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

NO.: CA406S180S DATE: January 8, 1996

SEALED SOURCE TYPE: Flood Source

MODEL: FL Series Flood Source

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

ISOTOPE: Cobalt 57

MAXIMUM ACTIVITY: 20 millicuries

LEAK TEST FREQUENCY: Six (6) months

PRINCIPAL USE: Medical Reference Sources (X)

CUSTOM SOURCE: ___ YES _X_ NO

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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.

The FL Series is offered in both rectangular and circular configurations. The rectangular FL Series flood source has an overall length from 20" to 31" (with an active length of 18" to 29") and an overall width from 16" to 20" (with an active width of 14" to 18"). 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 and date of assay.

DIAGRAM:

See Figures 1 and 2 on pages 6 and 7.

CONDITIONS OF NORMAL USE:

The Model FL Series flood sources are intended for use by trained personnel in a laboratory or clinical environment for quality control of nuclear medicine cameras. They should not be subjected to conditions of normal use which require a higher rating than ANSI 77C22414 (as defined in NBS Handbook 126, ANSI N542, "Sealed Radioactive Sources, Classification", 1977).

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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 uCi" 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 X 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)/μCi assuming a quality factor of one. Then multiplying by 1000 and then by 10 to convert data in units of (mrad/h)/μCi to the traditional gamma factor in units of R-cm^2/(h-mCi). Next, disc sources calculations assuming areas of 993 cm^2 and 3368 cm^2 (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 X 10^{-5} (mSv/h)/MBq with a total activity of 20 mCi at the three standard distances are as follows:

		Distance from source		
Nuclide	Activity	5 cm	30 cm	100 cm
Cobalt 57 (993 cm^2)	20 mCi	250	28.8	2.98
Cobalt 57 (3368 cm^2)	20 mCi	107	22.1	2.87

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QUALITY ASSURANCE AND CONTROL:

Program Description: The IPL Quality Assurance Manual (current copy on file with this issuing agency) contains details of the quality control procedures of these sources starting from raw materials to finished products. The program is designed to satisfy 10CFR Part 50 (B) and meets the requirements of ISO 9001. The program covers drawing control, pre-production design review, purchasing, training, calibration records, source numbering, incoming raw materials, assay quality control, leak testing, document control, and confirming orders. Specific elements are listed below:

A. Activity: Held to ± 15% of nominal activity.

B. Assay procedures: Sources are typically prepared using gravimetric aliquot from calibrated solutions and verified by assaying on calibrated instruments, typically a pressurized re-entrant ionization chamber. IPL participates in a measurement assurance program with NIST in order to establish and maintain traceability of calibrations to the NIST.

C. Radiopurity determination: Determined by gamma spectrometry of the source or the radionuclide batch.

D. Leak test procedures: Sources are wiped over their entire surface with a moistened paper disc which is then assayed. The criteria for acceptance is 1.0 nCi removable beta/gamma.

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

a. Distribution: These sources shall be distributed in accordance with the rules and regulations of the various state radiation control agencies which exercise regulatory authority.

b. Leak Test: These sources shall be leak tested at intervals not to exceed six months. Such tests must be capable of detecting 0.005 μCi of removable radioactivity, and be performed in accordance with the individual requirements of the radiation control agency which excercises regulatory authority.

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LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE: (cont'd)

c. Use: FL Series flood sources are intended to be used by trained personnel in a laboratory or clinical environment for quality control of nuclear medicine cameras. They should not be subjected to conditions of use which would require a higher ANSI rating than 77C22414.

d. Handling: Remote handling tools and localized shielding are generally not required.

e. Storage: They should be stored in the shielded storage case supplied by the manufacturer.

f. Cleaning: Sources may be cleaned with alcohol or water with a mild detergent.

g. Disposal: Decayed or otherwise unusable sources must be disposed of in accordance with the individual requirements of the radiation control agency which exercises regulatory authority.

h. This registration sheet 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 our review of the information and test data cited below, we conclude that the Model FL Series flood sources are acceptable for licensing purposes and the intended uses specified in this registry certificate. Furthermore, prototype sources of this design met or exceeded the performance test requirements specified for "Calibration sources - Activity greater than 30 uCi" (77C22414 vs. 77C22212), as defined in NBS Handbook 126, ANSI N542 "Sealed Radioactive Sources, Classification", 1977.

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REFERENCES:

The following supporting documents for the Model FL Series flood sources are hereby incorporated by reference and made part of this registry certificate:

1. IPL Quality Assurance Manual (current copy on file with this issuing agency).

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.

DATE: 1/11/96 REVIEWED BY: R. T. Tayama

DATE: 1/11/96 CONCURRED BY:

ISSUING AGENCY: California Department of Health Services

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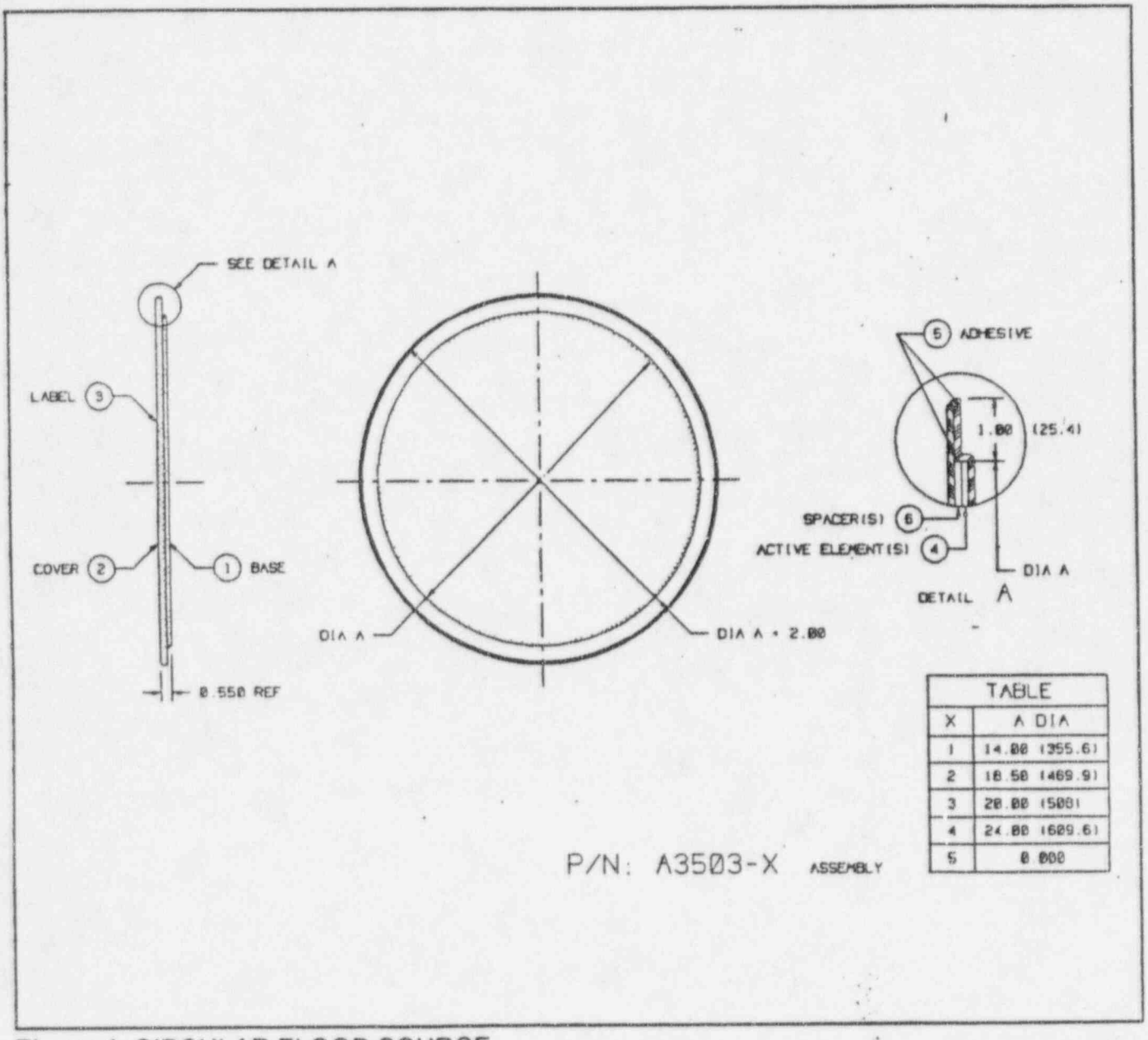

TABLE	
X	A DIA
1	14.00 (355.6)
2	18.50 (469.9)
3	20.00 (508)
4	24.00 (609.6)
5	0.000

Figure 1: CIRCULAR FLOOD SOURCE

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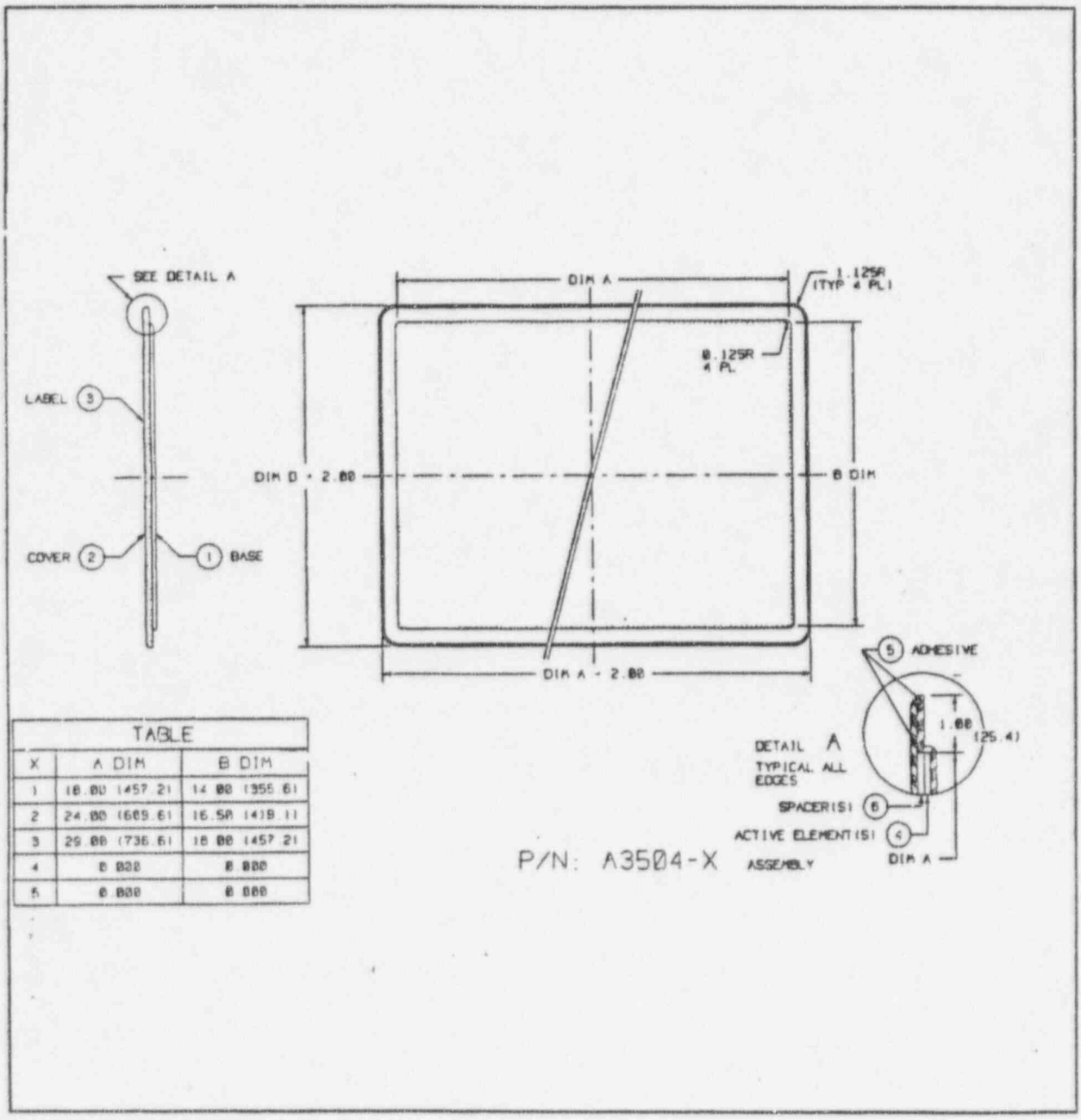

TABLE		
X	A DIM	B DIM
1	18.00 (457.2)	14.00 (355.6)
2	24.00 (609.6)	16.50 (419.1)
3	29.00 (736.6)	18.00 (457.2)
4	0.000	0.000
5	0.000	0.000

Figure 2: RECTANGULAR FLOOD SOURCE