REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

No.: CA-1080-D-103-S DATE: May 18, 2004

(Supercedes NR-0220-D-122-S)

DEVICE TYPE: Brachytherapy HDR Remote Afterloader

MODEL: **GammaMed (and plus and plus 3/24), MammoSource**

DISTRIBUTOR:

Varian Medical Systems, Inc.
3100 Hansen Way
Palo Alto, CA 94304

MANUFACTURER:

Varian Medical Systems Haan, GmbH
Bergische Strasse 16
D-42781 Haan
Germany

SEALED SOURCE
MODEL DESINATION: GammaMed 232

ISOTOPE:

Iridium-192

MAXIMUM ACTIVITY:

15 Curies (555 GBq)+/- 5%

LEAK TEST FREQUENCY: 6 Months

PRINCIPAL USE: (V) General Medical Use

CUSTOM DEVICE: YES ___ No __X__

Digitally signed by Chicu Natalia
Date: 2022.01.25 15:46:51 EET
Reason: MoldSign Signature
Location: Moldova

DEVICE TYPE: Brachytherapy HDR Remote Afterloader

DESCRIPTION:

The intended use of the GammaMed plus and the GammaMed plus 3/24, **GammaMed, and MammoSource** Brachytherapy High Dose Rate (HDR) Remote Afterloaders is to remotely control a radioactive sealed source for the purpose of safely delivering a dose of gamma radiation to a medical patient undergoing radiation therapy for the treatment of cancer.

The GammaMed **Afterloader series** is equipped with **1 to** 24 access channels through which a source assembly can be sequentially manipulated to a series of preset incremental positions for specified treatment dwell times. **The GammaMed Afterloader series, of which the GammaMed plus 3/24 is an example, are all based on the GammaMed plus High Dose Rate (HDR) Remote Afterloader (RAL) with 24 channels. The variable system of the GammaMed Afterloader allows different configurations in number of channels while functionally remaining identical to the GammaMed plus, except the MammoSource is limited to the use of one channel. All versions of the GammaMed afterloaders** can be upgraded to the **full** GammaMed plus by replacing the EPROM firmware, indexer plate, and the device labels. Since **all GammaMed Afterloaders are** functionally identical to the GammaMed plus, they are referred to as the GammaMed RAL in this document, unless otherwise noted.

The GammaMed RAL is 1050 mm high, 510 mm wide, and 585 mm deep. The total mass of the unit is 286 pounds (130 kg). The device houses a radioactive iridium-192 sealed source assembly, which is stored in a shielded container when not in use. The GammaMed RAL controls the handling and source assembly movement using drive motors, an indexer with position encoders, electronic control circuit boards, a battery pack, and a power supply. The GammaMed source assembly can be moved from the shielded position within the RAL device through one or more guide tubes attached to applicators that have been previously inserted into or placed onto the patient.

DEVICE TYPE: Brachytherapy HDR Remote Afterloader

DESCRIPTION (Cont'd):

The GammaMed RAL can utilize flexible and rigid applicators for a wide variety of brachytherapy techniques. The applicators to be employed in a particular treatment are connected to the RAL indexer by a Source Guide Tube (SGT). The SGT attaches to the RAL by means of a special quick connector to ensure proper connection. The source assemblies can only be transferred through a treatment channel if the SGT is properly attached to an encoded indexer channel.

The GammaMed RAL contains a dummy assembly and has construction similar to the source assembly, except the dummy assembly does not contain radioactive iridium. The dummy assembly is used to test the functional conditions for movement and positioning along the extended travel path before performing an actual planned treatment. Improper connections or positioning of the SGT, and/or applicators, identified by the dummy assembly will cause a system malfunction error, preventing source assembly movement until the malfunction condition has been resolved.

The source assembly is secured in the proper-shielded storage position by means of the friction drive wheel. Additionally, source movement is precluded by means of a fixed end stop in the retract direction and a storage plug inserted through an applicator channel in the expose direction. In the event of a failure of the powered drive assembly, the GammaMed RAL is equipped with an emergency retraction system to automatically retract the source assembly back to its shielded position and permit the manual hand retraction of the source assembly. The emergency hand crank can only rotate in one direction and only allows retraction of the source assembly. It is not possible to extension the source assemblies by using the emergency retraction hand crank.

DEVICE TYPE: Brachytherapy HDR Remote Afterloader

DESCRIPTION (Cont'd):

The GammaMed RAL is designed to be loaded onto a trolley for relocating of the source and device to another licensed facility. The trolley consists of a rectangular chassis with four large casters for easy movement. It has a manually operated brake that prevents the RAL unit from moving out of position during transport. The GammaMed RAL computer control console is built into the trolley table.

The GammaMed RAL is designed to minimize the entry of foreign materials such as dirt or liquids. The device can be readily and safely cleaned. Temperatures normally encountered in a medical treatment facility will have no adverse effect on the device. The materials in close proximity to the source will not be adversely affected by the gamma radiation.

The GammaMed RAL provides for an electrical connection to a treatment room door interlock system to ensure that the source assembly cannot be extended from the RAL shielding container when the treatment room door is open and that the source assembly would retracted back to the shielded position if the door were opened when the source is exposed. The door interlock system is not part of the GammaMed RAL device.

A key-operated switch prevents unauthorized operation of the GammaMed RAL. Before any radiation treatment can be initiated, the GammaMed RAL conducts an automatic diagnostic self-test of all components related to safe operation. The diagnostic program checks the limit sensor status, battery backup capacity, electronic controls, internal clock, and component connections. Safety lamps illuminate when the GammaMed RAL is ready to operate, indicating the external power is on, the battery is ready, the source is retracted and parked, the operating mode is normal and ready for use.

DEVICE TYPE: Brachytherapy HDR Remote Afterloader

DESCRIPTION (Cont'd):

The GammaMed RAL is designed such that source assembly cannot be moved from the shielded position until all the necessary SGTs are properly connected. Once the treatment exposure sequence has been initiated, the indexer checks and verifies that each SGT for the planned treatment is properly connected to each exit port by means of a proximity switch. If the proximity switch determines a SGT is not properly connected, an error message indicating, "No probe connected to channel XX" is displayed on the console computer. The exposure sequence program cannot be continued until the SGT for the faulted channel is properly connected and the start sequence is reinitiated. If the proximity switch senses a SGT has become improperly connected during operation, the source assembly will be retracted and the error message "No probe connected to channel XX " will appear.

To ensure that the correct SGT and applicators are properly connected and positioned, prior to exposure of the source assembly, the dummy assembly will be extended to the most distal treatment position, and then will attempt to advance 10 mm further. If the dummy assembly does not sense the closed end of the applicator, the exposure start sequence will be aborted. If the dummy assembly senses the end of the applicator, the dummy assembly will then retract and permit the source exposure sequence to begin.

Positioning of the source and dummy assemblies is based on the fact that the total length for all assemblies is a standard distance of 2100 mm. Assembly movement is controlled by means of an incremental position encoder and optical limit switches. If the limit switches determine that the source is not within 1 mm of the expected assembly travel length (1300 mm), an emergency abort is initiated and an error message is generated at the control console. Prior to treatment, the travel length of the dummy and source assemblies is verified for each selected channel. Once the travel length of the source assembly has been verified, the distal end of the applicator is used as the reference point for source positioning.

DESCRIPTION (Cont'd):

The incremental position encoder is microprocessor controlled and the measurement of source travel distance is controlled with an accuracy of ±1 mm. Source position can be incrementally changed in steps from 1 to 10 mm. The source can be stopped at 60 stopping points in each channel. The dwell time for each stopping point can be up to 9999 seconds. Although the source must reach the end of the applicator in order to begin the exposure sequence, it is not necessary that the exposure sequence begin at that point. The first dwell point can be selected up to 400 mm from the distal end of the SGT. The source must reach the final treatment destination in 10 seconds. If this does not occur, an error code will be indicated, and the source will automatically retract into the shield.

A battery backup assures that the iridium-192 source can be retracted back into its shielding in the event of a power failure. In addition, the exposure sequence cannot be started until main power is present and the capacity of the battery voltage is sufficient to assure that the source can be retracted.

The control system constantly tests the battery capacity before and during the treatment. If the computer or the main electronic controls fail, the battery backup comes into operation and retracts the iridium-192 source into it's shielding.

If any of the above ongoing tests indicates a malfunction, treatment is immediately discontinued. It is also possible to manually discontinue treatment at any time by depressing the INTERRUPT button. Pressing the EMERGENCY button or opening the door into the treatment area will also terminate the procedure and cause the source to be retracted. When pressing the EMERGENCY button, the source retracts within less than five seconds from the distal point to the shield.

DEVICE TYPE: Brachytherapy HDR Remote Afterloader

DESCRIPTION (Cont'd):

The treatment parameters, up to the instant of interruption, and the cause of the interruption are stored in the internal RAM and can be retrieved once the equipment is turned on. In case of a power failure (failure of both main power and battery back-up), the operator can retract the iridium-192 source back into its shielding with a manually operated one-way emergency crank. Since the crank is designed to operate in only one direction, it cannot be employed to advance the iridium-192 source.

An illuminated panel on the control console contains a RADIATION warning light, which indicates source "on" or "off" positions. This panel is clearly visible from the operator's position. An independent Geiger-Muller detector located in the remote afterloader activates the RADIATION warning light. The built-in radiation detection system utilizes a preset alarm threshold. If the radiation intensity at the detector exceeds approximately 300 mrem/hr (3 mSv/hr), the RADIATION lamp on the control panel will illuminate. The RADIATION lamp also illuminates when the GammaMed source leaves the shielded position.

When the RETRACT SOURCE command is initiated by an INTERRUPT or by an EMERGENCY at the control panel during normal operation (a situation sensed by the GammaMed by way of incremental monitoring and limit-switch controls), the controls determine whether the radiation detected by the counter has diminished within 2 seconds. If not, the RADIATION lamp remains illuminated and an error message including emergency procedures will be displayed and an audible alarm activated. In this situation, either the source is still outside the shielded container or some other source is generating a radiation field in the vicinity of the device.

The iridium-192 source can be changed semi-automatically in a special operating mode from the control console reducing the risk of radiation exposure to the operator. Access to this mode is secured with a key switch. Source-specific data in the software can be changed only in this mode.

LABELING:

DEVICE TYPE: Brachytherapy HDR Remote Afterloader

10 CFR §32.74(a)(3) requires a label be affixed to the source or device, or to the permanent storage container for the source or device, contains information on the radionuclide, quantity and date of assay, and a statement that the U.S. Nuclear Regulatory Commission has approved distribution of the (name of source or device) to persons licensed to use byproduct material identified in §35.57, 35.400, 35.500, and 35.600 as appropriate, and to persons who hold an equivalent license issued by an Agreement State.

10 CFR §32.74(a)(2)(viii) requires instructions for handling and storing the source or device from the radiation safety standpoint; these instructions are to be included on a durable label attached to the source or device or attached to a permanent storage container for the source or device.

10 CFR §20.1904 (a) requires that each container of licensed material bears a durable, clearly visible label bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL." The label must also provide sufficient information (such as the radionuclide(s) present, an estimate of the quantity of radioactivity, the date for which the activity is estimated, radiation levels, kinds of materials, and mass enrichment) to permit individuals handling or using the containers, or working in the vicinity of the containers, to take precautions to avoid or minimize exposures.

Each GammaMed source assembly is shipped with a metal identification plate label enclosed for labeling the device. The label contains a radiation caution symbol, the words "Caution, Radioactive Material", the name of the manufacturer, the model number, the serial number, the radionuclide and the capacity of the device container.

DEVICE TYPE: Brachytherapy HDR Remote Afterloader

DIAGRAMS:

Attachment 1: GammaMed RAL Exterior Front & Side View
Attachment 2: GammaMed RAL Exterior Front & Side View
Attachment 3: GammaMed RAL Cross Sectional Side View
Attachment 4: GammaMed RAL Indexer
Attachment 5: GammaMed RAL Shield Container
Attachment 6: GammaMed RAL Emergency Manual Drive
Attachment 7: GammaMed RAL Source Assembly Drive
Attachment 8: GammaMed RAL Dummy Assembly Drive
Attachment 9: GammaMed RAL Drive Diagram
Attachment 10: SGT / Applicator Connections
Attachment 11: Device Type A Package Label

CONDITIONS OF NORMAL USE:

The GammaMed RAL is designed to be used in conditions typically associated with hospitals and radiation oncology facilities. Additionally, the GammaMed RAL is a mobile medical device designed to be transported between multiple facility locations with an installed radioactive source. Prior to use after relocation, the GammaMed RAL operability must be verified by checking the following:

(1) Electrical interlocks on treatment area access points;

(2) Source exposure indicator lights on the RAL unit and control console;

(3) Viewing and intercom systems;

(4) Applicators, source transfer tubes, and transfer tube-applicator interfaces;

(5) Radiation monitors used to indicate room exposures;

(6) Source positioning (accuracy); and

(7) Radiation monitors used to indicate whether the source has returned to a safe shielded position.

DEVICE TYPE: Brachytherapy HDR Remote Afterloader

CONDITIONS OF NORMAL USE (Cont'd):

Before the first medical use of the GammaMed RAL, or following replacement of the source, reinstallation of the unit in a new location outside the facility, or any repair of the unit that includes removal of the source or major repair of the components associated with the source exposure assembly, full calibration measurements shall be performed, as applicable, for determination of:

(1) The output within ± 5 percent;

(2) Source positioning accuracy to within ±1 millimeter;

(3) Source retraction with backup battery upon power failure;

(4) Length of the source transfer tubes;

(5) Timer accuracy and linearity over the typical range of use;

(6) Length of the applicators; and

(7) Function of the source transfer tubes, applicators, and transfer tube-applicator interfaces.

Although the GammaMed RAL is designed to be a highly reliable device with built in safety features, it is possible that a source assembly can become lodged in the unshielded position by failing to automatically, or manually, retract to the shielded storage position. Authorized users are required to have applicable emergency response equipment available near each treatment room to respond to an unretractable exposed source. Users must maintain written emergency procedures for responding to an abnormal situation when the operator is unable to place the source in the shielded position, or remove the patient from the radiation field with controls from outside the treatment room.

DEVICE TYPE: Brachytherapy HDR Remote Afterloader

CONDITIONS OF NORMAL USE (Cont'd):

Emergency procedures must include instructions for responding to equipment failures, the names of the individuals responsible for implementing corrective actions, the process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure, the names and telephone numbers of the authorized users, the authorized medical physicist, and the Radiation Safety Officer (RSO). **The useful working life of the GammaMed RAL is 20 years.**

PROTOTYPE TESTING:

The GammaMed RAL unit was subjected to the standards and tests described in International Electrotechnical Commission: IEC 601-2-17, Medical Equipment, Part 2, Particular Requirements for the Safety of Remote Controlled Automatically Driven Gamma Ray Afterloading Equipment. Test Report No. 3336/97 independently conducted by RWTUV validates that the GammaMed RAL complies with applicable IEC 601-2-17 standards.

The GammaMed RAL unit was subjected to tests as described in 49 CFR 173.465 for a Type A package and complies with U.S. DOT-7A specifications. Normal transportation or accident conditions would have no adverse affects on the GammaMed RAL device containing the radioactive source while in transit.

DEVICE TYPE: Brachytherapy HDR Remote Afterloader

EXTERNAL RADIATION LEVELS:

Test results for radiation leakage measured from a GammaMed RAL device indicated for a maximum activity installed source (15 Curies or 555 GBq) that the GammaMed RAL complies with IEC and NRC standards for maximum dose rates for use in a restricted area. The following table summarizes the GammaMed RAL radiation leakage test results.

	Surface	5 cm	30 cm	100 cm
Top	2.1 mrem/hr (21 µSv/hr)	1.1 mrem/hr (11 µSv/hr)	0.2 mrem/hr (2 µSv/hr)	0.1 mrem/hr (1 µSv/hr)
Right	1.1 mrem/hr (11 µSv/hr)	0.7 mrem/hr (7 µSv/hr)	0.2 mrem/hr (2 µSv/hr)	0.1 mrem/hr (1 µSv/hr)
Front	2.4 mrem/hr (24 µSv/hr)	1.4 mrem/hr (14 µSv/hr)	0.9 mrem/hr (9 µSv/hr)	0.3 mrem/hr (3 µSv/hr)
Left	1.1 mrem/hr (21 µSv/hr)	0.7 mrem/hr (7 µSv/hr)	0.4 mrem/hr (4 µSv/hr)	0.1 mrem/hr (1 µSv/hr)
Rear	1.1 mrem/hr (11 µSv/hr)	1.8 mrem/hr (18 µSv/hr)	1.0 mrem/hr (10 µSv/hr)	0.2 mrem/hr (2 µSv/hr)
Bottom	1.3 mrem/hr (13 Sv/hr)	0.7 mrem/hr (7 µSv/hr)	0.2 mrem/hr (2 µSv/hr)	0.1 mrem/hr (1 µSv/hr)

QUALITY ASSURANCE AND CONTROL:

Varian Medical Systems Haan GmbH is certified by TUV CERT of RWTUV Systems GmbH as operating a Quality Management System compliant with International Organization for Standardization (ISO) 9001 and ISO 46001 (Certificate Registration No. 041056328). The GammaMed RAL has been assigned a CE Mark number 0044 under the European Union Medical Device Directive (Certificate Reg. No. 04 207-1865/02).

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

DEVICE TYPE: Brachytherapy HDR Remote Afterloader

QUALITY ASSURANCE AND CONTROL (Cont'd):

Prior to distribution and upon delivery, the GammaMed RAL undergoes a quality system inspection and testing for the following:

- General Inspection of the device for completeness and shipping damage.
- Inspection of the indexer, drive mechanisms, electronics, brake mechanism, and computer and associated hardware for proper installation and operation.
- Installation and test of the GammaWin software program and verification that the program detects faults and that all safety features of the program are performed correctly.
- Inspection of the source guide tubes and applicators for proper length and condition.
- Test of the source exchange function and test of normal operation.

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

1. The GammaMed RAL shall only be distributed to persons specifically licensed by the USNRC, or a USNRC Agreement State.
2. Only GammaMed 232 source assemblies, or sources assemblies with an approved Sealed Source & Device Registry for use with the GammaMed RAL, shall be installed.
3. Only persons specifically licensed by the USNRC, or a USNRC Agreement State, to maintain, adjust, or repair the GammaMed RAL shall perform work activities that involves the source shielding, the source driving unit, or other electronic or mechanical components that could expose the source, reduce the shielding around the source, or compromise the radiation safety of the unit or the source.

DEVICE TYPE: Brachytherapy HDR Remote Afterloader

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

4. Only persons specifically licensed by the USNRC, or a USNRC Agreement State, shall install, replace, relocate, or remove a sealed source or a source contained in a remote afterloader unit.

5. The GammaMed RAL shall only be used by specifically licensed authorized users in shielded radiation therapy treatment rooms designed with interlocked doors, viewing and intercom systems to permit continuous observation of the patient from the console, and an electrically interlocked system that will:

   - Prevent the operator from initiating the treatment cycle unless each treatment room entrance door is closed;
   - Cause the source to be shielded when an entrance door is opened; and
   - Prevent the source from being exposed following an interlock interruption until all treatment room entrance doors are closed and the source on-off control is reset at the console.

6. Prior to use after relocation proper operation of the remote afterloader, operability of the GammaMed RAL must be verified by conducting a simulated cycle of treatment. If the results of the operability checks indicate a malfunction of any system, the control console should be locked in the off position and the unit not used except as may be necessary to repair, replace, or check the malfunctioning system.

DEVICE TYPE: Brachytherapy HDR Remote Afterloader

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

7. GammaMed sources are not to be removed from the GammaMed remote afterloader shielded container for purposes other than:

   - Patient treatment procedures; or
   - Emergency source recovery procedures; or
   - Source calibration and quality assurance procedures; or
   - Source exchanges and service maintenance procedures.

8. Emergency response equipment shall be available near each treatment room to respond to a source remaining in the unshielded position or lodged within the patient following completion of the treatment. A copy of the emergency procedures shall be physically located at the unit console.

9. Training instruction on GammaMed operating and emergency procedures shall be provided initially, and at least annually, to all individuals who operate the unit, and as appropriate to the individual's with assigned duties involving emergency response. GammaMed licensees are required to ensure that operators, authorized medical physicists, and authorized users participate in drills of the emergency procedures, initially and at least annually.

10. Before releasing a patient treated with a remote afterloader unit, a survey with a portable radiation detection survey instrument shall be performed to confirm that the source has been removed from the patient and returned to the shielded position within the GammaMed RAL. The GammaMed RAL built-in radiation monitor is a redundant safety feature and is not deemed to meet the requirement for an independent room monitor or portable survey meter.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

(Supercedes NR-0220-D-122-S)

DEVICE TYPE: Brachytherapy HDR Remote Afterloader

SAFETY ANALYSIS SUMMARY:

Based on our review of the information and test data cited below, we conclude that GammaMed plus and GammaMed plus 3/24 model remote afterloader are acceptable for licensing purposes.

REFERENCES:

The following documents for Model GammaMed plus and GammaMed plus 3/24 remote afterloaders are hereby incorporated by reference and made a part of this registry document:

- Varian Medical Systems, Inc. letter dated November 7th, 2002, with enclosures thereto.
- Varian Medical Systems, Inc. letter dated May 28, 2003, with enclosures thereto.
- **Varian Medical Systems, Inc. letter dated October 17, 2003 and electronic mail of March 24, 2004 with enclosures thereto.**

ISSUING AGENCY: California Department of Health Services

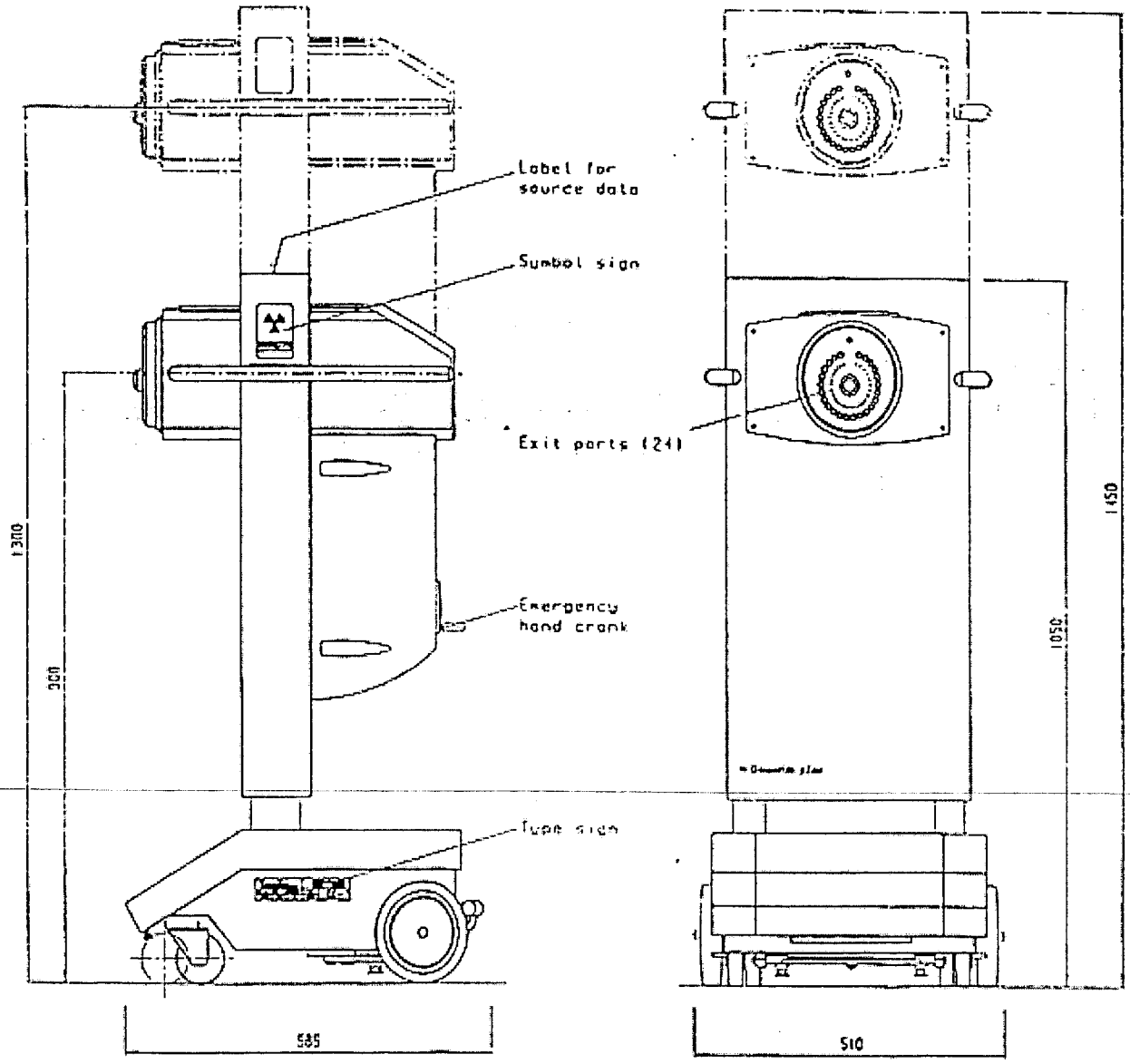
Date: 5/18/04 Reviewer: John G. Fassell
John G. Fassell, C.H.P.

Date: 5/18/04 Concurrence: Frieda Taylor
Frieda Taylor

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

No.: CA-1080-D-103-S DATE: May 18, 2004 Attachment 1

(Supercedes NR-0220-D-122-S)

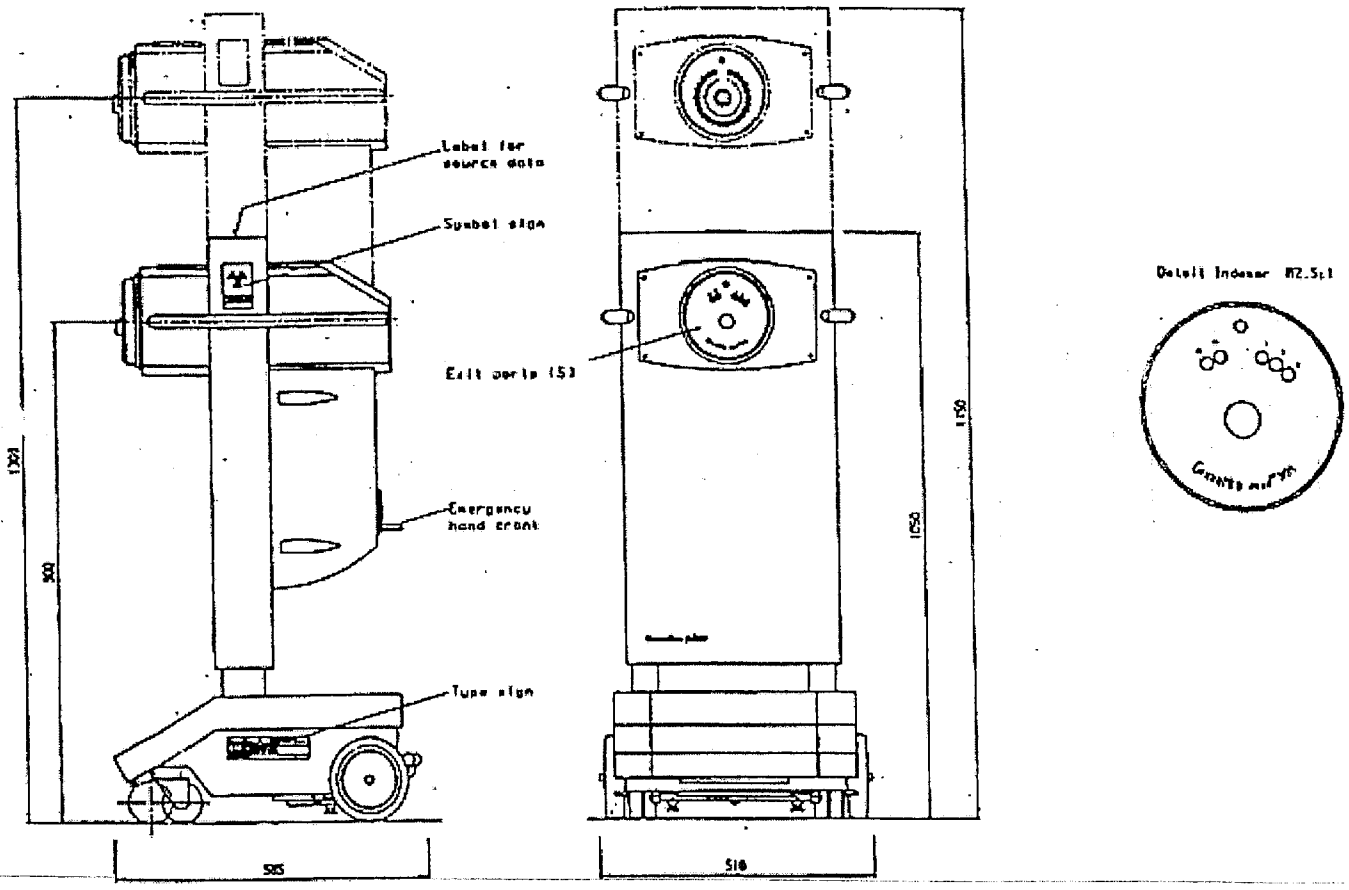


GammaMed RAL Exterior Front & Side View (dimensions in mm)

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

No.: CA-1080-D-103-S DATE: May 18, 2004 Attachment 2

(Supercedes NR-0220-D-122-S)

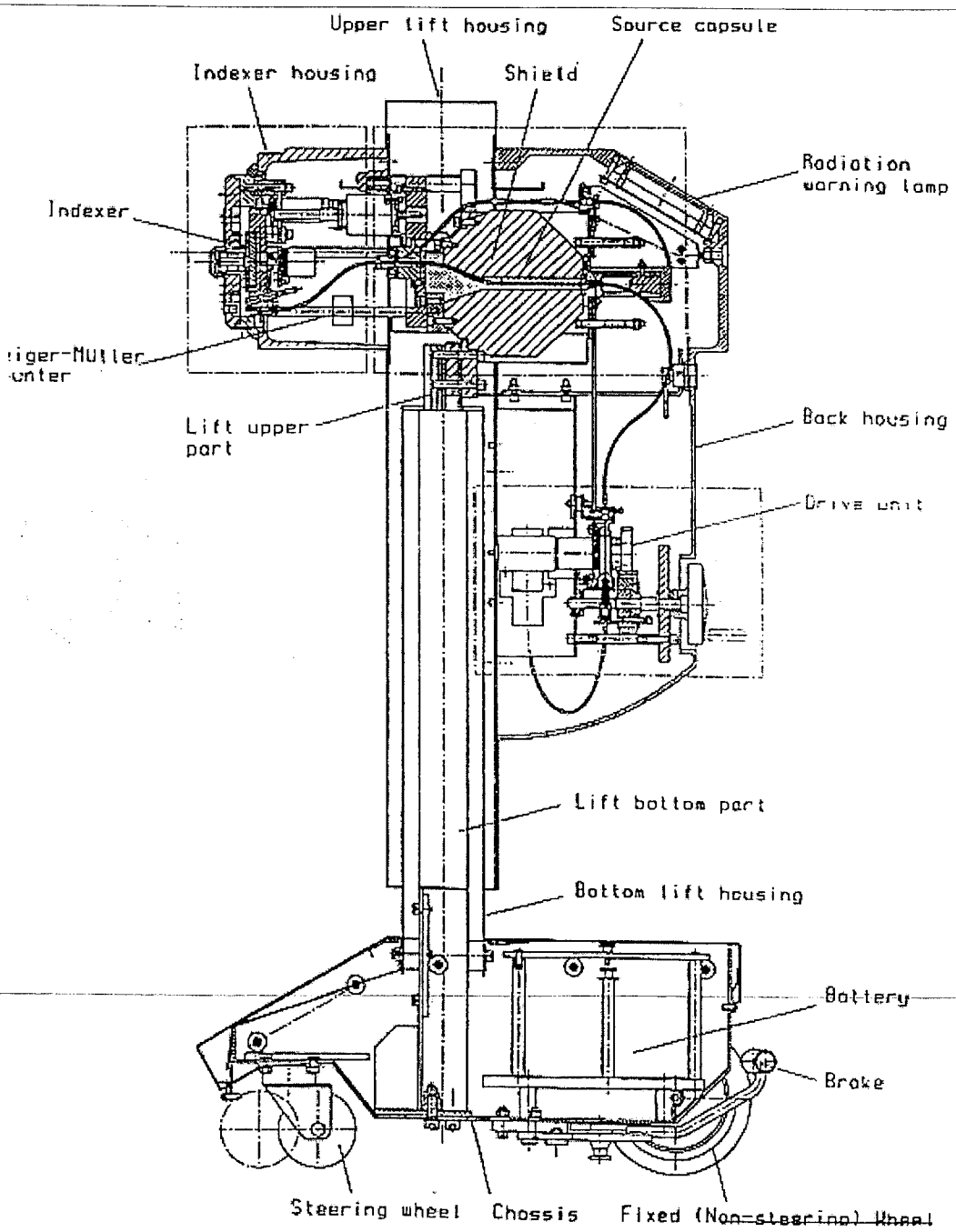


GammaMed RAL Exterior Front & Side View (dimensions in mm)

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

No.: CA-1080-D-103-S DATE: May 18, 2004 Attachment 3

(Supercedes NR-0220-D-122-S)



GammaMed RAL Cross Sectional Side View (dimensions in mm)

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
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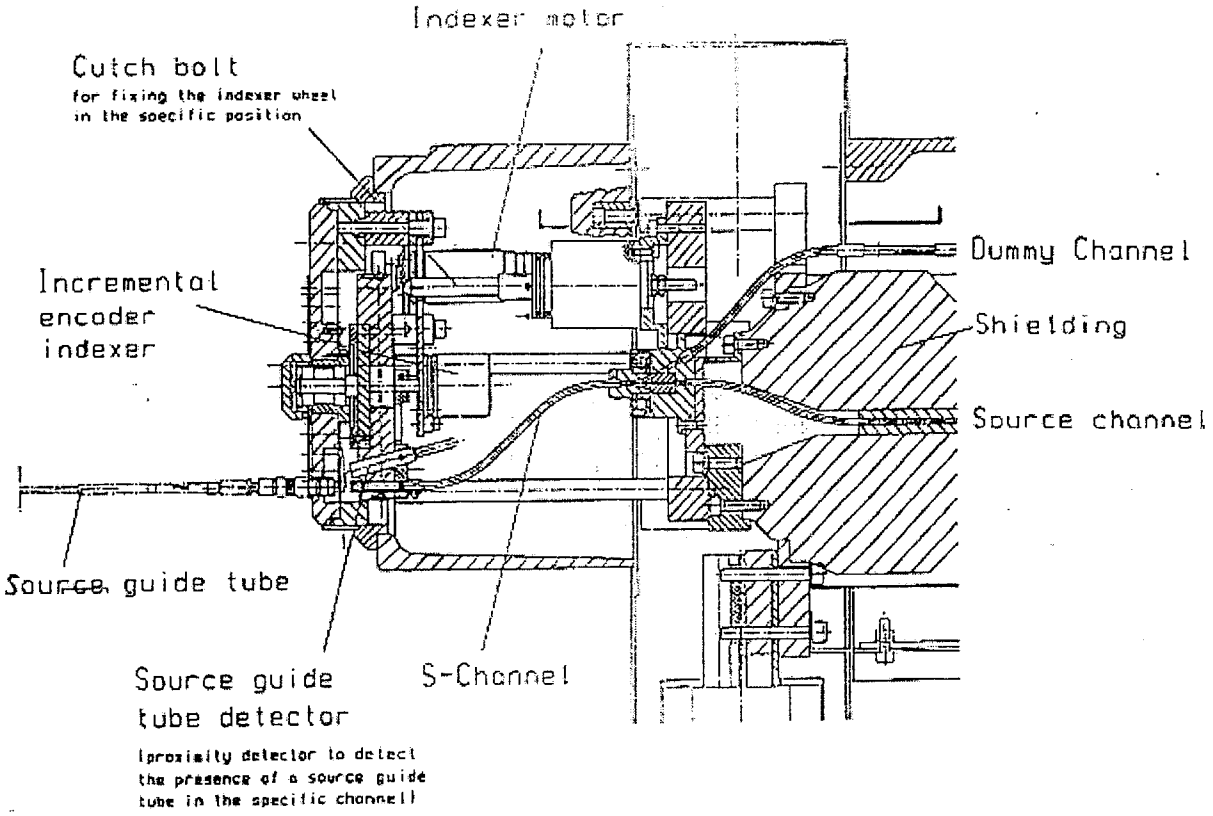
(Supercedes NR-0220-D-122-S)



GammaMed RAL Indexer (dimensions in mm)

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
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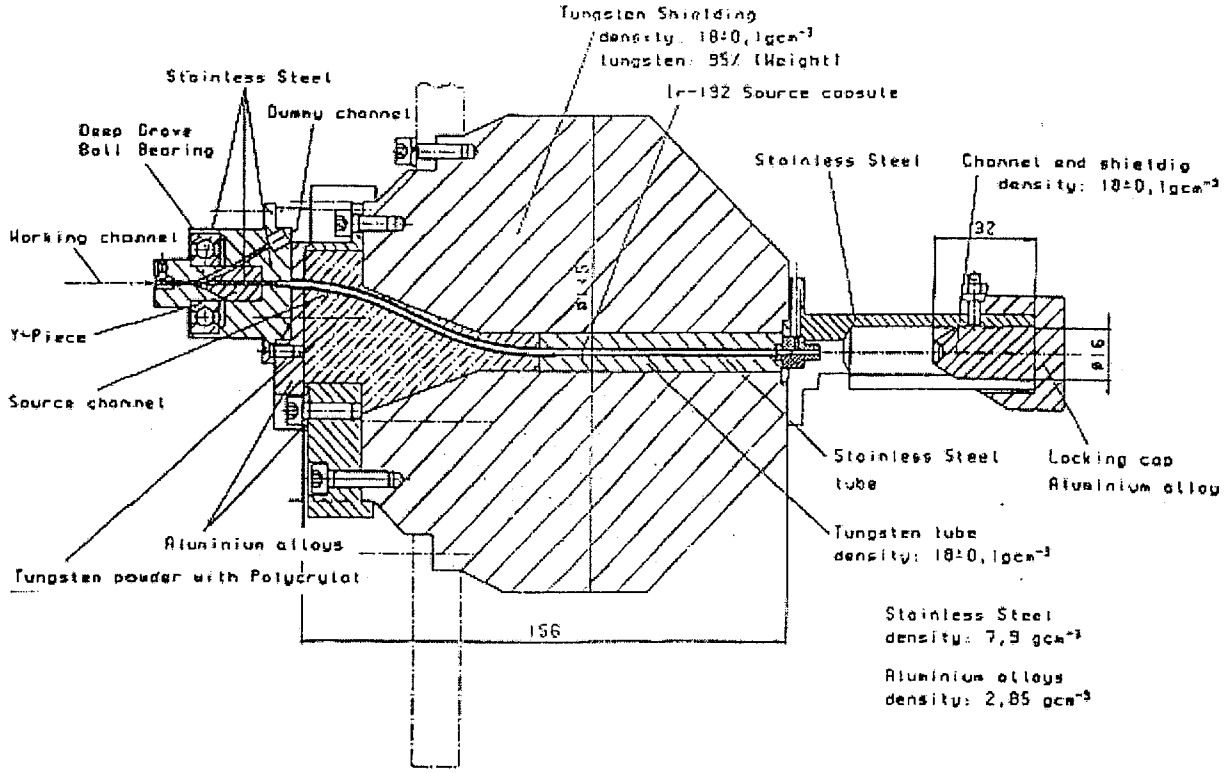
(Supercedes NR-0220-D-122-S)



GammaMed RAL Shield Container (dimensions in mm)

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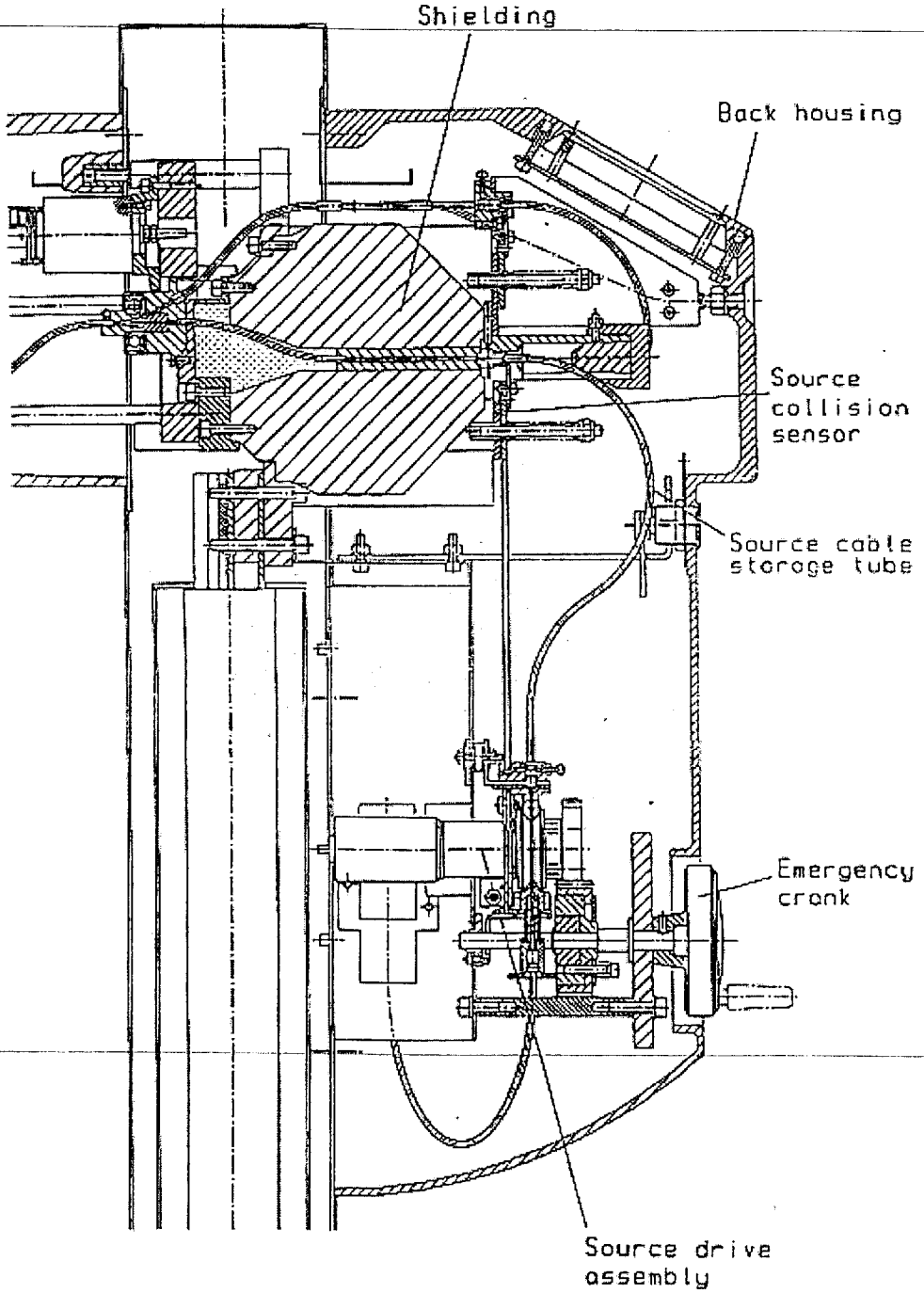
(Supercedes NR-0220-D-122-S)



GammaMed RAL Emergency Manual Drive (dimensions in mm)

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
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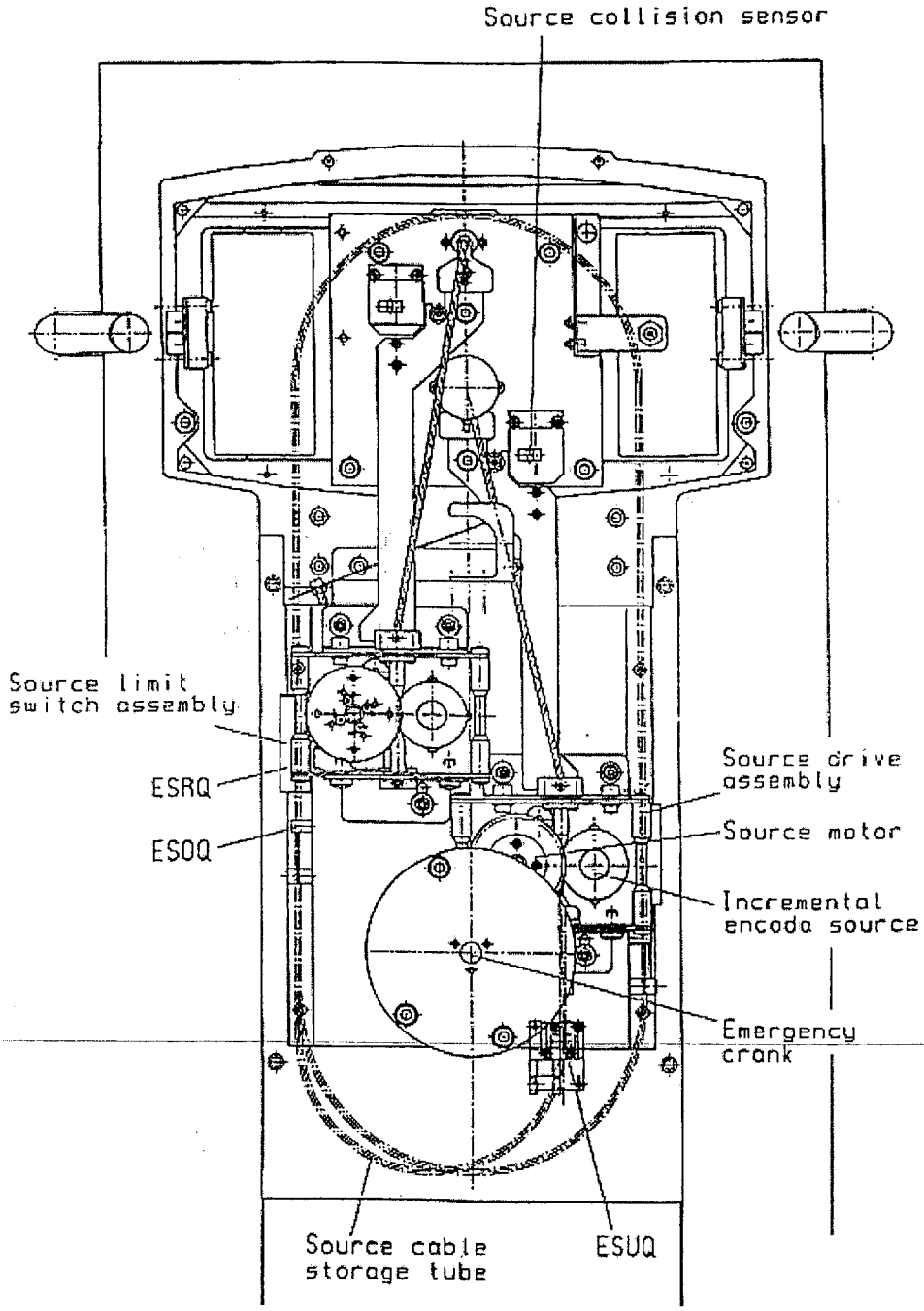

GammaMed RAL Source Assembly Drive

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

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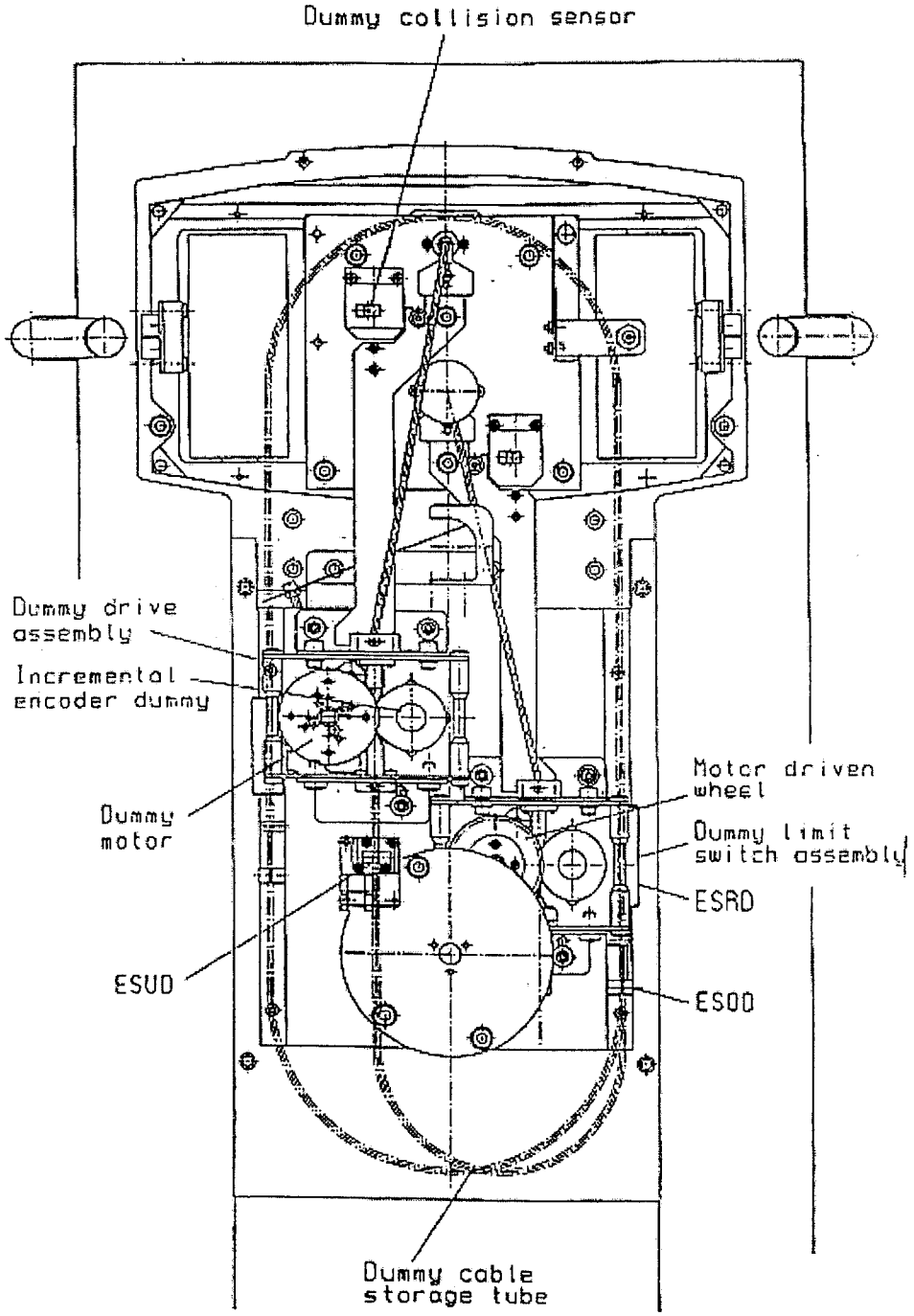
(Supercedes NR-0220-D-122-S)

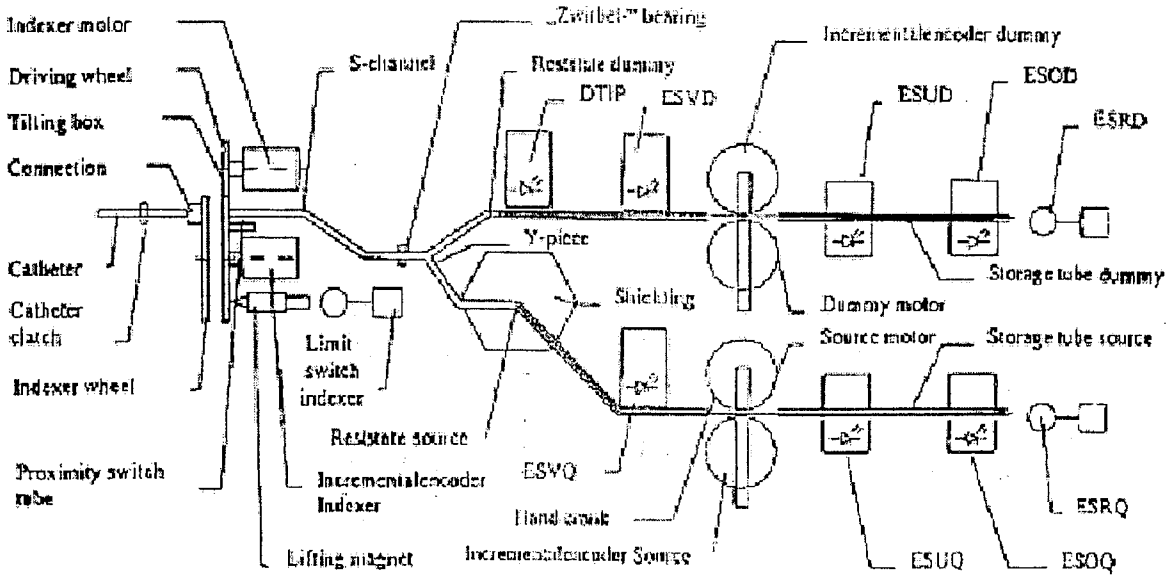


GammaMed RAL Dummy Assembly Drive

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

No.: CA-1080-D-103-S DATE: May 18,2004 Attachment 9

(Supercedes NR-0220-D-122-S)



GammaMed RAL Drive Diagram

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
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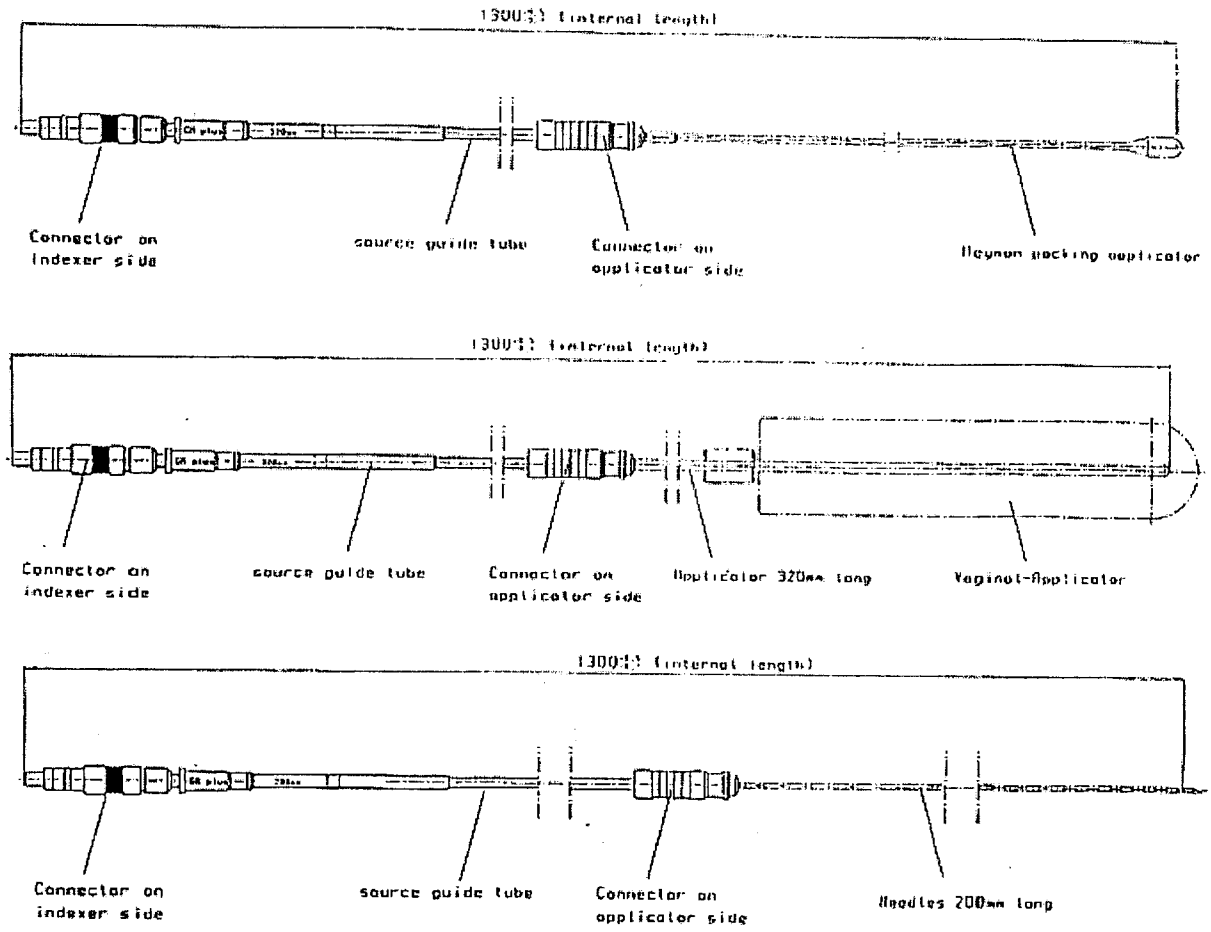
(Supercedes NR-0220-D-122-S)

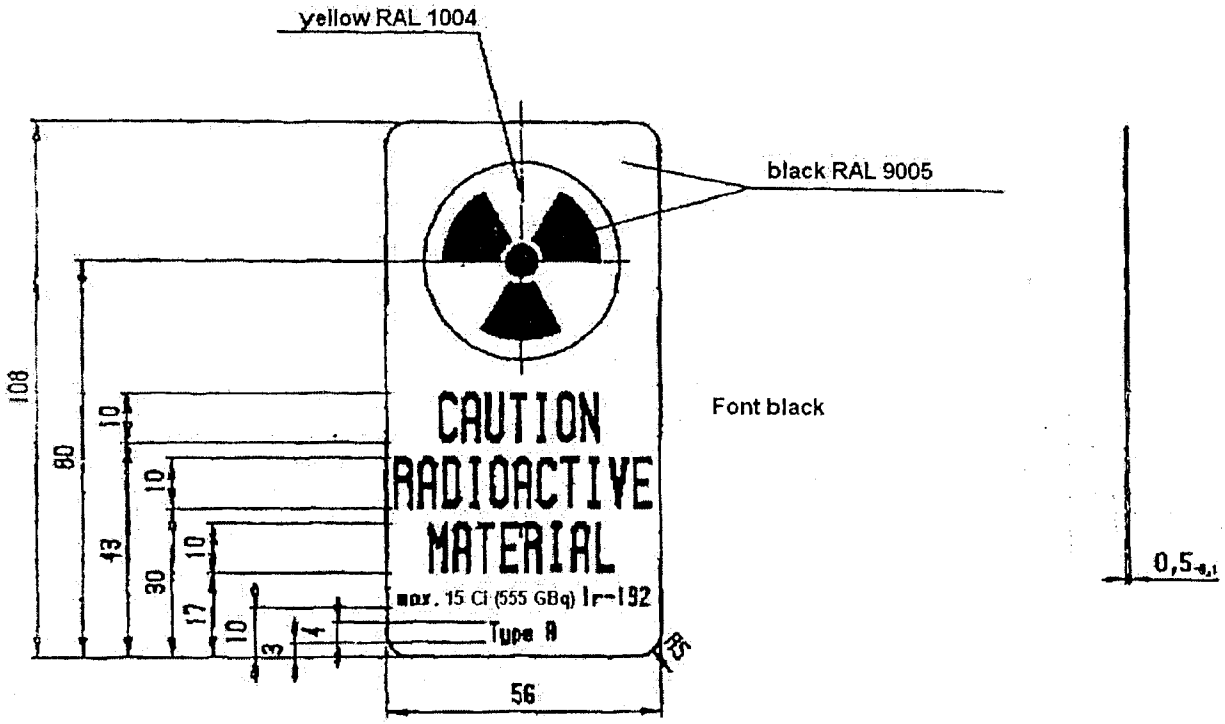


SGT / Applicator Connections (Connector is 9 mm wide at maximum)

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

No.: CA-1080-D-103-S DATE: May 18, 2004 Attachment 11

(Supercedes NR-0220-D-122-S)



Device Type A Package Label