

QUALITY ASSURANCE PROGRAM FOR SIEMENS SHIPPING CONTAINERS FOR THERAPY SOURCES

SIEMENS AG MEDICAL GROUP

1. ORGANIZATION

1.1 GENERAL

SIEMENS AG has closed all activities in design and manufacture of transport containers for cobalt and caesium sources. The activities described here are reduced to maintenance and QA of the existing containers for transportation of new and used sources for Medical Therapy equipment manufactured by SIEMENS AG.

SIEMENS-owned containers which are licenced according to international rules by the German authority, Physikalisch Technische Bundesanstalt Braunschweig (PTB) (Attachment 1), are used by the manufacturers of therapy sources (Attachment 2). These manufacturers are using the SIEMENS-containers to transport the sources ordered by SIEMENS. They have to follow the rules given by SIEMENS AG according Attachment 1, 3 and 4.

Prior to shipping every user has to check the containers according to attachment 3. He has to follow all national and international transportation regulations. The transportation of used sources from customers side back to the manufacturer is covered by the same procedures.

This section describes the organizational structure and functional responsibilities for the Quality Assurance Program. Persons and organizations assigned quality-related responsibilities have sufficient authority and organizational freedom to: identify, evaluate, and recommend solutions of corrective actions; and stop unsatisfactory work and control further processing, delivery, installation or utilization of nonconforming items until proper dispositioning has been established.

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The program is implemented by or at the direction of SIEMENS AG. Activities such as QA-testing may be performed by contractors to SIEMENS specifications.

The organizational structure and functional responsibility assignments are such that: (1) attainment of quality objectives is accomplished by individuals responsible for specifying quality or performing work to specifications and (2) verification of quality requirements in Erlangen West-Germany is accomplished through audits performed by Radiation Safety Officer of UB Med in Erlangen and the German authority PTB.

An abbreviated organization chart showing those components concerned with implementing this program is presented in attachment 5.

1.2 STAFF ORGANIZATION FUNCTIONS

The General Manager of CT and Therapy is responsible for establishing the QA policies, goals, and objectives. In order to assure compliance with those policies, the Director of International Sales Therapy has been assigned to set the objectives for the QA-Program.

1.3 LINE ORGANIZATION FUNCTIONS

The execution of the QA-program is separated from the sales-group. Maintenance and revision of the containers are handled in USA by the QA-department. Check of containers at customers side is done by Therapy Service/Technical Support under the supervision of the SIEMENS MEDICAL-SYSTEMS-Radiation Safety Officer.

2.1 QUALITY ASSURANCE PROGRAM

An overall QA-Program is established and implemented which encompasses those activities which are necessary to meet quality objectives. This program is applicable to PTB licensed containers Typ "B" used for shipping of Therapy sources. The program applies to activities affecting the components of the identified packaging to an extent consistent with their importance to safety. Those activities include purchasing, handling, shipping, storing, cleaning, assembling, inspecting, testing, operating, maintaining and repairing.

In the event differences of opinion arises between QA personnel and other personnel involving quality, the issue(s) is brought to the attention of appropriate levels of management for solutions.

Training and experience qualifications are defined for each position in SIEMENS AG. In addition, the program provides for indoctrination and training of personnel performing activities affecting quality in order to provide assurance that appropriate proficiency is achieved and maintained. This indoctrination and training is carried out through various documented procedures, personnel contacts and meetings. The purpose of the training is to assure that personnel responsible for quality-related activities are instructed as to the purpose, scope, and implementation of the quality-related manuals, instructions, and procedures. Personnel performing quality-related activities are trained and qualified in the principles and techniques of the activity being performed.

2.2 RESPONSIBILITIES OF:

2.2.1 QA TRANSPORT-CONTAINERS

Incomming Inspection: Inspection of returned containers and decision if repair is necessary. In: 1. Erlangen West Germany, 2. USA.

Maintenance and repair: Under supervision of QA.

Container Inspection:

- a.) Technical inspection of every container prior to release to stock and affixing test labels to checked containers.
- b.) 5 year's inspection according PTB-licence to renew usage-date.

Logging: All tests are to be logged according to the Licence of PTB.

2.2.2 Store and Shipment: Only tested and labeled containers can be released for shipment to customer or source-manufacturers.

2.2.3 Therapy Sales Group: Relations to departments of SIEMENS, to national and international institutions and authorities. Coordination and supervision of activities related to QA-Program.

- 2.2.4 Radiation Safety Officer: Audit of QA-Program in Erlangen.
- 2.2.5 Therapy Service: Inspection at customer's side according to the check-list, and sending all QA-test reports from the field to QA for record keeping.
- 2.2.6 Radiation Safety Officer SMS: Audit QA-Program in USA.

Translation from the German language (certified)

FEDERAL PHYSICAL TECHNICAL INSTITUTE

Licence

D/2001/B(U) (Revision 5)

Based on the application of Siemens AG, Erlangen, dated 5 May 1987 - file reference rw-ba - the container with the manufacturer's designation transport container S 1747 is licensed as package sample of the type B(U) for radioactive substances according to the following regulations:

Regulations for the Safe Transport of Radioactive Materials, 1973 Revised Edition (as amended) of the International Atomic Energy Agency (IAEA), § 806.

Code on the national and international transport of dangerous goods by road (Gefahrgutverordnung Straße - GGVS) dated 22 July 1985, (BGBI. I, page 1550, with appendix volume I to the BGBI. I, No. 40 dated 30 July 1985) enclosure A, marginal number 3672.

European agreement on the international transport of dangerous goods by road (ADR agreement) of 30 September 1957, in the version of 22 July 1985 (BGBI. I, page 1550), enclosure A, marginal number 3672.

Law on the European Agreement dated 30 September 1957, on the international transport of dangerous goods by road (ADR), dated 18 August 1969 (BGBI. II, page 1489), article 4, §1 No.2.

Code on the national and international transport of dangerous goods by rail (Gefahrgutverordnung Eisenbahn - GGVE) dated 22 July 1985 (BGBI. I, page 1560, with enclosure volume II to the BGBI. I No. 40 dated 30 July 1985), last changed by the 1st amendment regulation for the railway transport of dangerous goods of 21 August 1986 (BGBI. I page 1347), enclosure, marginal number 1672.

Order for international railway transport of dangerous goods (RID rules) - enclosure I to appendix B of the agreement on the international railway traffic (COTIF agreement) dated 9 May 1980 (BGBI. 1985 II, page 666), in the version of the code dated 22 July 1985 (BGBI. I, page 1560), enclosure, marginal number 1672.

Code on the transport of dangerous goods with maritime vessels, dated 05.07.1978, enclosure to the 1st maritime dangerous goods modification code dated 27.07.1982, class 7, section 12.1, subsection 3.

International Maritime Dangerous Goods Code (Class 7,12.1.3, page 7033).

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Enclosure A to the code on the transport of dangerous goods on the Rhine (ADNR) dated 23.11.1971, last modified by the 6th ADNR modification code dated 24.03.1983, Rn 6461(3).

Notification on the permission for conveying dangerous goods in aircraft dated 31.05.1968, L5 - 582 - 38 P/67 (Nachrichten für Luftfahrer, part 1, dated 13.06.1968, 16th volume No. 84) in connection with the Dangerous Goods Regulations of the International Air Transport Association (IATA), Section 5.7.44.

In connection with the guidelines of the Federal Minister for Transport dated 18.10.1977 (VkB1. 31. (1977) page 582).

License number of the package sample: D/2001/B(U)

Validity of the licence: up to 31.07.1990

Permissible contents:

Cobalt-60 and/or caesium-137 in SPECIAL FORM with a total activity of maximum 630 TBq (17000 Ci), whereby the activity of the radiation source in the upper shaft may not exceed 260 TBq (7000 Ci) and in the lower shaft 400 TBq (11000 Ci).

Design of the package:

According to certificate of the Federal Institute for Material Testing: 2003 B(U) dated 04.03.1977, in connection with the test certificate dated 08.10.1968 (file reference: 1.2/8879), expert opinion dated 16.01.87 (No. 1.5/21566) and supplement to opinion of 08.07.87, design S 1747 meets the requirements placed on type B(U) package (IAEA Regulations, §§ 228 to 241).

Description of the package:

The packing consists of an internal container with the lead shielding and a cylindrical outer container lined with wood. The internal container has two horizontal "shafts" arranged above one another to hold the heavy-metal drawers which contain the radiation sources. The remaining free space is filled with dummy drawers and suitable lead blocks according to the instructions of the manufacturer.

Package S 1747 has the following dimensions:

Length: approx. 1300 mm
Diameter: approx. 730 mm

Total weight: approx. 2000 kg

Schematic drawing:

1799188 S 1747 of 13.10.1977

Secondary provisions:

1. The package must be used and maintained according to the "Equipment plan for the shafts of the transport container type S 1747" dated 4 May 1984, and the "Check list for checking transport containers for radioactive therapy sources", issue 1986 of the applicant.
2. Every user must register with the Federal Physical Technical Institute before using the package for the first time and he must confirm that he has received the documents stated under 1.
3. The packages must be tested repeatedly at least at 5-year intervals according to the "Test instructions for transport containers type S 1747 for transporting radioactive therapy sources", issue January 1987 of the applicant with release stamp BAM-1.52 dated January 1987; the test certificates must be submitted to PTB/BAM.

Notes:

1. Packages with a total activity of more than 140 TBq (3800 Ci) may be transported only as wagon load in rail and road traffic. Further special measures during transport are not required.
2. This license does not exempt the consignor from the obligation of complying with any regulations of a country through which or in which the package is transported.
3. This license invalidates license D/2001/B(U) (Revision 4).

Legal information:

An objection can be made to this ruling within one month of notification. Objection must be filed in writing or for the record at the Federal Physical Technical Institute (Physikalisch-Technische Bundesanstalt), Bundesallee 100, 3300 Braunschweig.

Braunschweig, 13 July 1987

By order

Dr. M. Cosack

Enclosures

Appendix to license

Schematic drawing:

Transport container S 1747

Appendix to License No. D/2001/B(U) (Revision 5)

Rev.No.	Date of Issue	Validity Period	Reason for Revision
0	02.03.1978	02.03.1981	
1	07.05.1979	02.03.1981	Extension to maritime traffic
2	09.02.1981	09.02.1984	Extension of validity
3	20.01.1984	20.01.1987	Extension of validity
4	16.01.1987	31.01.1990	Extension of validity and stipulations regarding quality assurance
5	13.07.1987	31.07.1990	Change of secondary provisions

Als vom Präsidenten des Landgerichts Nürnberg-Fürth öffentlich bestellte und allgemein beeidigte Dolmetscherin und Übersetzerin für die englische Sprache versichere ich: vorstehende Übersetzung eines mir als Kopie vorliegenden Zulassungsscheines in deutscher Sprache ist richtig und vollständig.

Buckenhof, 5 August 1987

Roswitha Kotzurek
Roswitha Kotzurek

I, Roswitha Kotzurek, an officially appointed and sworn translator and interpreter for the English language do herewith assure that the foregoing translation of a German License, a copy of which was submitted, is true and correct and complete to the best of my knowledge and belief.

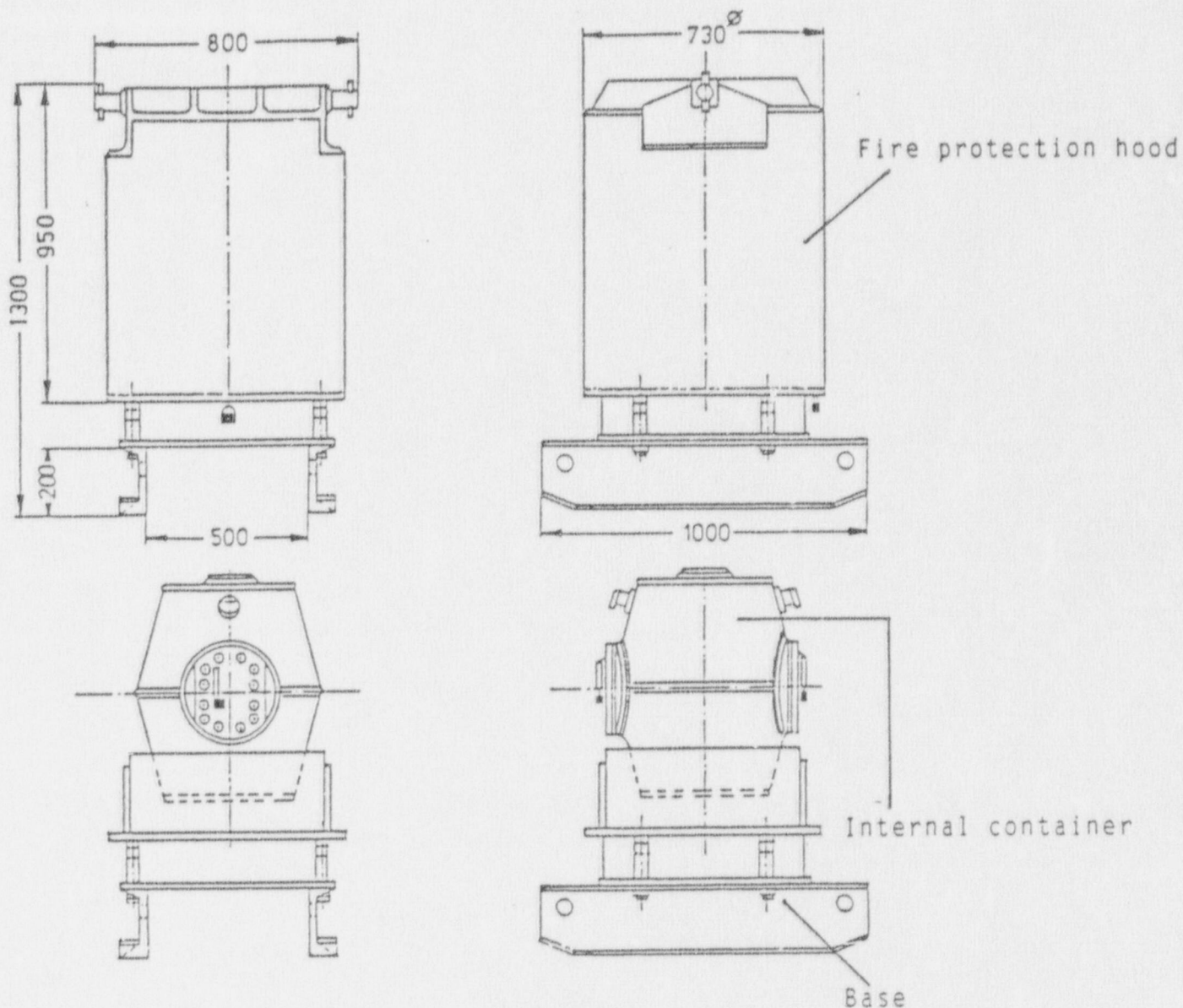
Buckenhof, 5 August 1987

Roswitha Kotzurek
Roswitha Kotzurek



Transport container

Package complete



Transport container S 1747/.....
Manufacturer: Siemens AG, Erlangen

Drawing No. 1799188 S 1747
Older drawing No. S.hi.47a
License No. D/2001/B(U)
Packing: type B

Contents: radioactive material in special form
Radionuclide: Co-60 and Cs-137
Maximum permissible total activity: 17000 Ci

Total weight: approx. 2000 kp

ATTACHMENT 2

Co-60 SOURCE SUPPLY COMPANIES FOR SIEMENS-OWNED CONTAINERS

General Electric Company
Vallecitos Nuclear Center
Vallecitos Road

Pleasanton/Calif. 94566
USA

Atomic Energy of Canada Ltd.
Commercial Products
P.O. Box 6200
Postal Station 3K2A 3V3

Ottawa/Canada

Kraftwerkunion
Seligenstädter Straße

8757 Karlstein
West-Germany

Amersham International plc
Isotope Production Unit

Harwell, Didcot, Oxfordshire
England

	CHECK LIST for shipping containers for radioactive therapy sources	PAGE 1
<p>Each shipping container of type 17 99 188 S 1747 is marked with a Serial Number on labels fitted to the fire-protection hood and to the inner container. This check list should be used to make sure that the container is shipped in perfect condition. The Item Numbers of the check list refer to the parts illustrated on page 4. Regular maintenance of each shipping container is mandatory. Shipment of therapy radiation sources is permitted only if the date of the next mandatory maintenance has not been exceeded. For authorized shipping containers, this date is indicated on the Identification Label at the fire-protection hood.</p>		
<p>1. Fire protection hood: Keep free of dirt. Check for damage.</p>	<p>Part No. 17 99 204 S 1747</p>	<input type="radio"/>
<p>2. Identification Label on fire-protection hood:</p>	<p>Part No. 17 99 469 S 1747</p>	
<p>Identif. Label Contents: Authorization Number D/2001/B(U), Serial No. and Date of next mandatory maintenance</p>	<p>Part No. 17 81 079 S 1747</p>	
<p>Identif. Label Contents: Weight of shipping container</p>	<p>Part No. 17 81 079 S 1747</p>	
<p>These labels should be properly affixed and entirely legible.</p>	<input type="radio"/>	
<p>3. Inner wooden lining of fire-protection hood: The wooden parts must be properly fitted and no part should be missing.</p>	<input type="radio"/>	
<p>4. Screw connection of fire-protection hood to bottom:</p>	<p>Part No. 17 99 246 S 1747</p>	
<p>12 special screws 12 fan washers of Quality A16.5 DIN 6798-St 6980</p>	<p>Part No. 17 99 246 S 1747</p>	
<p>These screws and washers must be greased and undamaged and none of them should be missing.</p>	<input type="radio"/>	
<p>5. Bottom: Keep free of dirt. Check for damage, especially the wooden lining.</p>	<p>Part No. 17 99 212 S 1747</p>	<input type="radio"/>
<p>6. Base: Check for damage which may affect the stability. Check attachment of base to bottom.</p>	<p>Part No. 20 90 942 S 1747</p>	<input type="radio"/>
<p>Bereich Medizinische Technik</p>		
<p>Siemens AG</p>	<p>The check list comprises 4 sheets</p>	<p>issue 1986</p>

CHECK LIST for shipping containers for radioactive therapy sources		PAGE 2
7. Sealing ring:	Part No. 17 99 378 S 1747	<input type="radio"/>
The sealing ring should be undamaged and properly situated in the groove so that it still protrudes over the flange surface.		
8. Insulating boards:	Part No. 17 91 056 S 1747	<input type="radio"/>
The height of the board package should be 120 mm, but not less than 110 mm.		
9. Screw connection between base and bottom:		<input type="radio"/>
4 screws of quality M16 x 120 DIN 931-8.8 6603		
4 fan washers of quality A 16.5 DIN 6798-St 6980		
These screws must be greased, undamaged and none of them should be missing.		
10. Inner container:	Part No. 17 99 196 S 1747	<input type="radio"/>
Keep free of dirt. Check for damage.		
11. Identification Label on inner container:		<input type="radio"/>
Identif. Label	Part No. 1019 SRN 825	
Contents: Serial No.		
The Serial No. of the inner container must coincide with the Serial No. of the fire-protection hood. The label should be safely affixed and properly legible.		
12. Cover for source-drawer channels:		<input type="radio"/>
2 covers	Part No. 17 99 634 S 1747	
Keep free of dirt. Check for damage.		
13. Cover sealing:		<input type="radio"/>
2 Klingerit gaskets	Part No. 17 99 683 S 1747	
The Klingerit gaskets should be affixed to the covers with adhesive. Check for damage.		
14. Cover screws:		<input type="radio"/>
24 screws	Part No. 35 39 129 S 1747	
of quality M 20 x 40 DIN 6912.8.8		
None of these screws must be missing.		
They should be undamaged and greased.		
15. The channel symbols I and II and the two red marking lines on the wooden lining of the bottom and on the inner container should be legible.		<input type="radio"/>
16. Condition of source-drawer channels:		<input type="radio"/>
The channels I and II must not be deformed. When inserting the source drawers, care is required, especially when using remote-control instruments, in order to avoid damage of the channels. The channels should be kept free of ridges, dust and grease.		
Bereich Medizinische Technik		
Siemens AG	The check list comprises 4 sheets	issue 1986

CHECK LIST
for shipping containers
for radioactive therapy sources

PAGE

3

17. Condition of centering flanges:

The surface of the centering flanges should be smooth because the Gammatron head has to be fastened here in an exactly defined geometric position for reloading. The recesses on the centering flanges should be free of ridges and undamaged.

18. Seal to prevent unauthorized opening of the shipping container:

Prior to shipping a therapy radiation source, a seal or a padlock should be attached to this eyebolt.

The shipping container with Serial No. S 1747 /

has been checked in accordance with this list and is ready for shipment. Any objections have to be reported prior to shipment to Siemens AG, Henkestraße 127 in D-8520 Erlangen, FRG, Dept. TDV 1. The two channels were loaded according to shipment mode No. of the equipment plan for the

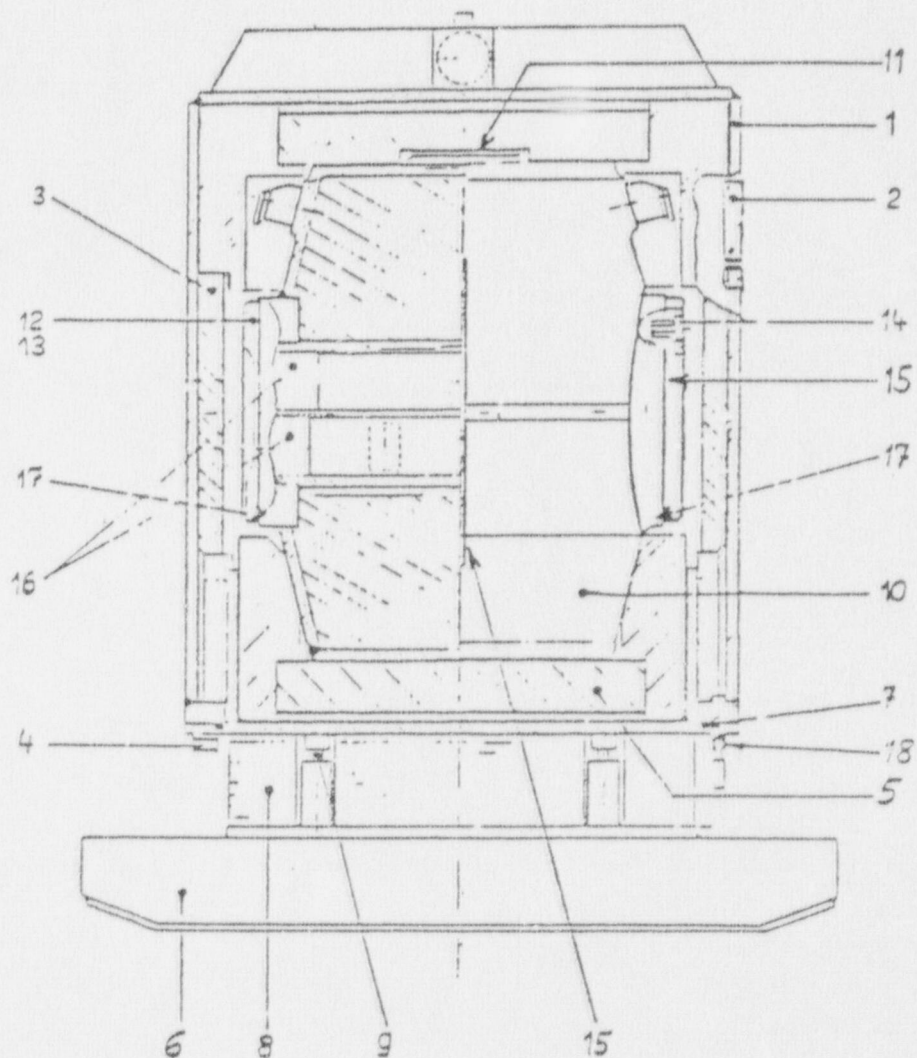
shipping container of type S1747, version of 4 May 1984. The non-adhesive outer contamination amounts to less than 3.7 Bq per square centimetre.

Place, date and signature and stamp or name of sender

CHECK LIST
for shipping containers
for radioactive therapy sources

PAGE

4



EQUIPMENT PLAN
for the channels of transport container
Type S 1747

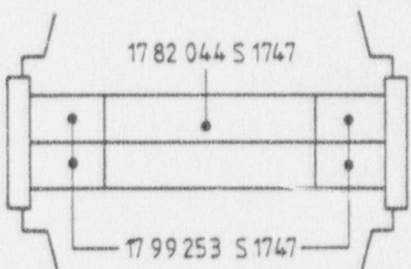
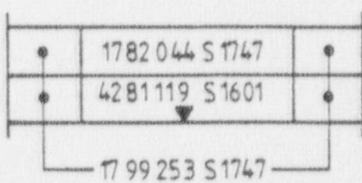
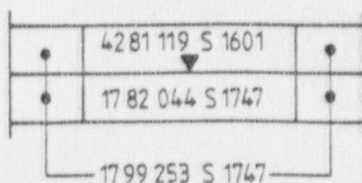
SHEET

1

For the forwarding of therapy radiation sources in transport container type S 1747, the two channels must be filled up completely with shielding material to prevent any unpermissibly high local dose values at the surface of the transport container.

Forwarding of radioactive therapy radiation sources is only permitted if both channels have been equipped according to one of the following modes of dispatch 2 to 16. Mode of dispatch 1 is envisaged for the dispatch of empty transport containers.

Radiation direction of the sources
▼

Mode of dispatch		Channel	Loading
1		I	Empty (without source carrier)
		II	Empty (without source carrier)
2		I	
		II	1 x Co ⁶⁰ up to 11000 Ci
3		I	1 x Co ⁶⁰ up to 6000 Ci
		II	

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Siemens AG

The equipment plan comprises 4 sheets

4 May 1984

EQUIPMENT PLAN
for the channels of transport container
Type S 1747

SHEET

2

Radiation direction of the sources
▼

Mode of dispatch		Channel	Loading
4		I	
		II	1 x Co ⁶⁰ up to 9000 Ci in round source carrier
5		I	1 x Co ⁶⁰ up to 6000 Ci in round source carrier
		II	
6		I	1 x Co ⁶⁰ up to 6000 Ci in round source carrier
		II	1 x Co ⁶⁰ up to 9000 Ci in round source carrier
7		I	1 x Co ⁶⁰ up to 6000 Ci in square source carrier
		II	1 x Co ⁶⁰ up to 9000 Ci in round source carrier
8		I	1 x Co ⁶⁰ up to 6000 Ci in round source carrier
		II	1 x Co ⁶⁰ up to 11000 Ci in square source carrier

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The equipment plan comprises 4 sheets

4 May 1984

EQUIPMENT PLAN
for the channels of transport container
Type S 1747

SHEET

3

Radiation direction of the sources
▼

Mode of dispatch		Channel	Loading
9		I II	I 1 x Co ⁶⁰ up to 6000 Ci II 1 x Co ⁶⁰ up to 11000 Ci In the case of unequal loading, stronger source in channel II
10		I II	I 1 x Cs ¹³⁷ up to 4250 Ci II 1 x Co ⁶⁰ up to 11000 Ci
11		I II	I II 1 x Cs ¹³⁷ up to 4250 Ci
12		I II	I 1 x Cs ¹³⁷ up to 4250 Ci II
13		I II	I 1 x Cs ¹³⁷ up to 4250 Ci II 1 x Cs ¹³⁷ up to 4250 Ci

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The equipment plan comprises 4 sheets

4 May 1984

EQUIPMENT PLAN
for the channels of transport container
Type S 1747

SHEET

4

Radiation direction of the sources
▼

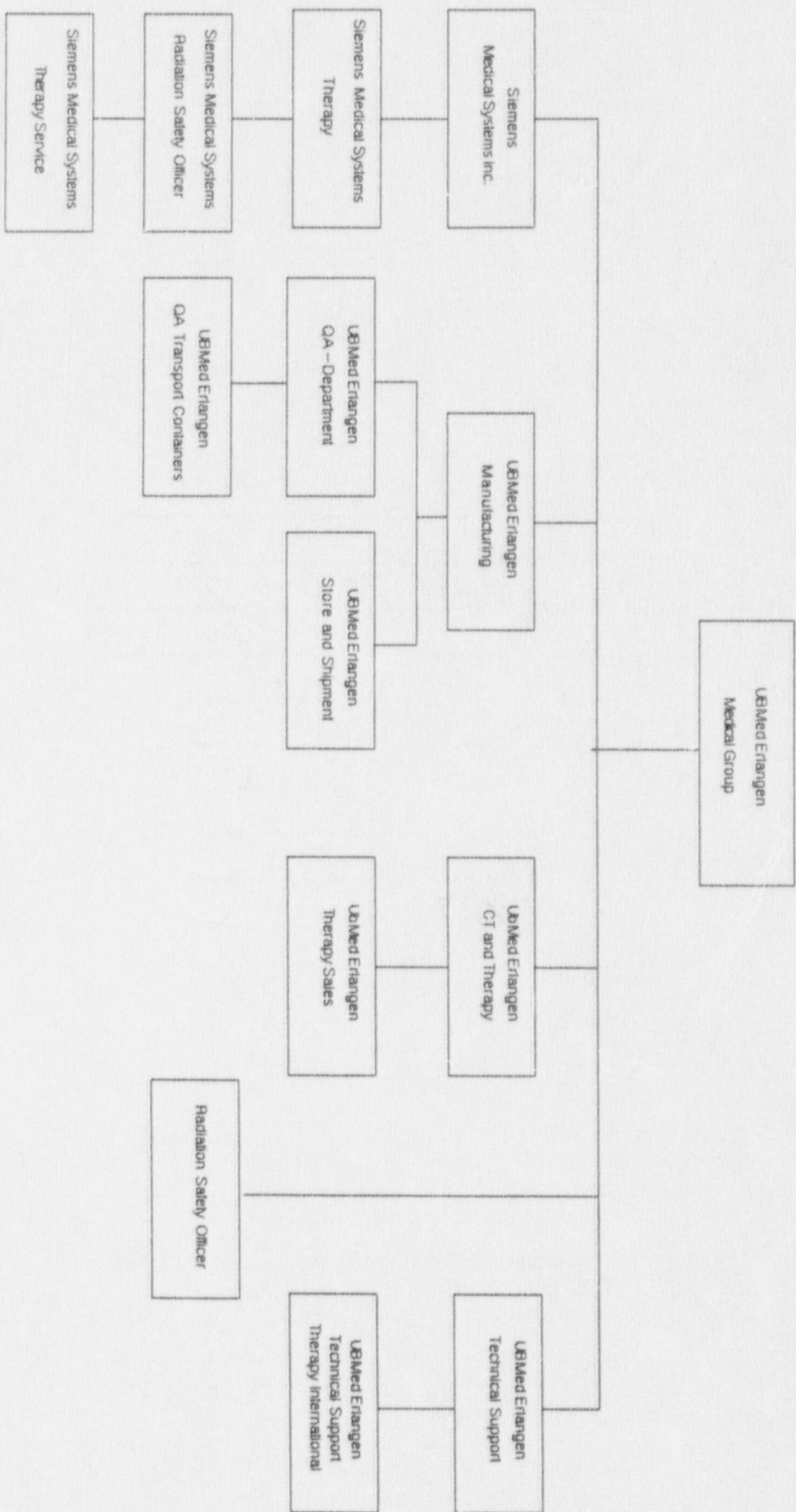
Mode of dispatch		Channel	Loading
14		<div>I</div> <div>II</div>	<div>I</div> 1 x Cs ¹³⁷ up to 4250 Ci <div>II</div> 2 x Cs ¹³⁷ up to 4250 Ci
15		<div>I</div> <div>II</div>	<div>I</div> 2 x Cs ¹³⁷ up to a total of 5000 Ci <div>II</div> 2 x Cs ¹³⁷ up to a total of 9000 Ci
16		<div>I</div> <div>II</div>	<div>I</div> 2 x Cs ¹³⁷ up to a total of 5000 Ci <div>II</div> 1 x Co ⁶⁰ up to 11000 Ci
		<div>I</div> <div>II</div>	
		<div>I</div> <div>II</div>	

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The equipment plan comprises 4 sheets

4 May 1984



DOCKET NO. 71-0551
CONTROL NO. 28754
DATE OF DOC. 10/27/87
DATE RCVD. 11/09/87
FCUF _____ PDR ✓
FCAF _____ LPDR _____
I & E REF. ✓
SAFEGUARDS _____
FCTC ✓ OTHER _____
DATE 11/09/87 INITIAL CEA