at a twice per second rate. In EXPOSURE RATE, the display is in mR/min, R/min, mR/hr, or R/hr. In EXPOSURE and PULSE EXPOSURE, the display is in mR or R; and, in PULSE DURATION the display reads milliseconds or seconds.

3.3.2 BAROMETRIC PRESSURE

This adjustment is omitted from the Model 1015F X-ray Monitor.

Figure 1. View of operating Controls
and Indicators

Figure 2 MDH with 6 –cm^3 ion chamber

3.3.3 FUNCTION

Other than in the OFF position, the function selector switches on the batteries and selects the operating function of the instrument. In the HOLD function, the instrument stores and displays the last reading that it made. In MEASURE, the instrument makes the measurement indicated by the mode selector. Moving the function selector from HOLD to MEASURE re-zeroes the current-to-frequency converter and clears the memory and display circuits preparatory to making new measurements. The instrument is ready to operate 1.2 seconds after being placed in the MEASURE function.

3.3.4 MODE

The mode selector selects the type of measurement to be made.

3.3.4.1. EXPOSURE

The EXPOSURE mode consists of measuring total exposure incident on the sensor during the time the function switch is set to MEASURE. Exposure is measured with a resolution of 0.02 mR, with the 3 more significant digits being displayed. The maximum exposure that can be displayed is 99.9 R; above this value the overflow code (see Diagnostic, Section 5) will occur. Because the basic resolution is 0.02 mR, the display "counts-by-two's" on the most sensitive (less than 10-mR) range. The display shows the exposure as it accumulates, with a new reading presented each 1.2 seconds.

3.3.4.2. EXPOSURE RATE

In the EXPOSURE RATE mode, the average exposure rate over a 1.2 second interval is measured, and the results are displayed directly in terms of mR or R per minute. The display receives the new reading once during each measurement interval. The exposure rate measurement has a resolution of 1 mR per minute and a maximum value of 650 R per minute. If the exposure rate exceeds the maximum limit, the overflow code (see Diagnostics, Section 5) will be displayed. The exposure rate value existing at any given time may be held for later reading by moving the function switch from MEASURE to HOLD at the desired time.

3.3.4.3. PULSE EXPOSURE

The PULSE EXPOSURE mode operates in conjunction with the PULSE DURATION mode to display the exposure present in a timed X-ray signal. The exposure measurement begins approximately 0.3 ms after the exposure rate exceeds 10 mR per second, and continues until the exposure rate falls below 10 mR per second and stays below that level for 2 seconds. The 2-second delay permits accurate measurements of radiation pulses from half-wave X-ray machines that produce gaps in the pulsed radiation.

3.3.4.4. PULSE DURATION

The PULSE DURATION mode operates in conjunction with the PULSE FRACTION THRESHOLD thumbwheel switch to make measurements of the pulse width of several X-ray signals. First and subsequent pulses are treated differently when measuring pulse width. The instrument determines the peak exposure rate of the first pulse with a rate exceeding the preset threshold and then measures the width of succeeding pulses at the switch-selected fraction of that peak value.

The pulse width measurement when the instrument is determining the peak exposure rate of the first pulse uses a fixed threshold of 10 mR/s. The displayed pulse width is the time between when the exposure rate first goes above that threshold and when it last drops below. The 2-second delay noted in Section 3.3.4.3 permits the instrument to ignore ripple, such as is commonly found in half-wave machines, but does not affect the duration measurement. The relatively long delay is chosen in order to insure a pulse width measurement even though the X-ray unit under test may be experiencing "contact bounce" problems. The uncertainty in the width measurement of the first pulse is approximately 5 ms.

The display informs the operator that the first pulse is being measured or displayed in either pulse measurement mode by placing the minus (-) symbol before the 3-digit display. A typical operating sequence could be as follows:

1. Place mode and function in PULSE DURATION or PULSE EXPOSURE and in MEASURE, respectively. The display will read -000.

2. Actuate the X-ray machine being evaluated to produce a peak exposure rate in excess of the 10-mR-per second threshold. The display reads -000 until the X-ray signal ceases. The display will read -ABC, after the pulse, where ABC is the width or exposure of this first X-ray signal detected. The instrument will have determined and stored the value of the peak exposure rate of the first signal as well as the total exposure and the pulse width. The mode switch may be freely moved between PULSE EXPOSURE and PULSE DURATION and display either of these values after the first signal measurement without affecting any of the stored values.

3. Set the PULSE FRACTION THRESHOLD switch to the desired fraction of the peak height of the initial radiation pulse.

4. Actuate the X-ray machine again at the same settings as before. The display will read 000 during the measurement. After the pulse ceases, the display reading of XYZ is the interval during which the input radiation level exceeds the selected fraction of the first pulse if the mode switch is in PULSE DURATION, or is the exposure in the pulse, as described in Section 3.3.4.3., measured using the 10-mR-per second threshold, if the mode switch is in PULSE EXPOSURE. A smoothing circuit corrects the measurements for ripple in the signal so that the width measurement interval begins at the time the pulse first passes the threshold, and the interval ends when the pulse last falls below the threshold. The measured value is displayed after the end of the X-ray signal. As before, the mode switch may be freely moved between PULSE EXPOSURE and PULSE DURATION to observe on the display either reading.

5. Additional readings for further X-ray bursts may be made at any setting of the PULSE FRACTION THRESHOLD switch and refer to the same initial pulse, until the function switch is moved to HOLD and then back to MEASURE. After 1.2 seconds, the instrument is again in the state described in step 1.

6. If, during any measurement, the X-ray signal fails to reach the threshold value established in the first pulse measurement and the PULSE FRACTION THRESHOLD thumbwheel, the display will read 000 for duration.

3.4 ANALOG X-RAY SIGNAL OPTION

As an optional feature, a signal is available that is representative of the X-ray exposure rates on the ion chamber. By connecting this signal to a CRT, it is possible to examine the time history of the X-ray machine output. The analog signal has a scale factor of 1 volt for each 10 R/s of radiation. The output impedance looks like a 3300-pF capacitor driven from a 100-kL source, and should be able to be used with any oscilloscope without interfacing circuitry.

The displayed signal has been separately filtered and will respond to a step function by going from 0-90 percent of peak in about 1 millisecond. Thus, most discrepancies in X-ray machine performance that distort output would be observable on the CRT. The low energy response of the ion chamber aids in obtaining a true picture of the radiation.

3.5 CALIBRATE MODE OPTION

This option is not installed in the 1015F units.

4.0 THEORY OF OPERATION

Figure 3 shows the major functional elements of the instrument in simplified block diagram form. X-rays passing through the chamber produce ions that are collected by the 300-V bias potential connected to the wall of the chamber and cause a current to flow from the bias voltage supply to the current-to-frequency converter. The current is quite small, given by the volume of air in the chamber and the definition of the Roentgen, and amounts to 4 x 10-14 A at an exposure rate of 1 mR per minute.

The current to the converter depends upon the rate of exposure and upon the number of air molecules within the chamber, but not upon the chamber bias voltage, so long as there is enough voltage to sweep the ions from the chamber as they are produced. The dependence on the number of air molecules requires a correction for barometric pressure and for air temperature. The temperature correction is made by a circuit within the converter, while the barometric pressure correction must be made by calculation.

The current entering the converter causes it to produce a pulse train with a frequency proportional to exposure rate. This converter includes provision for adjustments that compensate for temperature and for calibration if necessary. The output of the current-to-frequency converter is then one pulse for each 0.02 mR of radiation exposure. The remainder of the instrument is essentially a pulse counter. The exposure may be totaled up by counting the converter pulses; the exposure rate in mR per minute may be established by counting the pulses for 1.2 seconds, because 1 pulse/1.2 seconds equal 1 mR/min; and the instantaneous exposure rate within a timed X-ray signal may be determined by examining the pulse-to-pulse spacing.

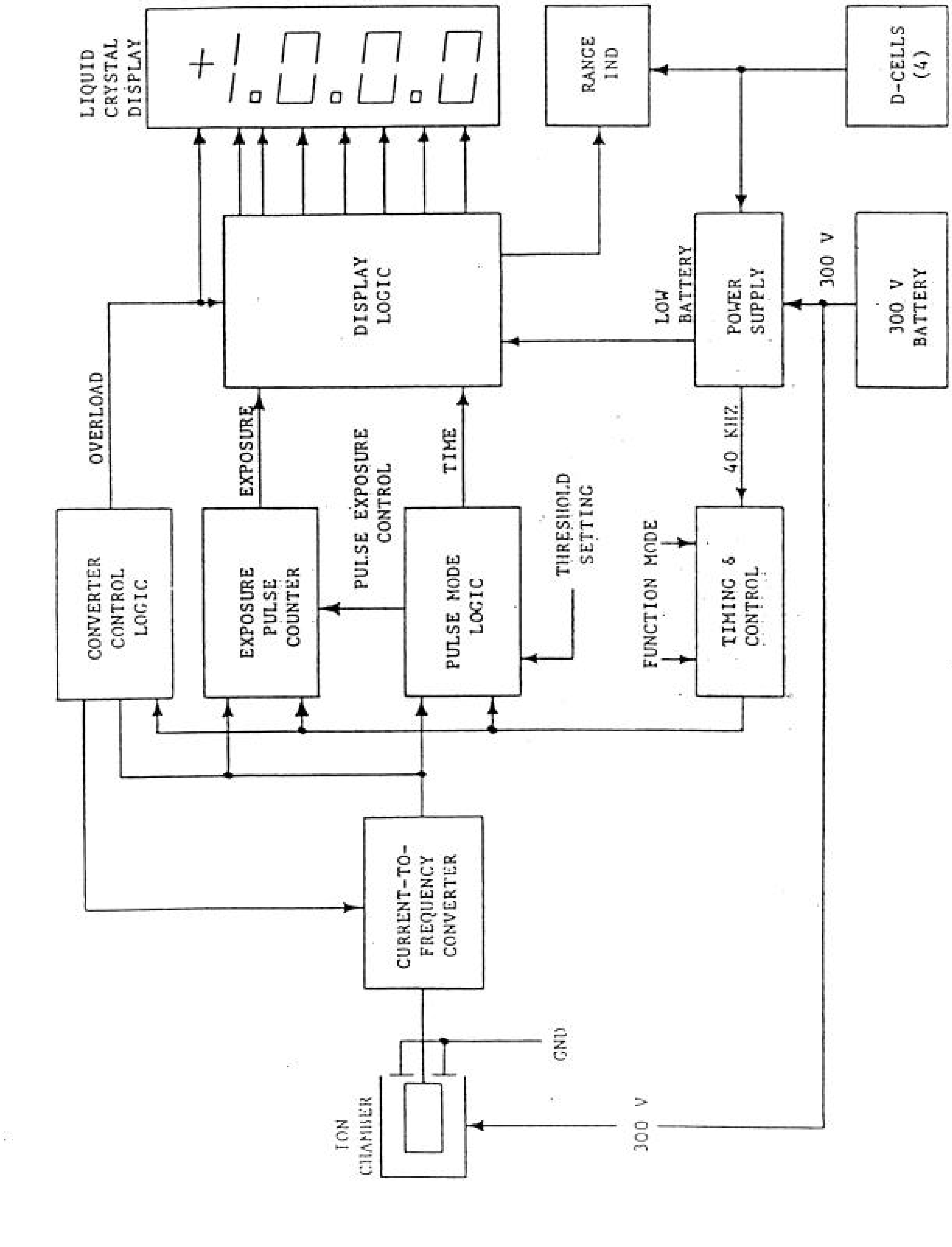


Figure 3. X-ray Monitor Block Diagram

The digital pulses from the current-to-frequency converter along with the power supply voltages and various control signals, pass along the 20-foot shielded interconnecting cable.

The logic located in the main control and display unit includes about 90 integrated circuits for generating control signals and presenting the required data on the display. The digital pulses are gated by various selection signals and applied to the exposure counter where they are counted and stored. These pulses are routed into the pulse measurement logic for the measurement of pulse width and pulse exposure. Time-base pulses from a crystal controlled oscillator are routed to the time counter in order to display pulse width.

As stated before, one digital pulse is created for each 0.02 mR of radiation exposure. In the EXPOSURE RATE mode, the pulses are counted for 1.2 seconds. Each pulse in that 1.2-s interval is thus equal to a 1-mr/min reading in this mode. The logic calls for reset of the converter, which can handle up to 13 R, every 1.25. Since 13 R every 1.2s is equal to 650 R/min, this is the maximum valid reading in this mode. Above this level, the overflow indication will appear (see Diagnostic, Section 5).

In the EXPOSURE mode, the pulse are counted continuously, with the display being updated every 1.2 seconds. The minimum reading for 1 count is 0.02 mR. In this mode, the converter is automatically reset after accumulating 13 R. During this reset operation, it is effectively shut off for a few milliseconds.

The display will present readings up to 99.9 R, after which the overflow indication will appear (see Diagnostics, Section 5).

In the PULSE EXPOSURE mode, the display reads 000 until the pulse is completed, as distinguished from the EXPOSURE mode, where updating occurs every 1.2 seconds. This occurs because the PULSE EXPOSURE mode has no update provision (in order to retain timing accuracy by avoiding confusion between the update interval and the end of the pulse itself). The maximum pulse exposure capability is 13 R, limited by the converter, where a trade-off has been made between full-scale exposure and the minimum exposure can be resolved.

The display logic examines the count of converter pulses or time pulses and picks out the 3 more significant non-zero digits for display. The placement of the decimal points on the display and the actuation of the range indicating LED's are performed at the same time that these digits are picked out.

A dc-to-dc converter generates +8 V, -6 V, and -20 V from the nominal 6-V output from the 4 D cell battery. A quartz crystal stabilized oscillator fixes the converter frequency to 40.00 kHz. The dc-to-dc converter includes regulator circuitry to maintain the output voltages fixed as the main battery voltage changes. The reference voltage for the regulator is a 1.36-V mercury cell; and, because of its small current drain, it should last for at least 2 years.

5.0 DIAGNOSTICS

Equipment condition or performance is sometimes such that the results of measurement should be considered carefully, and a number of built-in diagnostic aids are available to help the operator. These tools and other procedures are described below.

5.1 Turn-On Transients

Power applies to the MOSFET causes noisy operation for about 5 minutes. The equipment works properly with noisier readout during this time and meets all specification after this time. The specification for the minimum observable exposure rate -- 1 mR/min -- might be as high as 5 to 10 mR/min for these first few minutes.

5.2 Overflow

If measurements are attempted that exceed the range of the instrument, an overload code, consisting of a 1000 on the liquid crystal display in conjunction with both range lights flashing, will appear. If the overload condition occurs because the current-to-frequency converter is unable to maintain linear operation a plus (+) sign will appear to the left of the 1000.

The conditions under which overload will be displayed depend upon the operating mode selected. For EXPOSURE RATE, the limit is 650 R/min, corresponding to 13 R in 1.2 seconds. For EXPOSURE, overload occurs at 100 R, corresponding to maximum value that can be accumulated. For PULSE DURATION and PULSE EXPOSURE, overload occurs when either 13 R or 100 seconds is reached during measurements of a single pulse.

In any mode, the current-to-frequency converter overload, +1000, occurs when the converter maximum operating frequency of typically 4.5 MHz is insufficient to keep up with the input current from the ion chamber. To permit exposure measurements of short, high intensity X-ray pulses, a 300-ms time constant is included between the ion chamber and the converter. This time constant permits the exposure produced by a 500-R/s exposure rate, 50-ms-wide pulse to be correctly measured because the peak exposure rate of such a signal after passing through a 300-ms filter never exceeds 80 R/s, or 4 MHz from the converter.

5.3 Battery Low

The 3-digit liquid crystal display blinking at the rate of once per second indicates the D cells, the 300-V battery or both are low and should be replaced.

If the indication appears during a given operating period, the condition might be temporary, and the instrument might be capable of operating within specification for some additional time without replacing batteries. For example, a very high exposure rate produces an added power drain that could cause the battery output voltage to drop momentarily below the limit, resulting in a low battery indication. If lower exposure rates are then experienced, the batteries might recover and be satisfactory. To determine if the equipment is operating usefully within specification when blinking starts, turn the instrument function switch to OFF, and then turn back to HOLD or MEASURE. If the blinking stops, the instrument can continue to be used at lower exposure rates, but the batteries should be replaced at the earliest opportunity.

Table I. Specifications for Model 1015F X-ray Monitor When Used with Model 10X5-6 Ion Chambers

---

RANGES

- Exposure Rate:	1 mR/min to 650 R/min
- Exposure:	0.02 mR to 99.9 R
- Pulse Exposure:	1 mR to 13 R
- Pulse Duration:	1 ms to 99.9 s

ACCURACY

- Energy Dependence:	±10%, 20 keV to 1.33 meV
- Exposure Rate Dependence:	±5%, 0.4 mR/s to 80 R/s average and up to 500 R/s for 50-ms pulses
- Noise Level:	0.02 mR or 1 mR/min
- Resolution:	1% or 0.02 mR for exposure, 1 mR/min for exposure rate, and 0.1 ms for pulse duration
- Exposure and Exposure Rate Calibration Accuracy:	±5% using Cobalt-60 at 1013 mb atmospheric pressure (internally compensated for temperature)
- Uncertainty in Pulse Amplitude Discrimination Level:	5%, rms
- Pulse Duration Accuracy:	0.02% of measured pulse duration 0.5 ms for rectangular pulse of 200 mR/s measured at 50% of the peak exposure rate

OPERATING ENVIRONMENT

- Temperature:	5°C to 45°C
- Humidity:	Up to 95% RH, without condensation

MISCELLANEOUS SPECIFICATIONS

- Measurement Interval:	1.2 seconds
- Pulse Duration Measurement Internal Threshold:	10 mR/s
- Digitizing Resolution:	0.02 uR/pulse

Table II. Specifications for Model 1015F X-ray Monitor
When Used with Model 10X5-180 Ion Chambers

RANGES

- Exposure Rate:	1 mR/hr to 650 R/hr
- Exposure:	0.002 mR to 9.99 R
- Pulse Exposure:	0.033 mR to 0.433 R
- Pulse Duration:	1 ms to 99.9 s

ACCURACY

- Energy Dependence:	±10%, 30 keV to 1.33 meV
- Exposure Rate Dependence:	±5%, 20 mR/hr to 2000 R/hr
- Noise Level:	0.002 mR or 1 mR/hr
- Resolution:	1% or 0.002 mR for exposure, 1 mR/hr for exposure rate, and 0.1 ms for pulse duration
- Exposure and Exposure Rate Calibration Accuracy	±5% using Cobalt-60 at 1013 mb atmospheric pressure (internally compensated for temperature)
- Uncertainty in Pulse Amplitude Discrimination Level:	5%, rms
- Pulse Duration Accuracy:	0.02% of measured pulse duration ±0.5 ms for rectangular pulse of 200 mR/s measured at 50% of the peak exposure rate

OPERATING ENVIRONMENT

- Temperature:	5°C to 45 °C
- Humidity:	Up to 95% RH, without condensation

MISCELLANEOUS SPECIFICATIONS

- Measurement Interval:	2.4 seconds
- Pulse Duration Measurement Internal Threshold:	1/3 mR/s
- Digitizing Resolution:	2/3 mR

EQUIPMENT DESCRIPTIONS

PART IV

LIGHT LOCALIZER MEASUREMENTS

Center for Devices and Radiological Health

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Medical X-ray Light Localizer Measurements using the UDT Digaphot Photometer

GENERAL DESCRIPTION

The United Detector Technology Inc. "Digaphot" is a palm size, portable photometer with digital readout for measuring illuminance from 0.5 to 1000 foot-candles. The photometer, photopically and cosine-corrected, measures approximately 11 x 6.5 x 6.5 centimeters in size and weighs only a few ounces (figure 1).

The photometer consists of a silicon photodiode with multielement subtractive filters, an amplifier, a precision 10-turn potentiometer with a 3-1/2-digit dial readout utilizing a zero comparator, and other supporting electronics. The rated absolute accuracy traceable to NBS is 10 percent.

The Digaphot is intended and calibrated for routine compliance illuminance light measurements as related to the Diagnostic Medical X-ray Performance Standard and for general area illumination surveys. The performance standard requires an illuminance of 15 foot-candles (160 lux*) as the minimum average over the four quadrants of the light field at a distance of 100 cm from the X-ray source or at the maximum source-image distance, whichever is less.

CALIBRATION

The Digaphots are calibrated against a 1000-watt tungsten illuminance standard lamp source. Each unit is calibrated at two levels (15 and 100 fc). The due date for recalibration is also listed on the side of the instrument. The Digaphots are to be recalibrated at 1-year intervals.

PROCEDURE

During all measurements, extreme care should be taken to avoid placing objects near or in the field of view of the photometer. Such objects will severely affect the reading on the meter. Also avoid any excessive shock to the instrument.

To measure the light level on a working surface, place the Digaphot on the surface, switch the power switch to ON, and turn the dial knob in the direction shown by either the HIGH or LOW indicator. The knob is turned in the direction of the illuminated arrow. Slowly adjust the knob in the balance region in such a way as to cause both indicators to light with equal brightness. The level of illumination is now shown on the dial directly in units of foot-candles.

> NOTE: If the Battery Low (Batt.Low) indicator is on, replace the battery (NEDA Type 1604D) or if the unit is equipped with a rechargeable battery, recharge the battery immediately. The battery life is limited to about 10-12 hours of operation.

*10.76 lux equals 1 foot-candle.

SURVEY PROCEDURES

The following procedures are applicable for light localizer measurements:

(1) Position the X-ray machine light localizer such that the light is 106 cm (or at the maximum source-image distance, whichever is less) above the tabletop with the light field directed downward onto the tabletop or image receptor. The extra 6 cm takes into account the height of the photometer. Adjust the light localizer controls to produce an approximate 10 " x 10" light field at the tabletop.

(2) Reduce the room lighting to the minimum level. The actual light localizer output value will be the difference between the reading with the light localizer on the reading with the light localizer off (Actual = Readingon - Readingoff).

(3) Position the Digaphot in the upright position (Fig.2) on the tabletop and record the illuminance at the approximate center in each of the four quadrants. Be sure that the light meter is perpendicular to the light source. Average these four readings to obtain the uncorrected average illuminance.

(4) If the horizontal meter orientation (Fig. 3) is used, follow the same procedure above.

NOTE: All meters are calibrated at a distance that corresponds to the upper surface of the meter. Therefore, the distance from the light source to the light meter should correspond to the upper surface of the meter.

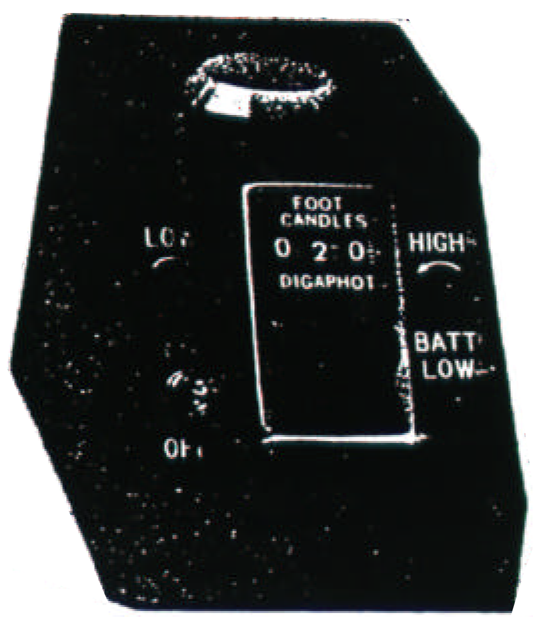

Figure 1: Digaphot Photometer

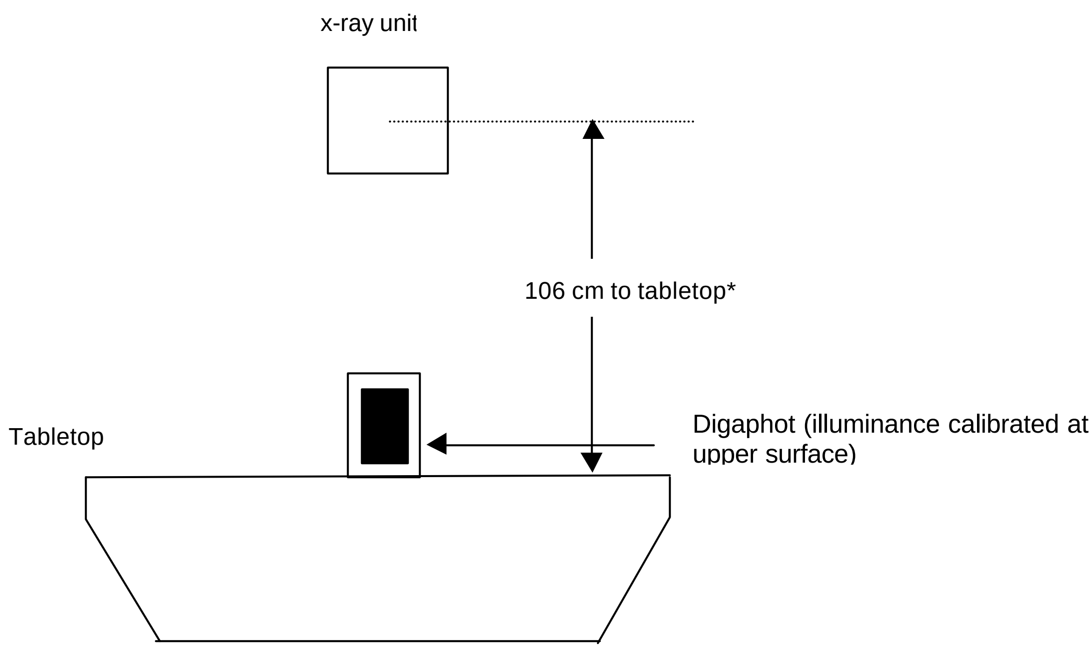

Figure 2 Digaphot positioned for measurements in the upright position

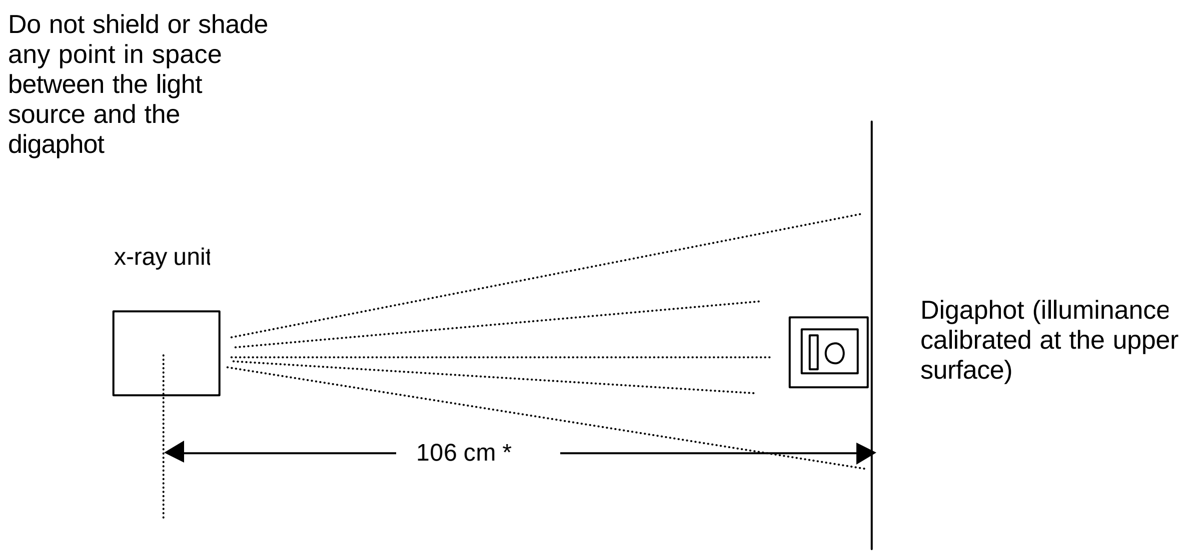

Figure 3 Digaphot Positioned for Measurement in the Horizontal Position

* 106 cm includes the height of the Digaphot. The distance stated in the Regulations is 100 cm or the maximum source to image distance, whichever is less.

EQUIPMENT DESCRIPTIONS

PART V

EXPOSURE AND DEVELOPMENT PROCEDURES FOR LINAGRAPHIC PAPER

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EXPOSURE AND DEVELOPMENT PROCEDURES FOR LINAGRAPHIC PAPER

In a typical situation a sheet of linagraphic paper is removed from the packet in a room whose lighting has been subdued. The paper is loaded into a plastic X-ray film cassette, exposed to X-rays, and developed. As the paper photodevelops, the pink background changes to buff color and the exposed area turns dark blue. The resultant radiographic image is then ready for evaluation.

INSTRUCTIONS FOR USE

(1) Remove a sheet of linagraphic paper from the container under subdued light conditions (less than 0.8 foot-candles).

(2) Load the paper into a plastic X-ray film cassette.

(3) Place the loaded cassette in the primary beam (bright pink side toward source).

(4) Expose to approximately 1 R of radiation at film plane.

(5) Remove the paper from the plastic cassette. Expose to low-intensity fluorescent light for a few seconds (such as in a normally-lit room) to fix the image.

(6) Develop the paper by exposure to high intensity fluorescent light for 1 to 2 minutes.

(7) Mark the image with a sharp-pointed pencil to ascertain image size.

(8) Fading can be slowed down by storing the image in an amber plastic folder. To retain the image permanently, store in a light-tight box.

EQUIPMENT DESCRIPTIONS

PART VI

OPERATOR'S MANUAL FOR GM-RATEMETERS

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OPERATOR'S MANUAL

FOR

TBM-1 RATEMETER

GENERAL

The TBM-1 Geiger-Mueller Ratemeter is a modified logarithmic instrument covering the range from below 1 mR/hr to 500 mR/hr. It is powered by a single 9 volt transistor battery. It is so designed that readings will not decrease in radiation fields at least 100 times the top scale reading. It is housed in a phenolic case similar to that of the familiar VOM. Two push buttons comprise the entire controls. The "test" button indicates the condition of the battery as shown on the meter. The "read" button turns the instrument on so that it may detect radiation. The "read" button is the push and release type. When it is in the "in" position the instrument is on. When it is in the "out" position the instrument is off.

MAINTENANCE

Should the instrument read zero or lower than anticipated in a radiation field, push the test button. A reading below the marked section of the meter indicates a low battery. Change Battery B-1.

ENERGY DEPENDENCE

The GM tube responds to energies as low as 20 keV applied axially at point "+" on the front end of the case. The "+" mark on the back of the instrument should not be used since this orientation does not align the thin end window of the GM tube with the radiation source. The directionality of this instrument is severe, and therefore, the end "+" mark should be aligned as carefully as possible with the source or suspected source of radiation. Because of the severe energy dependence of the GM meter, no attempt has been made to calibrate the instrument. The GM meter should be used for scanning to find "hot spots," but it should not be used for quantitative measurements.

BATTERY

The 9V "transistor" battery is a heavy duty type (Eveready #1222 or equivalent) and is capable of giving 150 hours of normal instrument service before requiring change. Its shelf life is in excess of 1 year. However, it is recommended that if the instrument is stored longer than 30 days, the battery be removed from the case. This is accomplished by removing the four screws at the bottom of the case, lifting the battery from its sponge rubber cradle and unclipping the leads.

OPERATOR'S MANUAL FOR MODEL 251B GM
SURVEY METER

1.0 GENERAL

The 251B survey instrument is a small, lightweight, rugged Geiger counter. Power for the instrument is provided by two "D" cells (standard flashlight batteries, which supply 1.5V each). The instrument will operate properly for supply voltages as low as 2.76V, which ensures extended battery life. Radiation measurements are displayed on a meter movement, with linear scale marked 0 - 10. A selector switch provides ranges of 0 - 10 (XI), 0 - 100 (X10), and 0 - 1000 (X100). The instrument is equipped with three adjustments for separate calibration on each range.

2.0 SPECIFICATIONS

(1) Detector (LND 71412 Tube):

- (a) Fill Gas: NE + Halogen
- (b) Dead Time: 50 microseconds
- (c) Housing: 446 SS w/SN filter
- (d) Operating Voltages: 600 Volts
- (e) The tube has an energy response that is flat within 15% over a range from 50 keV to 1.5 meV.

(2) Meter Movement:

- (a) Type: 0 - 100 microamp DC meter
- (b) Enclosure: Lexan
- (c) Scale: 0 - 100

(3) Mechanical for Entire Instrument:

- (a) Weight: 2.5 lbs., 1.133 kilograms
- (b) Dimensions: Length: 8", 20.32 cm
  Height: 4", 10.16 cm
  Width: 3.25", 8.25 cm
- (c) Case: (1) Fiberglass impregnated polyester
  (2) Cover sealed with inlay rubber sponge cord

(4) Battery Life:

(a) Over 500 hours of continuous usage with alkaline cells

(b) Varies according to type of batteries used, operating temperature, and age of batteries

3.0 OPERATION

(1) Preparation for Use:

(a) Turn the switch to "BATT" as both a check of the batteries and proper operation of the instrument including the detector. Within a few minutes the meter should indicate above the check position (to the right). To avoid possible meter damage and to extend battery life, promptly select the desired switch position after observing a positive battery check indication.

> IMPORTANT: the meter will indicate zero until a random radiation event from normal background radiation causes the detector to discharge. At that time the meter will move to the circuit check indication. At times the meter may indicate zero for a few minutes before a radiation event causes the tube to discharge. Therefore, turn the switch to "batt" and allow the instrument to remain at that position for several minutes if necessary to be assured that the instrument is not working properly or the batteries are discharged.

(b) The meter will function properly when the meter indicates above the check position. However, should the indication be less than full scale, the batteries should be replaced at the first available opportunity.

(2) Operating the Instrument:

(a) Begin all radiation measurements with the instrument control switch set to the "100" position. At the "100" position, the instrument is operating on the least sensitive scale. This reduces the possibility that the meter will peg off scale or saturate. Rapid or energetic pegging can cause damage to the meter. MORE IMPORTANTLY, SATURATION IN A HIGH INTENSITY RADIATION FIELD CAUSES THE METER INDICATION TO FALL TO ZERO. AT THE "100" POSITION, THE INSTRUMENT WILL NOT SATURATE IN FIELDS UP TO 1R/HR IN INTENSITY.

(b) The "10" or "1" positions may be used if additional sensitivity is required. The instrument is most sensitive in the "1" position.

(3) Reading the scales:

(a) Simply read the measurement indicated on the linear scale and multiply by the number for the selected position.

(b) the instrument is not calibrated, and therefore, cannot be used for radiation measurements in units of exposure. However, the instrument may be used for comparative measurements to determine a position of greatest intensity over a broad area of exposure.

(4) Position of Exposure:

The Geiger tube is mounted at the extreme front centerline of the meter behind the etched cross hairs. For radiation measurements, hold the instrument with the cross hairs perpendicular to the source of radiation.

OPERATOR’S MANUAL

FOR

MODEL 308A-5 RATEMETER

INTRODUCTION

The Xetex 308A, replaces the Gamma Industries (GI) 550B in the test kit equipment and its operation is similar to the GI model. However, there are some differences. Please note that the sensitive area of the instrument is on the right side, marked by a small cross, instead of in the front as on the GI ratemeter. The Xetex meter also has a LED to help localize a “hot” spot and different scale markings then the GI meter. When perfroming the “Surveyor Protection Test” for fluoroscopic systems with the Xetex meter, follow-up measurtements with the MDH ion chamber should be made whenever the ratemeter indication is greater than 150 (i.e. 15 on the x10 scale).

The Model 308A-5 Analog Ratemeter is a miniature monitor designed to make accurate exposure rate measurements around most gamma and x-ray sources. Three switch selected ranges of X1, X10 and X100 are displayed on any easy to read taut-band meter. The range switch also has battery check and power off positions. The instrument has excellent zero stability. Calibration is straightforward with a single multi-turn potentiometer for each range. Low power CMOS integrated circuits are used to assure long, trouble-free operation. A single 9-volt transistor radio type battery, located in an externally accessible compartment supplies power for the unit for over 200 hours.

BATTERY INSTALLATION

IMPORTANT: Switch the instrument to the “OFF" position before proceeding. Remove the slide cover on the battery compartment. Then, remove the old battery and disconnect the snap connector. To prevent an accidental reverse polarity situation, initially orient the snap connectors at right angles to the battery terminals. After making up one connection, swing the snap connector around to permit making up the other one, Any standard nine-volt transistor radio type battery will work well in the instrument, but for longest life, an alkaline type (Mallory MN1604, or equivalent) is recommended. After installing the battery, replace the cover and the instrument is ready for use.

OPERATION OF THE INSTRUMENT

The instrument should be turned "ON" away from the radiation field. First turn the selector switch to the "BATT" position. The meter should read above the BATT line to indicate satisfactory battery condition. The switch should then be rotated to the X1 position and the background reading observed. The count light should flash. After setting the instrument to the proper range, it is ready for use.

In making surveys, the location and orientation of the detector should be kept in mind. The sensitive volume of the detector is located at the top right side of the instrument where the target symbol (+ inside a circle) is located.

SPEAKER

A chirp will be heard corresponding to each GIVI tube pulse and LED lamp flash. The chirp volume is set for good audibility at a distance from the instrument and serves as an aid when mapping surveys or monitoring background radiation. The speaker reduces battery life somewhat, depending on count rate.

CALIBRATION

The calibration potentiometers are reached by removing the cover on the back of the instrument housing. There is a separate four-turn potentiometer for each range as shown in Figure 1. Before calibrating the instrument, the battery condition should be checked and a new battery installed if necessary. The instrument background should then be checked on the X1 range as described above. Then remove the back of the instrument (see below) and attach a calibrated pulser through a .001 mF, 1000 V blocking capacitor to the GM tube input on the board. The pulser should provide only negative pulses with a maximum height not exceeding the battery or power source used for the instrument (6 to 9 VDC). A pulse width of about 50 μs is recommended. Set the rate of the pulse generator to 660 Hz and adjust the X1 00 calibration potentiometer so that the meter reads 58. Adjust the X1 0 and X1 ranges similarly using a pulse rate of 66 Hz and 6.6 Hz, respectively. After pulse rate calibration, place instrument in a known radiation field and rotate potentiometers to achieve desired meter response. The instrument is now ready for use.

MAINTENANCE AND REPAIR

The 308A-5 should require nominal maintenance in normal use. However, if repair becomes necessary, several precautions should be observed. The instrument uses integrated circuits with CMOS elements and, consequently, anti-static and grounding precautions must be taken whenever the printed circuit board is removed from the unit for servicing. This should only be done when proper facilities are available.

NOTE: To expose the printed circuit board, first disconnect and remove the battery. Then remove the single screw holding the back in place. Carefully lift off the back, noting that the GM tube is attached to the printed circuit board with 3" flying leads.

A circuit schematic and parts layout is included in this manual.

General Specifications

Radiation Detected	X and Gamma Rays
Detector Type	Energy compensated GM tube
Accuracy/Linearity	15% of full scale referred to-Cs-137 from 1 mR/h to I R/h
Response Time	Four seconds or less below 50 mR/h Two seconds or less above 50 mR/h
Energy Dependence	+/- 15% from 60 keV to 1.3 MeV +/- 30% from 40 keV to 59 keV
Meter	100 uA taut band type with no unit markings
Count Light	LED lamp flashes with each count
Operating Temperature	0* to 501C
Controls	Off; battery test; range switch; zero adjust knob, and calibration controls (one for each range)
Battery	9 V transistor radio type (Mallory MN 1604)
Battery Life	200 hours (typical)
Dimensions	2.81 x 6.09 x 1.53 inches (71 x 155 x 39 mm)
Weight	11.5 ounces (0.33 kg)

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