UNIVERSITY *of* MISSOURI

ENVIRONMENTAL HEALTH AND SAFETY

August 18, 2016

U.S. Nuclear Regulatory Commission
Region III – Division of Nuclear Materials and Safety
Attn: Materials Inspection Branch
c/o Debora Piskura
Senior Health Physicist
2443 Warrenville Road
Lisle, Illinois 60532

Subject: Event No. 52121 – 30-Day Written Notification for Leaking Sealed Source

Mrs. Piskura:

Please accept this written notification for discovery of a total of three (3) Cesium-137 (Cs-137) Trocar Brachytherapy needles found to be leaking beyond acceptable reporting requirements of 10 CFR 30.50 (c) (2). Verbal notification of these leaking sealed sources was provided to the Nuclear Regulatory Commission (NRC) Operations Center on July 22, 2016 under Event No. 52121 for the first discovery of two sources and then again on July 26, 2016 when the third leaking needle was discovered following the completion of the implantation phase of an equine therapy. All three of the leaking needles were taken out of service, and placed in shielding awaiting further assessment and preparation for disposal upon completion of the equine therapy. Some minor contamination of bench top paper occurred and was easily remediated. No personnel contamination or overexposures occurred as a result of these leaking needles.

Detailed Discussion

Initially, on July 18, 2016 at 10:30 am during a pre-implant leak test and inventory procedure, two (2) of the total fourteen (14) Trocar CS-137 needles were found to be leaking greater than the 0.005 microcurie limit. These two (2) leaking needles were immediately isolated from the remaining needles to be used in the upcoming equine brachytherapy procedure that morning. They were returned to their original conical tube holders, placed in shielding and administratively taken out of service pending additional assessments. The first two leaking needles had a combined activity of 10 mCi of Cs-137 as of July 18, 2106.

Subsequently on July 26, 2016, following the removal of all implanted seeds from the equine treatment, follow-up leak tests and a re-inventory was performed of all of the Cs-137 needles as a verification and reassessment step. During the repeat leak tests one (1) additional needle was found to be leaking beyond the regulatory limit. The activity for the additional leaking needle, as of July 18, 2106, was 7.1 mCi. As with the first two, this leaking needle was taken out of service, put into its storage container, and placed back into shielding awaiting proper disposal.

On both occasions, MU notified the NRC non-emergency events office as well as our NRC Region III principle inspector Mrs. Deborah Piskura upon discovery of the leaking sources.

Detailed information regarding the leaking sources.

Internal ID #	Manufacturer	Date of Manufacture	Model	Original Activity (mCi)	Current Activity (mCi) on 07/18/2016	Leak Test Results (microcuries must be <0.005) *
50	Nuclear Associates	05/31/1982	69-649-6	15.67	7.1	2.8
51	Nuclear Associates	05/31/1982	69-649-6	15.67	7.1	0.02
61	3M	05/31/1971	6B6G-LD	8.2	2.9	0.0056

*Leak tests performed on both a Perkin Elmer Tricarb 5110 Liquid Scintillation Analyzer, and our Gamma Products G-5000 Alpha Beta Proportional with an Integral Nal Multichannel Analyzer Counting Systems. Value listed is highest G-5000 calculated activity of the multiple leak test smears per needle.

With the help of Mrs. Piskura we were able to find a Sealed Source Device Registry (SSDR) for the leaking 3M needle (Internal ID #61). This older seed (manufactured in 1971) was listed as a 3M part number that is covered under the newer SSDR NR-460-S-928-S, dated Feb 16, 1996. See attachments.

However we have yet to find a matching SSDR for the other two leaking Nuclear Associates (Internal ID #50, and #51) Cs-137 Trocar needles. What we do have are the Nuclear Associates (Victoreen affiliate) Calibration and Leak Test sheets from June 14, 1982 and will include those as part of this report. See attachments.

These needles were last stored in conical tubes, which are ~ 1 cm in diameter, ~10 cm tall, and are outfitted with a screw top cap. One tube is used for each needle. These tubes were then placed into a foam cut out storage array that held the 14 tubes (containing needles) in an upright positon, and the foam array held them all inside a very heavy lead shielded storage/transfer box. The storage/transfer box (with needles) itself is normally stored in a lead brick cave alcove in a lower cabinet space under the fume hood, in the Hot Lab room B125A of the University of Missouri (MU) Veterinary Nuclear Medicine Clydesdale Hall facility.

Upon completion of these infrequent equine brachytherapy procedures, a post procedural leak test and inventory of the sources is performed, and then the sources are placed into an administrative "storage" condition with a tamper seal placed on the lid of the lead storage box. Once this is done, the normal leak tests are suspended in lieu of verifying the physical presence of the box with an intact tamper seal and recording contact radiation readings on the outside of the lead box. Due to the their infrequent use and for ALARA purposes, we keep these sources in this "storage" condition until they are needed again, and then, as we did as part of this event discovery, a pre-implant leak

test will be performed on the needles prior to the VMD selecting which group of needles will be appropriate for an upcoming implant.

Contrary to this normal administrative storage condition, it was discovered by the Environmental Health and Safety (EHS) Environmental Health Technician (EHT) upon arrival on Monday (July 18) morning to perform the first "out of storage" leak test that the tamper seal had been cut. The EHT then asked the Veterinarian Medical Doctor (VMD), who was assisting with the leak tests, if he had cut the tamper seal. The VMD indicated that in preparation for the upcoming equine therapy that he had cut the seal on the previous Friday (July 15) so he could perform a visual and physical inventory of all needles (in their source tubes) to ensure he had enough needles (of right size, dimensions, and therefore strength activity) to perform the brachytherapy. He attested that when he completed the visual inventory that he then put them all back in the lead storage box and put all back in the lead cave under the fume hood. Since the door to the hot lab is a normally locked door and it was a weekend, we have no reason to believe anyone else (who may have had access to that room) would have handled the needles until the leak test on Monday morning.

Upon discovery by the RSO that the tamper seal had been cut, the RSO discussed with the VMD that in the future the tamper seal should be left alone until the "leak test" is ready to be performed at the time of cutting the seal, and that even though the sources "belong" to him, the tamper/security seal is a Radiation Safety Program (RSP) item that speaks to the chain of custody and integrity of the sources in the box from when the last seal was installed, and that these seals are not to be arbitrarily cut without involving EHS or at a minimum notifying them that the tamper seal had been purposely cut.

During the initial and follow-up leak tests, several portable instrument radiation surveys as well as removable contamination checks were performed in the room. Initially no contamination was discovered by the EHS EHT on the morning of the implant and leak tests. However later in the week, when the sources were either in the shielded cave below or located in the equine for therapy and therefore a lower background, a Veterinarian Medicine (VM) radiation worker found a spot of contamination while performing normal end of week surveys. The contaminated hot spot was on the absorbent bench top paper near the dose preparation shielding setup. The spot was documented, easily remediated, and the resultant contaminated wastes were placed in a solid waste container and left in the room pending further assessment and proper disposal. Additionally, a meter survey and removable contamination smears checks were performed by two EHS EHT's following the hot spot remediation, and no additional contamination was found. It is postulated that the high background from the leak testing of the Cs-137 needles on the morning of Monday July 18 prevented the EHS EHT from initially finding the small hot spots.

At the end of the successful equine procedure all needles (except for the 3 leakers and two other bent needles that were selected for disposal) were re-inventoried, leak tested, and have been placed in the storage/transfer box under the fume hood in the lead alcove. Again with the information we have at the time of this report, no personnel nor any other contamination occurred beyond the two hot spots on the bench top paper where the initial leak test was performed and based upon the review of monthly dosimeters (whole body and two finger rings) worn by the VMD (which were sent off for emergency reads) no overexposures occurred. The left finger resulted in 483 mrem, the right finger 191 mrem, and the whole body for the month of July was 38 mrem. The VMD's left finger ring did exceed our RSP ALARA alert level 1 and will be discussed at the upcoming RSC meeting, but again this 483 mrem is less than the legal limit of 15,000 mrem and the VMD is

the most conservative example for exposures during these activities of leak tests, and source handling for the equine brachytherapy.

Probable Cause

During the initial response to perform the leak test in support of the emergency equine therapy, the EHT discovered that most of the conical plastic tubes in which the needles were being stored, had various levels of liquid in them covering the needles. Per discussion with the VMD, it was determined that this fluid was likely Chlorohexidine, which had been purposely poured in the tubes at the end of the last equine brachytherapy (e.g., November 2014) as an antiseptic/antimicrobial solution to help "clean them up" from the previous implant. While it is not against the handling procedures of the SSDR at least for the 3M needle by default these ceramic Cs-137 microsphere metal encapsulated sealed sources are not to be stored in any solution for two years. The longest quality control liquid emersion test was for 16 hours per the SSDR sheet. Since we don't have the SSDR for the other two Nuclear Associates leaking sources, we cannot speak to their required handling specifications. Again, the long storage while immersed, the old age (34 – 44 year), and handling every other year or so, plus any unseen damage by upset equine brachytherapy patients are suspect.

Corrective Actions To Prevent Reoccurrence (CATPR) – Proposed as the RSC has yet to review and approve any CATPR's

Leaking Needles

1. We have removed the leaking needles and placed them in the waste stream for disposal by our waste broker unless we can find an alternate solutions, e.g. a vendor takes them back. We will also work with 3M to see if they will take the one 3M leaking needle back as their SSDR indicates they will. The two Nuclear Associated needles will likely need to go a different waste route.
2. We will likely continue to use the Pharmaceutical product, which was used as disinfectant, antiseptic post implant to sterilize the needles, but the needles will be long-term "stored" in a *dry condition* after the short-term sterilization step. This latest sterilization cycle and dry storage has yet to be done as we are awaiting the VMD to return from vacation. Once he returns we plan to perform a final re-inventory, leak tests, and perform a minor sterilization step by dipping the needles in the sterilization solution, then blotting dry and placing them individually in new storage tubes for long-term storage until the next equine study. All items will be tested for any contamination before tamper seal is placed on the box for long-term storage.
3. A long-term solution is to replace these very old needles with more current models that have been recently manufactured, and at the completion of the therapy return all seed/needles to vendor similarly to what we currently do for human brachytherapy. This will require better scheduling and planning for therapies by the Veterinary Medicine group but with today's Brachytherapy vendors, much improved quality control and shipping speeds, this is very viable option. This option will be the RSO's recommendation to the RSC for a long term solution.

Tamper Seal

1. We will provide training to the VMD and his staff on the requirement to not cut any future EHS installed tamper seals without first coordinating with EHS RS. Additionally we will update the special conditions to put this expectation on his authorization.
2. When we get to the phase of placing the remaining needles into long-term storage we will take high quality digital pictures of each needle with a reference length as well as calculate current activities and extrapolate the Cs-137 needles' activity every year for the next 10 years on an electronic record and provide that record to the VMD to help him plan his next brachytherapy procedure in the near future or until an alternate equine brachytherapy method is chosen.

Contamination of bench top paper

1. We suspect the hot spot found on the bench top paper on the counter top of the hot lab was a drip of the Chlorohexidine solution from one of the tubes that contained a leaking needle. The CATPR for this issue will be leak testing needles first, then dipping the needles into the Chlorohexidine for a satisfactory period to achieve sterilization, then dry the needle with a KimWipe, survey the Kim Wipe for any residual contamination and then finally place the dry needle into a new storage tube for its long-term storage with a tamper seal after all items are verified contamination free and dry. This will prevent any liquid from being present in tube with the needle and the liquid becoming contaminated should a needle fail again in the future.

A complete review of this event, the proposed corrective actions will occur at the next scheduled Radiation Safety Committee, currently scheduled for August 25th 2016.

If you have any questions or concerns, please contact me at (573) 882-7018 or crawfordw@missouri.edu.

Respectfully submitted,

Jack Crawford
Radiation Safety Officer

Attachments

License No. 24-00513-32
Docket No. 03002278

cc: S. Jurisson (MU Professor of Chemistry and Chair of RSC)
G. Ward (MU Vice Chancellor of Operations)
T. Houts (MU EHS Director)
S. Engelhardt (Engelhardt and Associates)
RSO File

Attachments

- SSDR for 3M Cs-137 Source Needle Model 6B6G – LD – 5 pages (16Feb96)

- Radioactive Source Certificated for 3M Cs-137 Source Needle Model 6B6G – 3 pages (03Sep74)

- Leak Test and Certificate of Calibrations for Nuclear Associates (Division of Victoreen) – 2 pages (14Jun82)

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

NO.: NR-460-S-928-S DATE: February 16, 1996

SEALED SOURCE TYPE: Tube Source

MODEL: Series 6510, 6570, 6550 (formerly 6B6G)

MANUFACTURER/DISTRIBUTOR: 3M Health Physics Services
3M Center, Building 224-2E-06
St. Paul, MN 55144-1000

ISOTOPE:

Cesium-137

MAXIMUM ACTIVITY:

500.0 millicuries (18.50 GBq)

LEAK TEST FREQUENCY: 6 Months

PRINCIPAL USE: (V) General Medical Use

CUSTOM SOURCE: _____ YES ___X___ NO

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

SEALED SOURCE TYPE: Tube Source

DESCRIPTION:

The 6510 Series, 6550 Series, and 6570 Series (formerly known collectively as the 6B6G) miniaturized tube sources are all based on the same basic source capsule. The 6510 Series sources, have an eyelet on one end of the capsule, while the 6570 Series sources have no eyelet. For the 6550 Series sources, the capsule is brazed to a wire, with the distal end consisting of a beveled handle with a screw-lock mechanism for sealing into Heyman after-loading capsules.

Fabrication of the basic capsule upon which capsule these miniaturized tube sources are based starts with cesium-137 chloride that has been absorbed into small ceramic particles. The isotope is permanently fixed to the ceramic particles using a heat treatment to create 3M Brand Radiating Microspheres. The microspheres are loaded into an inner stainless steel capsule. After loading the microspheres, a 0.028 in. (0.700 mm) stainless steel ball is pressed into each end of the tube and welded/brazed in place, sealing the microspheres inside.

The entire inner assembly is inserted into a stainless steel outer capsule. A plug is then inserted and brazed/welded in place. The entire source capsule is then nickel plated. The completed overall source assembly is 0.752 in. (19.10 mm) long and 0.065 in. (1.650 mm) in diameter, with an active length of 0.472 in. (12.00 mm).

When used in the 6550 Series Heyman source, this source capsule is brazed to a 0.035 in. (0.900 mm) diameter, stainless steel wire. The wire extends out 10.25 in. (260.4 mm) from the eyelet end of the source capsule. At the distal end, the wire is attached to a beveled handle with a screw-lock mechanism for sealing it into Heyman after-loading capsules.

DIAGRAM:

See Attachments 1 and 2

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

SEALED SOURCE TYPE: Tube Source

LABELING:

Each miniaturized source is engraved on its side with its nominal activity and serial number. In addition, the handles of the Heyman after-loading sources are engraved with their nominal activity and serial number.

As both types of sources decay below nominal activity, however, they fall into a "non-standard" activity category. The strengths of both the "standard" and "non-standard" sources are documented in the Calibration Certificate accompanying the sources at the time of distribution.

CONDITIONS OF NORMAL USE:

The sources are used for intracavitary treatment of cancer, which is accomplished by placing the radioactive source into a device, referred to as an applicator. Sources may be placed in the applicator either before (preloaded) or following (afterloaded) insertion of the applicator in the body cavity to be irradiated. The treatment is normally performed in a hospital room, so the environment is tightly controlled.

PROTOTYPE TESTING:

3M claims that since the design and construction of miniature tube and Heyman sources is identical to those of 3M Health Physics Services' Cs-137 needle sources (Models 6530 and 6540), the same prototype tests apply for both sets of sources. Two 6530 Series needle sources, loaded with approximately 5.0 mCi (185.0 MBq) of Cs-137, were subjected to each of the following prototype tests:

1. Temperature Test: Two 6530 Series sources were placed in a 1,558.4°F ± 36°F (848°C ± 20°C) oven and left there for 77 minutes. Upon removal from the oven, the sources were dropped into water at 57.2°F (14°C). Visual inspection of the sources after heating revealed no obvious structural defects. The wipe and leak tests were also negative. However, the soak test revealed more than 0.0005 μCi (18.50 Bq) or removable activity for both sources

SEALED SOURCE TYPE: Tube Source

PROTOTYPE TESTING: (Continued)

(0.0037 μCi (136.9 Bq) and 0.00063 μCi (23.31 Bq) for the two sources tested).

2. Impact Test: Two 6530 Series sources were dropped from a height of 29.53 feet (9.000 m) onto a flat, 0.500 in. (1.270 cm) thick steel plate. Visual inspection of the sources after the impact test revealed no obvious defects. The wipe, leak, and soak tests were all negative for these two sources.

3. Percussion Test: A 0.984 in. (2.500 cm) diameter steel bar weighing 3.198 lbs (1.451 kg) was dropped through a 1.378 in. (3.500 cm) inner diameter guiding sleeve onto each of the sources used in the Impact Test. The sources were lying horizontally on a 1.000 in. (2.540 cm) thick lead brick. One source was positioned so the center of the bar hit the source's center, and the other source was positioned so the edge of the bar hit the center of the source. Upon visual inspection after the percussion test, both sources tested were bent and crushed. No defects were observed in the latter source. The wipe, leak and soak tests were all negative for these two sources.

4. Bending Test: Each of the two sources was gripped over 1/3 of its length in a 4.000 in. (10.16 cm) vise, whose jaws were lined with a double layer of foam tape to protect the bend area on each source from the edge of the vise. A pair of needle-nose pliers, whose jaws were covered with surgical rubber tubing, was used to bend the source over a radius of about 0.118 in. (3.000 mm), 90° to the long axis of the source, then back straight. The wipe, leak, and soak tests were all negative for these two sources.

5. Tensile Strength Test: The two tested sources were clamped to a permanent fixture using a chuck. Then, a 24.47 lbs (11.10 kg) weight was hung from the eyelet end of each source and left there for one minute. The wipe, leak, and soak tests were all negative for these two sources.

SEALED SOURCE TYPE: Tube Source

PROTOTYPE TESTING: (Continued)

After each test, each source was wipe/smear tested, soak tested, and leak/bubble tested. The allowable limit for the wipe and soak tests was 0.0005 μCi (18.50 Bq) of removable activity. The soak test involved immersing the sources in 0.338 fl. oz. (10 ml) of distilled water at 122°F ± 18°F (50°C ± 10°C) for at least 16 hours. The leak test involved immersing the sources in glycerin at about 302°F (150°C) for at least 1 minute. The presence of any bubbles was an indication of failure of this test.

EXTERNAL RADIATION LEVELS:

The manufacturer calculated the following dose rates for typical sources.

	DOSE RATE AT		
Est. Output Activity mCi (MBq)	5 cm (1.97 in.) mR/hr (mSv/hr)	30 cm (11.8 in.) mR/hr (mSv/hr)	100 cm (39.4 in.) mR/hr (mSv/hr)
11.6 (429.2)	1,524 (15.24)	42.30 (0.423)	3.810 (0.038)
25.1 (928.7)	3,288 (32.88)	92.30 (0.923)	8.220 (0.082)
37.2 (1,376)	4,880 (48.80)	135.5 (1.355)	12.20 (0.122)
57.1 (2,113)	7,492 (74.92)	208.0 (2.080)	18.70 (0.187)
72.6 (2,686)	9,520 (95.20)	264.0 (2.640)	23.80 (0.238)
93.0 (3,441)	12,200 (122.0)	338.9 (3.389)	30.50 (0.305)

NOTE: The output activity allows for 1 percent attenuation through the stainless steel walls of the source.

QUALITY ASSURANCE AND CONTROL:

The following quality control procedures were followed during production of these sources:

1. Each inner capsule was leak tested after it was sealed. A negative leak test meant that no air leaks or holes were

SEALED SOURCE TYPE: Tube Source

QUALITY ASSURANCE AND CONTROL: (continued)

detected while the capsule was immersed in 248°F - 302°F (120°C - 150°C) glycerine for at least 10 seconds.

2. Each inner capsule was wipe tested after it was sealed. The allowable limit was 0.0002 μCi (7.400 Bq) of removable Cs-137.

3. After each inner capsule was sealed, it was soak tested in 6-7 ml of distilled water at 68°F (20°C) for 16 hours. The allowable limit was 0.0002 μCi (7.400 Bq) of detectable Cs-137.

4. Each source was wipe tested, after the outer capsule was sealed, as in test 2, above.

5. Each source was leak tested, after the outer capsule was sealed, as in test 1, above.

6. The outer capsules of 6510 Series and 6570 Series sources were assayed for radioactivity. The sources had to be between 2-20 percent above their nominal activity.

7. The outer housings of 6550 Series sources were soak tested for removable radioactivity. The maximum allowable limit was 0.0005 μCi (18.50 Bq) of removable Cs-137.

8. Each completed source was visually inspected to ensure it was nickel plated smoothly and completely with no discoloration, and to check for uniform smooth welds between the outer housing and plug.

9. Each completed source was assayed to ensure its activity was 0-15 percent above the nominal activity.

10. Prior to shipment, each source was visually inspected for proper plating and labeling, assayed for radioactivity as in test 9, above (if it was more than 3 months since the last assay), leak tested, and soak tested, with an allowable limit of 0.0005 μCi (18.50 Bq) of removable contamination. Any sources not meeting these final checks were rejected.

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

SEALED SOURCE TYPE: Tube Source

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

- These sources may be used only by persons specifically licensed by the NRC or an Agreement State.
- Handling, storage, use, transfer, and disposal: to be determined by the licensing authority.
- At the time of distribution of both "standard" and "non-standard" activity cesium-137 sources, a Calibration Certificate will accompany the shipment of each source which shows the actual measured output activity in millicuries of cesium-137 and the calculated milligram radium equivalent cesium-137 activity.
- These sources shall be leak tested at intervals not to exceed 6 months using techniques capable of detecting 0.005 microcurie (185.0 Bq) of removable contamination.
- REVIEWER NOTE: Please ensure the safety procedures outlined in 10 CFR Part 35 Subpart G are adhered to, especially as they pertain to the handling of the sources.
- This registration sheet and the information contained within the references shall not be changed without the written consent of the NRC.

SAFETY ANALYSIS SUMMARY:

The 6510 Series, 6570 Series, and 6550 Series (formerly 6B6G) sources are not current products manufactured or distributed by 3M Health Physics Services. However, 3M Health Physics Services will continue to receive 6510, 6570, and 6550 Series sources for disposal.

Based on our review of the 6510 Series, 6570 Series, and 6550 Series (formerly 6B6G) sources, and the information and test data cited below, we continue to conclude that these sources are acceptable for specific licensing purposes.

Furthermore, we continue to conclude that the 6510, 6570, and 6550 Series sources would be expected to maintain their containment integrity for normal conditions of use and accidental conditions which might occur during uses specified in this certificate.

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

SEALED SOURCE TYPE: Tube Source

REFERENCES:

The following supporting documents for the 6510 Series, 6570 Series, and 6550 Series (formerly 6B6G) sources are hereby incorporated by reference and are made a part of this registry document:

- 3M Health Physics Services' letters dated August 6, 1991, April 4, 1991, July 24, 1989, August 15, 1988, January 17, 1985, and application dated May 1, 1980, with enclosures thereto

ISSUING AGENCY:

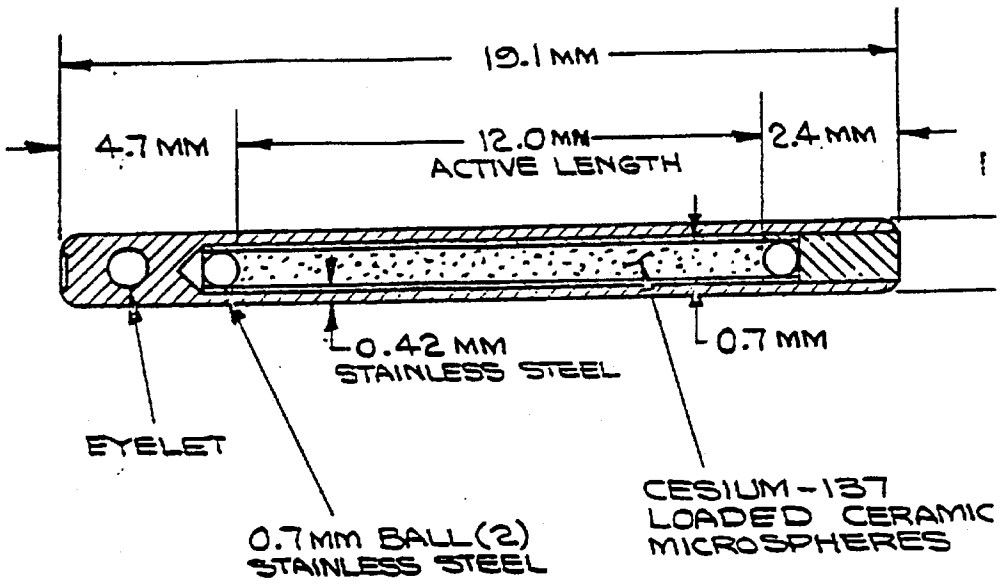
U.S. Nuclear Regulatory Commission

Date: February 16, 1996 Reviewer: Douglas A. Broaddus

Date: February 16, 1996 Concurrence: Steven L. Baggett

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

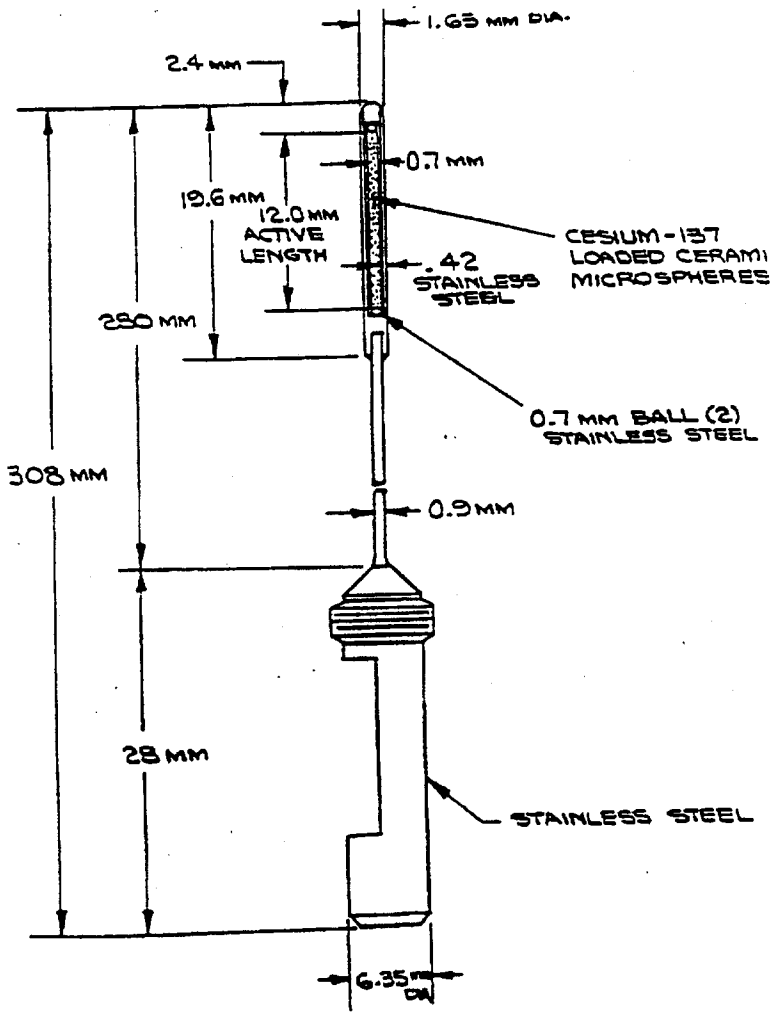
NO.: NR-460-S-928-S DATE: February 16, 1996 ATTACHMENT 1



Schematic Diagram of 3M Cesium-137 Miniaturized Tube Source

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

NO.: NR-460-S-928-S DATE: February 16, 1996 ATTACHMENT 2



Schematic Diagram of 3M Cesium-137 Heyman Afterloading Source

Nuclear Products 3M COMPANY
3M CENTER · ST. PAUL, MINNESOTA 55101

VETERINARY MEDICAL SURGERY
UNIVERSITY OF MISSOURI
Columbia, MO 65201

3M 211975
PO C-090768

RADIOACTIVE SOURCE CERTIFICATION

The following radioactive sources are certified by Minnesota Mining and Manufacturing Company to have been subjected to the tests described below and to have given the results listed.

Model Number	Serial Number	Nominal mg. Ra. Eq.	3M Assay* mg. Ra. Eq.	Nominal mCi Cs-137
6B6G-LD	Full-Strength	3.0	3.42	8.2
6B6G-LD	Full-Strength	3.0	3.43	8.2
6B6G-LD	Full-Strength	3.0	3.42	8.2
6B6G-LD	Full-Strength	3.0	3.42	8.2

Wipe test, each: $<0.0001\mu Ci$ removable activity
Soak test, each: $<0.0005\mu Ci$ removable activity
Leak test, each (immersion): Negative
3M Print Number A-1921-1081

*0.5mm Platinum Filtration
No other certification is to be implied.

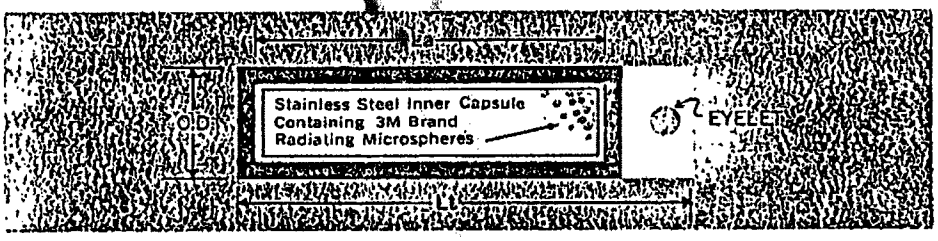
Q.C. Supervisor Kenneth M. Paddock Date 3 Sept. 1974

THE SOURCES

Medical sources containing Cs-137 tagged 3M microspheres are available in both needle and capsule configurations. Because of the long useful life of Cs-137 sources, these devices are permanently closed with a corrosion resistant, hermetic seal. They are calibrated in milligram equivalents of radium (0.5 mm Pt. Filtration). Decay correction tables are provided.

Source activities are within 10% of the stated nominal value. Furthermore, any source ordered with a group of similar sources will vary less than 10% from any other in that group. A certificate of calibration accompanies each shipment. Loadings other than those shown in the tables are available on request.

NICKEL PLATED STAINLESS STEEL CAPSULE (MODEL 6D6C)

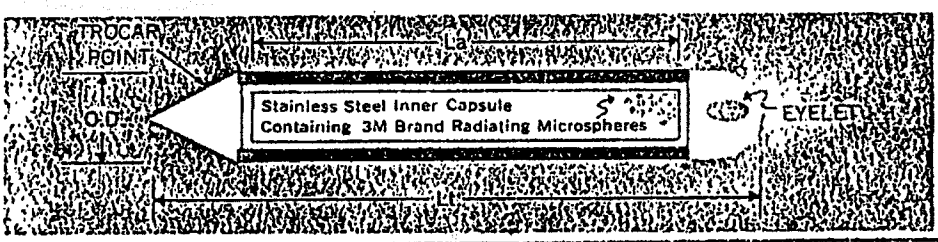


SIZE	TOTAL LENGTH (Lt)	ACTIVE LENGTH (La)	O.D.	MAXIMUM ACTIVITY (mg. Radium Equivalent) (0.5 mm Pt. Filtration)
CA	20 mm	14 mm	3.1 mm	40
CC	16 mm	10 mm	3.1 mm	25

Size CA fits the Ernst and most other cervical applicators; size CC is for applicators of shorter length. The loadings per capsule vary from 5 mg radium equivalent minimum to the maximum indicated in the Table.

The capsules are furnished with the activity (in mg Radium equivalents) and the serial number permanently engraved on the source housing. The certification form which accompanies each source is cross referenced to the serial number and contains other pertinent information (calibrated loading, date of manufacture, etc.) necessary in tracing and accounting for the source.

NICKEL PLATED STAINLESS STEEL NEEDLES WITH TROCAR POINTS (MODEL 6B6G)



SIZE	TOTAL LENGTH (Lt)	ACTIVE LENGTH (La)	NOMINAL ACTIVITY (mg. Radium Equivalent) (0.5 mm Pt. Filtration) FULL STRENGTH (0.66 mg Ra eq/cm)	HALF STRENGTH (0.33 mg Ra eq/cm)
LA	27 mm	15 mm	1.0	0.5
LB	34.5 mm	22.5 mm	1.5	0.75
LC	42 mm	30 mm	2.0	1.0
LD	57 mm	45 mm	3.0	1.5

These needles, designed for interstitial implantation, have an O.D. of 1.65 mm and a linear Cs-137 activity of about 2.0 mc/cm (full strength) and 1.0 mc/cm (half strength). The needles are loaded approximately 10% above nominal to permit a longer useful life. The half strength needles are identified by gold plating.

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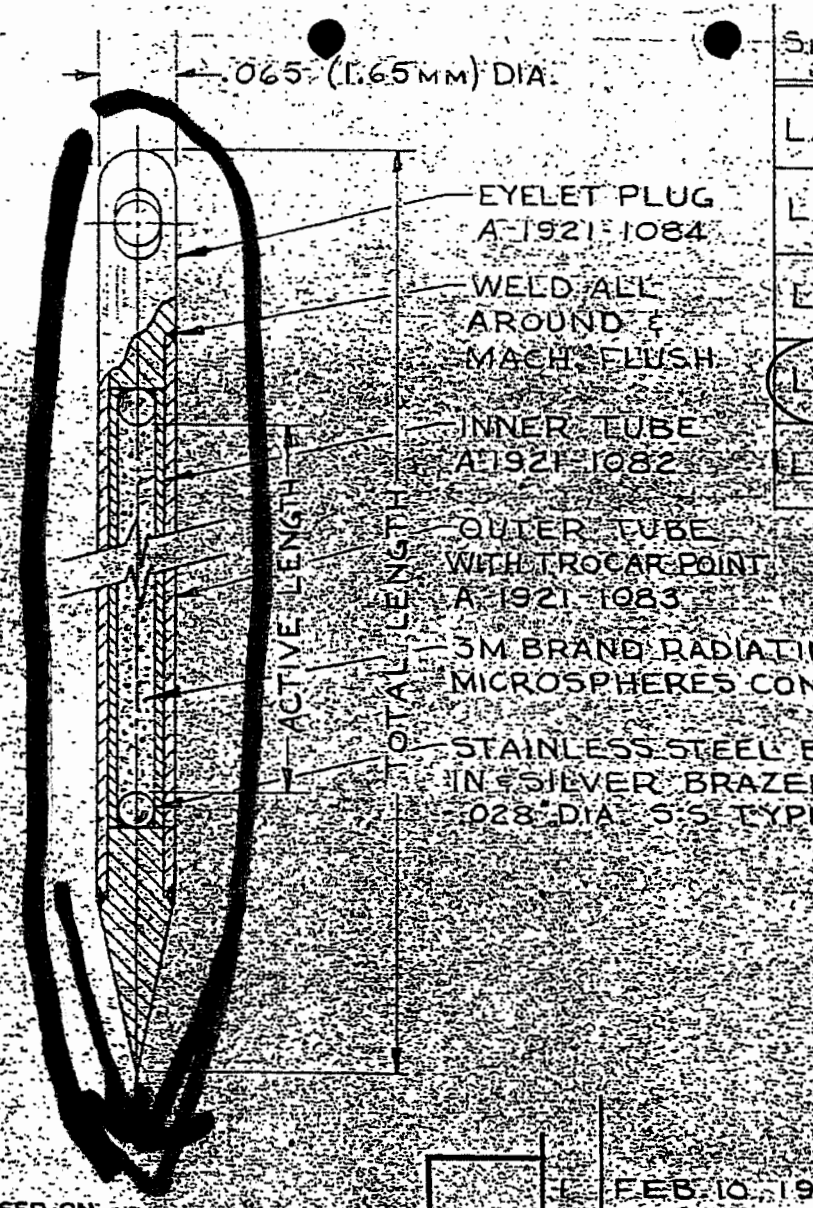

SIZE	ACTIVE LENGTH	TOTAL LENGTH
LA	.591 (15 MM)	1.06 (27 MM)
LB	.886 (22.5 MM)	1.36 (34.5 MM)
LC	1.182 (30 MM)	1.65 (42 MM)
LD	1.773 (45 MM)	2.24 (57 MM)
LH	.394 (10 MM)	.86 (22 MM)

4.3.47
CH.

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USED ON:

FEB. 10, 1971
REDRAWN FROM A-1921-386

ISSUE	ISSUE DATE AND CHANGE RECORD	REV.	CH.

TOLERANCES EXCEPT AS NOTED
MACHINED DIMENSIONS .00 ± .000 ±
ANGULAR DIM. ±
WELDMENT DIM. UNDER 30° ± 30° & OVER ±
± .

MAXIMUM SURFACE ROUGHNESS EXCEPT AS NOTED

SCALE 8" = 1"
DR. J. D. SWENSON
CH.
APP.

DIVISION NUCLEAR PRODUCTS PROJ.

TITLE
Cs-137 MEDICAL NEEDLE
3M MODEL NO. 6B6G

MINNESOTA MINING & MANUFACTURING CO.
ST. PAUL, MINNESOTA

A 1921-1081

RADIATION THERAPY DEPT.
NUCLEAR ASSOCIATES
Division of VICTOREEN, INC.
100 Voice Road • Carle Place, N.Y. 11514
(516) 741-6360

Sex
Gattinger

RT-16455-R
RT-82851-1-R

LEAK TEST and
CERTIFICATE OF CALIBRATION

#50251

ISSUED TO: UNIV. OF MISSOURI

Brachytherapy Interstitial Source

Active Length: 6.0 cm.

Model Number: 69-649-6

Mg ra-eq ^{137}Cs per cm: 0.66 **

Number of Sources 3 *

Color Code: Gold

Mean Activity: 15.67 ^{137}Cs mCi, equivalent to 6.13 mg radium on June 14, 1982

*Maximum-Minimum % Deviation From Mean: $^{+0.51}_{-0.77}$

The ^{137}Cs contains less than 1% ^{134}Cs and has a half-life of 30.0 years. Conversion performed by a Γ factor ratio of 2.557 (^{137}Cs RHM = 0.3226, radium RHM = 0.825 with 0.5 mm platinum filtration). Ref. National Council on Radiation Protection and Measurements (NCRP) #41, Pg. 8, Appendix A.

METHOD OF CALIBRATION

Calibrated by the measurement of the electrical current produced in a well-type 4π gamma ionization chamber. The response of the chamber to gamma radiation had been previously calibrated with standards traceable to the National Bureau of Standards. The accuracy of determination is ± 2% and the precision of determination is ± 1%. All determinations are at the 95% confidence level.

SEALED SOURCE TEST

Prototype sources have been successfully tested to (1) American National Standards Institute (ANSI) N44.1 - 1973; (2) U.S. Atomic Energy Commission 10 CFR Part 71 "Special Form"; (3) U.S. Department of Transportation 49 CFR Parts 100-199, 46 CFR, Part 146 and 14 CFR Part 103 "Special Form"; and (4) International Atomic Energy Agency (IAEA) Safety Series No. 6 "Special Form".

RADIOACTIVITY LEAKAGE/CONTAMINATION TEST

The source was tested for surface contamination and radioactive leakage immediately after manufacture and just prior to shipment, pursuant to ANSI N44.2 - 1973, Procedure A1.3, Immersion Test:

IMMERSION TEST

At time of shipment no source exceeds 222 DPM.
All determinations are at the 95% confidence level.

The source was determined to be free of leakage or contamination as specified by applicable regulations and specifications.

Nuclear Associates certifies that this sealed source has been manufactured in conformance with approved specifications and has been tested as described herein.

**See other side if certificate is for non-uniformly loaded source.

Non-Uniformly Loaded Source

Target mg ra-eq ^{137}Cs per cm

Eyelet end _____ _____ _____ _____ _____ _____

Date: June 18, 1982

For Nuclear Associates
RADIATION THERAPY DEPT.

By: Thomas Seminoff

Thomas Seminoff

4-282 69-64,-66