



U.S. Department
of Transportation
**Pipeline and
Hazardous Materials
Safety Administration**

**COMPETENT AUTHORITY CERTIFICATION
FOR A TYPE B(U)
RADIOACTIVE MATERIALS PACKAGE DESIGN
CERTIFICATE USA/9338/B(U)-96, REVISION 2**

East Building, PHH-23
1200 New Jersey Avenue Southeast
Washington, D.C. 20590

This certifies that the radioactive material package design described has been certified by the Competent Authority of the United States as meeting the regulatory requirements for a Type B(U) packaging for radioactive material as prescribed in the regulations of the International Atomic Energy Agency¹ and the United States of America².

1. Package Identification - 3977A.
2. Package Description and Authorized Radioactive Contents - as described in U.S. Nuclear Regulatory Commission Certificate of Compliance No. 9338, Revision 2 (attached).
3. General Conditions -
 - a. Each user of this certificate must have in his possession a copy of this certificate and all documents necessary to properly prepare the package for transportation. The user shall prepare the package for shipment in accordance with the documentation and applicable regulations.
 - b. Each user of this certificate, other than the original petitioner, shall register his identity in writing to the Office of Hazardous Materials Technology, (PHH-23), Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, Washington D.C. 20590-0001.
 - c. This certificate does not relieve any consignor or carrier from compliance with any requirement of the Government of any country through or into which the package is to be transported.

¹ "Regulations for the Safe Transport of Radioactive Material, 1996 Edition (Revised), No. TS-R-1 (ST-1, Revised)," published by the International Atomic Energy Agency(IAEA), Vienna, Austria.

² Title 49, Code of Federal Regulations, Parts 100-199, United States of America.

CERTIFICATE USA/9338/B(U)-96, REVISION 2

- d. Records of Quality Assurance activities required by Paragraph 310 of the IAEA regulations¹ shall be maintained and made available to the authorized officials for at least three years after the last shipment authorized by this certificate. Consignors in the United States exporting shipments under this certificate shall satisfy the applicable requirements of Subpart H of 10 CFR 71.
4. Marking and Labeling - The package shall bear the marking USA/9338/B(U)-96 in addition to other required markings and labeling.
5. Expiration Date - This certificate expires on March 31, 2019. On June 30, 2018, this certificate supersedes all previous revisions of USA/9338/B(U)-96.

This certificate is issued in accordance with paragraph 808 of the IAEA Regulations and Section 173.471 of Title 49 of the Code of Federal Regulations, in response to the August 07, 2017 petition by Croft Associates Limited, Abingdon, Oxfordshire, UK, and in consideration of other information on file in this Office.

Certified By:



William Schoonover
Acting Associate Administrator for Hazardous Materials Safety

Aug 11 2017

(DATE)

Revision 2 - Issued to endorse U.S. Nuclear Regulatory Commission
Certificate of Compliance No. 9338, Revision 2.

**CERTIFICATE OF COMPLIANCE
FOR RADIOACTIVE MATERIAL PACKAGES**

1. a. CERTIFICATE NUMBER	b. REVISION NUMBER	c. DOCKET NUMBER	d. PACKAGE IDENTIFICATION NUMBER	PAGE	PAGES
9338	2	71-9338	USA/9338/B(U)-96	1	OF 8

2. PREAMBLE

- a. This certificate is issued to certify that the package (packaging and contents) described in Item 5 below meets the applicable safety standards set forth in Title 10, *Code of Federal Regulations*, Part 71, "Packaging and Transportation of Radioactive Material."
- b. This certificate does not relieve the consignor from compliance with any requirement of the regulations of the U.S. Department of Transportation or other applicable regulatory agencies, including the government of any country through or into which the package will be transported.

3. THIS CERTIFICATE IS ISSUED ON THE BASIS OF A SAFETY ANALYSIS REPORT OF THE PACKAGE DESIGN OR APPLICATION

- a. ISSUED TO (*Name and Address*)
Croft Associates Limited
Building F4, Culham Science Centre
Culham, Abingdon
Oxfordshire, OX14 3BD, United Kingdom
- b. TITLE AND IDENTIFICATION OF REPORT OR APPLICATION
Croft Associates Limited application dated
September 29, 2012, as supplemented.

4. CONDITIONS

This certificate is conditional upon fulfilling the requirements of 10 CFR Part 71, as applicable, and the conditions specified below.

5.

(a) Packaging

- (1) Model No.: 3977A
- (2) Description

The Model No. 3977A is a package for the transport of radioisotopes used in a wide range of therapeutic and diagnostic applications and research. The packaging consists of an outer stainless steel keg and an inner containment vessel surrounded by insulating cork packing. There are four specific inserts, designated as Shielding Insert Design Nos. 3982, 3985, 3987 and 4081, authorized for use in the Model No. 3977A. The outer keg provides impact and thermal protection. Containment is provided by the containment vessel. Shielding is provided by the containment vessel and shielding inserts.

The keg has a stainless steel outer shell and a stainless steel liner, between which insulating cork is fitted. The keg lid is attached to the body by eight stainless steel studs and nuts, with a single O-ring weather seal. An inner cork liner is fitted between the keg liner and the top and sides of the containment vessel, consisting of a cork body and cork top, with no cork between the bottom of the containment vessel and the keg liner.

The containment vessel consists of a body and lid. The body has a stainless steel outer wall, base, and flange/cavity wall. The flange/cavity wall is welded to the outer wall to form a cavity into which DU shielding is placed. The DU shielding thickness is approximately 46 mm at the base of the CV and 47.6 mm along the side of the CV except at the top where the lid seats. The DU shielding thickness at the top is 22.5 mm thick. After the DU shielding is installed, the base is then welded to the outer wall. There are two CV lid configurations: a standard configuration and a split lid configuration. For the standard CV lid, the stainless steel lid shielding casing, with 45.9 mm of DU inside, is welded to the

**CERTIFICATE OF COMPLIANCE
FOR RADIOACTIVE MATERIAL PACKAGES**

1. a. CERTIFICATE NUMBER	b. REVISION NUMBER	c. DOCKET NUMBER	d. PACKAGE IDENTIFICATION NUMBER	PAGE	PAGES
9338	2	71-9338	USA/9338/B(U)-96	2	OF 8

5.(a) (2) Description (Continued)

stainless steel CV lid top. For the split CV lid, a shielding plug, composed of 49.8 mm of DU enclosed within a stainless steel body and a stainless steel top, sits within the CV and a stainless steel CV lid is installed. Both the standard and the split lid are secured by eight, M-10x1.5x20, alloy steel recessed hexagon socket head cap screws. The containment vessel is sealed by two concentric fluoroelastomer O-rings, and the lid is equipped with a leak test port.

There are four shielding inserts designed for use in the Model No. 3977A packaging. Design No. 3982, HS-12x95-Tu, is a tungsten insert with inner cavity size of 12 mm diameter by 95 mm height. The approximate mass of the insert is 9.2 kg. Design No. 3985, HS-31x114-Tu, is a tungsten insert with inner cavity size of 31 mm diameter by 114 mm in height. The approximate mass of the insert is 7.9 kg. Shielding insert Design Nos. 3982 and 3985 are only used with the standard CV lid arrangement. The third shielding insert, Design No. 3987, HS-55x128-SS, is a stainless steel insert with inner cavity size of 55 mm diameter by 128 mm height. A titanium liner shall be employed with the HS-55x128-SS insert. The approximate mass of the insert is 1.8 kg with a liner installed. The fourth shielding insert, Design No. 4081, is only used with the split CV lid arrangement. Design No. 4081, HS-50x85-SS, is a stainless steel insert with inner cavity size of 50 mm diameter by 85 mm height. Design No. 4081 is used in conjunction with a snap ring, which attaches the shielding insert to the shielding plug associated with the split CV lid design, and a tungsten liner which provides additional shielding from the radioactive material transported.

The radioactive material shall be enclosed in a convenient product container such as a quartz vial, aluminum capsule or stainless steel bottle. Irradiated items may be carried in a plastic can, a metal can or wrapping to minimize the contamination of the insert.

The approximate dimensions and mass of the package are:

Overall package outer diameter	424 mm
Overall package height	585 mm
Containment vessel outer diameter	200 mm
Containment vessel height	302.5 mm
Containment vessel cavity inner diameter	65.8 mm
Containment vessel cavity inner height	157.1 mm
Maximum package mass	163 kg

**CERTIFICATE OF COMPLIANCE
FOR RADIOACTIVE MATERIAL PACKAGES**

1. a. CERTIFICATE NUMBER	b. REVISION NUMBER	c. DOCKET NUMBER	d. PACKAGE IDENTIFICATION NUMBER	PAGE	PAGES
9338	2	71-9338	USA/9338/B(U)-96	3	OF 8

(3) Drawings

Packaging which employs a standard lid is constructed and assembled in accordance with Croft Associates Limited Drawing Nos:

1C-5940, Rev. H	Cover Sheet for Safkeg HS Design No. 3977A (Licensing Drawing)
0C-5941, Rev. E	SAFKEG HS Design No. 3977A (Licensing Drawing)
0C-5942, Rev. C	Keg Design No. 3977 (Licensing Drawing)
0C-5943, Rev. B	Cork Set for Safkeg HS (Licensing Drawing)
1C-5944, Rev. C	Containment Vessel Design No. 3978 (Licensing Drawing)
1C-5945, Rev. D	Containment Vessel Lid (Licensing Drawing)
1C-5946, Rev. E	Containment Vessel Body (Licensing Drawing)
2C-6920, Rev. A	Silicone Sponge Rubber Disc (Licensing Drawing)

Packaging which employs a split lid is constructed and assembled in accordance with Croft Associates Limited Drawing Nos:

1C-7500, Rev. C	Cover Sheet for Safkeg HS Design No. 3977A – Mallinckrodt Version (Licensing Drawing)
0C-7501, Rev. C	SAFKEG HS Design No. 3977A – Mallinckrodt Version (Licensing Drawing)
0C-7502, Rev. A	Keg Design No. 3977 – Mallinckrodt Version (Licensing Drawing)
0C-7503, Rev. A	Cork Set for Safkeg HS – Mallinckrodt Version (Licensing Drawing)
1C-7504, Rev. A	Containment Vessel Design No. 3978 – Mallinckrodt Version (Licensing Drawing)
1C-7505, Rev. A	Containment Vessel Lid – Mallinckrodt Version (Licensing Drawing)
1C-7506, Rev. A	Containment Vessel Body – Mallinckrodt Version (Licensing Drawing)
1C-7507, Rev. A	Containment Vessel Plug – Mallinckrodt Version (Licensing Drawing)

The shielding inserts are constructed and assembled in accordance with Croft Associates Limited Drawing Nos:

2C-6173, Rev. D	HS-12 x 95-Tu Insert Design No. 3982 (Licensing Drawing)
2C-6174, Rev. D	HS-31 x 114-Tu Insert Design No. 3985 (Licensing Drawing)
2C-6176, Rev. F	HS-55X128-SS Insert Design No. 3987 (Licensing Drawing)
2C-7508, Rev. C	HS-50 x 85-SS Insert Design No. 4081 (Licensing Drawing)
2C-7509, Rev. B	Snap Ring
2C-7510, Rev. A	Tungsten Liner

**CERTIFICATE OF COMPLIANCE
FOR RADIOACTIVE MATERIAL PACKAGES**

1. a. CERTIFICATE NUMBER	b. REVISION NUMBER	c. DOCKET NUMBER	d. PACKAGE IDENTIFICATION NUMBER	PAGE	PAGES
9338	2	71-9338	USA/9338/B(U)-96	4	OF 8

5.(b) Contents

(1) Type and form of material

Solid material must have a melting point greater than 250 °C and must not be volatile below 250 °C.

- (i). Solids, normal or special form material, as limited in Table 1, within insert Design No. 3982. All contents may be shipped as individual elements or compounds except for Cs, Hg, I, Na, and P. Cs, Hg, I, Na, and P contents must be shipped as compounds.
- (ii). Solids, normal or special form material, as limited in Table 2, within insert Design No. 3985. All contents may be shipped as individual elements or compounds except for Cs, Hg, I, Na, and P. Cs, Hg, I, Na, and P contents must be shipped as compounds.
- (iii). Gases, normal form material, as limited in Table 3, within insert Design No. 3985 as individual elements. The product container shall be a quartz vial sealed by fusing or aluminum capsules.
- (iv). Liquids, normal form, as limited in Table 4, within insert Design No. 4081 as sodium molybdenate in a matrix solution of NaNO₃ 1M and NaOH 0.2M (Na₂MoO₄ [NaNO₃ 1M/NaOH 0.2M]). The product container shall be stainless steel.
- (v). Liquids, normal form, as limited in Table 5, within insert Design No. 3987 as either alkali or acidic salt solutions. For acidic salt solutions, only HCl, H₂SO₄ and HNO₃ solutions of 0.1 N are allowed. The product container shall be a quartz vial or aluminum capsule wrapped in LDPE or similar material with equivalent radiation resistance.

(2) Maximum quantity of material per package

Decay heat not to exceed 30 watts per package for both solid and gaseous contents. Decay heat not to exceed 5 watts per package for liquid contents. Mixtures of nuclides are allowed providing the sum of the proportionate amounts of each nuclide with respect to the quantities shown in the respective table does not exceed unity. The contents include the progeny of the radionuclides listed in Tables 1 through 4; however, the quantities in the tables are for the listed radionuclides without progeny present (i.e., at the time of loading, only the radionuclides explicitly listed in the table may be present up to the quantities shown in the tables).

**CERTIFICATE OF COMPLIANCE
FOR RADIOACTIVE MATERIAL PACKAGES**

1. a. CERTIFICATE NUMBER	b. REVISION NUMBER	c. DOCKET NUMBER	d. PACKAGE IDENTIFICATION NUMBER	PAGE	PAGES
9338	2	71-9338	USA/9338/B(U)-96	5 OF	8

5.(b) (2) (continued)

(i) For the contents described in 5(b)(1)(i):

Total mass of contents and insert not to exceed 9.3 kg. Maximum mass of radioactive material is 45 g.

TABLE 1

Radionuclide	Maximum TBq	Radionuclide	Maximum TBq	Radionuclide	Maximum TBq
Ac-225	2.51E+00	I-131	3.26E+02	Re-186	1.56E+02
Ac-227	7.24E-01	In-111	4.25E+02	Re-188	7.25E-01
Ac-228	4.28E-01	Ir-192	1.81E+02	Rh-105	8.12E+02
Am-241	3.51E-01	Ir-194	2.05E+00	Se-75	4.61E+02
As-77	7.90E+02	Lu-177	1.03E+03	Sm-153	6.12E-01
Au-198	2.56E+02	Mo-99	5.27E+01	Sr-89	1.22E+01
Ba-131	1.88E+02	Na-24	2.63E-02	Sr-90	1.73E+00
C-14	7.20E+00	Np-237	1.17E-03	Tb-161	1.61E+01
Co-60	2.38E-01	P-32	5.58E+00	Th-227	1.01E+01
Cs-131	6.71E+03	P-33	2.44E+03	Th-228	6.79E-02
Cs-134	7.05E+00	Pb-203	5.20E+02	Tl-201	1.45E+03
Cs-137	1.44E+02	Pb-210	8.04E+00	W-187	2.24E+01
Cu-67	6.91E+02	Pd-109	2.96E+02	W-188	6.43E-01
Hg-203	3.57E+01	Ra-223	6.83E+00	Y-90	1.73E+00
Ho-166	2.04E+00	Ra-224	8.86E-02	Yb-169	4.42E+02
I-125	3.19E+03	Ra-226	9.91E-02	Yb-175	1.11E+03
I-129	2.93E-04				

Note: Boron and beryllium shall not be loaded with the contents in Table 1.

**CERTIFICATE OF COMPLIANCE
FOR RADIOACTIVE MATERIAL PACKAGES**

1. a. CERTIFICATE NUMBER 9338	b. REVISION NUMBER 2	c. DOCKET NUMBER 71-9338	d. PACKAGE IDENTIFICATION NUMBER USA/9338/B(U)-96	PAGE 6	PAGES OF 8
---	--------------------------------	------------------------------------	---	------------------	----------------------

5.(b) (2) (continued)

(ii) For the contents described in 5(b)(1)(ii):

Total mass of contents and insert not to exceed 8.6 kg. Maximum mass of radioactive material is 345 g.

TABLE 2

Radionuclide	Maximum TBq	Radionuclide	Maximum TBq	Radionuclide	Maximum TBq
Ac-225	5.47E-01	I-131	3.26E+02	Re-186	2.66E+01
Ac-227	1.63E-01	In-111	4.25E+02	Re-188	2.61E-01
Ac-228	9.30E-02	Ir-192	1.81E+02	Rh-105	8.12E+02
Am-241	7.92E-01	Ir-194	4.83E-01	Se-75	4.61E+02
As-77	7.90E+02	Lu-177	1.03E+03	Sm-153	5.71E+02
Au-198	5.69E+01	Mo-99	9.56E+00	Sr-89	2.59E+00
Ba-131	3.06E+01	Na-24	6.38E-03	Sr-90	4.15E-01
C-14	5.52E+01	Np-237	8.97E-03	Tb-161	3.70E+00
Co-60	4.68E-02	P-32	1.25E+00	Th-227	2.09E+00
Cs-131	6.71E+03	P-33	2.44E+03	Th-228	1.67E-02
Cs-134	1.32E+00	Pb-203	5.20E+02	Tl-201	1.45E+03
Cs-137	1.58E+02	Pb-210	1.66E+00	W-187	4.28E+00
Cu-67	6.91E+02	Pd-109	4.81E+01	W-188	2.19E-01
Hg-203	5.58E+02	Ra-223	2.07E+00	Y-90	4.15E-01
Ho-166	4.60E-01	Ra-224	2.19E-02	Yb-169	4.42E+02
I-125	3.19E+03	Ra-226	2.34E-02	Yb-175	1.11E+03
I-129	2.24E-03				

Note: Boron and beryllium shall not be loaded with the contents in Table 2.

(iii) For the contents described in 5(b)(1)(iii):

Total mass of contents and insert not to exceed 8.6 kg. Maximum mass of radioactive material is less than one gram. Maximum volume of contents, including the product container material and packing, is less than 10 cc.

TABLE 3

Radionuclide	Maximum TBq	Radionuclide	Maximum TBq
Kr-79	1.15E+01	Xe-133	1.04E+03

**CERTIFICATE OF COMPLIANCE
FOR RADIOACTIVE MATERIAL PACKAGES**

1. a. CERTIFICATE NUMBER	b. REVISION NUMBER	c. DOCKET NUMBER	d. PACKAGE IDENTIFICATION NUMBER	PAGE	PAGES
9338	2	71-9338	USA/9338/B(U)-96	7 OF	8

5.(b) (2) (continued)

(iv) For the contents described in 5(b)(1)(iv):

Total mass of contents and insert not to exceed 4.9 kg. Maximum mass of radioactive material is 0.8 kg. Maximum specific activity shall be less than 60 Ci/ml and the maximum volume shall be 75 ml.

TABLE 4

Radionuclide	Maximum TBq
Mo-99	3.7E+01

(v) For the contents described in 5(b)(1)(v):

Total mass of contents and insert not to exceed 3.6 kg. Maximum mass of radioactive material is 0.9 kg.

TABLE 5

Radionuclide	Maximum TBq
I-131	7.4E+00

6. For the contents described in 5(b)(1)(v), the shipment period begins when the containment vessel is closed and must be completed within 10 days.
7. In addition to the requirements of Subpart G of 10 CFR Part 71:
 - (a) New O-ring seals must be installed in insert Design No. 4081 and insert Design No. 3987 prior to each shipment of the contents described in 5(b)(1)(iv) and 5(b)(1)(v).
 - (b) The package shall be prepared for shipment and operated in accordance with the Package Operations in Section 7.0 of the application, as supplemented.
 - (c) The package must meet the Acceptance Tests and Maintenance Program in Section 8.0 of the application, as supplemented.
8. The package authorized by this certificate is hereby approved for use under the general license provisions of 10 CFR 71.17.
9. Revision No. 1 of this certificate may be used until June 30, 2018.
10. Expiration date: March 31, 2019.

**CERTIFICATE OF COMPLIANCE
FOR RADIOACTIVE MATERIAL PACKAGES**

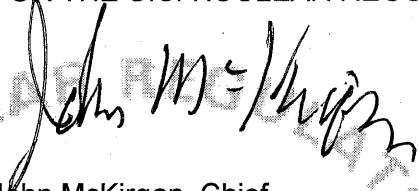
1. a. CERTIFICATE NUMBER	b. REVISION NUMBER	c. DOCKET NUMBER	d. PACKAGE IDENTIFICATION NUMBER	PAGE	PAGES
9338	2	71-9338	USA/9338/B(U)-96	8	OF 8

REFERENCES

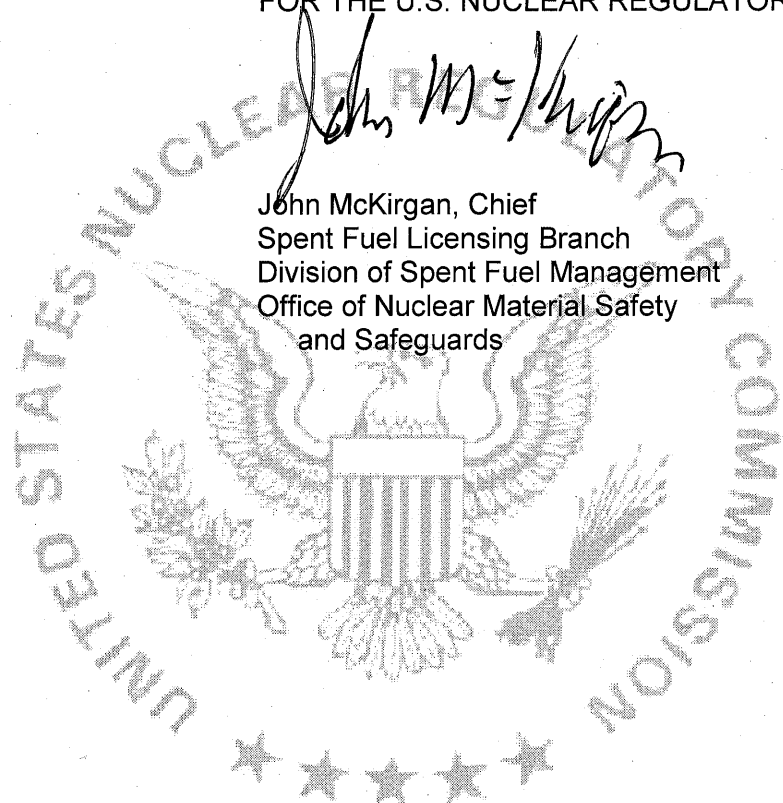
Croft Associates Limited application dated September 29, 2012.

Supplements dated: December 20, 2012; April 23, September 20, November 21, and 28, December 13, 16, and 17, 2013; January 6, 10, 27, and 31, and February 11, 2014; December 14, 2015; and March 21, May 23, July 6, September 9, and October 27, 2016; January 26, March 22, and May 12, 2017.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION


John McKirgan, Chief
Spent Fuel Licensing Branch
Division of Spent Fuel Management
Office of Nuclear Material Safety
and Safeguards

Date: July 21, 2017





U.S. Department
of Transportation

East Building, PHH-23
1200 New Jersey Avenue SE
Washington, D.C. 20590

**Pipeline and
Hazardous Materials
Safety Administration**

CERTIFICATE NUMBER: USA/9338/B(U)-96, Revision 2

ORIGINAL REGISTRANT(S):

Dr. Robert A. Vaughan
President
Croft Associates Limited
Building F4
Culham Science Centre
Culham
Abingdon, Oxfordshire OX14 3DB
UK

Sarah Bryson
Operations Manager
Croft Associates Limited
Building F4
Culham Science Centre
Culham
Abingdon, Oxfordshire OX14 3DB
UK

REGISTERED USER(S):

Mr. R.D. Donny Dicharry
President
Source Production and Equipment Company, Inc.
113 Teal Street
St. Rose, 70087-9691
USA

Henk Doornebos
Manager Distribution
Mallinckrodt Medical BV
Westerduinweg 3, 1755 LE
PO Box 3
1755 ZG
Petten, NL
The Netherlands

Kelly Richardt
Regulatory and Quality Manager
Source Production and Equipment Company, Inc.
113 Teal St.
St. Rose, 70087
USA

Dr. Robert Vaughan
President
Croft, Inc.
240 Camino Encantado
Los Alamos, 87544
USA

Carter Roberts
Type B Quality Assurance Supervisor
University of Missouri-Columbia
Research Reactor Center
University of Missouri-Columbia
Research Park
Columbia, 65211
USA

Amber Gaddy
Compliance Specialist
University of Missouri-Columbia
1513 Research Park
Columbia, 65211
USA

Mr. Juul Rijpkema
Manager Regulatory Compliance and Transport Security
Mallinckrodt Medical BV
Westerduinweg 3, 1755 LE
P.O. Box 3
1755 ZG
Petten, NL
The Netherlands

John Ernst
Assoc. Director, Regulatory Assurance
University of Missouri-Columbia
Research Reactor
1513 Research Park
Columbia, 65211
USA

Jackie Cox
Manager, RAM Shipping
University of Missouri-Columbia
1513 Research Park Drive
Columbia, 65211
USA

Frank Vanderlinden
Material Logistics
SCK CEN
Research Centre Mol
Boeretang 200
2400 Mol
Mol, Antwerp
Belgium

Arvid Tesselaar
Manager Radiochemical Centre
Mallinckrodt Medical BV
Westerduinweg 3, 1755 LE
P.O. Box 3
1755 ZG
Petten, NL
The Netherlands