

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES

SAFETY EVALUATION OF SEALED SOURCE

NO. GA-0269-S-103-S

DATE: March 19, 2001

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SEALED SOURCE TYPE: Medical Teletherapy Source

DESCRIPTION:

The Elekta Models 43047 and 43685 are doubly encapsulated welded sealed sources. The inner and outer capsules are fabricated from 300-series stainless steel and have identical dimensions as detailed in Table 1, later in this section. The only differences between the two models are that (1) the models use different series of stainless steel, and (2) the shape of the bottom of the inner capsules and tubes have been modified to facilitate manufacturing improvements. When in use, the sealed source is retained in a source holder consisting of an aluminum bushing and a stainless steel threaded lid. The assembled source in its source holder is included as Attachment 1.

The active volume of the sealed source contains cobalt-60, normally in pellet form [nominally 1 mm (0.039 inch) in diameter with a length of 1 mm (0.039 inch)]. The sealed source may also contain cobalt-60 in the form of a powder or a solid rod.

Table 1 -- Component Dimensions

| Attribute | Nominal Dimension | |
|---------------------------------------|-------------------|--------|
| | (inches) | (mm) |
| Inner capsule outer diameter | 0.1965 | 4.991 |
| Inner capsule bore diameter | 0.0465 | 1.181 |
| Inner capsule length | 0.945 | 24.0 |
| Inner capsule min. material thickness | | |
| At weld | 0.016 | 0.42 |
| Outer capsule outer diameter | 0.3146 | 7.991 |
| Outer capsule bore diameter | 0.1975 | 5.016 |
| Outer capsule length | 1.07 | 27.2 |
| Outer capsule min. material thickness | | |
| At end cap | 0.018 | 0.4575 |
| Body, at counterbore of cap | 0.019 | 0.496 |
| At weld | 0.016 | 0.42 |

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LABELING:

The sources are engraved with a unique serial number on the upper end cap face and on the main body. The bushing into which the source is loaded is engraved with the same serial number. As this is a medical teletherapy source, additional labeling is not required.

The sealed source is shipped with documentation identifying the source model number and serial number, nuclide, ISO/ANSI classification, special form certificate number, assay date, activity, and leak test certification.

DIAGRAMS:

Attachment 1 -- Assembled source capsule and source holder (bushing)

CONDITIONS OF NORMAL USE:

The Elekta Models 43047 and 43685 are to be used in medical teletherapy devices. An example of a teletherapy device into which these sources is loaded is the Elekta Leksell Gamma System Model 23004 Type B/B-2 and Model 24001 Type C (refer to GA-269-D-102-S).

PROTOTYPE TESTING:

Prototypes of the sources have been tested in accordance with ANSI N542/ISO 2919 and have achieved a classification of C64534, which exceeds the requirement of C53524. The following list indicates the standards to which the sealed sources were tested:

- Temperature.....-40°C (-40°F) for 60 minutes; 800°C (1472°F) for 1 hour
- Thermal shock.....800°C to 20°C (1472°F to 68°F)
- External Pressure25 kPa absolute (3.625 psia) to 7 MPa absolute (1015 psia)
- Impact5 kg (11 lb) from 1 meter
- Vibration25 to 50 Hz at 5 g peak amp for 30 minutes, and 50 to 90 Hz at 0.635 mm peak-to-peak amp, and 90 to 500 Hz at 10 g
- Puncture 50 grams (10.6 oz) from 1 meter

Sealed sources were leak tested following each test using the Helium and Vacuum Bubble tests as described in ANSI N542, handbook 126.

Both sealed source designs meet the requirements for Special Form Radioactive Material.

The Model 43047 source design is similar to the source registered as CA-0312-S-106-S. That source has been in use for more than 10 years, with approximately 30,000 sources distributed without reported complaints or defects.

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EXTERNAL RADIATION LEVELS:

A calculation of dose rates was carried out using a gamma radiation constant of 1.32 R/hr (13.2 mSv/hr) per Curie at 1 meter. A source containing 36 Ci (1332 GBq) would expect to yield the following dose rates:

| Distance from Source | Radiation Level | |
|----------------------|-----------------|---------|
| | R/hr | mSv/hr |
| 5 cm (1.97 inch) | 19,000 | 190,000 |
| 30 cm (11.8 inch) | 530 | 5,300 |
| 100 cm (39.4 inch) | 48 | 480 |

QUALITY ASSURANCE AND CONTROL:

The manufacturer maintains a quality assurance and control program that includes the following items:

- Use of materials suppliers with documented quality programs
- Receipt inspection of individual components
- In-process inspection at identified steps
- Assembly and welding in accordance with controlled and validated manufacturing procedures
- Inspection and leak testing of completed sources

All components can be traced with a unique batch number. Bushings and completed source capsules have matching serial numbers.

The distributor arranges for the 100% inspection of all critical dimensions for the sealed source components. Visual inspection is completed on manufactured components. Documentation is reviewed for conformance with specified inspection protocols and materials certificates are reviewed for conformance with drawing requirements.

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SEALED SOURCE TYPE: Medical Teletherapy Source

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

- Sealed sources shall be distributed to persons specifically licensed by the State of Georgia, the NRC, or an Agreement State.
- The source shall not be exposed to environmental conditions that exceed the limits of its ANSI classification, ANSI C64534.
- Sealed sources shall be leak tested 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: To be determined by the licensing authority. In view that the sealed sources used in these devices exhibit high dose rates, the sources shall be handled by experienced licensed personnel using adequate remote handling equipment and procedures.
- This registration sheet and the information contained within the references shall not be changed without the written consent of the Georgia Department of Natural Resources, Radioactive Materials Program.

SAFETY ANALYSIS SUMMARY:

The Model 43047 and 43685 sealed sources have been tested in accordance with accepted standards for the classification of radioactive sealed sources. Test conditions were selected which correspond to the designed conditions of use and foreseeable accident conditions. Prototype sources which were subjected to the test conditions maintained their integrity. Additionally, the design of these sealed sources is similar to another source that has been in use for over 10 years without any reported failures or complaints.

Based on the review of the Model 43047 and 43685 sealed sources, and the information and test data cited below, we conclude that these sealed sources are acceptable for licensing purposes. Furthermore, we conclude that the sealed sources would be expected to maintain containment integrity for normal conditions of use and accidental conditions that might occur during uses specified in this certificate.

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REFERENCES:

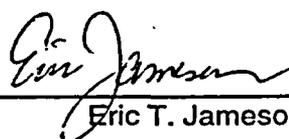
The following supporting documents for the Model 43047 and 43685 sealed sources are hereby incorporated by reference and are made a part of this registry document.

- Elekta's application for sealed source evaluation, with enclosures, dated February 23, 2000, signed by Paul Sumner, Director of Regulatory Affairs and Quality Assurance.
- Elekta's letters with enclosures dated November 3, 2000, and December 6, 2000, signed by Paul Sumner, Director of Regulatory Affairs and Quality Assurance.

ISSUING AGENCY: Georgia Department of Natural Resources
Radioactive Materials Program

This document is not a license to receive, possess or distribute radioactive material. Receipt, possession and distribution of radioactive material, sources and devices containing radioactive material, are subject to the terms and conditions of applicable regulations and licenses issued by NRC or Agreement States.

Date: March 19, 2001

Reviewer: 
Eric T. Jameson

Date: March 20, 2001

Concurrence: 
Rodríguez E. Harrell

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Attachment 1

Assembled Source Capsule and Source Holder (Bushing)

