

**United
Technologies****Research Center**

Date: July 9, 2001

To: Bill Ward
U.S. Nuclear Regulatory Commission
Phone: (301) 415-7038
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Number of pages (including cover sheet): 15

Subject: Supporting Documents to Registration Certificate NR-655-D-101-S

Per our telecon, enclosed is the December, 16 1988 letter.

Please contact me if you have any questions.

Thank you,
Glenn Janowsky
United Technologies Research Center



**UNITED
TECHNOLOGIES
RESEARCH
CENTER**

East Hartford
Connecticut 06108

December 16, 1988

U. S. Nuclear Regulatory Commission
Nuclear Materials Safety & Safeguards Branch
Region I
King of Prussia, PA 19406

Attention: John Glenn

Subject: Application for Device Registration Certificate Amendment
and Materials License Amendment

Reference: (a) NRC Device Registration Certificate NR-655-D-101-S
(b) NRC Materials License 06-07522-01, Amendment No. 41
issued to United Technologies Corporation, United
Technologies Research Center
(c) Letter to D. Mackenzie (NRC) from L. Packer (UTRC)
dated January 19, 1987
(d) Letter to J. Glenn (NRC) from L. Packer (UTRC) dated
April 30, 1987

Enclosures: (A) Gd-153 sealed source test results from DuPont
(B) Check for Application Fees

Dear Sir:

Please amend the reference (a) Registration Certificate for the
United Technologies Research Center (UTRC) LTG1 Layer Thickness Gage
to include the changes listed below.

1. Sealed Source Model Designation

Add two additional sealed source designations so that the Gadolinium-
153 sealed source capsule used in the LTG1 can be any one of the
three listed below (i.e., add sources B and C):

A. Model Gd-1S

GNI, Inc.
202 Medical Center Blvd
Webster, TX 77598

B. Model PHI-153

Isotope Products Laboratories
1800 North Keystone St
Burbank, CA 91504

C. Model NER 8430

DuPont
Medical Products Dept
331 Treble Cove Road
N. Billerica, MA 01862

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Currently, these three vendors supply sealed sources to UTRC specifications for Layer Thickness gaging applications. In two cases (GNI and Isotope Products), UTRC fabricates the two-piece, 316 stainless steel capsule for the vendor; DuPont fabricates its own capsules. The vendors load the Gadolinium-153 pellet into the capsule and seal it by welding. DuPont has completed the ANSI testing of its source and is in the process of registering it with NRC; the source successfully passed the C63232 testing. Isotope Products has submitted the previous GNI ANSI test data for registration of its source in California. Details of construction and test data for the DuPont NER 8430 source are included in Enclosure A.

GNI's GD-1S sources have been in continuous use for over six years in UTRC's LTG1 and prototypes. No source capsule has ever failed and resulted in a leak of radioactive material. The source from Isotope Products is identical to the GNI source in design and construction. The DuPont capsule has only minor changes in design, non-critical to source safety and use, and was successfully tested to the specified ANSI C63232 classification. Both sources are expected to perform safely in the LTG1. They are being included in this amendment since UTRC was recently advised that GNI will no longer fabricate GD-1S gadolinium sources.

UTRC hopes that this amendment can be successfully expedited as it impacts on the source replacements for several LTG1s currently in use by a specific licensee, Pratt & Whitney (NRC license 06-07522-02).

2. Maximum Source Activity

Increase the maximum allowable Gadolinium-153 source activity from 350 to 420 millicuries.

The nominal activity of the sources UTRC orders is 350 millicuries, and will remain so. However, the above vendors have indicated that the actual activity of these sources will be within $\pm 15\%$ to 20% of nominal. While it is rarely the case that sources are exchanged immediately upon receipt of the new one (i.e., a source at the high end of the tolerance band would have time to decay somewhat before installation), the maximum allowable activity for the LTG1 sources should be increased to 420 millicuries to facilitate the immediate use of a source which assays at the high end of this range, if necessary.

Because of the source shielding presently installed, raising the maximum activity to this level will have very little effect on the maximum radiation levels outside the 10 cm LTG1 beam path. For example, the maximum radiation level on the prototype device listed in the current registration certificate (Reference a) would be expected to increase from 0.4 mr/hr to only about 0.5 mr/hr at 5 cm with the shutter open. This level is still consistent with UTRC's requirement that, in practise, the radiation level will be limited to less than 2 mr/hr at a distance of 30 cm from the gage with the shutter open and with the detector in place (as stated in Reference c, Item #3).

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3. Limitations and/or Other Considerations of Use

Delete "vendors" from the list of users to which UTRC will distribute the gage (Reference a, page 1). This section will now read:

The Layer Thickness Gage (LTG1) is specifically designed and constructed by UTRC for use only by United Technologies Corporation (UTC) divisions and subsidiaries.

Also make a similar change to Reference (a), page 4 under item "Limitations and/or Other Considerations of Use."

When NRC/Division of Fuel Cycle and Material Safety has successfully concluded their safety analysis and issued an amended registration certificate, please amend the Reference (b) license accordingly for those items listed above.

In addition, UTRC would like to clarify and expand on its procedures relative to servicing the LTG1, particularly in the area of source changes. The Reference (d) communication, Item #5, specifically addressed the question of where source capsule exchanges would occur and what safety procedures would be followed; this procedure is reiterated below. [Note: "Qualified UTRC personnel" are those listed in Item #11 of the Reference (b) license.]

Sealed source capsules will be exchanged into collimators only on UTRC premises, not at the user's facilities. Source capsule exchanges will be done only by qualified UTRC personnel. The actual transfer from storage pigs to collimators will be done behind lead-glass bricks, with only brief exposure of the licensed user's hand to gamma rays. Proper personnel monitoring devices are worn whenever unshielded sealed sources are being handled. We are presently using a film badge, such as obtained from Siemens Gammasonics (Des Plaines, IL), as the primary monitoring device, changed monthly. We will continue to use a film badge or a TLD dosimeter (such as obtained from Quantum Products, Silver Spring, MD) as the personnel monitoring device.

However, UTRC intends to exchange sources at an off-site user location when, in the normal course of operations, the original LTG1 source has decayed beyond its useful life and must be replaced by a new source. The procedures for doing so are listed below. To the extent required, some disassembly of the LTG1 will occur during these procedures.

Procedure 1 (UTRC preferred procedure)

- (1) UTRC will assemble (at UTRC) a complete replacement source housing, already sealed and containing the replacement source, replacement collimator, collimator holder and cooling jackets. A leak test analysis will be done and a leak test certificate prepared.

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- (2) UTRC will transport the source in the assembled housing to the user site. The housing has full radiation shielding and the shutter mechanism is in the off position. A commonly used UTRC procedure for packaging and transporting gadolinium-153 off-site to a user location was given in Item 10, Reference (d), and is repeated below:

UTRC will ship the source housing assembly in an approved D.O.T. 7A shipping carton, conforming to all conditions and limitations specified in 49 CFR 173.422 for excepted radioactive material, instruments and articles, n.o.s. UN2911. The transport index is determined by measuring dose rate at 1 meter from the package containing the fully shielded source; measured levels are background. The package contains a copy of the leak test certificate inside. The package is shipped Radioactive 1 -White Label (no transport index required). The Shippers Certificate is filled out and attached to the outside of the box. UTRC may also elect to transport the gage to and from the customer's site, locked in a company vehicle or company authorized vehicle. All licensed material will be transported in accordance with 10 CFR, Part 71.

- (3) UTRC will remove the original LTG1 source housing from the gage assembly bracket and install the replacement.
- (4) UTRC will perform a contamination survey at the user site to confirm that no contamination remains from the original source. Leak test wipes will be prepared. Operations in the area will be resumed when either:
- a. Negative leak test results are obtained by qualified UTRC personnel counting the wipes at the user site using a portable wipe test counter (such as the Victoreen Model 05-578; see data sheets attached) able to detect contamination on each wipe sample of 2000 dpm.
 - or: b. The wipes will be checked on-site using a sensitive contamination meter such as a Victoreen Minimonitor-125 G-M meter. If the results are negative, UTRC will advise the user that the area is uncontaminated and that operations can be resumed. The wipes will then be taken to UTRC for the standard, complete leak test analysis.
- (5) UTRC will transport the original source housing back to UTRC where it will be disassembled prior to source disposal. [Note: The original Gd-153 source activity may have decayed sufficiently so that the source will qualify as "limited quantities of radioactive materials" as defined in 49 CFR Part 173.423 (i.e., < 200 mCi). If this is the case, the source may be packaged and transported conforming to all conditions and limitations specified in 49 CFR Part 173.421 for excepted radioactive material, limited quantity, n.o.s., UN2910.]

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Procedure 2 (alternate procedure)

- (1) UTRC will seal the replacement source capsule into a replacement collimator at UTRC. A leak test analysis will be done and a leak test certificate prepared.
- (2) UTRC will transport the properly packaged, sealed, source collimator assembly to the off-site user location. [See also Procedure 1 Item (2) above]
- (3) At the user location, UTRC will remove the source housing from the installed LTG1 (with the shutter in the off position) and place it inside of a plastic bag.
- (4) With the housing inside the plastic bag, the collimator holder will be removed from the cooling jacket assembly. A leak test wipe will be prepared by wiping the surface of the exposed collimator. A proper personnel monitoring device will be worn during this operation.
- (5) The wipe will be counted using a portable wipe test counter (such as the Victoreen Model 05-578; see data sheets attached) able to detect contamination on each wipe sample of 2000 dpm.
- (6) If the leak test results are positive, no further disassembly will be done, the plastic bag will be closed and packaged and returned to UTRC for decontamination and source exchange.
- (7) If the leak test results are negative, the original collimator will be removed from the collimator holder and placed in a lead pig. The replacement collimator assembly will be installed and the source housing reassembled and remounted on the LTG1 bracket.
- (8) UTRC will perform a final contamination survey at the user site to confirm that no contamination remains from the original source. Leak test wipes will be prepared. Operations in the area will be resumed when negative leak test results are obtained using the portable wipe test counter mentioned above.
- (9) UTRC will transport the original source collimator assembly back to UTRC where it will be disassembled prior to source disposal. [See also Procedure 1 Item (5) above]

Only qualified UTRC personnel will perform Procedure #2. Procedure #1 will be performed only by qualified UTRC personnel or under the supervision of qualified UTRC personnel; in this procedure, the source is fully shielded with the shutter in the "OFF" position.

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Enclosure (B) is a check drawn to the Nuclear Regulatory Commission in the amount of \$640.00 to cover the application fee:

Category 9A	\$580.00	Device Evaluation Amendment
Category 3P	\$60.00	Service License Amendment

I hope this information will be sufficient to allow you to review and act favorably on the requested amendments. Questions of a technical nature relating to this application should be directed to L. L. Packer at (203) 727-7009. Questions of an administrative nature should be directed to I. Charles Mathews at (203) 727-7023.

Very truly yours,

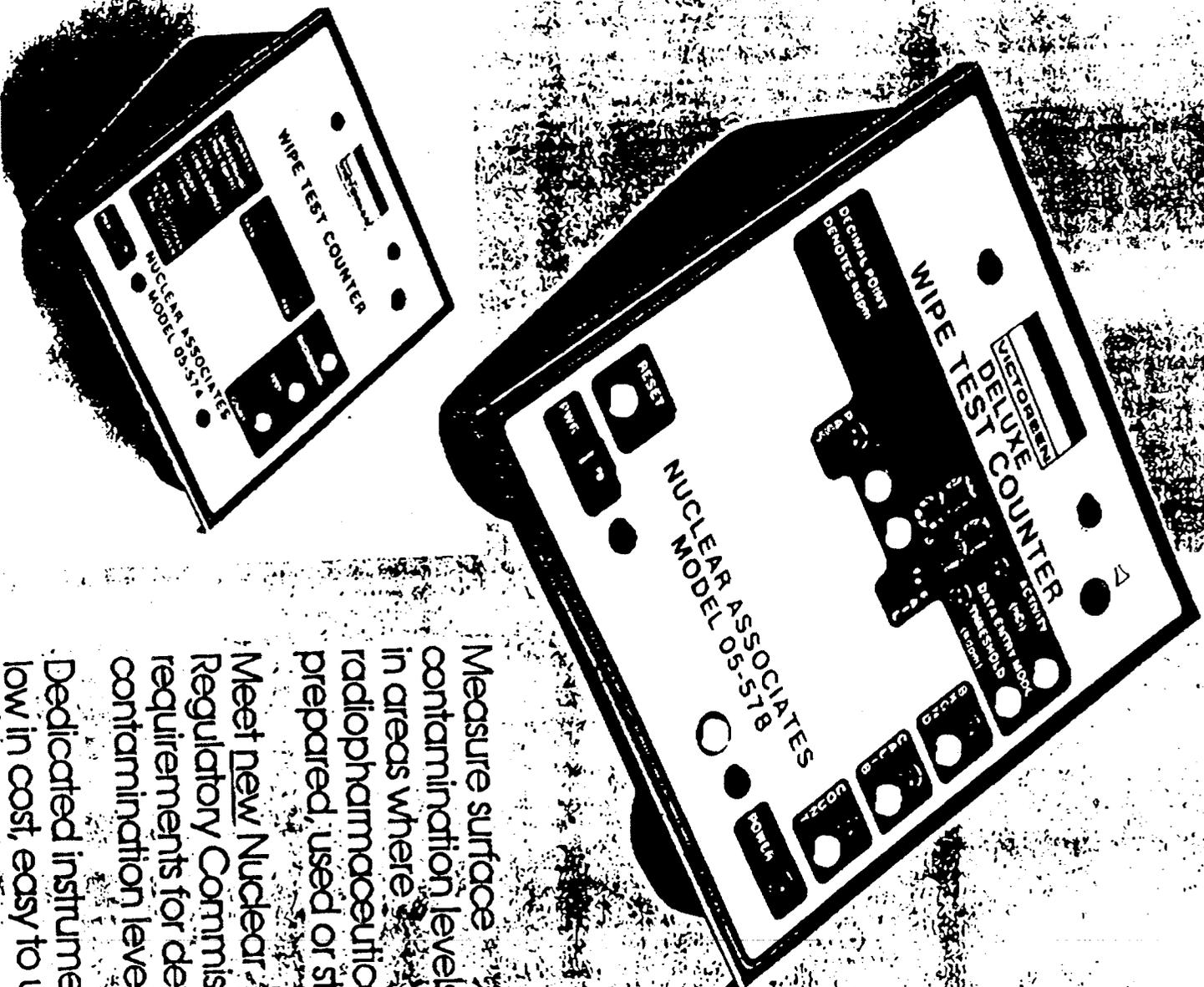
UNITED TECHNOLOGIES CORPORATION
Research Center

F. S. Owen
Associate Director of Research

Now there's an easy way to meet the new NRC requirements for wipe testing!

NEW!

Wipe Test Counters

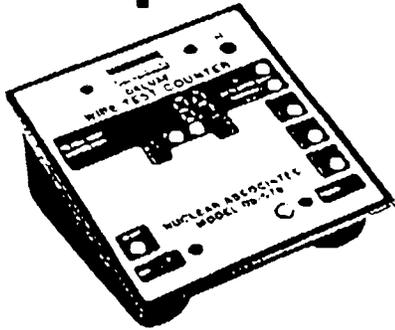


Measure surface contamination levels in areas where radiopharmaceuticals are prepared, used or stored.

Meet new Nuclear Regulatory Commission requirements for determining contamination levels.

Dedicated instruments are low in cost, easy to use.

NEW! Wipe Test Counters



Both the Deluxe and Standard Wipe Test Counters have been designed to meet the new NRC requirements for determining surface contamination levels (see Table 1).

Low cost and easy to use, these Wipe Test Counters count 1/2" diameter wipe samples. They utilize an integral thin-window Geiger-Müller tube to detect gamma and strong beta radiation. A microprocessor converts the data to disintegrations per minute (dpm).

Results are indicated by a green light (PASS) if contamination is less than 2000 dpm...a red light (FAIL) if contamination is 2000 dpm or above. This satisfies NRC requirements.

In addition to the "pass/fail" indicators, the Deluxe Wipe Test

Counter has a 4-digit LED digital display indicating the level of contamination in Kcpm. The pass/fail threshold can be adjusted for levels other than 2000 dpm...e.g. iodine contamination level (200 dpm) and for sealed sources. The deluxe model can also be used as a scaler in displaying counts up to 9999. Counting intervals are selectable for 1, 5, or 20 minutes.

Both the deluxe and standard instruments include a ¹³⁷Cs, 1 μCi test source, plus a package of 200 1/2" diameter pre-numbered wipes and blank glassine envelopes.

SPECIFICATIONS

Dimensions: 6" L x 6" W x 4" H.

Weight: 32 oz.

Power: 110V AC or 220V AC.

- 05-578 Deluxe Wipe Test Counter with LED display, check source, and 200 wipes... \$695.00
- 05-578-2200 Same as above, for 220V operation..... 715.00
- 05-574 Standard Wipe Test Counter with check source, and 200 wipes..... 475.00
- 05-574-2200 Same as above, for 220V operation..... 495.00
- 03-201 Test Wipes, pkg. of 200... 15.00

Source:	Nuclear Regulatory Commission
Publication:	10CFR35
Title:	"Medical Use of By-product Material"
Effective Date:	April 1, 1987
Paragraph 35.70 (E):	"A licensee shall survey for removable contamination, once each week, all areas where radiopharmaceuticals are routinely prepared for use, administered or stored."
Paragraph 35.70 (F):	"A licensee shall conduct the survey required by paragraph (E) of this section so as to be able to detect contamination on each wipe sample of 2000 disintegrations per minute."

HERE'S HOW EASY IT IS TO MEET THE NEW NRC REQUIREMENTS:

Step 1:

Press "Background." This initiates a background count which takes about 20 minutes. When the background light goes off the count has been completed. This needs to be done only once before the first sample in a group.

Step 2:

A test source is supplied with the instrument. Place the test source in the sample tray and press the "Calibration" or "Test" button. At the end of a minute the light will go off and the instrument will be calibrated.

Step 3:

Place a wipe test sample in the holder and press the "Count" button. The red light will start to blink indicating the count is in progress. At the end there will be a green or red signal light. The green light indicates pass (less than 2000 dpm) the red light indicates fail (2000 dpm or higher).

NUCLEAR ASSOCIATES



A Division of VICTOREEN, INC.
 8100 VOICE ROAD
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 (516) 741-8360
 A Subsidiary of Shelter-Globe

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ENCLOSURE A

ANSI TEST RESULTS
DUPONT NER 8430 SOURCE

United Technologies ¹⁵³Gd Prototype SourcesModel Number NER 8430Summary ReportSource Manufacture

Approximately 0.5mCi ¹⁵³Gd Cl₃ was deposited into each of two test sources and dried onto glass fiber filler paper. The capsules were then assembled and T.I.G. welded per Du Pont dwg #33A-043. The sources were then cleaned and leak tested per ANSI Std N542-1977 procedures A2.2.1 and A2.1.3.

ANSI Classification Testing (C63232)Temperature Test

Part A: The sources were lowered to ~ (-75)⁰C by immersion in dry ice and left at temperature for 20 minutes. The sources were then retested for capsule integrity and radioactivity leakage.

Test Results

Procedure A2.2.1 - both passed

Procedure A2.1.3: Source #1 5.4×10^{-6} uCi
#2 2.7×10^{-6} uCi

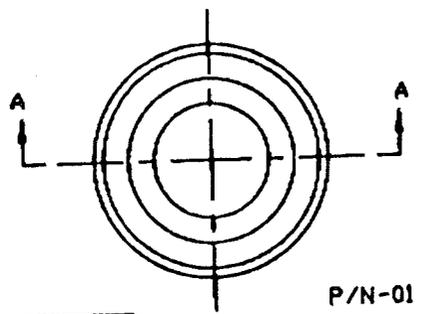
Part B: The sources were then heated to 800⁰C and left at temperature for 1 hour after which they were returned to <20⁰C by immersion in ice water. The sources were then retested for capsule integrity and radioactivity leakage.

Test Results

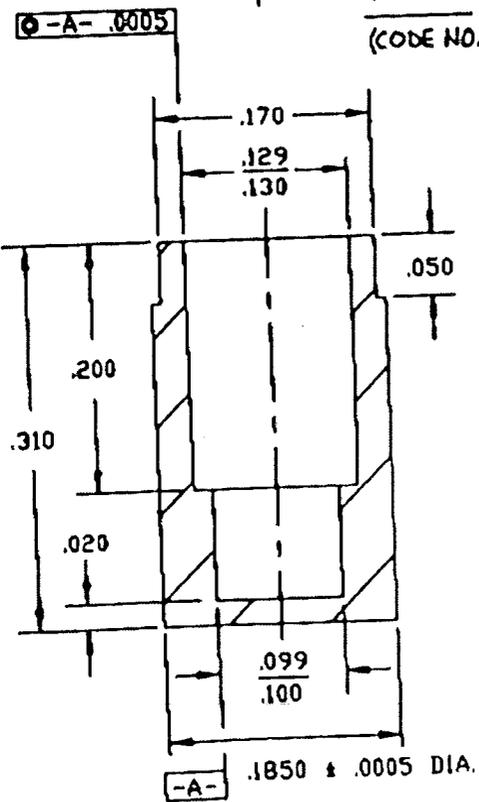
Procedure A2.2.1 - both passed

Procedure A2.1.3 Source #1 <bkg
#2 6.8×10^{-4} uCi

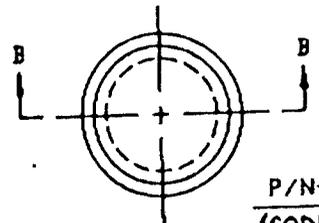
REVISIONS				
LET	DESCRIPTION	BY	DATE	APPROVED
	FIRST ISSUE		9/6/88	P. G. Gable
			3/17/88	J. Harris
			7/1/88	J.P. Lewis
			10/15/88	J. Harris



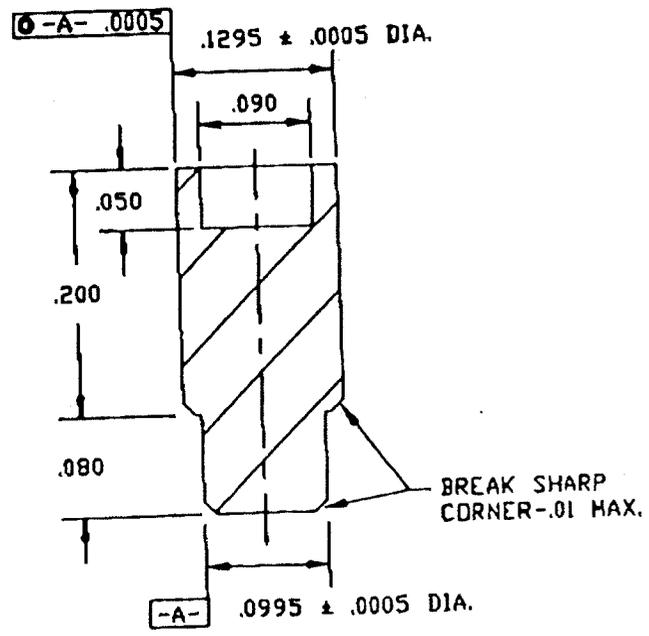
P/N-01
(CODE NO. 078306)



SECTION A-A



P/N-02
(CODE NO. 078307)



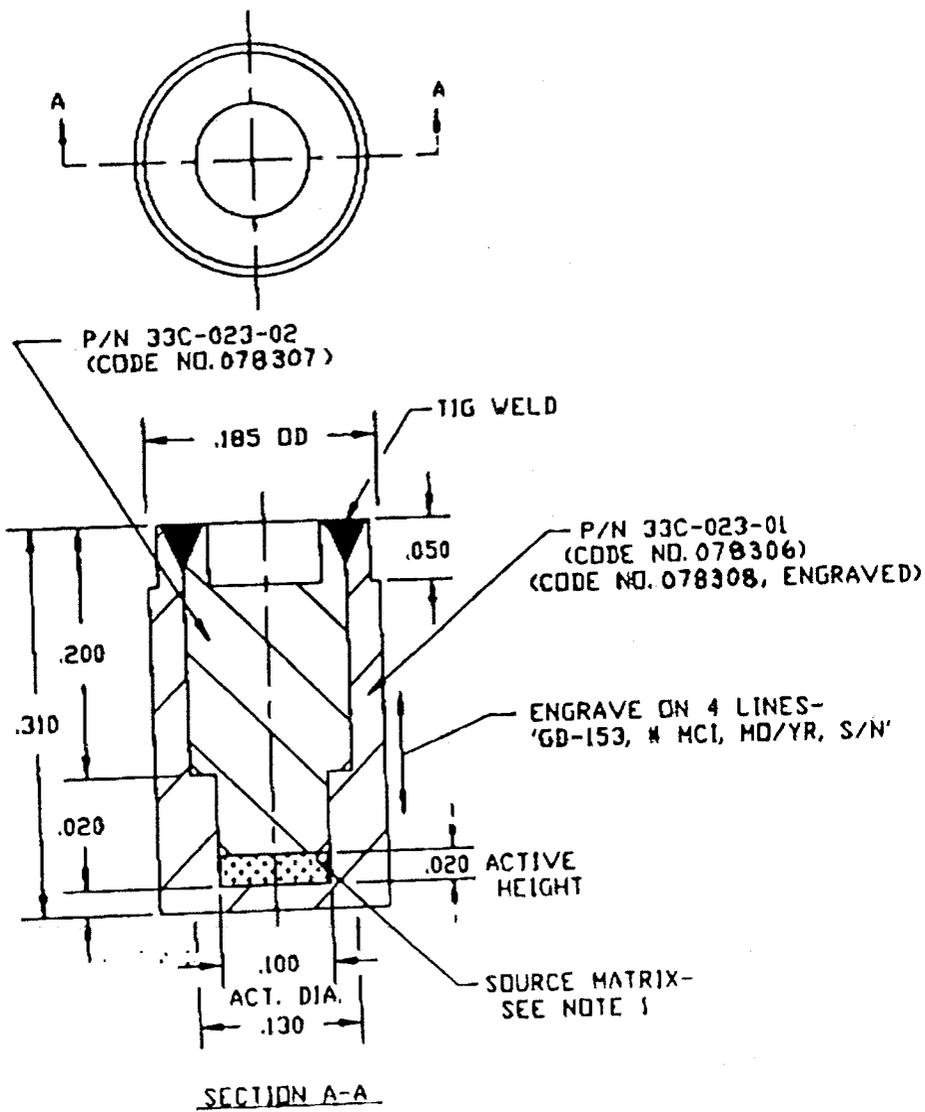
SECTION B-B

ITEM NO.	QTY	PART OR IDENTIFYING NO.	DESCRIPTION	QTY
<p>316L STN. STL</p> <p>DUPONT Medical Products</p> <p>TOLEFRAME: S. SUMARES 6/30/88 IN 1910 1905 1/4 10'</p> <p>NER-B430 GD-153 SOURCE COMP.</p> <p>33C-023</p>				
33A-043		33C-023		

REVISIONS				
REV	DESCRIPTION	BY	DATE	APPROVED
	FIRST ISSUE		9/6/81	[Signature]
			9/7/81	[Signature]
			9/10/81	[Signature]
				[Signature]

NOTES

1. SOURCE RADIOACTIVITY SPECIFICATIONS:
 NUCLIDE: GD-153
 FORM: GD-OXIDE COMPRESSED PELLET (2.2 MM DIA.)
 RADIONUCLIDIC PURITY: >99.99%
 MINIMUM SPECIFIC ACTIVITY: 30 CI/GM
2. NOMINAL ACTIVITY TO BE 350 MCI ± 15%, REFERENCED TO LABEL DATE.
3. SOURCE CONTENT TO BE DETERMINED BY 4π ION CHAMBER MEASUREMENT. RADIONUCLIDIC PURITY TO BE DETERMINED BY GAMMA SPECTROSCOPY.
4. LEAK TEST PER ANSI N542-1977 PROCEDURES A2.1.3 (IMMERSION TEST) AND A2.1.1 (SMEAR TEST). LIMIT TO BE $< 1 \times 10^{-3} \mu\text{Ci}$.
5. ANSI N542-1977 PERFORMANCE CLASSIFICATION C63232.



ITEM NO.	QTY	PART OR IDENTIFYING NO.	DESCRIPTION	REV.
316L STL.			Medical Products	
			NER-0430 GD-153	
			SOURCE ASS'Y	
			33A-013	