NRC FORM 374
(7-94)

U.S. NUCLEAR REGULATORY COMMISSION



# MATERIALS LICENSE

Amendment No. 05

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.



| Licensee | |
|---|---|
| 1. CIS-US, Inc. | In accordance with the letter dated January 7, 1997, |
| 2. 10 De Angelo Drive<br>Bedford, Massachusetts 01730 | 3. License Number 20-20973-03MD is amended in its entirety to read as follows: |
| | 4. Expiration Date July 31, 2003 |
| | 5. Docket or Reference No. 030-29781/20-27966-02MD |

| 6. Byproduct, Source, and/or Special Nuclear Material | 7. Chemical and/or Physical Form | 8. Maximum Amount that Licensee May Possess at Any One Time Under This License |
|---|---|---|
| A. Iodine 131 | A. Iobenguane Sulfate for Injection | A. Not applicable |
| B. Iodine 131 | B. Iodohippurate Sodium for Injection | B. Not applicable |
| C. Iodine 131 | C. Sodium Iodide Capsules | C. Not applicable |
| D. Iodine 131 | D. Sodium Iodide Solution | D. Not applicable |
| E. As specified in Condition 10 | E. As specified in Condition 10 | E. Not applicable |
| F. Iridium 192 | F. As specified in Condition 11 | F. Not applicable |

9. Authorized use

A. through D. Pursuant to 10 CFR 32.72, the licensee is authorized to distribute the licensed material described in Items 6.A. through 6.D., and 7.A. through 7.D. of this license to persons licensed pursuant to 10 CFR 35.100, 35.200 and 35.300 or under equivalent licenses of Agreement States.

E. Pursuant to 10 CFR 32.74, the licensee is authorized to distribute the sources specified in Condition 10 of this license to persons licensed pursuant to 10 CFR 35.57, or under equivalent licenses of Agreement States.

F. Pursuant to 10 CFR 32.74, the licensee is authorized to distribute the licensed material described in Condition 11 of this license to persons specifically licensed pursuant to 10 CFR 35 (?5.400), or under equivalent licenses of any Agreement State.

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MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number: 20-20973-03MD

Docket or Reference Number: 030-29781/20-27966-02MD

Amendment No. 05

CONDITIONS

10. Each dose calibrator reference source distributed under this license shall not contain, as of the assay date, more than the quantity of byproduct material as listed in the following table:

| Isotope | Source Model Number | Maximum Activity Per Source |
|---|---|---|
| Cobalt 60 | CIS-US 6418 | 50 microcuries |
| Barium 133 | CIS-US 6317 | 250 microcuries |
| Cesium 137 | CIS-US 6215 | 150 microcuries |
| Cesium 137 | CIS-US 6216 | 250 microcuries |

11. Each device (Remote Afterloader Source Assembly) distributed pursuant to the conditions of this license shall be in accordance with the following table:

| Device Model Number | Isotope | Source Model Number | Maximum Activity Per Source |
|---|---|---|---|
| 721 | Iridium 192 | 772 | 20 curies |
| 722 | Iridium 192 | 772 | 20 curies |
| 723 | Iridium 192 | 773 | 20 curies |
| 724 | Iridium 192 | 772 | 20 curies |

12. The licensee is authorized to distribute the licensed materials described in Items 6.A. through 6.D. and 7.A. through 7.D., and Condition 10 of this license from the licensee's facilities at 5 De Angelo Drive and 10 De Angelo Drive, Bedford, Massachusetts.

13 The licensee is authorized to distribute the licensed materials described in Condition 11 of this license from the licensee's facilities at 35 Flagship Drive, North Andover, Massachusetts.

14. The licensee shall notify the U.S. Nuclear Regulatory Commission within thirty (30) days of the termination of a "Notice of Claimed Investigational Exemption for a New Drug" (IND) or the withdrawal of approval of a "New Drug Application" (NDA) for any licensed material described in Items 6 and 7 of this license.

15. This license does not authorize possession or use of licensed material.

16. Any proposed changes in packaging, labelling, shielding, or instructions for use and storage shall be submitted for review to the Nuclear Materials Safety Branch, U.S. Nuclear Regulatory Commission, Region I, 475 Allendale Road, King of Prussia, Pennsylvania 19406 and approval of the changes shall be received by the licensee prior to implementing the changes.

**MATERIALS LICENSE**
**SUPPLEMENTARY SHEET**

License Number: 20-20973-03MD

Docket or Reference Number: 030-29781/20-27966-02MD

Amendment No. 05

17. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. The Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

A. Application dated February 27, 1992
B. Letter dated April 28, 1993
C. Application dated May 13, 1994
D. Letter dated December 29, 1994
E. Letter dated February 21, 1995
F. Letter dated January 4, 1996

For the U.S. Nuclear Regulatory Commission

Date JAN 29 1997

By Original Signed By:
Keith D. Brown, Ph.D

Nuclear Materials Safety Branch
Region I
King of Prussia, Pennsylvania 19406

JAN 29 1997

David B. Reader
Executive Vice President
CIS-US, Inc.
10 DeAngelo Drive
Bedford, MA 01730

Dear Mr. Reader:

This refers to your license amendment request. Enclosed with this letter is the amended license. Please note that as part of this amendment, in accordance with 10 CFR 30.36, effective February 15, 1996, the expiration date of your license has been extended by a period of five years. Your new expiration date is stated in Item 4 of the license.

Please review the enclosed document carefully and be sure that you understand and fully implement all the conditions incorporated into the amended license. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region I Office, Licensing Assistance Team, (610) 337-5093 or 5239, so that we can provide appropriate corrections and answers.

Thank you for your cooperation.

Sincerely,

Original Signed By:
Keith D. Brown, Ph.D

Keith D. Brown, Ph.D.
Division of Nuclear Materials Safety

License No. 20-20973-03MD
Docket No. 030-29781
Control No. 124085

Enclosure:
Amendment No. 05

OFFICIAL RECORD COPY ML 10

DOCUMENT NAME: R:\WPS\MLTR\L2020973.03D

To receive a copy of this document, indicate in the box: "C" = Copy w/o attach/encl "E" = Copy w/ attach/encl "N" = No copy

| OFFICE | DNMS/RI | N | DNMS/RI | | | | | |
|---|---|---|---|---|---|---|---|---|
| NAME | Brown/kdb 2/28 | | | | | | | |
| DATE | 01/28/97 | | 01/ /97 | | 01/ /97 | | 01/ /97 | |

OFFICIAL RECORD COPY

**CIS-US, Inc.**

Subsidiary of CIS bio international

030-29781

January 7, 1997

U.S. Nuclear Regulatory Commission, Region I
Att: Licensing Assistance Section
475 Allendale Road
King of Prussia, PA 19406

Sub: **Application for expedited amendments;** Materials Licenses Nos. 20-20973-03 MD and 20-27966-02 MD.

Dear Sir/Madam:

We enclose two form 313 applications for amendment of the subject licenses, and remittance of two category 3.C amendment fees in the aggregate amount of one thousand and forty dollars ($1040.00). The intended result of these actions is termination of 20-27966-02 MD upon transfer of its amended licensure into 20-20973-03 MD by amendment of the latter. Completion of such prior to cessation of NRC actions on Massachusetts Agreement Materials licenses is urgently requested.

Thank you for your prompt attention and timely prosecution of these amendments. Please contact us as soon as possible regarding any actions on our part which will further expedite your review.

Sincerely,

Paul M. Tyree, for
John J. Munro III
Director, Radioactive Source Operations,
Safety and Transportation

encl: described above (2 copies ea.)
fees remittance, 53-235/113 No. 2273



cis-us, inc. • 10 de angelo drive • bedford, ma 01730 • tel. (617) 275-7120 • fax (617) 275-2634

NRC FORM 313 U.S. NUCLEAR REGULATORY COMMISSION
(6-93)
10 CFR 30, 32, 33
34, 35, 36, 39 and 40

# APPLICATION FOR MATERIAL LICENSE

APPROVED BY OMB: NO. 3150-0120
EXPIRES 6-30-96

ESTIMATED BURDEN PER RESPONSE TO COMPLY WITH THIS INFORMATION COLLECTION REQUEST: 9 HOURS. SUBMITTAL OF THE APPLICATION IS NECESSARY TO DETERMINE THAT THE APPLICANT IS QUALIFIED AND THAT ADEQUATE PROCEDURES EXIST TO PROTECT THE PUBLIC HEALTH AND SAFETY. FORWARD COMMENTS REGARDING BURDEN ESTIMATE TO THE INFORMATION AND RECORDS MANAGEMENT BRANCH (MNBB 7714), U.S. NUCLEAR REGULATORY COMMISSION, WASHINGTON, DC 20555-0001, AND TO THE PAPERWORK REDUCTION PROJECT (3150-0120), OFFICE OF MANAGEMENT AND BUDGET, WASHINGTON, DC 20503.

**INSTRUCTIONS:** SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.

**APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:**

DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY
OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

**ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:**

**IF YOU ARE LOCATED IN:**

**CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, PENNSYLVANIA, RHODE ISLAND, OR VERMONT, SEND APPLICATIONS TO:**

LICENSING ASSISTANT SECTION
NUCLEAR MATERIALS SAFETY BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PA 19406-1415

**ALABAMA, FLORIDA, GEORGIA, KENTUCKY, MISSISSIPPI, NORTH CAROLINA, PUERTO RICO, SOUTH CAROLINA, TENNESSEE, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO:**

NUCLEAR MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION II
101 MARIETTA STREET, NW, SUITE 2900
ATLANTA, GA 30323-0199

**IF YOU ARE LOCATED IN:**

**ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO:**

MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
799 ROOSEVELT ROAD
GLEN ELLYN, IL 60137-5927

**ARKANSAS, COLORADO, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, SOUTH DAKOTA, TEXAS, UTAH, OR WYOMING, SEND APPLICATIONS TO:**

NUCLEAR MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TX 76011-8064

**ALASKA, ARIZONA, CALIFORNIA, HAWAII, NEVADA, OREGON, WASHINGTON, AND U.S. TERRITORIES AND POSSESSIONS IN THE PACIFIC, SEND APPLICATIONS TO:**

030-29781

RADIOACTIVE MATERIALS SAFETY BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION V
1450 MARIA LANE
WALNUT CREEK, CA 94596-5368

**PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTIONS.**

1. THIS IS AN APPLICATION FOR *(Check appropriate item)*

- [ ] A. NEW LICENSE 20-20973-03 MD
- [x] B. AMENDMENT TO LICENSE NUMBER _____
- [ ] C. RENEWAL OF LICENSE NUMBER _____

2. NAME AND MAILING ADDRESS OF APPLICANT *(Include Zip code)*

CIS-US, Inc.
10 DeAngelo Drive
Bedford, MA 01730

3. ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

CIS-US, Inc.
35 Flagship Drive
North Andover, Massachusetts 01845

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

John J. Munro, III

TELEPHONE NUMBER (508) 683-5211

SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

| | | | |
|---|---|---|---|
| 5. | RADIOACTIVE MATERIAL<br>a. Element and mass number; b. chemical and/or physical form; and c. maximum amount which will be possessed at any one time. | 6. | PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED |
| 7. | INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE | 8. | TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS<br>See Items 5,6 & 10, Pg 2 |
| 9. | FACILITIES AND EQUIPMENT | 10. | RADIATION SAFETY PROGRAM |
| 11. | WASTE MANAGEMENT | 12. | LICENSEE FEES *(See 10 CFR 170 and Section 170.31)*<br>FEE CATEGORY 3.C<br>AMOUNT ENCLOSED $ 520.00 |

13. CERTIFICATION *(Must be completed by applicant)* THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, 36, 39 AND 40, AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948, 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

| CERTIFYING OFFICER -- TYPED/PRINTED NAME AND TITLE | SIGNATURE | DATE |
|---|---|---|
| David B. Reader, Exec. Vice President | | 01/07/97 |

## FOR NRC USE ONLY

| TYPE OF FEE | FEE LOG | FEE CATEGORY | AMOUNT RECEIVED | CHECK NUMBER | COMMENTS |
|---|---|---|---|---|---|
| | | | $ | | 124085 |
| APPROVED BY | | | | DATE | |

CIS-US, Inc.
Ten DeAngelo Drive
Bedford, MA 01730
(617) 275-7120



**5. RADIOACTIVE MATERIAL**

| a. Material | b. Chemical and/or physical form | c. Maximum amount that may be possessed at any one time. |
|---|---|---|
| As specified in Condition 11 of USNRC License No. 20-27966-02MD, Amend. 02 | As specified in Condition 11 of USNRC License No. 20-27966-02MD, Amend. 02 | Not applicable |

**6. USE OF RADIOACTIVE MATERIAL**

5. a. b. Distribution, as authorized for USNRC License No. 20-27966-02MD, Amendment 02

**10. RADIATION SAFETY PROGRAM**

**10.2 Sealed Sources**

5. a. b. The distribution of Iridium-192 Remote Afterloader Source Assemblies licensed pursuant to 20-27966-02MD, Amendment 02, is to be transferred into the subject license, 20-20973-03MD, by this amendment.

CIS-US, Inc.
Ten DeAngelo Drive
Bedford, MA 01730
(617) 275-7120



**5. RADIOACTIVE MATERIAL**

| a. Material | b. Chemical and/or physical form | c. Maximum amount that may be possessed at any one time. |
|---|---|---|
| Iridium -192, as specified in License Condition 11. | Remote Afterloader Source Assembly. Assembly and Source Models amended as described below (Item 10.2) | Not applicable |

**6. USE OF RADIOACTIVE MATERIAL**

5. a. b. Distribution, as presently authorized-no changes.

**10. RADIATION SAFETY PROGRAM**

**10.2 Sealed Sources**

5. a. b. Changes:

1. Delete Assembly (Device) Model Number 723. Discontinued model archived; see SSDR No. NR-555-S-104-S, Amend. 5/24/96, Page 3,6th ¶.
2. Source Capsule Model 774 has been evaluated and listed on NR-555-S-104-S (attached) to provide user-selection of preferred dosimetry characteristics of Source Assembly Models 721, 722 and 724.
3. Amended table of authorized Remote Afterloader Source Assemblies (devices) distributed per License Condition 11:

| Source Ass'y (Device) Model | Isotope | Source Model Number(s) | Maximum Activity Per Source |
|---|---|---|---|
| 721 | Iridium 192 | 772 or 774 | 20 curies |
| 722 | Iridium 192 | 772 or 774 | 20 curies |
| 724 | Iridium 192 | 772 or 774 | 20 curies |

The subject license, as amended, is to be terminated upon transfer of its licensure into license No. 20-20973-03MD by amendment thereto.

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

NO: NR-555-S-104-S DATE: May 24, 1996 

SOURCE TYPE: Remote Afterloader Source Assembly

MODEL: 721, 722, 723, 724

MANUFACTURER/DISTRIBUTOR: **CIS-US, Inc.**
**(formerly RTS Technology, Inc.)**
35 Flagship Drive
North Andover, MA 01845

ISOTOPE: Iridium-192

MAXIMUM ACTIVITY: 20 curies (740 GBq)

LEAK TEST FREQUENCY: 6 months

PRINCIPAL USE: (V) General Medical Use

CUSTOM DEVICE: YES _____ NO X

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

NO: NR-555-S-104-S DATE: May 24, 1996 

SOURCE TYPE: Remote Afterloader Source Assembly

DESCRIPTION:

Models 721, 722, 723, and 724 source assemblies are designed for use in remote afterloader brachytherapy applications. Each source assembly consists of a source capsule, a cable(s), and an end cap. The source assemblies are intended for use with the GammaMed family of remote afterloaders.

Each source assembly may contain up to 20 curies (740 GBq) of iridium-192 in solid pellet form. The iridium-192 is singly encapsulated in either a model 772, 773, or 774 source capsule. These capsules are fabricated from either AISI Types 347, 316, or 316L or DIN 8556 Types 1.4551 or 1.4404 stainless steel and are welded to a stainless steel cable. Approved source assembly configurations are shown below:

| Source Assembly | Capsule Model | Cable Length | Cable Diameter | Cable Type |
|---|---|---|---|---|
| 721 | 772 or 774 | 82.3 in/209 cm | 0.043 in/1.1 mm | Standard |
| 722 | 772 or 774 | 7.9 in/ 20 cm | 0.043 in/1.1 mm | Standard |
| | | 58.7 in/149 cm | 0.071 in/1.8 mm | Standard |
| 723 | 773 | 66.5 in/169 cm | 0.071 in/1.8 mm | Standard |
| 724[1] | 772 or 774 | 7.1 in/ 18 cm | 0.043 in/1.1 mm | Flexible |
| | | 75.2 in/191 cm | 0.043 in/1.1 mm | Standard |

For each source capsule, an Ir-192 pellet is inserted into a cylindrical capsule body that is closed at one end and a plug is press fit into the open end, fully enclosing the pellet. For the Model 774 source capsule, the plug is at the distal end of the capsule and is seal welded in place. However, the capsule body of the 774 capsule is attached to the cable by laser welding prior to insertion of the pellet. For the model 772 and 773 source capsules, the plug is at the cable end of the capsule. Welding of the plug and attachment to the cable is accomplished in one step by a single seal and attachment welding process.

---

[1] Model 724 sources with serial numbers less than 6000 have a flexible cable length of 7.7" (19 cm) and a standard cable length of 74.6" (189 cm). Overall length of the sources are the same. The change was made to render the source assembly identical to those made for the GammaMed 12i in Europe.

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



SOURCE TYPE: Remote Afterloader Source Assembly

DESCRIPTION: (cont'd)

The Model 772 source capsule measures 0.047 inches (1.18 mm) in diameter and can vary in length from 0.10 inches (2.61 mm) to 0.24 inches (6.0 mm) depending on source activity. The Model 773 source capsule measures 0.071 inches (1.8 mm) in diameter and 0.15 inches (3.75 mm) in length. The Model 774 source capsule measures 0.047 inches (1.18 mm) in diameter and can vary in length from 0.081 inches (2.05 mm) to 0.207 inches (5.25 mm) depending on source activity.

For the 722 and 724 source assemblies the source cable consists of two cable segments welded together to meet the requirements of the particular GammaMed unit. The short source cable segment of the 724 source assembly is "flexible" cable. This cable segment provides for greater flexibility at the source capsule end of the assembly.

A stainless steel end cap is welded to the opposite end of each source cable. Each end cap is laser etched with "CIS" (formerly "RTS") and a unique serial number.

Total length of the Model 721, 722, 723, and 724 source assemblies are 82.68 inches (210 cm), 66.93 inches (170 cm), 66.93 inches (170 cm), and 82.68 inches (210 cm), respectively.

The Models 721 and 724 are dimensionally identical and may be used in the GammaMed 12i and GammaMed 12it remote afterloaders. The Model 722 may be used in the GammaMed IIi remote afterloader.

The model 723 source assembly was intended for use in either the GammaMed II or GammaMed IIi remote afterloaders. However, the manufacturer reported that no Model 723 source assemblies were ever distributed in the U.S. and no longer intends to market this model.

Source assemblies are installed into the appropriate remote afterloader by persons specifically licensed. Once installed in the afterloader, movement of the source assembly is automated according to the treatment plan and is accomplished by means of a dual roller system and position sensors. The GammaMed units are designed to prevent impact of the source assembly with the end of the closed-end catheter.

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



SOURCE TYPE: Remote Afterloader Source Assembly

LABELING:

Each source is assigned a unique serial number. A source identification label is provided with each source assembly for attachment to the device in which the source assembly will be installed. The label is to be attached by the use of two screws. This label indicates the manufacturer, source model number, serial number, the radionuclide, the activity of the source and the date the activity was measured. Each source assembly is additionally laser etched on the end cap with "CIS" (formerly "RTS") and the unique serial number.

DIAGRAM:

See Attachments 1 - 6.

CONDITIONS OF NORMAL USE:

These source assemblies are used in conjunction with the GammaMed family of remote afterloaders. They will be used for research and clinical objectives by trained personnel in the treatment of human cancers. The GammaMed II, GammaMed IIi and GammaMed 12i remote afterloaders will be used in fixed locations within hospitals of clinics. Therefore the source assemblies used with these devices would be subjected to environmentally controlled conditions associated with these locations.

The GammaMed 12it is relocatable within a limited spectrum. During relocation the source assembly will be secured within the device and would therefore only be subjected to moderately increased vibration associated with transport.

The source assemblies may be used only in conjunction with the following capsule models and remote afterloader devices.

| Source Assembly | Capsule Models | Device Model |
|---|---|---|
| 721 | 772 or 774 | GammaMed 12i or 12it |
| 722 | 772 or 774 | GammaMed IIi |
| 723 | 773 | GammaMed IIi or II |
| 724 | 772 or 774 | GammaMed 12i or 12it |

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



SOURCE TYPE: Remote Afterloader Source Assembly

PROTOTYPE TESTING:

The manufacturer tested Model 772, 773, and 774 source assemblies to the requirements of ANSI N542-1977. All capsules achieved a classification of 77C53312. All capsules were leak tested before and after prototype testing with satisfactory results. The internal void volume of the 774 source assembly was insufficient to perform a standard volumetric leakage assessment method. Therefore, a modified 774 source capsule, identical in design and construction to a standard 774 source capsule except slightly longer, was substituted for an actual 774 capsule. The extra length provided a worst configuration for testing, but provided sufficient void volume to perform a leakage assessment using a liquid nitrogen bubble test method.

In addition Model 721, 722, 723, and 724 source assemblies were tested to determine the maximum tensile force required to induce failure. Results of the tests showed that the Models 721, 722, and 724 source assemblies, with a model 772 source capsule, could withstand a tensile force of up to 30 lbs (133 N), and with a model 774 source capsule, could withstand a tensile force of up to 45 lbs (200 N). The Model 723 source assembly was shown to be able to withstand a tensile force up to 77 lbs (343 N).

Cyclic tensile tests were also conducted on Model 721, 722, 723, and 724 source assemblies to determine their ability to withstand a repetitive tensile force. A tensile load of 13 lbs (58 N) was repeatedly applied and released 100 times for each source assembly. No failures of the source assemblies were noted.

Life-cycle tests were conducted on Model 721 and 724 source assemblies containing model 772 source capsules. A Model 721 was subjected to more than 30,000 complete operational cycles without failure while a Model 724 was subjected to more than 20,000 complete operational cycles before failure at the cable to cable weld. These source models are not expected to be subjected to more than 20,000 cycles during their typical useful life.

The above tensile and life-cycle tests of the model 724 source assemblies with model 772 source capsules were conducted with the earlier cable lengths specification. Source assemblies with the new cable lengths specification have been in use in Europe with the GammaMed 12i with no reported failures.

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



SOURCE TYPE: Remote Afterloader Source Assembly

PROTOTYPE TESTING: (cont'd)

In addition, the manufacturer reported that an Isotopen-Technik Dr. Sauerwein GmBH source capsule, essentially identical to the model 774 source capsule design, was subjected to an endurance test of 51,837 cycles without failure. The manufacturer claims that the differences between these capsule designs would not be significant to the results of the endurance test and, therefore, the model 774 source capsule would also be expected to achieve similar results.

The GammaMed afterloaders are designed and used such that impact of the source assembly tip with the end of the closed-end catheter would be prevented. Therefore, the manufacturer did not perform impact prototype testing on the tip of these source assemblies.

EXTERNAL RADIATION LEVELS:

The manufacturer reported the following dose rates for an iridium-192 source assembly with an activity of 20 curies:

| Distance | Dose Rate |
|---|---|
| 1.97 in. (5 cm) | 3840.0 R/hr (38.4 Sv/hr) |
| 11.8 in. (30 cm) | 106.7 R/hr (1.07 Sv/hr) |
| 39.4 in. (100 cm) | 9.6 R/hr (96.0 mSv/hr) |

QUALITY ASSURANCE AND CONTROL:

The manufacturer has submitted an acceptable Quality Assurance and Control program consisting of:

- All source capsule components and all source assembly components are inspected on a 100% basis for conformance to design requirements. Each source capsule weld is visually inspected for proper closure. Each source capsule is twice wipe tested for removable radioactive contamination.

- The activity of each source assembly is measured

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

NO: NR-555-S-104-S DATE: May 24, 1996 

SOURCE TYPE: Remote Afterloader Source Assembly

QUALITY ASSURANCE AND CONTROL: (cont'd)

- The GammaMed units contain a drive system which is designed to limit the tensile force which can be transmitted to the source assembly to 4.5 lbs (20 N) by use of a slip clutch. A tensile load of 11 lbs. (49 N) is applied to the attachment of each source capsule to the cable for a period of two minutes in order to test for proper attachment.

- Failure of any these tests or inspections will prevent use of the source assembly.

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

- The source assemblies shall be distributed only to persons specifically licensed by the NRC or an Agreement State.

- REVIEWER NOTE: The source assemblies shall only be used with devices as listed in this document or with other devices as specified in a registration certificate issued by the NRC or an Agreement State.

- The source assemblies shall be tested for leakage at intervals not to exceed 6 months using techniques capable of detecting 0.005 microcurie (185 Bq) of removable contamination.

- Handling, storage, use, transfer, and disposal are to be determined by the licensing authority. In view that these sources exhibit high dose rates when unshielded these sealed sources should be handled by experience personnel only, specifically licensed to perform these activities.

- These source assemblies shall not be subjected to environmental or other conditions of use which would exceed an ANSI N542-1977 classification of 77C53312 or an axial tensile force that would exceed the maximum imparted by a typical GammaMed unit [approximately 4.5 lbs (20 N)].

- This registration sheet and the information contained within the references shall not changed without the written consent of the NRC.

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

NO: NR-555-S-104-S DATE: May 24, 1996 PAGE: 8 OF 8

SOURCE TYPE: Remote Afterloader Source Assembly

SAFETY ANALYSIS SUMMARY:

Based on our review of the information and test data cited below, we continue to conclude that source assembly Models 721, 722, 723, and 724 are acceptable for specific licensing purposes.

Furthermore, we continue to conclude that these sources would be expected to maintain their containment integrity for normal conditions of use and accident conditions which might occur during uses specified in this certificate.

The manufacturer indicated that no Model 723 source assemblies had ever been distributed in the U.S. or will be distributed in the future.

REFERENCES:

The following documents for Model 721, 722, 723, and 724 source assemblies are hereby incorporated by reference and made a part of this registry document:

- RTS Technology, Inc. letters dated June 7, 1989, November 15, 1989, November 17, 1989, November 22, 1989, February 27, 1990, October 4, 1991, September 18, 1992, January 29, 1993, December 7, 1993, April 12, 1995, November 3, 1995, and December 19, 1995, with enclosures thereto.
- CIS-US, Inc. letter dated May 1, 1996, with enclosures thereto.

ISSUING AGENCY:

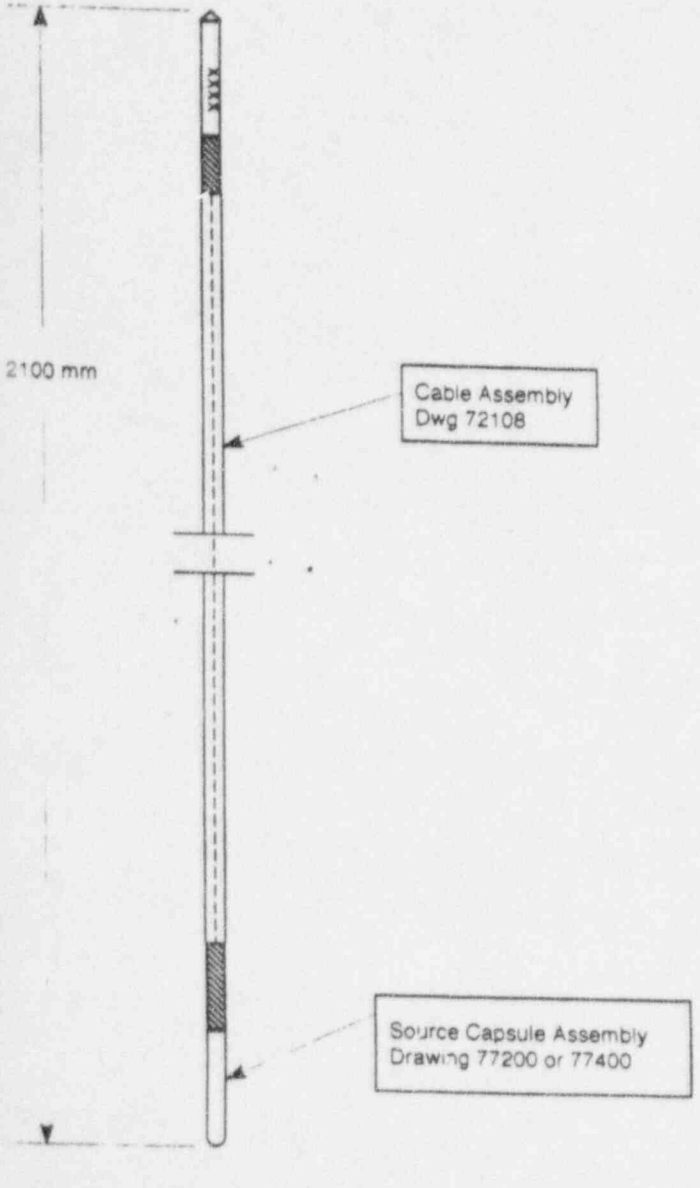
U.S. NUCLEAR REGULATORY COMMISSION

DATE: May 24, 1996 REVIEWER: Douglas A. Broaddus
Douglas A, Broaddus

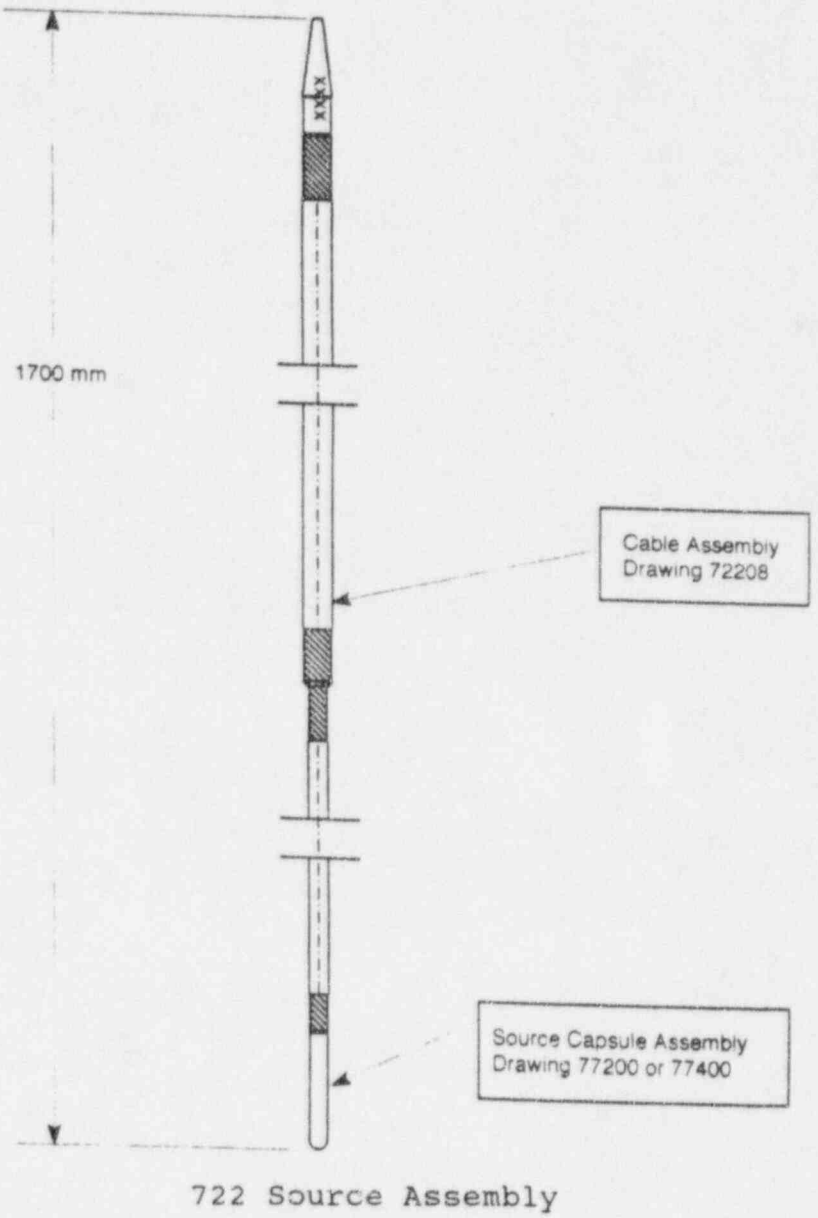
DATE: May 24, 1996 CONCURRENCE: Steven L. Baggett
Steven L. Baggett

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

NO.: NR-555-S-104-S DATE: May 24, 1996 ATTACHMENT 1



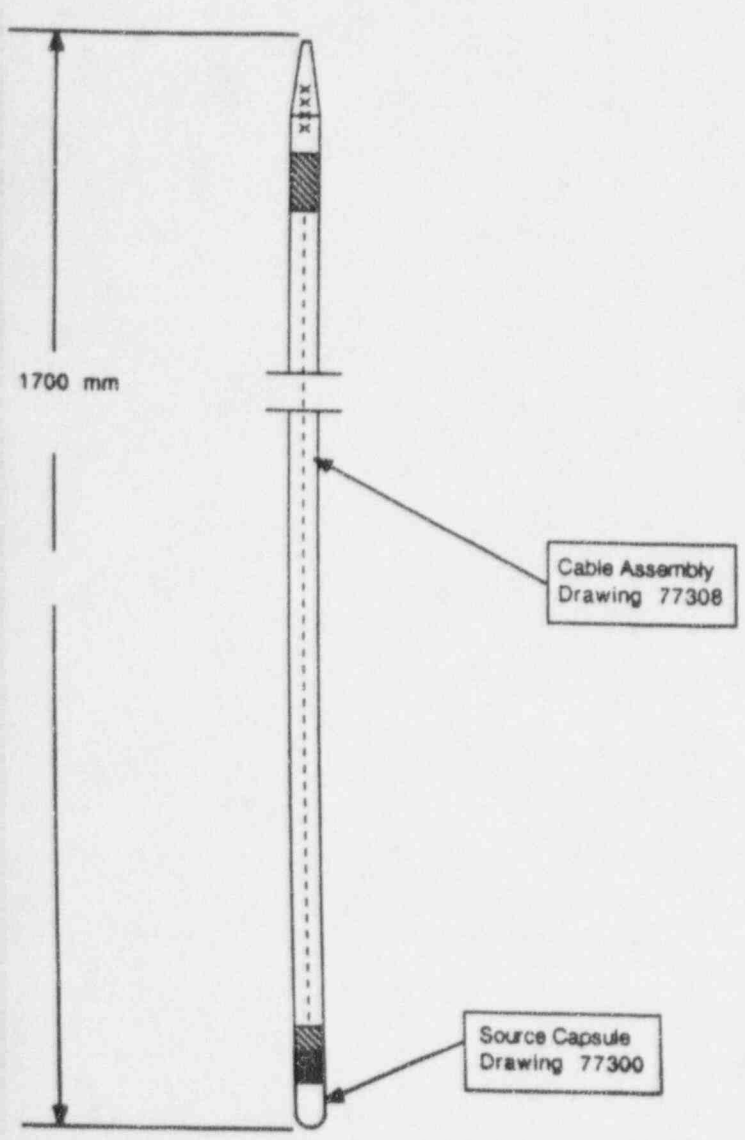

721 Source Assembly



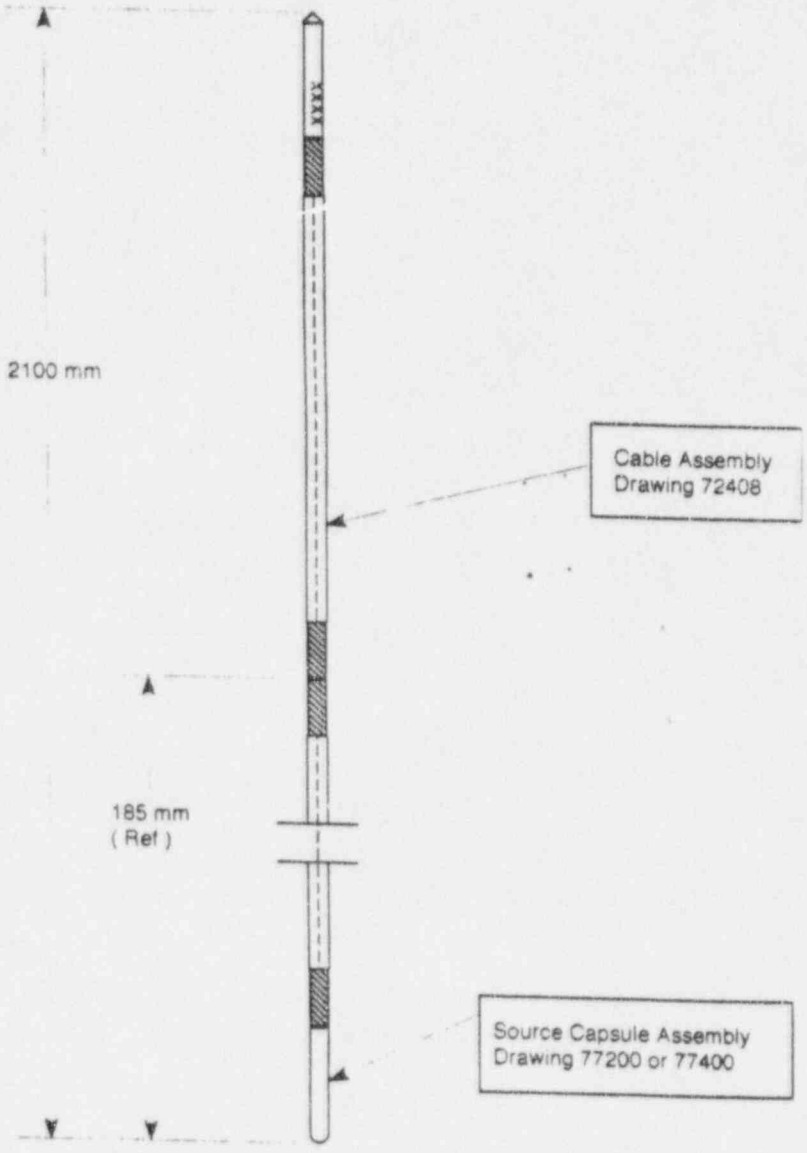

722 Source Assembly

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

NO.: NR-555-S-104-S DATE: May 24, 1996 ATTACHMENT 2



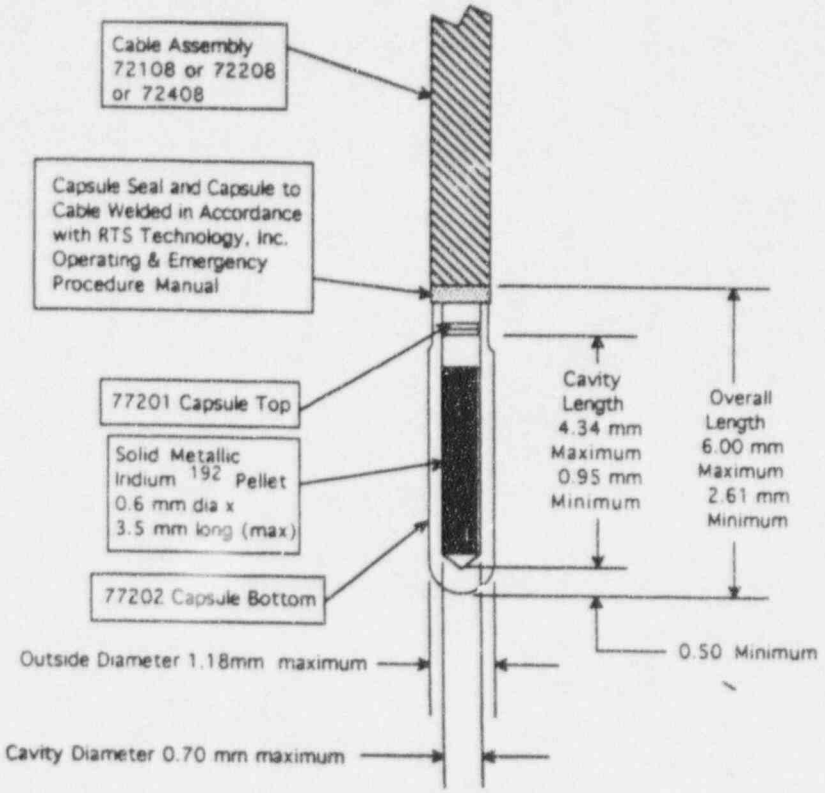

723 Source Assembly



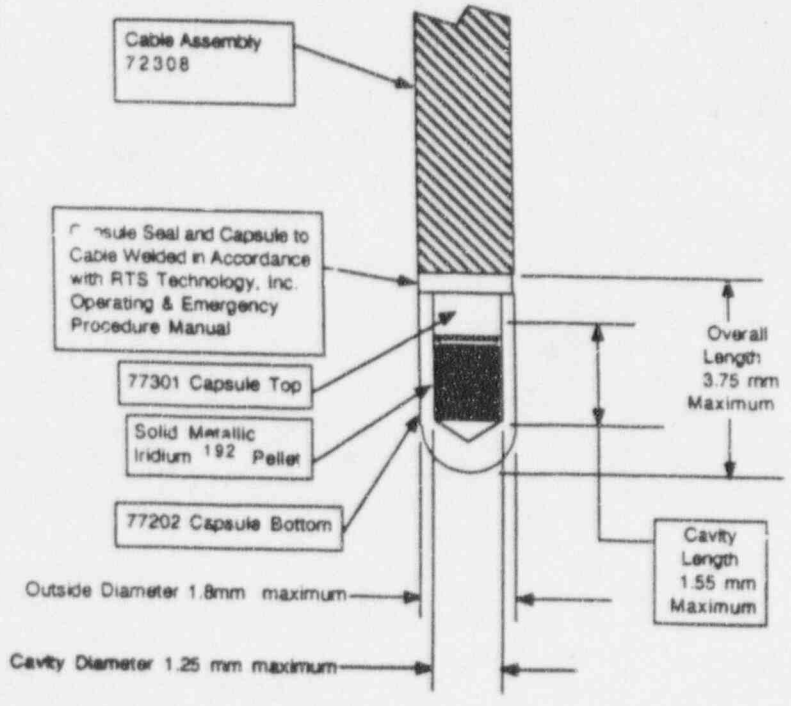

724 Source Assembly

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

NO.: NR-555-S-104-S DATE: May 24, 1996 ATTACHMENT 3



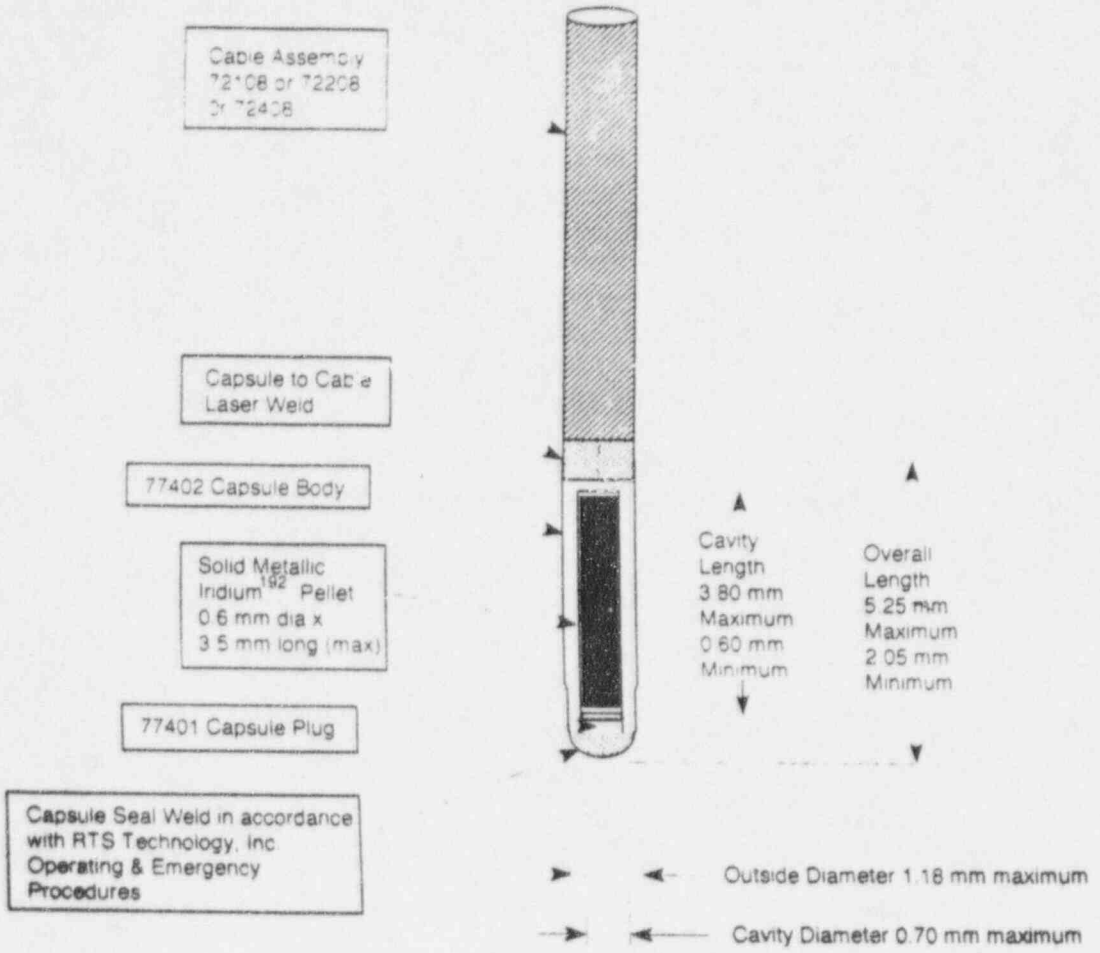

77200 Capsule Assembly




77300 Capsule Assembly

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

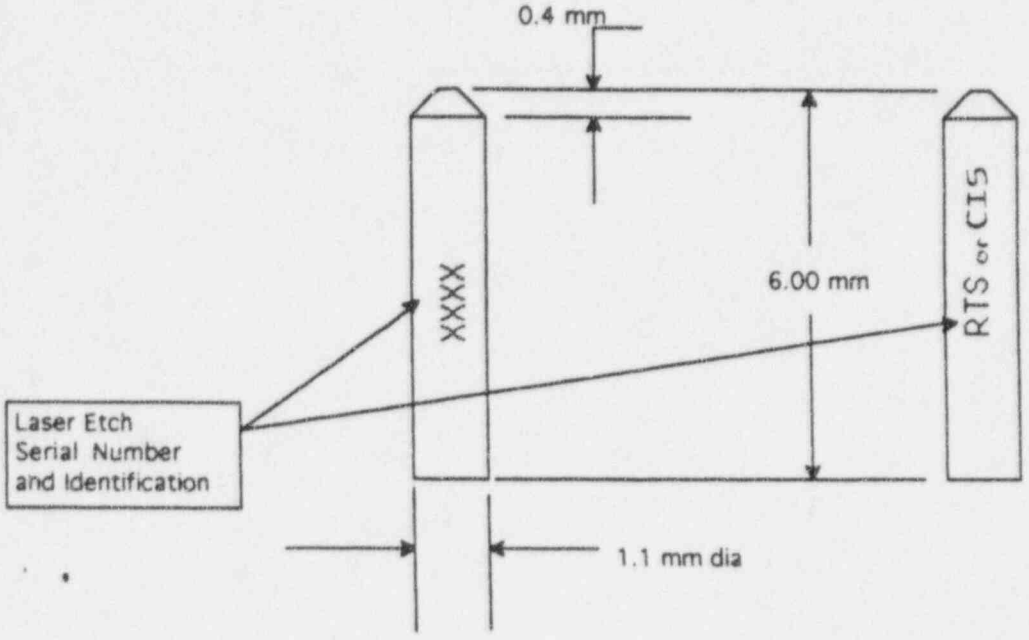
NO.: NR-555-S-104-S DATE: May 24, 1996 ATTACHMENT 4



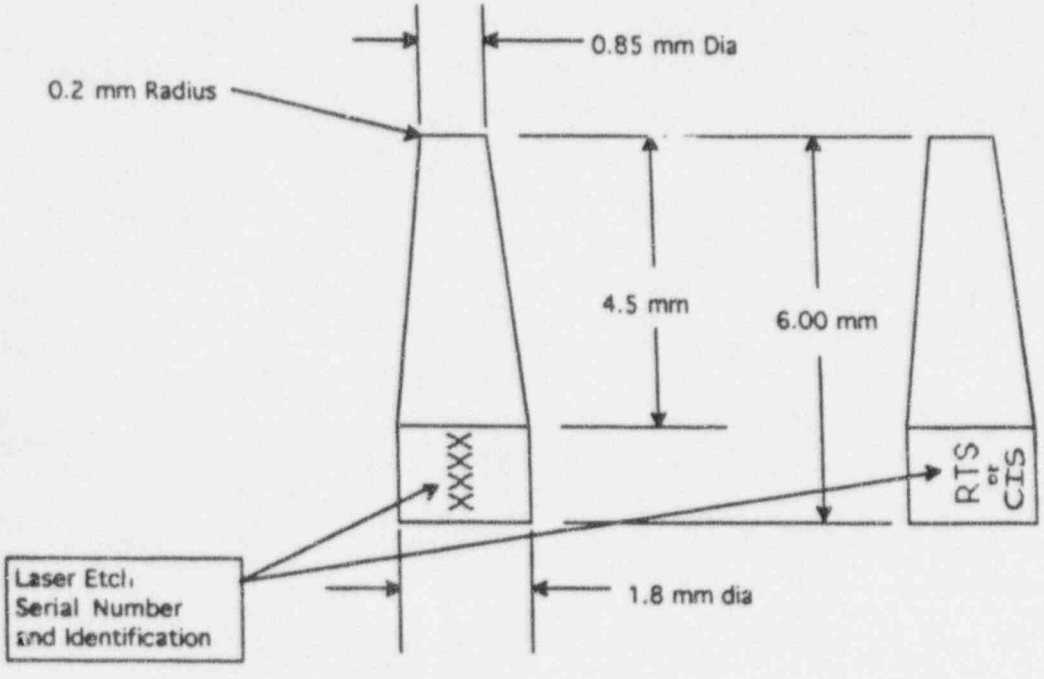

77400 Capsule Assembly

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

NO.: NR-555-S-104-S DATE: May 24, 1996 ATTACHMENT 5



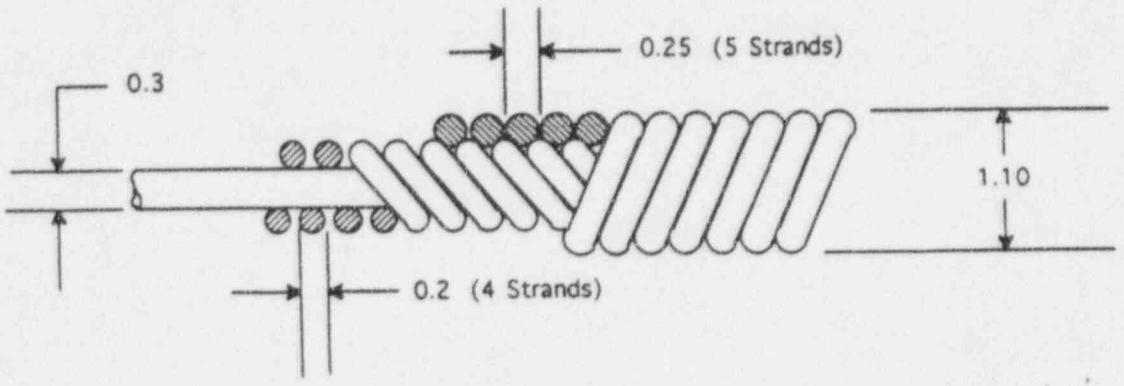

Cable End used on the 721 and 724 Source Assemblies



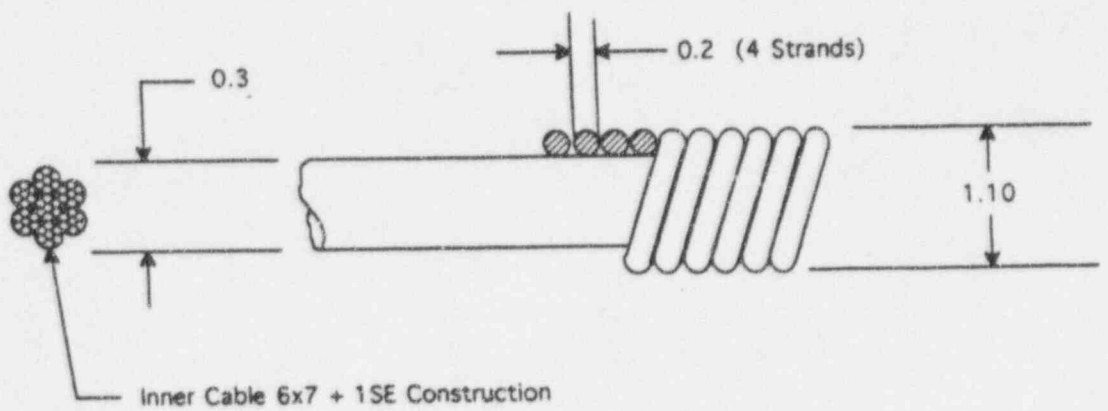

Cable End used on the 722 and 723 Source Assemblies

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

NO.: NR-555-S-104-S DATE: May 24, 1996 ATTACHMENT 6




Standard Cable




Flexible Cable

**Notes**

1. All Dimensions in Millimeters

# DIVISION OF ACCOUNTING AND FINANCE
# REQUEST FOR REFUND TO EMPLOYEE/VENDOR

JAN 2 7 1997

THE EMPLOYEE/VENDOR IDENTIFIED BELOW HAS OVERPAID THE NUCLEAR REGULATORY COMMISSION FOR GOODS AND/OR SERVICES PROVIDED AND IS DUE A REFUND

EMPLOYEE/VENDOR/PAYEE CODE: _____

NAME: CIS-US, INC.

ADDRESS: ATTN: JOHN J. MUNRO, III

ADDRESS: 10 DeANGELO DRIVE

CITY: BEDFORD STATE: MA ZIP: 01730

TRANS CODE: PX

| | | | |
|---|---|---|---|
| TRANS TYPE: FE | FUND: X5280 | JOB CODE: _____ | AMOUNT: $520.00 |
| TRANS TYPE: IR | FUND: R1435 | JOB CODE: INTR | AMOUNT: _____ |
| TRANS TYPE: IR | FUND: R1099 | JOB CODE: ADCH | AMOUNT: _____ |
| TRANS TYPE: IR | FUND: R1099 | JOB CODE: FINE | AMOUNT: _____ |

TOTAL REFUND AMOUNT: $520.00

COMMENTS: LIC 20-20973-03MD/CK 2273/3C AND OVRPYT

(limit comments to 40 characters, including spaces)

PREPARED BY: Brenda Brown DATE: 1/27/97

AUTHORIZED BY: Sandra Kimberly DATE: 1/27/97

ORIGINAL INV. NO: _____ DATE PAID: _____ AMOUNT: _____

REFUND ENTERED INTO COLLECT BY: _____

REFUND DETERMINED BY: _____ DATE: _____

**PLEASE ATTACH APPROPRIATE SUPPORTING DOCUMENTATION**

I (97)
Jan 9
LTR DTD 1/7/97 $520
3C AND FEE IS
124085

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

(FOR LFMS USE)
INFORMATION FROM LTS

PROGRAM CODE: 02511
STATUS CODE: 0
FEE CATEGORY: 3C
EXP. DATE: 20030731
FEE COMMENTS: 3C EFF 6/9/94
DECOM FIN ASSUR REQD: N

LICENSE FEE TRANSMITTAL

A. REGION I

1. APPLICATION ATTACHED
APPLICANT/LICENSEE: CIS-US, INC.
RECEIVED DATE: 970108
DOCKET NO: 3029781
CONTROL NO.: 124085
LICENSE NO.: 20-20973-03MD
ACTION TYPE: AMENDMENT

2. FEE ATTACHED
AMOUNT: $1,040.00
CHECK NO.: 2273

3. COMMENTS
REFERENCE 124086.

SIGNED M. A. Serbian
DATE 1/3/97

B. LICENSE FEE MANAGEMENT BRANCH (CHECK WHEN MILESTONE 03 IS ENTERED /__/)

1. FEE CATEGORY AND AMOUNT: 3C $520

2. CORRECT FEE PAID. APPLICATION MAY BE PROCESSED FOR:
AMENDMENT /
RENEWAL
LICENSE

3. OTHER

SIGNED
DATE

JAN 14 AM 9:3?

I (97)
Log John G
Remitter
Check No. 2273
Amount $1,040 Refunded $520
Fee Category 3C
Type of Fee AMD
Date Check Rec'd 1/2/97
Completed 1/7/97
BB

(Also see 124086)

1/17/97
124086 is a term request for CIS-US, INC. 20-27966-02MD
I called licensee told him there is no charge for the termination. Fee in $520 would be refunded.
DB

07 for 1/17/97 - Also notified Mike, RI
BB