

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SOURCE.
(AMENDED IN ITS ENTIRETY)

NO.: CA0406S180S

DATE: June 5, 2001

PAGE: 1 of 5

SEALED SOURCE TYPE: Flood Source

MODEL: FL Series Flood Sources

MANUFACTURER/DISTRIBUTOR: Isotope Products Laboratories
1800 North Keystone Street
Burbank, California 91504
(818) 843-7000 (voice)
(818) 843-6168 (fax)

ISOTOPE:

Cobalt 57

MAXIMUM ACTIVITY:

25 millicuries

LEAK TEST FREQUENCY:

Six (6) months

PRINCIPAL USE: (X) Medical Reference Sources

CUSTOM SOURCE: _____ YES X NO

NMB512

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DESCRIPTION:

The FL Series flood source is composed of a resin matrix active element sealed within a two piece thermoplastic capsule. The capsule halves are attached using adhesive sealants. An optional rubber seal ring may also be used for aesthetic purposes and to provide a secondary seal. Some models include handles.

The FL Series is offered in both rectangular and circular configurations. The rectangular FL Series flood source has an overall length from 10.5" to 31" (with an active length of 8.5" to 29") and an overall width from 11" to 24" (with an active width to 9" to 21"). The circular FL Series flood source has an overall diameter from 16" to 26" (with an active diameter of 14" to 24").

The chemical form of the radionuclide in the active element is an organic complex of cobalt in a resin matrix.

LABELING:

The source is engraved or labeled with "IPL", Co-57, model number, nominal activity, serial number, date of assay and the words "CAUTION-RADIOACTIVE MATERIAL".

DIAGRAM: (See Attachments)

- | | |
|---------------|---|
| Attachment 1: | Circular Flood Source |
| Attachment 2: | Rectangular Flood Source |
| Attachment 3: | Circular Flood Source with formed handles. |
| Attachment 4: | Rectangular Flood Source with formed handles. |
| Attachment 5: | Rectangular Flood Source with screwed on handles. |
| Attachment 6: | Rectangular Flood Source. |
| Attachment 7: | Special Rectangular Flood Source. |

CONDITIONS OF NORMAL USE:

The source is designed and manufactured for use in a laboratory or clinical environment for quality control of nuclear medicine cameras. The Model FL series flood sources should not be

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subjected to conditions of normal use which require a higher rating than ANSI N542-1977 classification ANSI 77C22414.

PROTOTYPE TESTING:

The active element of the FL Series flood source design passed the performance tests for a classification of 77C22414 per ANSI N542-1977. This meets or exceeds the required rating of 77C22212 for "Calibration sources - Activity greater than 30 μ Ci" as defined in NBS Handbook 126, ANSI N542, "Sealed Radioactive Sources, Classification", 1977.

EXTERNAL RADIATION LEVELS:

The specific gamma ray dose constant of 4.087×10^{-5} (mSv/h)/MBq, from the revised edition of the Health Physics and Radiological Health Handbook (Shleien, 1992) was first converted to the traditional gamma factor (i.e., multiply the specific gamma ray dose constant by 3.7 to convert data in units of (mSv/h)/MBq to (mrad/h)/ μ Ci assuming a quality factor of one. Then multiplying by 1000 and then by 10 to convert data in units of (mrad/h)/ μ Ci to traditional gamma factor in units of R-cm²/(h-mCi). Next, disc sources calculations assuming areas of 993 cm² and 3368 cm² (representing the smallest and largest active element areas and with the activity uniformly distributed) were chosen to approximate exposure rates for the FL Series flood sources at the 3 standard distances of 5 cm, 30 cm, and 100 cm (calculations on file with the issuing agency). The exposure rates in mR/h calculated using the specific gamma ray dose constant of 4.087×10^{-5} (mSv/h)/MBq with a total activity of **25 mCi** at the three standard distances are as follows:

<u>Nuclide</u>	<u>Activity</u>	<u>Distance from source (mR/hr)</u>		
		<u>5 cm</u>	<u>30 cm</u>	<u>100 cm</u>
Cobalt 57 (993 cm ²)	25 mCi	312.5	36.0	3.7
Cobalt 57 (3368 cm ²)	25 mCi	133.8	27.6	3.6

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QUALITY ASSURANCE AND CONTROL:

Isotope Products Laboratories maintains a quality assurance and control program which has been deemed acceptable for licensing purposes by the California Department of Health Services. A copy of the program is on file with the California Department of Health Services.

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

1. The source shall be distributed to persons specifically licensed by the NRC or an Agreement State.
2. Handling, storage, use, transfer, and disposal: To be determined by the licensing authority.
3. The 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 microcuries (185 Bq) of removable contamination. Such tests to be performed in accordance with the requirements of the radiation control agency which exercises regulatory authority.
4. This registration certificate and the information contained within the references shall not be changed without the written consent of the California Department of Health Services.

SAFETY ANALYSIS SUMMARY:

Based on review of the Model FL Series flood source, its ANSI classification, and the information and test data cited below, we continue to conclude that the source is acceptable for licensing purposes.

REFERENCES:

This certificate of registration is based on information and test data contained in the following supporting documents which are hereby incorporated by reference and made part of this registry document:

1. Isotope Products Laboratories Quality Assurance Manual (current copy on file with this issuing agency).

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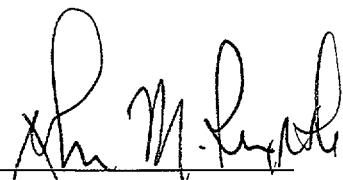
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2. Isotope Products Laboratories letter dated September 22, 1995 with attached drawings, test data, and draft registry certificate.
3. Isotope Products Laboratories letter with attachments dated October 20, 1995.
4. Isotope Products Laboratories fax dated January 8, 1996 with attached area source calculations.
5. Isotope Products Laboratories letters dated April 16, 1998 and May 13, 1998 with attachments thereto.
6. **Isotope Products Laboratories letter dated September 12, 2000.**

DATE: June 5, 2001

REVIEWED BY: _____


John M. Rexroth

DATE: June 5, 2001

CONCURRED BY: _____


Xiaosong Yin

ISSUING AGENCY: California Department of Health Services

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ATTACHMENT : 1

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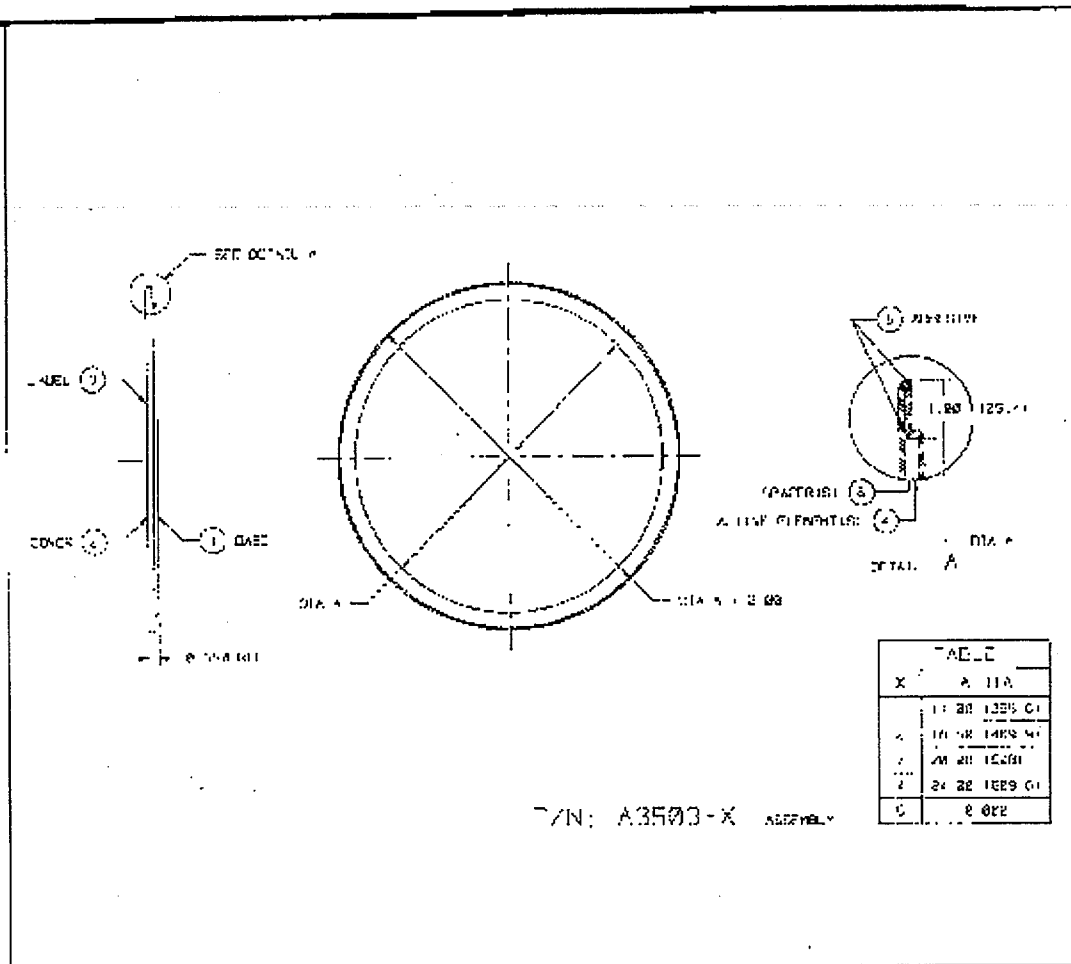


Figure 1: CIRCULAR FLOOD SOURCE

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ATTACHMENT: 2

SEALED SOURCE TYPE: Flood Source

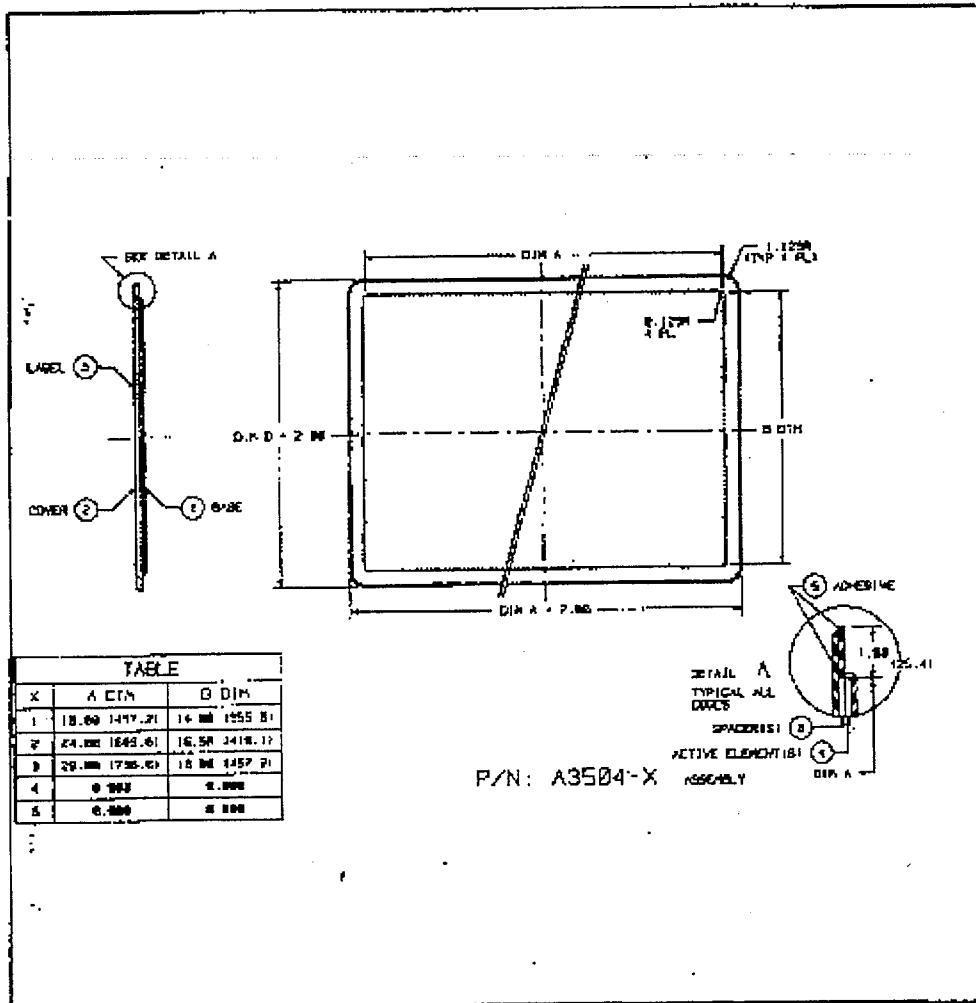


Figure 2: RECTANGULAR FLOOD SOURCE

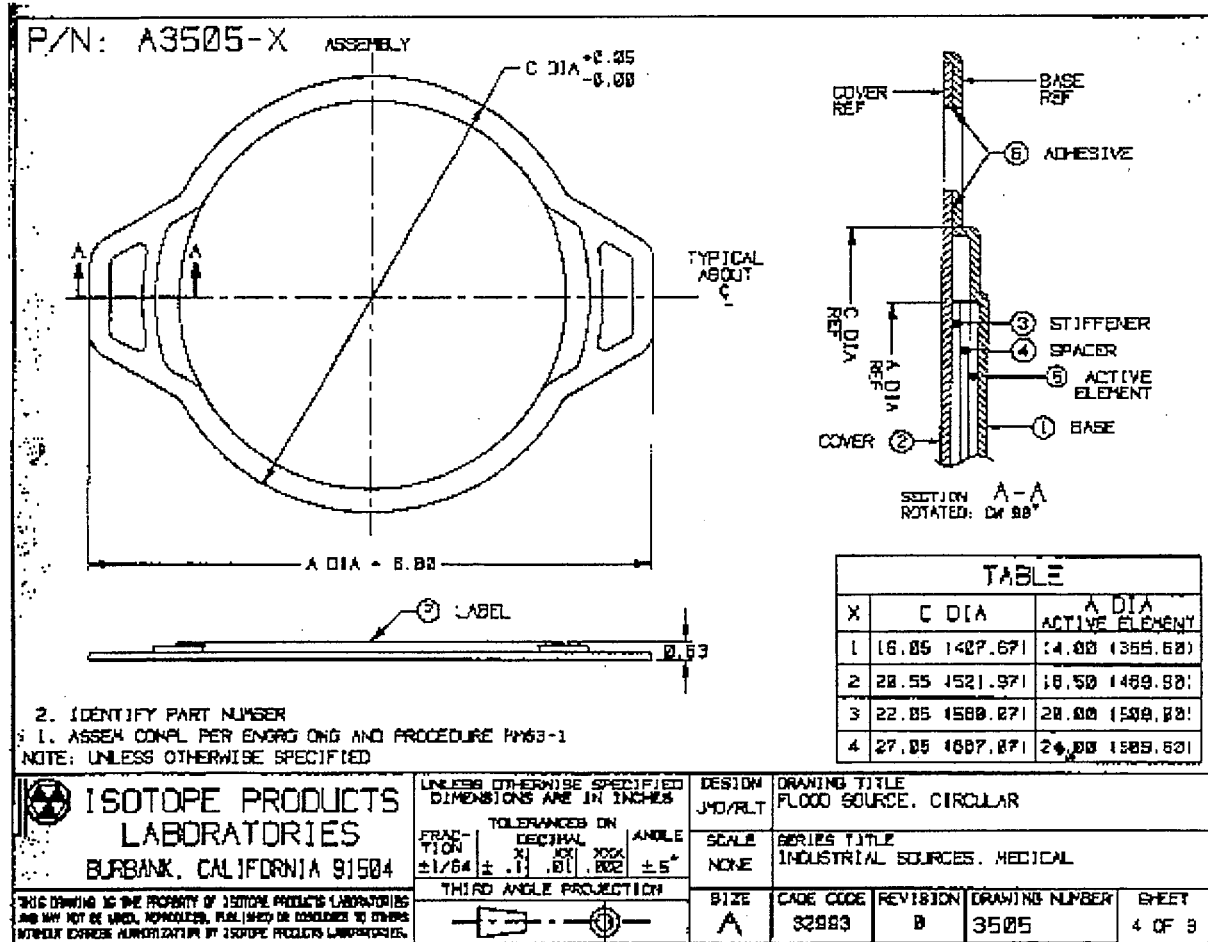
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ATTACHMENT: 3

SEALED SOURCE TYPE: Flood Source



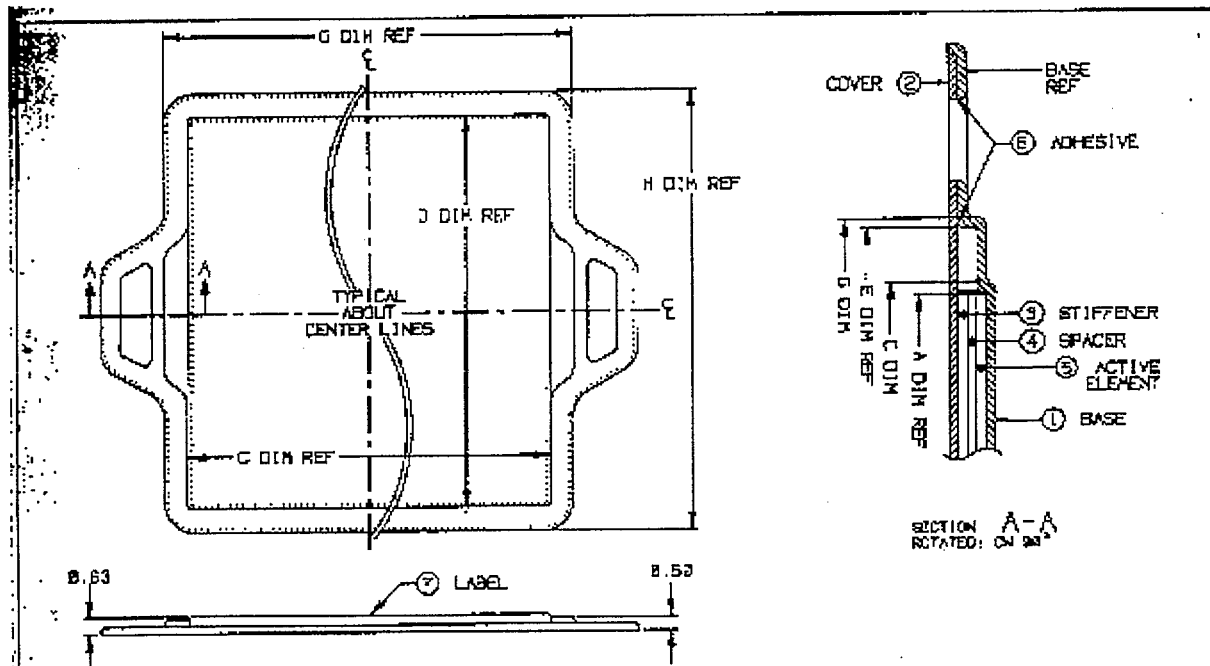
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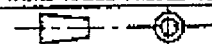
ATTACHMENT: 4

SEALED SOURCE TYPE: Flood Source



- 2. IDENTIFY PART NUMBER
- 1. ASSEM COMPL PER ENGRG DWG AND PROCEDURE PM83-1
- SEE SHEET 53 FOR (X) DASH NUMBERS
- NOTE: UNLESS OTHERWISE SPECIFIED

P/N: A3526-X ASSEMBLY

 ISOTOPE PRODUCTS LABORATORIES BURBANK, CALIFORNIA 91504	UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN INCHES		DESIGN JHD/RLT	DRAWING TITLE FLOOD SOURCE, RECTANGULAR				
	TOLERANCES ON FRACTION DECIMAL ANGLE $\pm 1/64$ $\pm .01$ $\pm .001$ $\pm .5^\circ$		SCALE NONE	SERIES TITLE INDUSTRIAL SOURCES, MEDICAL				
THIRD ANGLE PROJECTION				SIZE A	CAGE CODE 32983	REVISION 2	DRAWING NUMBER 3506	SHEET 4 OF 5

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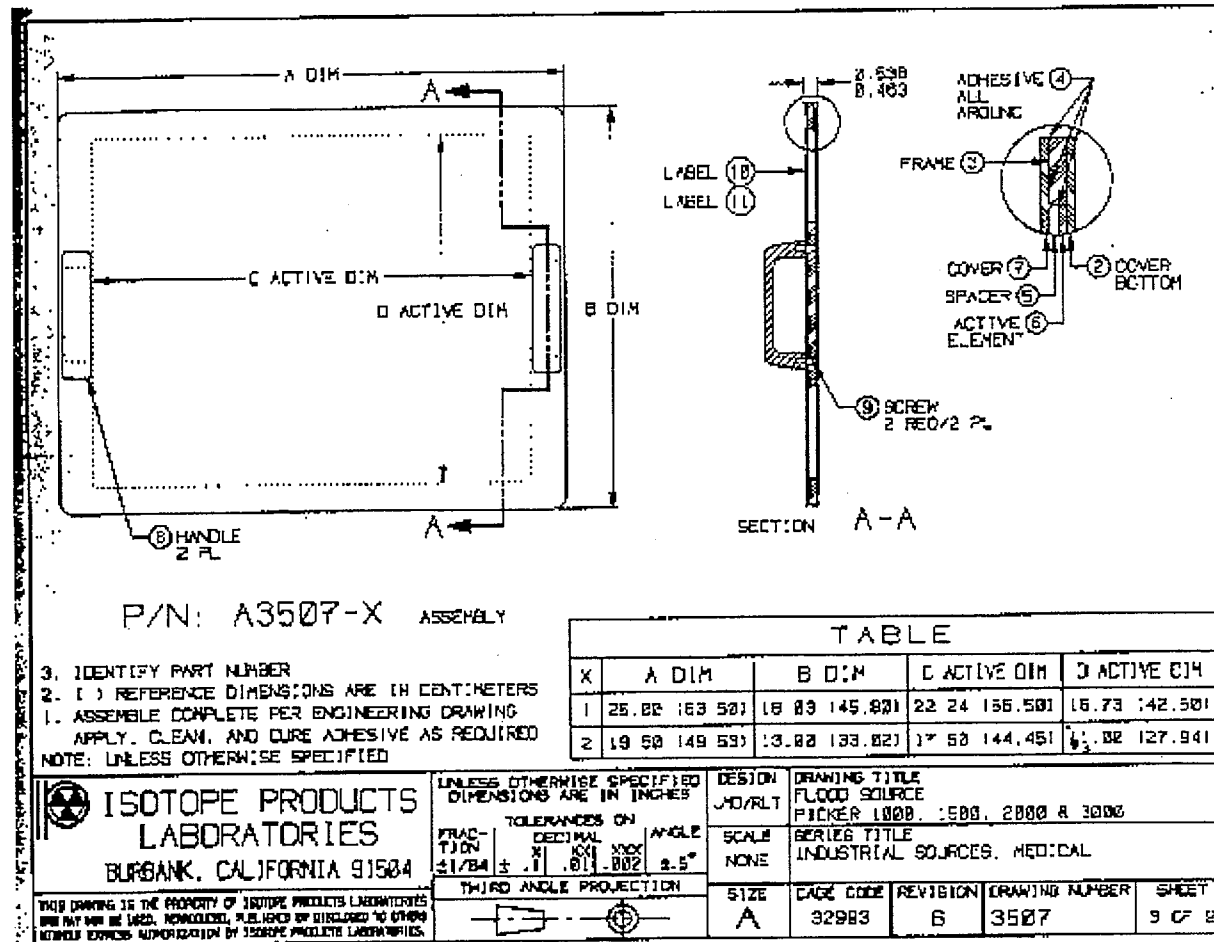
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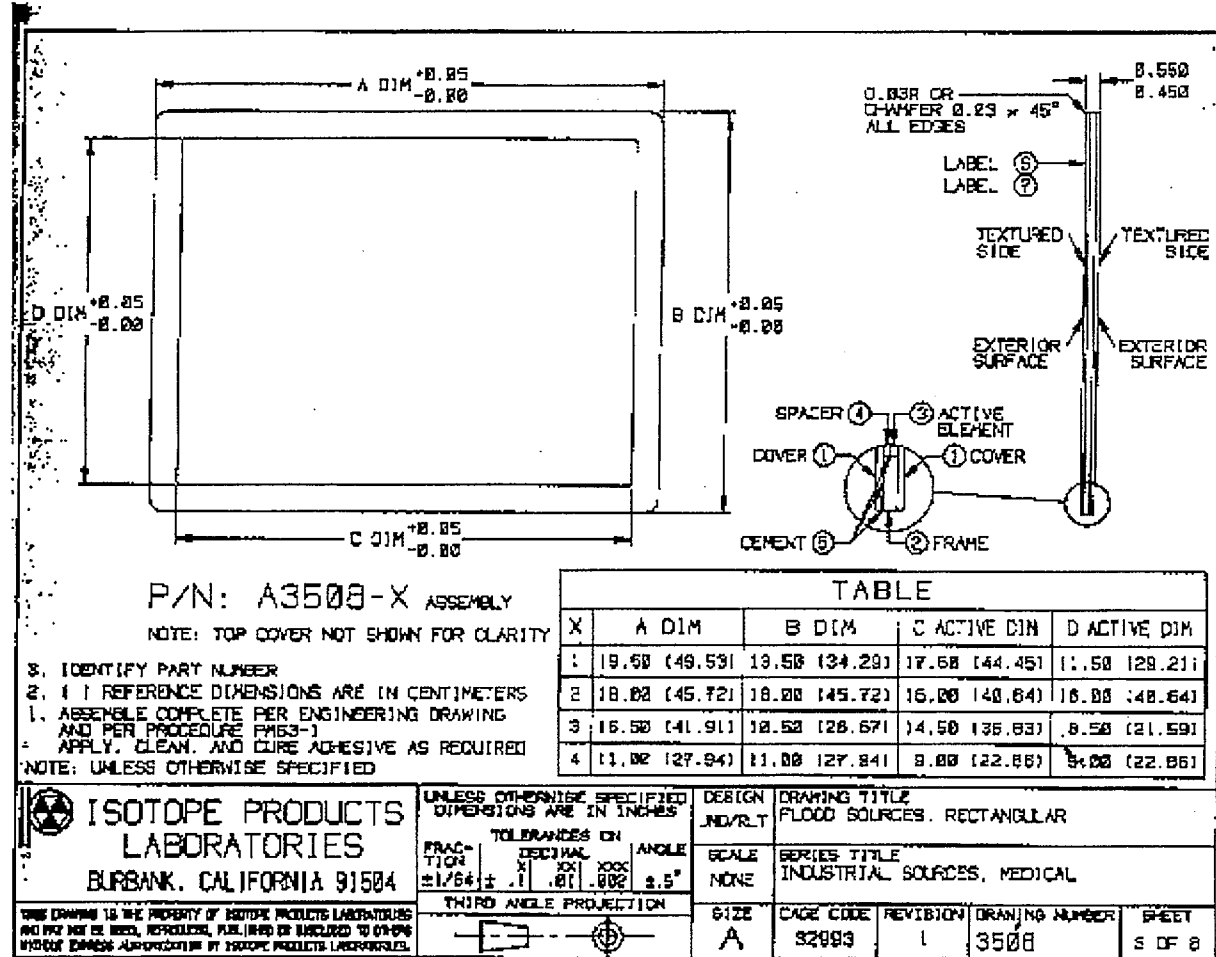
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ATTACHMENT: 7

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