

APR 14 1994

Robert M. Hallisey, Director
Radiation Control Program
Department of Health
305 South Street, 7th Floor
Jamaica Plain, MA 02130

Dear Mr. Hallisey:

The enclosed sealed source certificates received from your Office, require some revision in order to be entered into the NRC nationwide registration system.

A completed NRC certificate is provided for your use as a model. Please have both certificates retyped using the format of the enclosed NRC certificate NR-476-S-158-S. Your certificate numbers should be assigned as follows:

1. MA-476-S-166-S for models NES-8007 & 8032.
2. MA-476-S-167-S for models NES-8470, 8480 & 8490.

Additionally, enclosed are the sealed source and device system Regulatory Guides 10.10 and 10.11, and the reviewer's checklist.

If you have any questions regarding this letter, please call me or Lloyd Bolling at 301-504-2327.

Sincerely,

PSI

Paul H. Lohaus, Deputy Director
Office of State Programs

Enclosures:
As stated

Distribution:
Dir RF S-65
RBangart
PLohaus
LBolling
SS&D File

DCD (SP01)
PDR YES NO

*see previous concurrence

OFC	OSP:SA	OSP:DD <i>PSI</i>	NMSS		
NME	LBolling:dr	PLohaus <i>PSI</i>	RBaer		
DTE	04/08/94*	04/11/94* <i>PSI</i>	04/11/94*		

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150021

9404180016 940314
PDR STPRG ESQMA
PDR

SUMMARYMANUFACTURER

The DuPont Merck Pharmaceutical Company
Radiopharmaceutical Division
331 Treble Cove Road
North Billerica, MA 01862

DISTRIBUTOR

(Same)

RADIOACTIVE MATERIAL

Cobalt-57

MODEL NO.NOMINAL ACTIVITYMAXIMUM ACTIVITY

NES-8007

1 Millicurie

25 millicuries

NES-8032

*

25 millicuries

* -Nominal activity level to be specified on customer purchase order.

USE

This cobalt-57 line source is intended for use in nuclear medicine procedures for gamma camera system calibrations, and may also be used in other applications where a linear radiation field is required.

This cobalt-57 line source is most appropriately defined as a calibration or reference source by NARM Guide 10 on Medical Sources, Section B.4 on page 57 of the "Guides for Naturally Occurring and Accelerator Produced Radioactive Material" (HHS Publication FDA 81-8025).

SOURCE DESCRIPTION

Please refer to the DuPont Merck Control Drawing No. 180-176 for a detailed description of these line sources. These line sources are both of identical design with the only difference being the radioactivity content. The sources consist of Co-57 as cobalt metal uniformly dispersed in high impact epoxy casting resin (E @ C Stycast 1264 or equivalent) which is drawn into a stainless steel tube and cured. The stainless steel tube is inserted into an outer rigid acrylic tube with end caps bonded at both ends to form a seal.

RADIATION MEASUREMENTS

The contact dose rate at the surface, at 5 cm, and at 30 cm from the surface of the line source containing 1 mCi of Co-57 is 60 mrem/hr, 15 mrem/hr, and 1.5 mrem/hr respectively. The dose rates were measured using a Ludlum survey meter with a model 44-58 beta-gamma detector, with an instrument calibration accuracy of + - 10 %.

QUALITY CONTROL

The cobalt-57 line sources have been designed and will be manufactured to provide maximum safety and service, having satisfied the ANSI safety performance classification 77C22212 as recommended for reference sealed sources.

LABELING AND INSTRUCTIONS

As per the Dupont Merck Control Drawing No.18-176, and evidenced by the labeling submitted with the registration amendment request by the manufacturer, the line sources will be labeled showing the radionuclide, activity, source model and serial numbers, and date of manufacture.

A technical Data Sheet in the form of a customer Radiation Instruction Sheet will be provided with each source stating recommendations for the safe handling, use and storage of this radioactive source.

LICENSING RECOMMENDATIONS

As mentioned previously these source models are most closely defined as a reference source as described in NARM Guide 10 for Medical Sources.

The radioactive material contained in this product is accelerator produced; hence, the radiation control agencies in the various states exercise regulatory authority for receipt, possession, use, and transfer.

Evaluated by:

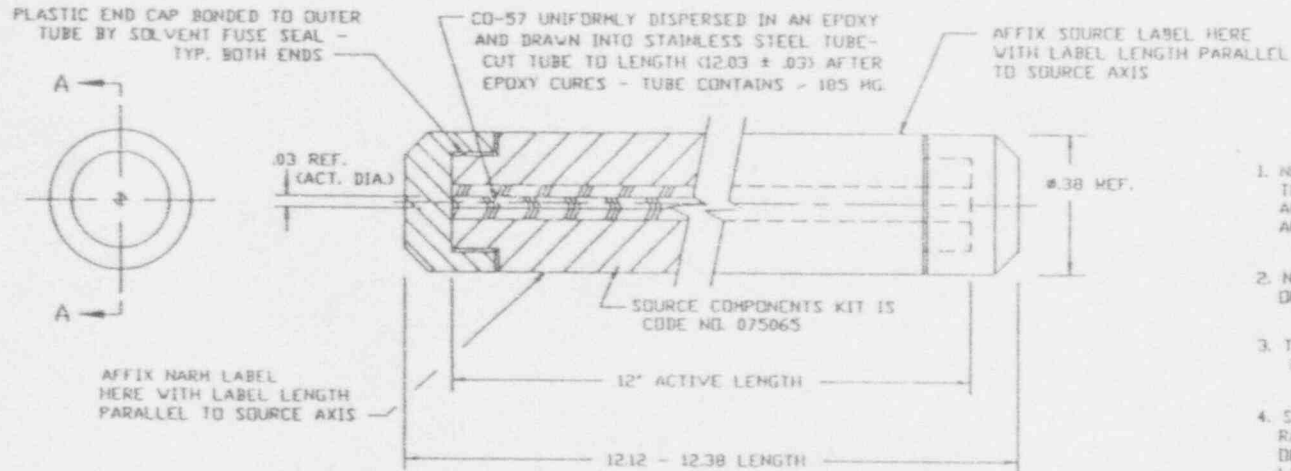
Massachusetts Department of Public Health
Radiation Control Program
305 South Street
Jamaica Plain, MA 02130
(617) 727-6214

NARM

The Nuclear Regulatory Commission does not have the authority to regulate the radioactive material in this document, and the NRC is not responsible for its content. It is distributed and maintained by NRC as a service to state radiation control agencies.

NARM

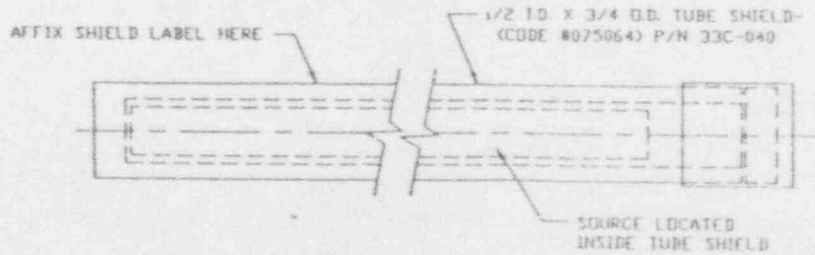
REVISIONS				
REV.	DESCRIPTION	BY	DATE	APPROVED
I	REVISE PER EDCO NO. 92205-20 (SOURCE RE-DESIGN) 7/14/93	JES	9/3/93 7/17/93	<i>[Signature]</i> <i>[Signature]</i>



SECTION A-A

NOTES

1. NOMINAL ACTIVITY TO BE PER TABLE BELOW. NOMINAL ACTIVITY TOLERANCE TO BE +20%, -10% REFERENCED TO LABEL DATE. SOURCE ACTIVITY CONTENT TO BE DETERMINED BY CONCENTRATION (MC/GM) X AMOUNT DISPENSED (GM) INTO SOURCE TUBE.
2. NOMINAL ACTIVITIES OTHER THAN THOSE IN TABLE TO BE SPECIFIED ON PURCHASE ORDER. MAXIMUM ACTIVITY TO BE 25 MCI.
3. TOTAL CO-56/SB CONTENT TO BE LESS THAN 0.15% CO-57 CONTENT, REFERENCED TO LABEL DATE.
4. SOURCE UNIFORMITY TO BE DETERMINED BY MEASUREMENT OF RADIATION EMISSION FROM 1 INCH SEGMENTS (12) AND CALCULATION OF COEFFICIENT OF VARIANCE (ONE STANDARD DEVIATION / MEAN). LIMIT TO BE 5% MAXIMUM.
5. CONTAMINATION / LEAKAGE TESTING OF EACH SOURCE TO YIELD $< 5 \times 10^{-4}$ uCi. REFERENCE UMD-205.
6. ANSI N542-1977 PERFORMANCE CLASSIFICATION 77C2212.
7. LABELLING AND INSERTS PER BILL OF MATERIALS (BOM).



PACKAGING ASSEMBLY

ASS'Y P/N	MODEL NUMBER	NOMINAL ACTIVITY
-01	NES-0007	1 MCI
-02	NES-0032	SEE NOTE 2

REV	QTY	DATE	PART OR IDENTIFYING NO.	DESCRIPTION	QTY																																										
<table border="1"> <tr> <td colspan="2">NATIONAL COMPONENTS</td> <td colspan="4">DU PONT MERCK PHARMACEUTICAL CO.</td> </tr> <tr> <td colspan="2">KIT CODE NO. 075065</td> <td colspan="2">TOLERANCE</td> <td>DRIVING</td> <td>DATE</td> </tr> <tr> <td colspan="2">SOURCE 180-176</td> <td>± 0.10</td> <td>± SQUARES</td> <td>5/14/93</td> <td></td> </tr> <tr> <td colspan="2">B002477</td> <td>± 0.05</td> <td>CHECKED</td> <td></td> <td></td> </tr> <tr> <td colspan="2">PROP ASSEMBLY</td> <td>FACT. 11/84</td> <td>APPROVED</td> <td></td> <td></td> </tr> <tr> <td colspan="2">NEXT ASSEMBLY</td> <td>ANGLES ± 30'</td> <td>ENG.</td> <td></td> <td></td> </tr> <tr> <td colspan="2"></td> <td>SCALE: NONE</td> <td>BY: OF</td> <td></td> <td></td> </tr> </table>						NATIONAL COMPONENTS		DU PONT MERCK PHARMACEUTICAL CO.				KIT CODE NO. 075065		TOLERANCE		DRIVING	DATE	SOURCE 180-176		± 0.10	± SQUARES	5/14/93		B002477		± 0.05	CHECKED			PROP ASSEMBLY		FACT. 11/84	APPROVED			NEXT ASSEMBLY		ANGLES ± 30'	ENG.					SCALE: NONE	BY: OF		
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CO-57 C.O.R. LINE SOURCE ASSEMBLY																																															
				B	ENG. NO. 180-176																																										
					REV. 1																																										

MANUFACTURER

The DuPont Merck Pharmaceutical Company
 Radiopharmaceutical Division
 331 Treble Cove Road
 North Billerica, MA 01862

DISTRIBUTOR

(Same)

RADIOACTIVE MATERIAL

Cobalt-57

MODEL NO.	NOMINAL ACTIVITY	MAXIMUM ACTIVITY
NES-8470	5 millicuries	25 millicuries
NES-8480	10 millicuries	25 millicuries
NES-8490	*	25 millicuries

* - Nominal activity level to be specified on customer purchase order.

USE

These cobalt-57 flood source models are intended for use in nuclear medicine procedures for gamma camera system calibrations, and may also be used in other applications where a uniform field is required.

These cobalt-57 flood sources are most appropriately defined as a calibration or reference source by NARM Guide 10 on Medical Sources, Section B.4. on page 57 of the "Guides for Naturally Occurring and Accelerator Produced Radioactive Material" (HHS Publication FDA 81-8025).

SOURCE DESCRIPTION

The sources consist of Co-57 as cobalt metal uniformly dispersed in high impact epoxy casting resin (E&C Stycast 1264 or equivalent) which is cured and placed into an ABS plastic encapsulation having overall dimensions 19.3" X 15.3" X 0.7".

RADIATION MEASUREMENTS

The contact dose rate at the surface, at 5 cm, and at 30 cm from the surface of the flood source containing 5 mCi of Co-57 is 66 mrem/hr, 44 mrem/hr, and 7.5 mrem/hr respectively. The dos rates were measured using a Ludlum survey meter with a Model 44-58 beta-gamma detector, with an instrument calibration accuracy of + - 10 %.

QUALITY CONTROL

The cobalt-57 flood sources have been designed and will be manufactured to provide maximum safety and service, having

satisfied the ANSI safety performance classification 77C22312 as recommended for medical reference sources.

LABELING AND INSTRUCTIONS

The flood sources will be labeled showing the radionuclide, activity, source model and serial numbers, and date of manufacture.

Technical Data Sheets in the form of a "Performance Evaluation Sheet and Leak Test Certificate" and a "Radiation Safety and Instructions Sheet" will be provided with each source giving the user recommendations for the safe handling, use and storage of this radioactive source.

LICENSING RECOMMENDATIONS

As mentioned previously, these source models are most closely defined as a reference source as described in NARM Guide 10 for Medical Sources.

The radioactive material contained in this product is accelerator produced; hence, the radiation control agencies in the various states exercise regulatory authority for receipt, possession, use, and transfer.

EVALUATED BY:

MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH
RADIATION CONTROL PROGRAM
305 SOUTH STREET
JAMAICA PLAIN, MA 02130
(617) 727-6214

NARM

The Nuclear Regulatory Commission does not have the authority to regulate the radioactive material in this document, and the NRC is not responsible for its content. It is distributed and maintained by NRC as a service to state radiation control agencies.

NARM

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

NO: MA-115-FS

DATE: December 1, 1993

PAGE 1 OF 3

DEVICE TYPE: Flood source

MODELS: NES-8470, NES-8480, NES-8490

MANUFACTURER/DISTRIBUTOR:

The DuPont Merck Pharmaceutical Company
Radiopharmaceutical Division
331 Treble Cove Road
North Billerica, MA 01862

SEALED SOURCE MODEL DESIGNATION:

ISOTOPE: Cobalt-57 ANSI CLASSIFICATION: N542-1977 C22312

<u>Model No.</u>	<u>Nominal Activity</u>	<u>Maximum Activity</u>
NES-8470	5 millicuries	25 millicuries
NES-8480	10 millicuries	25 millicuries
NES-8490	*	25 millicuries

* - Nominal activity level to be specified on customer purchase order.

LEAK TEST FREQUENCY: Six (6) months

PRINCIPAL USE: (X) Medical Reference Source: for use in calibration of gamma camera systems in nuclear medicine.

CUSTOM DEVICE: ___ YES ___ X NO

DESCRIPTION:

These sources consist of Co-57 as cobaltous chloride uniformly dispersed in high impact epoxy casting resin (E&C Stycast 1264 or equivalent) which is cured and placed in an ABS plastic cover, dimensions 19.3 in. X 15.3 in. x 0.7 in., consisting of two formed halves that snap together.

LABELING:

Each source is conspicuously labeled "Co-57 Flood Source" and bears the warning "CAUTION: RADIOACTIVE MATERIAL" as well as the radiation symbol in magenta and yellow, the manufacturer's name and logo, and the instruction "See Use and Handling Instructions". The radioactive content, in millicuries, and the date of manufacture is shown.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

NO.: MA-115-FS

DATE: December 1, 1993

PAGE 2 OF 3

DRAWINGS: See attachments 1, 2, 3 and 4.

CONDITIONS OF NORMAL USE:

1. The flood source provides a uniform radiation field in performing a nuclear medicine gamma camera flood field study. A flood field study is the recording of camera field uniformity performance for correcting any camera malfunction before it interferes with a diagnostic procedure.
2. The flood source useful life is approximately two years.

PROTOTYPE TESTING:

Prototype sources were subjected to four environmental tests as prescribed by ANSI N542-1977, Table 1, for classification C22312 (Medical Reference Source).

EXTERNAL RADIATION LEVELS:

Contact dose rate: 13.2 mr/hr/millicurie
At five centimeters: 8.8 mr/hr/millicurie
At 30 centimeters: 1.5 mr/hr/millicurie

QUALITY ASSURANCE AND CONTROL:

The DuPont Merck Pharmaceutical Company provides for design control, procurement control, process quality control, and final quality assurance. Transfer of flood sources is performed in conformance with all regulatory requirements.

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

1. The source should not be subjected to environmental conditions which exceed its ANSI performance classification. Normal use precludes abrasion, corrosion, impact, or puncture.
2. The probable effect of severe environmental conditions, such as accidents and fire would be minimal release of radioactivity since the Co-57 is incorporated into the cured epoxy matrix. Although the ABS cover, even as it commenced to melt, would prevent dispersion of radioactivity, temperatures exceeding 200 degrees C. would result in combustion of the resin in which the cobalt-57 is dispersed, as well as of the plastic cover.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

NO.: MA-115-FS

DATE: December 1, 1993

PAGE 3 OF 3

SAFETY ANALYSIS SUMMARY:

Based on our review of the manufacturer's information and test data, it is concluded that subject flood sources may be used safely by appropriately trained individuals, and are designed and manufactured in a manner to provide adequate assurance that no part of the radioactive content will be released during normal use, nor as the result of any credible adverse situation which might occur attendant to normal use.

This Certificate of Registration of the Models NES-8470, NES-8480, NES-8490 device design is based on information and test data contained in DuPont Merck's application and supporting documents which are hereby incorporated by reference and made a part of this registry document dated December 1, 1993.

References:

DuPont Merck Application dated October 21, 1993

Letter (F. Roy, DuPont Merck) dated Nov. 23, 1993

DATE: _____

REVIEWED BY: _____
Agostino Savastano

DATE: _____

CONCURRENCE: _____
L. R. Adams, Ph.D.
Dept. of Labor & Ind.

ISSUING AGENCY:

Massachusetts Department of Public Health, Radiation Control Program.

NA-115-FS - incorrect #?

Description: Does case lock: can ^{non-destructive} consumer open w/o special tools?

Drawings: Not attached -

Prototype Testing: Statement of testing results?

Statement of review of testing report
by ME(PE) -

Is testing report on file?

QA/QC: Are procedures on file? Reviewed by
PE? Good Manufacturing (FDA) procedures

Limitations: Source should not be leached for use. . . .
Impact: Drop to floor from hands (~4 ft)?

accidents and fire: if broken or crushed, are fine
or respirable particles released? Does matrix
fracture? shatter?

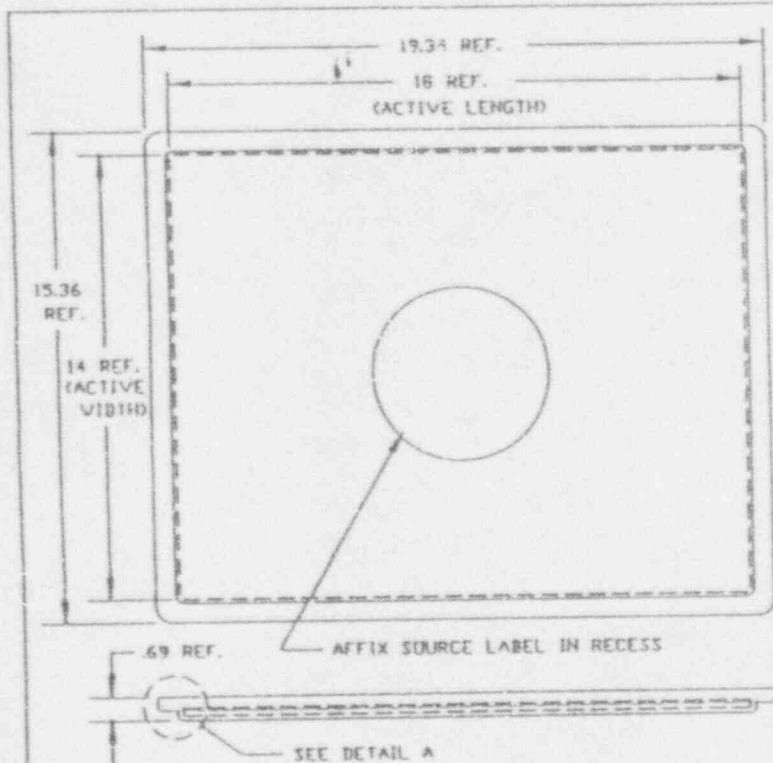
Storage in supplied container - shielded?
- other?

REGISTRY OF SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE

NO.: MA-115-FS

DATE: DECEMBER 1, 1993

ATTACHMENT 1

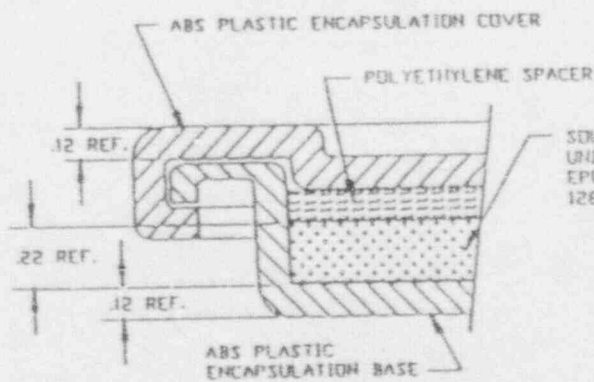


ASSY P/N	MODEL NUMBER	NOMINAL ACTIVITY
-01	NES-0470	5 MCI
-02	NES-0480	10 MCI
-03	NES-0490	SEE NOTE 7

REVISIONS				
NO.	DESCRIPTION	BY	DATE	APPROVED
	FIRST ISSUE			

NOTES

- SOURCE ACTIVITY TOLERANCE TO BE +20% -10% REFERENCED TO LABEL DATE. MAXIMUM ACTIVITY TO BE 25 MCI.
- RADIATION EMISSION UNIFORMITY TO BE MEASURED PER PROCEDURE NO. 50-300-002 AND DETERMINED BY COEFFICIENT OF VARIANCE (ONE STANDARD DEVIATION / MEAN). LIMIT TO BE 12.
- FINAL ASSEMBLY CONSISTS OF A SOURCE IN A STORAGE CONTAINER (N030400) WITH LABELLING AND INSERTS PER BILL OF MATERIALS.
- TOTAL CO-56/58 CONTENT TO BE LESS THAN 0.15% CO-57 CONTENT REFERENCED TO LABEL DATE.
- ANSI N542-1977 PERFORMANCE CLASSIFICATION 77C22312.
- SHEAR TEST OF ENTIRE SURFACE OF FLOOD SOURCE TO YIELD $< 5 \times 10^{-4}$ UCI. REFERENCE UMD-205.
- NOMINAL ACTIVITY TO BE SPECIFIED ON PURCHASE ORDER FOR SOURCES HAVING NOMINAL ACTIVITIES OTHER THAN THOSE IN TABLE. MAXIMUM ACTIVITY TO BE 25 MCI.



NOTE: ENCAPSULATION COMPONENTS KIT (COVER, BASE AND SPACER) IS CODE NO. 030470.

DETAIL A
(SCALE 2:1)

REV. NO.	DATE	DESCRIPTION	BY	DATE	APPROVED

8002470	8001969	8001970
8002470	8001969	8001970
8002470	8001969	8001970

DU PONT WERCK		DU PONT WERCK PHARMACEUTICAL CO.	
TELEPHONE	1-810	DATE	6/28/93
ADDRESS	1-810	QUANTITY	1
PRICE	1/18	APPROVED	
ORDER NO.	307	DATE	
QUANTITY	1	DATE	

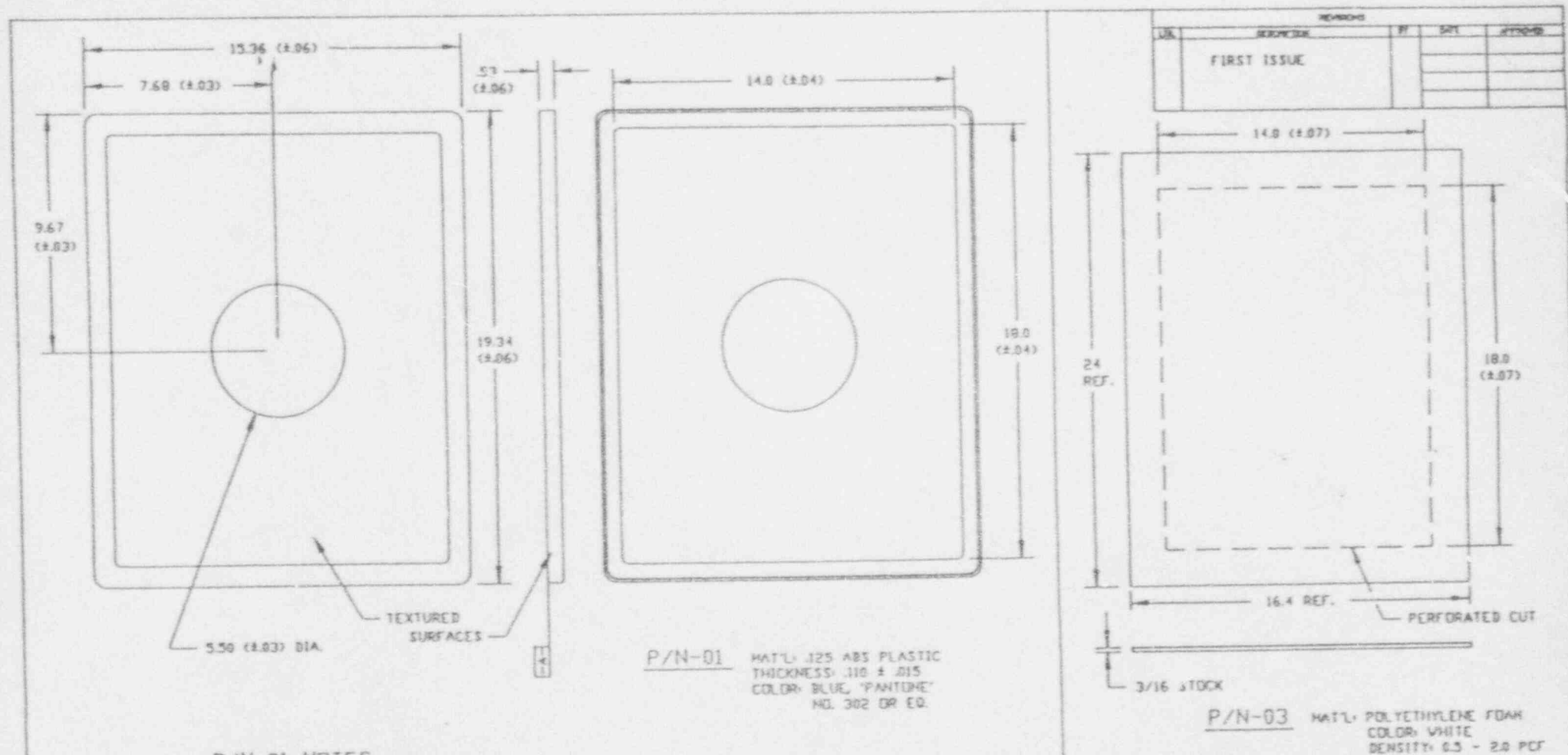
CO-57 R18 FLOOD SOURCE ASS'Y (SMALL RECTANGULAR)	8001970
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REGISTRY OF SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE

NO.: MA-115-FS

DATE: DECEMBER 1, 1993

ATTACHMENT 2



P/N-01 NOTES

1. SURFACE -A- TO BE FLAT WITHIN 0.125".
2. TOP SURFACE AND VERTICAL SIDE SURFACES TO HAVE TEXTURED FINISH.
3. COLOR SHADE OF P/N-01 AND P/N-02 TO BE MATCHED.

REV	DATE	DESCRIPTION	BY
1	7/26/93	FIRST ISSUE	

DU PONT MERCK		DU PONT MERCK PHARMACEUTICAL CO.	
DATE	BY	DATE	BY
11/1/93	J. SHERMAN	7/26/93	
CHKD	APPROVED		
DATE	BY		
11/1/93			
DATE	BY		
11/1/93			
NO. OF	REV.	REV.	REV.
1	1	1	2

PACK SERIAL	ALLOCATION DATE	DATE	BY
B001970	SOURCE		
	B001969		
TEST SERIAL			

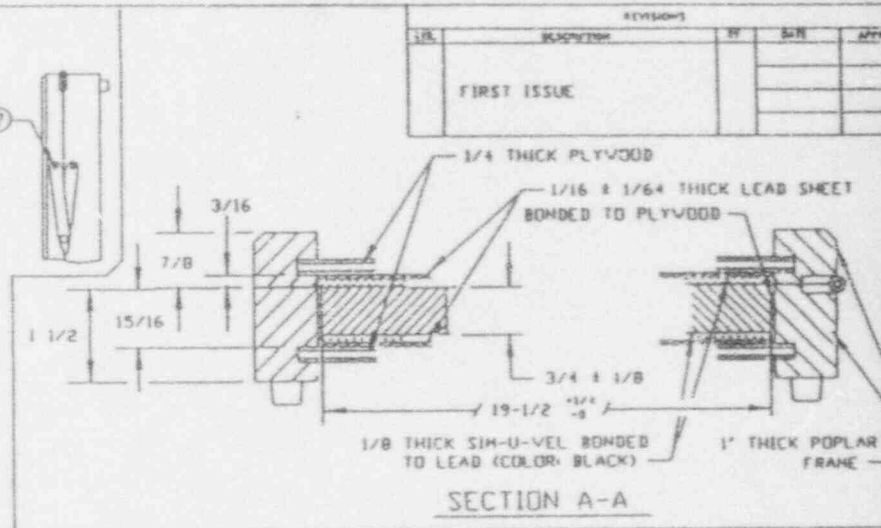
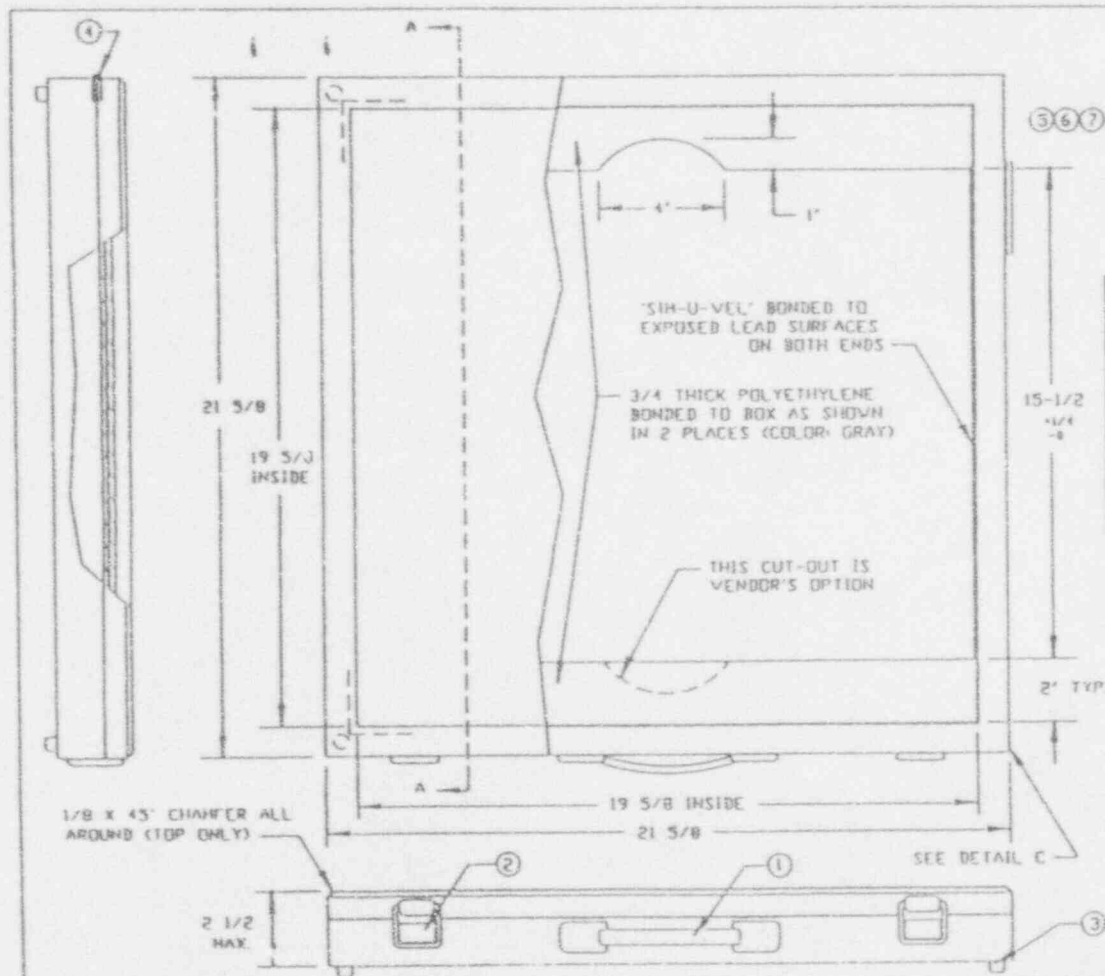
RIB ENCAPSULATION	DATE	BY
(SMALL RECTANGULAR		
COMPONENTS KIT		
B	DATE	BY
	B001969	

REGISTRY OF SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE

NO.: MA-115-FS

DATE: DECEMBER 1, 1993

ATTACHMENT 4

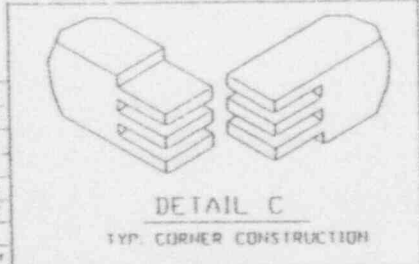


REVISIONS				
REV.	DESCRIPTION	BY	DATE	APPROV.
FIRST ISSUE				

NOTES

- INSIDE DIMENSIONS ARE REQUIRED. OUTSIDE DIMENSIONS ARE REFERENCE ONLY AND MAY VARY ACCORDING TO BOX CONSTRUCTION.
- FINISHED WEIGHT IS APPROXIMATELY 20 LBS.
- WORKMANSHIP: DUPONT RESERVES THE RIGHT TO REQUIRE NO CHARGE REPLACEMENT OF ANY BOXES WHICH DOES NOT CONFORM TO THE AVERAGE ACCEPTABLE QUALITY LEVEL OF ALL BOXES SUPPLIED BY THE VENDOR. AT THE VENDOR'S OPTION A FIRST ARTICLE QUALITY STANDARD MAY BE PROVIDED TO DUPONT TO ESTABLISH ACCEPTABLE QUALITY LEVEL.
- THIS PART IS CODE NO. 03B400.
- ALL HARDWARE TO HAVE BRIGHT NICKEL-PLATED FINISH.
- ITEM NO. 5 TO LOCK COVER IN OPEN POSITION AT -90°.
- ALL WOOD TO BE DARK COLOR AND UNIFORM GRAIN.
- ALTERNATE HARDWARE TO BOX BELOW IS ACCEPTABLE UPON PRIOR APPROVAL OF DUPONT-HERCK.

ITEM NO.	PART OR IDENTIFYING NO.	DESCRIPTION	QTY
7		#6 FLAT WASHER (STN.ST.)	2
6		#6 X 3/4 L. SHI METAL SCREW (STN.ST.)	2
5	1240 X 1/2	LUDWIG COVER STAY	1
4	1244 X 10	LUDWIG CONTINUOUS HINGE	1
3	15V	ATLANTIC INDIA RUBBER CO.	4
2	74W	EXCELSIOR HARDWARE HASP ASSY	2
1	919-415-173	PJLC INDUSTRIES HANDLE (100 N CAP.)	1



REF. NO.	QTY	PART OR IDENTIFYING NO.	DESCRIPTION
MATERIALS			
AS NOTED		DU PONT MERCK PHARMACEUTICAL	
TOLERANCE		DESIGN	DATE
FRAC. 1/16		J. SUNDARES	7/30/93
DEC. 1/100		CHECKED	
APPROVED		R18 FLOOD SOURCE STORAGE BOX	
SCALE: 1 X 1		REV. NO. B002478	

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE

NO. : NR-476-S-158-S

DATE: APR 21 1992

PAGE 1 OF 5

SEALED SOURCE TYPE: Spot Marker Source

MODEL: NES-8060

MANUFACTURER/DISTRIBUTOR:

Du Pont Merck Pharmaceuticals Co.
331 Treble Cove Road
N. Billerica, MA 01862

ISOTOPE:

Barium-133

MAXIMUM ACTIVITY:

200 microcuries

LEAK TEST FREQUENCY:

6 Months for sources with activity
greater than 100 microcuries

PRINCIPAL USE: (X) Medical Reference Source

CUSTOM SOURCE: _____ YES _____ X _____ NO

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE

NO.: NR-476-S-158-S

DATE: APR 21 1992

PAGE 2 OF 5

SEALED SOURCE TYPE: Spot Marker Source

DESCRIPTION:

The Model NES-8060 sealed source is intended for use in nuclear medicine procedures for gamma camera system calibration and for location reference spot imaging.

The source consists of barium-133 uniformly dispersed in an epoxy resin and encapsulated in two pieces of "Lucite". The source is sealed with a solvent fuse seal (methylene chloride) and has overall dimensions of 1 inch in diameter by 1/4 inch thick.

LABELING:

The source and its storage container meet the labeling requirements of Section 32.74(a)(2)(viii) and (a)(3), 10 CFR Part 32.

The source is silkscreened in red, or engraved and filled with white, red or black, with its model number, isotope, activity, date of assay, and DUPONT. The other side of the source has an adhesive label attached which includes a magenta radiation symbol and the words "CAUTION: RADIOACTIVE MATERIAL" on a yellow background. The adhesive label covers the fuse seal of the source and therefore gives the appearance the source is constructed from a solid piece of Lucite.

The storage container label contains the model number, activity, isotope, date of assay, lot number, manufacturer's name, radiation symbol, and the words "CAUTION: RADIOACTIVE MATERIAL" and "See instruction sheet for use and handling information".

DIAGRAM:

See attachment 1.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE

NO.: NR-476-S-158-S

DATE: APR 21 1992

PAGE 3 OF 5

SEALED SOURCE TYPE: Spot Marker Source

CONDITIONS OF NORMAL USE:

The source is designed for use in nuclear medicine procedures for gamma camera system calibration and for location reference spot imaging. Typically the source will be used in laboratories and hospital treatment rooms in which the environment is suitable for humans. The source shall not be subjected to extreme or severe environmental conditions.

PROTOTYPE TESTING:

Prototypes of Models NES-258 and NES-259 sealed sources were tested in 1975 to the specifications of ANSI N5.10-1968. The sealed sources achieved a classification of C22212.

The Model NES-8060 is exactly the same design and construction as the Models NES-258 and NES-259. The only difference is an increase in activity. Therefore, the Model NES-8060 qualifies for an ANSI 5.10-1968 classification of C22212.

EXTERNAL RADIATION LEVELS:

The contact dose at the disc surface of a 100 μ Ci, Model NES-8060 source is 1000 mR/hr as measured by a LiF TLD wafer.

QUALITY ASSURANCE AND CONTROL:

Du Pont Merck Pharmaceuticals maintains a quality assurance and control program which has been deemed acceptable for licensing purposes by NRC. A copy of the program is on file with the Source Containment and Devices Branch.

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

- The sealed source shall be distributed to specific licensees of NRC or Agreement States.
- Handling, storage, use, transfer, and disposal: To be determined by the licensing authority.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE

NO.: NR-476-S-158-S

DATE: APR 21 1992

PAGE 4 OF 5

SEALED SOURCE TYPE: Spot Marker Source

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE (Cont.):

- The source shall not be subjected to environmental conditions which exceed its ANSI classification.
- Sealed sources with activities greater than 100 μCi shall be leak tested at intervals not to exceed 6 months using techniques capable of detecting 0.005 μCi of removable contamination.
- This registration sheet and the information contained within the references shall not be changed without the written consent of the NRC.

SAFETY ANALYSIS SUMMARY:

Based on review of the Model NES-8060 sealed source, the information and test data cited below, and the fact that the Model NES-8060 source is the exact same design and construction as the Models NES-258 and NES-259 which were licensed by NRC in 1975, we conclude that the sealed source is acceptable for specific licensing purposes.

Furthermore, we conclude that the sealed source would be expected to maintain its containment integrity for normal conditions of use and accidental conditions which might occur during uses specified in this certificate.

REFERENCES:

The following supporting documents for the Model NES-8060 sealed source are hereby incorporated by reference and are made a part of this registry document.

- Du Pont Merck's letters dated April 13, 1992, and March 16, 1990, with enclosures thereto.

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SEALED SOURCE TYPE: Spot Marker Source

ISSUING AGENCY:

U.S. Nuclear Regulatory Commission

Date: APR 21 1992

Reviewer: 

Date: APR 21 1992

Concurrence: 

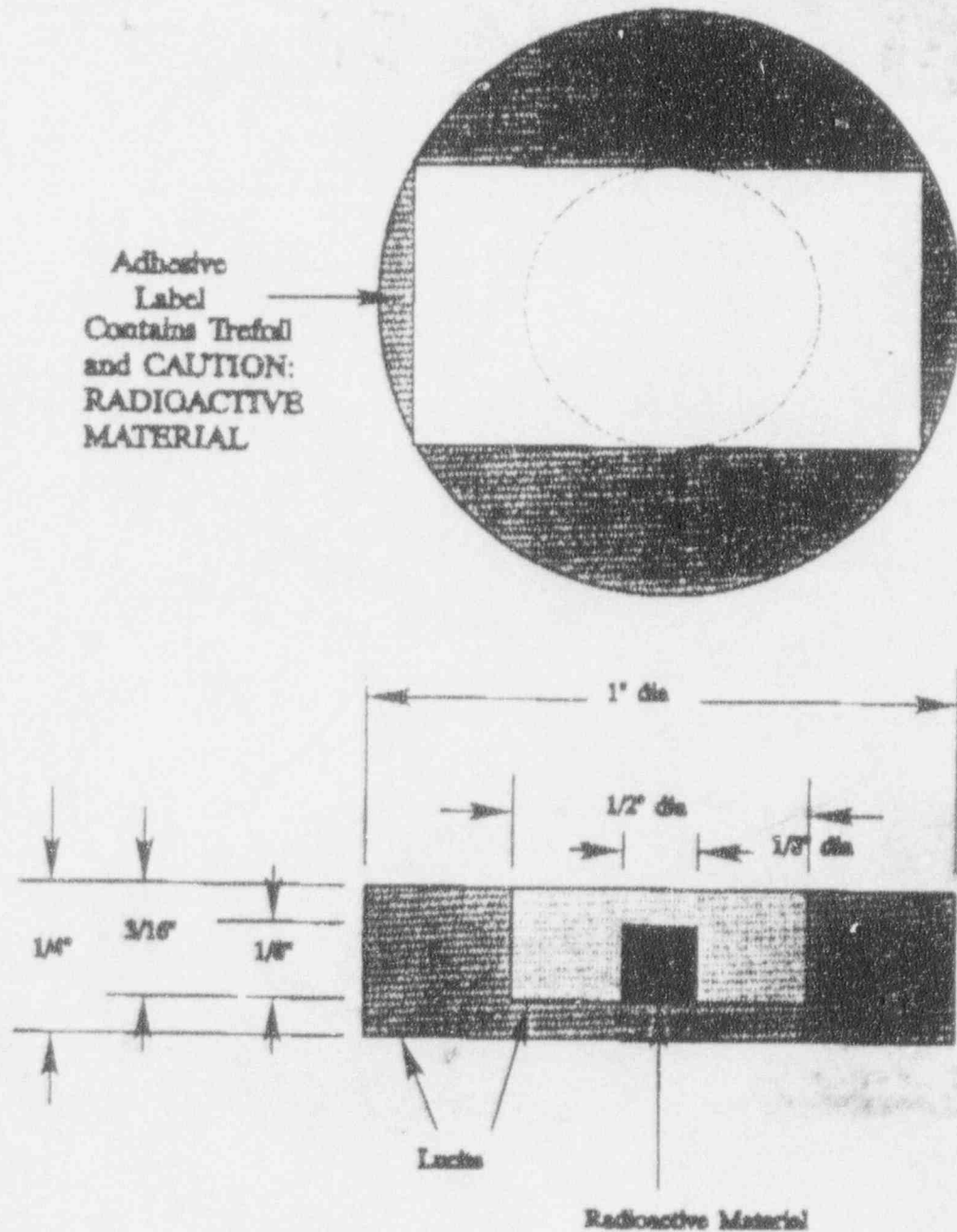
REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
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ATTACHMENT 1

Model NES-8060



MANUFACTURER/DISTRIBUTOR: _____ REGISTRATION #: _____

MODEL #: _____ REFERENCES: _____

DESCRIPTION	OK/DEF (✓/D - RESP DATE)	COMMENTS
FIRST PAGE		
Registrant's name and address		
Manufacturer's and distributor's name and address		
Custom user's name and address		
Model number		
Type (from Reg. Guide 10.10 or 10.11)		
User's authority to possess (specific, general, both, exempt)		
Radionuclides, activity (Max w/% error), form, manufacturer, model, NRC registered (note on registration certificate if source is registered as part of the device)		
DESCRIPTION		
If registrant is requesting to register more than one source/device on a certificate, are designs similar enough to do so?		
Device/source design with complete engineering drawings (dimensions, tolerances, list of materials)		
Assembly methods (screw, welds, etc.); verify integrity		
Source mounting (size and integrity) and security		
Is source ANSI classification sufficient: Radiography - Unprotected - 43515 Radiography - In Device - 43313 Medical - Radiography - 32312 Medical - γ Teletherapy - 53524 γ Gauges - Unprotected - 43333 γ Gauges - In Device - 43232 β Gauges, Low Energy γ Gauges, or X-ray fluor - 33222 Oil Well Logging - 56522 Portable Moist/Density - 43333 Neutron Applications - 43323 γ Irradiators (II, III, IV) - 43424 γ Irradiators (I) - 43323 Chromatography - 32211 Static Eliminators - 22222 Smoke Detectors - 32222 (from ANSI N542-1977)		
Definition of shutter operation (locked in Off position, not locked in On position)		
On-Off indicators (description, qty., location)		

DESCRIPTION	OK/DEF (✓/D - RESP DATE)	COMMENTS
Safety interlocks, guards, etc. to prevent access to beam or high radiation levels		
Corrosion between unlike materials (aluminum & steel, depleted uranium & steel, etc.) see "Corrosion" information		
Well logging sources must be nondispersible and nonsoluble. (see JBCarrico for listing of sealed sources approved for well logging)		
See "ANSI and Other Standards" list for references for particular source/device designs (e.g. radiography, brachytherapy, etc.)		
LABELING		
Copy of label		
Materials, dimensions, colors (note on registration certificate if labeling is exempt from the color requirements of 10 CFR Part 20)		
Permanent attachment and location(s) - visible to users?		
Contents: Model#, Serial#, Isotope, Activity, Manufacturer, Date of Assay, Trefoil, "CAUTION - RADIOACTIVE MATERIAL" (Depleted Uranium information must be included)		
CONDITIONS OF USE		
Expected life of the source/device (years, operations)		
Maximum allowable temperature, vibration, shock, corrosion, etc. (during operation and accidental)		
How the device will be used		
Meets dose limits of Part 32 for G and E distribution		
PROTOTYPE TESTING		
Tests methods and conditions (for source and device)		
Tests results		
Years of use (incidents, failures, etc.)		
Similarities to other sources/devices if they are used as basis.		

DESCRIPTION	OK/DEF (✓/D - RESP DATE)	COMMENTS
RADIATION PROFILES		
Survey instrument used (type, window, sensitivity, etc.)		
Conditions		
Distance from source/surface (per ANSI 538-1979)		
Shutter On and Off/source shielded		
Scatter (product in beam)		
Guards and shields in place		
Verify radiation surveys for γ radiation meet inv^2 law.		
Verify radiation surveys for non- γ radiation have not been calculated using inv^2 law.		
QUALITY ASSURANCE		
Materials, subassemblies, services		
Assembly methods (screws, welding, etc.)		
Dimensions and tolerances		
Activity, radiation levels, leak tests		
QA Manual		
INSTALLATION		
Fixed, portable, movable, fixed installation but portable source housing		
Inherent shielding, inaccessibility		
Interlocks, locks, barriers		
Beam access: size of air gap/opening to beam (verify size with new GL rule)		
Mounting integrity		
SAFETY INSTRUCTIONS		
Operation, maintenance, calibration, damage/failure, specific warnings, leak test, and radiation surveys		

DESCRIPTION	OK/DEF (✓/D - RESP DATE)	COMMENTS
ACCOMPANYING DOCUMENTATION		
Leak tests results and radiation surveys		
Transportation documents		
Operation, maintenance, calibration, damage/failure, specific warnings, leak test, and radiation survey instructions if applicable		
For GL dist. Verify NRC Regions and Agreement State listing is up-to-date and copies of all pertinent regulations		
SERVICING		
Manufacturer provides or user performs: <input type="checkbox"/> Installation <input type="checkbox"/> Calibration <input type="checkbox"/> Relocation <input type="checkbox"/> Leak Test <input type="checkbox"/> Maintenance <input type="checkbox"/> Radiation Survey <input type="checkbox"/> Repair <input type="checkbox"/> Training <input type="checkbox"/> Source Change/Installation		
FOREIGN MANUFACTURERS		
Drop ship		
Who and where is source installed		
Leak test and radiation surveys		
QA in the U.S.		