Nucletron

Flexisource®

136147
136095

Handling Procedure

CE 0344

Doc.No. 777.00105MAN-04

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Referenced documents

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(for logistic issues; for example, missing labels, missing transport crate)

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Table of Contents

1. Source Handling Procedure

WARNING

The source handling procedure must be carried out by Nucletron-trained and -certified source handlers. You must take maximum radiation safety precautions to work safely.

The purpose of this procedure is to ensure safe transportation conditions and compliance to (transportation) regulations, when returning sources or empty containers.

The procedure has the following elements:

1. Receiving new sources, see **Section 1.1, page 6**.
2. Loading/unloading sources from/into the afterloader, see the Flexitron User Manual.

Nucletron Part Number	Isodose Control Part Number	Title
777.00103 MAN	09-00-999	Flexitron User Manual
777.00143 MAN		Flexitron PDR User Manual
777.00160 MAN		Flexitron User Manual

3. Returning (depleted or new) sources, see **Section 1.2, page 8**.
4. Returning empty containers, see **Section 2, page 16.**

Note

Elements 1, 2 and 4 can be prepared by a trained and authorized hospital representative.

The Flexisource transport container is suitable for transportation of the Flexisource Iridium capsule (Ø 0.86mm x 4.5mm), 37 GBq Ir-192 (1Ci) and the Flexisource Iridium capsule (Ø 0.86 mm x 4.5 mm), 370 GBq Ir - 192 (10 Ci).

Table 1 lists the part numbers that are used in this procedure.

Nucletron Part Number	Isodose Control Part Number	Description
136.095		Flexisource Iridium capsule (Ø 0.86mm x 4.5mm), 37 GBq Ir-192 (1Ci)
136.147		Flexisource Iridium capsule (Ø 0.86mm x 4.5mm), 370 GBq Ir-192 (10Ci)

Nucletron Part Number	Isodose Control Part Number	Description
136.192	09-20-001	Source Container for the Flexisource
559.054	00-01-749	Transport bucket (plastic) with sealing plugs
777.00139 MAN	n/a	Source Return Document (SRD) for Flexisource
190.041	n/a	Empty Container Return Document
599.028	n/a	Orange QA Label

Table 1: Part Numbers Used in this Procedure

Note

The local Radiation Safety Officer can add region specific rules.

Information to contact the Nucletron Head Office:

- Traffic department: tel. (31) 318 557 111 (for logistical issues; e.g. missing labels, missing transport bucket, etc.)
- Service Support: tel. (31) 318 557 111 (for technical and quality issues)

1.1 Receiving a new source

A new source is delivered inside a transport container. This container is transported inside a transport bucket (**Figure 1**).

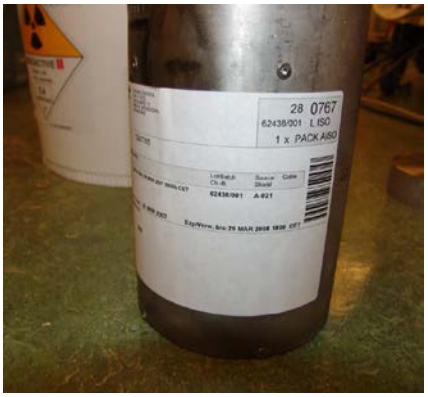

Figure 1: Labels on the transport bucket and container

On the transport bucket are:

- "II-Yellow" labels, indicating the contents (radionuclide type), activity of the source and the Transport Index (TI).
- Labels with hospital address and shipping details.

On the container there is a label with:

- Source type, source serial number and container serial number.
- Address of the hospital.
- Activity on calibration date and lot number of source.

1. Measure the surface dose on the transport bucket (see **Figure 1**) of the received source. If the dose rate at any point around or on top of the transport bucket is above 350 µSv/h or 35 mrem/h, then immediately store the transport bucket in a secure area and contact Nucletron for further instructions.
2. Measure the Transport Bucket contamination by using a dry filter paper or wad of dry cotton wool to wipe an area of 300 cm^2 on the side of the Transport Bucket surface. Use moderate pressure while wiping the bucket. Determine the activity level per cm^2 of wiped area. The activity must be less than 0.4 Bq/ cm^2.
3. Observe the address label and verify if the address on the label matches the hospital address. If the source is addressed to another hospital, do not proceed with the source exchange but contact your local Nucletron office or Nucletron representative.
4. Remove the sealing plug that locks the lid of the transport bucket.
5. Unscrew the lid of the transport bucket and check if the source exchange documents are present:
   - A Certificate for Sealed Sources with all relevant information for the source.
   - A label that must be attached to the treatment unit after loading the new source, indicating the source data (see **Figure 2**).
   - Flexisource Handling Procedure (this document, number 777.00105 MAN).
   - Delivery note.

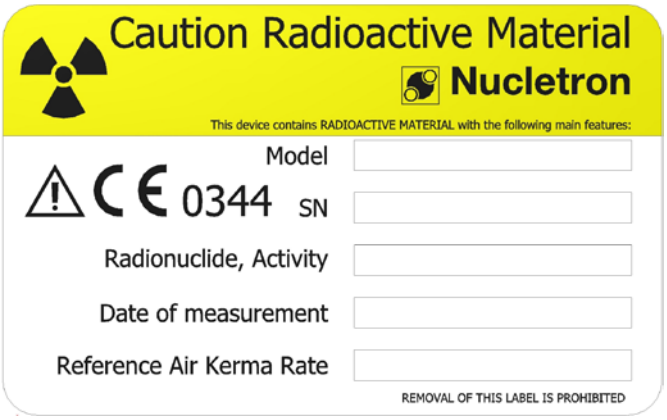

Figure 2: Source data label

6. Check the labels and documents for the return shipment. If they are not present, contact your local Nucletron office or Nucletron representative. These labels and documents are:
   - Source Return Document (SRD) for Flexisource (777.00139 MAN) and “Yellow” or CMR shipping document.
   - Shipper’s Declaration For Dangerous Goods.
   - Sheet with II-Yellow label and address labels for returning the source.
   - Invoice for the return shipment.
   - Envelope marked “Return Documents”
7. Remove the top piece of foam; check that two red (one spare) sealing plugs are present.

Figure 3: Transport container inside bucket with top piece of foam removed

8. Check if the serial number of the container is the same as the number on the source certificate. If they are not the same, contact your local Nucletron office or Nucletron representative.
9. Proceed with the source exchange procedure, as described in the user manual of the Flexitron afterloader.
10. Remove all labels from the transport bucket.

1.2 Returning a source

Use the Source Return Document (SRD) for Flexisource (777.00139 MAN) to prepare a source for return shipment.

Keep the time period between measuring the container and the return shipment of the depleted source as short as possible (preferably within one week).

1. **Remove labels (if not already done) and check transport bucket.**
   - Check if the transport bucket is not damaged (no punctures or cracks are allowed). If the bucket is in bad shape then do not use this transport bucket for return shipment but request a new one from the Nucletron Traffic department (see page 6).
   - Remove the labels (of the previously transported source) from the outside of the container and transport bucket.
   - Check that the container is complete and intact.
2. **Source Return Document (SRD).** Use either the SRD that was provided with the source or fill in electronic copy. Note: On the paper form, please write clearly and use enough pressure to ensure the copies are readable.
   - Fill in the hospital name and address.
   - Fill in the container number. You can find this number on the side of the container.
   - Fill in the source serial number and source type. You can find the serial number on the Certificate for Sealed Sources of the depleted source, on the source data label and on the tail of the source cable.
   - Fill in the serial number of the afterloader.
3. **SRD Item 1: Nucletron-certified source handler.** The correctness and completeness of the SRD and shipping documents must be checked and the SRD must be signed by a person who is trained and authorized by Nucletron.
4. Proceed with the source unload procedure as described in the Flexitron User Manual.
5. **SRD Item 2: Check if the source cable is undamaged and locked.**
6. **SRD Item 3: Verification of Source information label.** Attach the source data label (that was removed from the afterloader) to the side of the container in such a way that the container serial number remains visible. This identifies the source being shipped back. Verify that the label indicates the correct source serial number and activity.

   If the source serial number has not been identified previously, then verify the number by reading it off of the tail end of the cable (this would require the use of a magnifying glass). If no original label is available then use a blank label, write the source serial number, isotope and activity on it and attach it to the side of the container.
7. **SRD Item 4: Container handle is placed and padlock is closed.** Place the lid on the container and lock it with the handle and padlock. if not yet done, place the Transport Container in the Transport Bucket. Put the foam insert on top of the Transport Container. Place the lid on the Transport Bucket; turn the lid clock wise to close it. Do not yet place the sealing plug.

8. **SRD Item 5: Dose rate top.** Measure the dose rate D_s on top of the Transport Bucket (on the lid). Make sure that the detector opening of the survey meter is positioned exactly in the center of the lid and note the value. Typical measurement ranges for 18.5 GBq and 185 GBq Iridium-192 sources are given in **Table 2**.
9. **SRD Item 6: Dose rate side.** Measure the dose rate D_s on the side (on the surface) of the transport bucket. To determine the maximum dose value, measure at 11 cm from the floor all around the bucket. There is a small hotspot at one location where the dose rate is approx. two to three times higher than at other positions.

   In any case, D_s may not be higher than 200 μSv/h. If it is higher, then store the Transport Bucket in a secure area and contact your local Nucletron representative for further instructions.

   Note the highest measured value of D_s on the document. Make sure you use the correct unit of measurement (μSv/h or mrem/h).

18.5 GBq Iridium-192 Source	185 GBq Iridium-192 Source
6-10 μSv/h	60-100 μSv/h

Table 2: Typical Measurement Ranges for the Dose Rate on the transport bucket's surface

Note

For the dose rate measurements, wait until a stable reading is received (minimally 15 seconds, depending on the measurement equipment).

10. **SRD Item 7: Dose rate at 1 m.** Measure the dose rate D_{1m} at 1 m from the surface of the transport bucket, at the same angle corresponding with the maximum value of D_s obtained at the side of the container. Note the value of D_{1m} on the document.
11. **SRD Item 8: Transport bucket contamination.** Use a dry filter paper or wad of dry cotton wool to wipe an area of 300 cm^2 on the transport bucket surface. Use moderate pressure while wiping the bucket. Determine the activity level per cm^2 of wiped area (non-fixed radioactive contamination). This must be ≤ 0.4 Bq/cm^2.

WARNING

If there is more contamination than 0.4 Bq/cm^2, then check the area and yourself for radiation. Inform the Radiation Safety Officer of the hospital. Store the transport bucket in a secure area and contact Nucletron for further instructions.

12. **SRD Item 9: Measurement within specification.** Check if all measurements are within specification.
13. **SRD Item 10: Transport Index (TI).** Determine the TI, a unitless number that equals the value of D_{1m} expressed in mrem/h (note that 1 mSv/h=100 mrem/h and 1 μSv/h=0.1 mrem/h). The TI must be rounded up to the first decimal place on documents and labels (e.g. 0.11 must be rounded up to 0.2). The TI should be ≤ 0.6 (≤ 0.6 mrem/h or ≤ 6μSv/h).

WARNING

If the Transport Index (TI) is determined higher than 0.6, it could indicate that the source is not positioned far enough into the container. If this is the case, then store the transport bucket in a secure area and contact Nucletron for further instructions. The source should not be shipped or leave the premises under any circumstances.

14. **SRD Item 11: Source activity.** Fill in the source activity in GBq (1 Ci = 37 GBq, 1 mGy/h = 9.09 GBq). You can use the source activity given by the afterloader, or use **Table 3** to calculate the approximate current source activity of the depleted source, taking source decay in consideration.

Determine the number of days since the day of source calibration and find the associated multiplication factor in the table to calculate the current source activity.

Days	0	1	2	3	4	5	6	7	8	9
0	1	0.991	0.981	0.972	0.963	0.954	0.945	0.937	0.928	0.919
10	0.911	0.902	0.894	0.885	0.877	0.869	0.861	0.853	0.845	0.837
20	0.829	0.821	0.814	0.806	0.799	0.791	0.784	0.777	0.769	0.762
30	0.755	0.748	0.741	0.734	0.727	0.721	0.714	0.707	0.701	0.694
40	0.688	0.681	0.675	0.669	0.662	0.656	0.650	0.644	0.638	0.632
50	0.626	0.620	0.615	0.609	0.603	0.597	0.592	0.586	0.581	0.576
60	0.570	0.565	0.560	0.554	0.549	0.544	0.539	0.534	0.529	0.524
70	0.519	0.514	0.510	0.505	0.500	0.495	0.491	0.486	0.482	0.477
80	0.473	0.468	0.464	0.460	0.455	0.451	0.447	0.443	0.439	0.435
90	0.431	0.427	0.423	0.419	0.415	0.411	0.407	0.403	0.400	0.396

Table 3: Iridium-192 Decay Calculation Table

15. **SRD Item 12: Attach the new labels to the transport bucket:**

- **Address label.** The new label is addressed to Mallinckrodt, the delivery address for the return shipment. The label should have preprinted sender information. If not, fill in the hospital/clinic name and address next to "Shipper" (see **Figure 4**). Attach the label to the transport bucket.

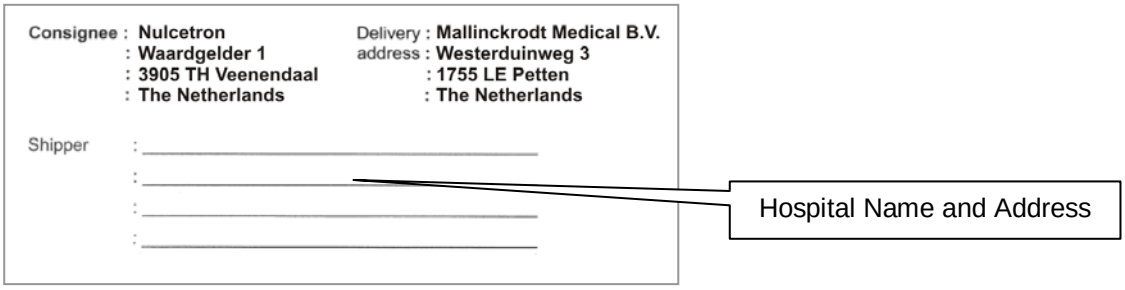

Figure 4: Address Label for Source Return Shipment

- **"II-Yellow" labels.** On two "II-Yellow" labels (that are marked "Return") fill in the source activity in GBq and the transport index TI (see **Figure 5**). Attach the two labels to the side of the transport bucket (180° opposite to each other).

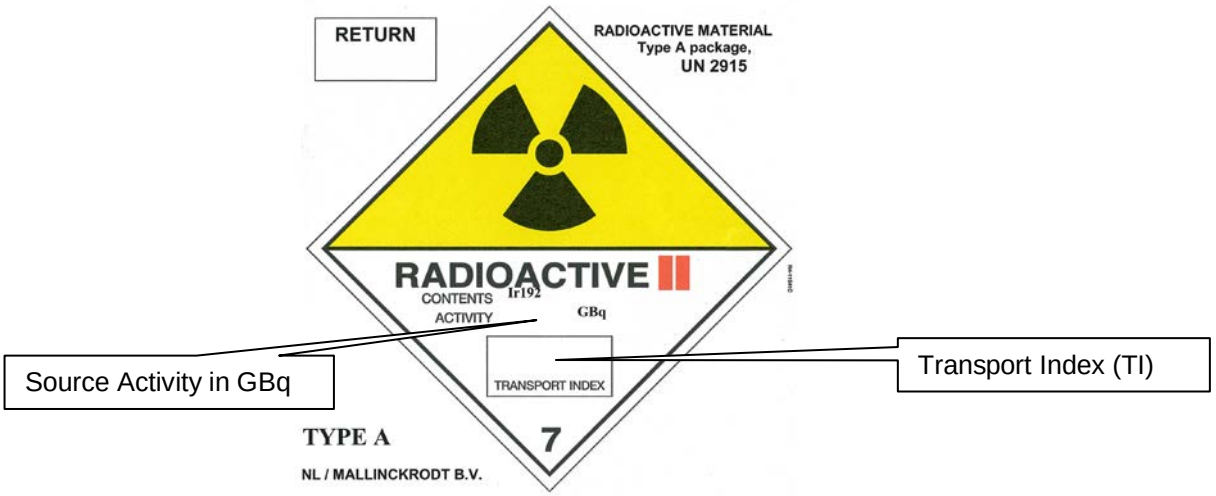

Figure 5: II-Yellow Label for Return Shipment of Depleted Source

WARNING

Return the source only to Mallinckrodt Medical B.V.! Do not send the source to Nucletron in Veenendaal.

16. **Shipper's Declaration For Dangerous Goods form.** This form is used for air transport by an international airline operator (see **Figure 6**). Complete and sign the form, see also International Air Transport Association (IATA) Dangerous Goods Regulations, Section 10, §10.8 for detailed instructions on how to fill in the Shipper's Declaration For Dangerous Goods form.

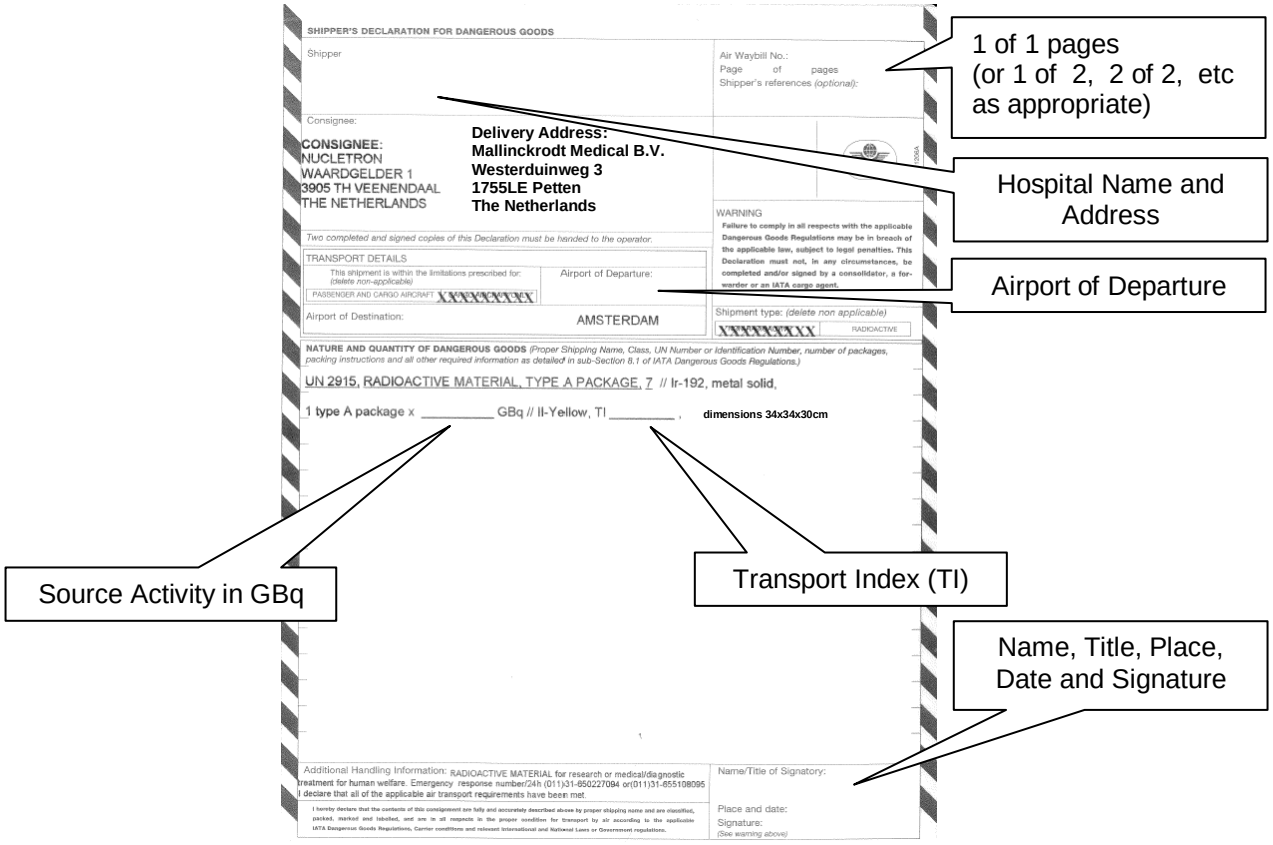

Figure 6: Shipper's Declaration For Dangerous Goods Form

17. **Local transport forms.** If needed, complete and sign the shipping documents for local transport to the IATA airline operator who will provide the international transport.
18. **"Yellow" shipping document**. The document is used exclusively for ground transport within Europe (not for transport by air or sea). Complete and sign the document.

19. **Invoice.** If needed, complete the invoice for return shipment (see **Figure 7**). This is needed for customs clearance.

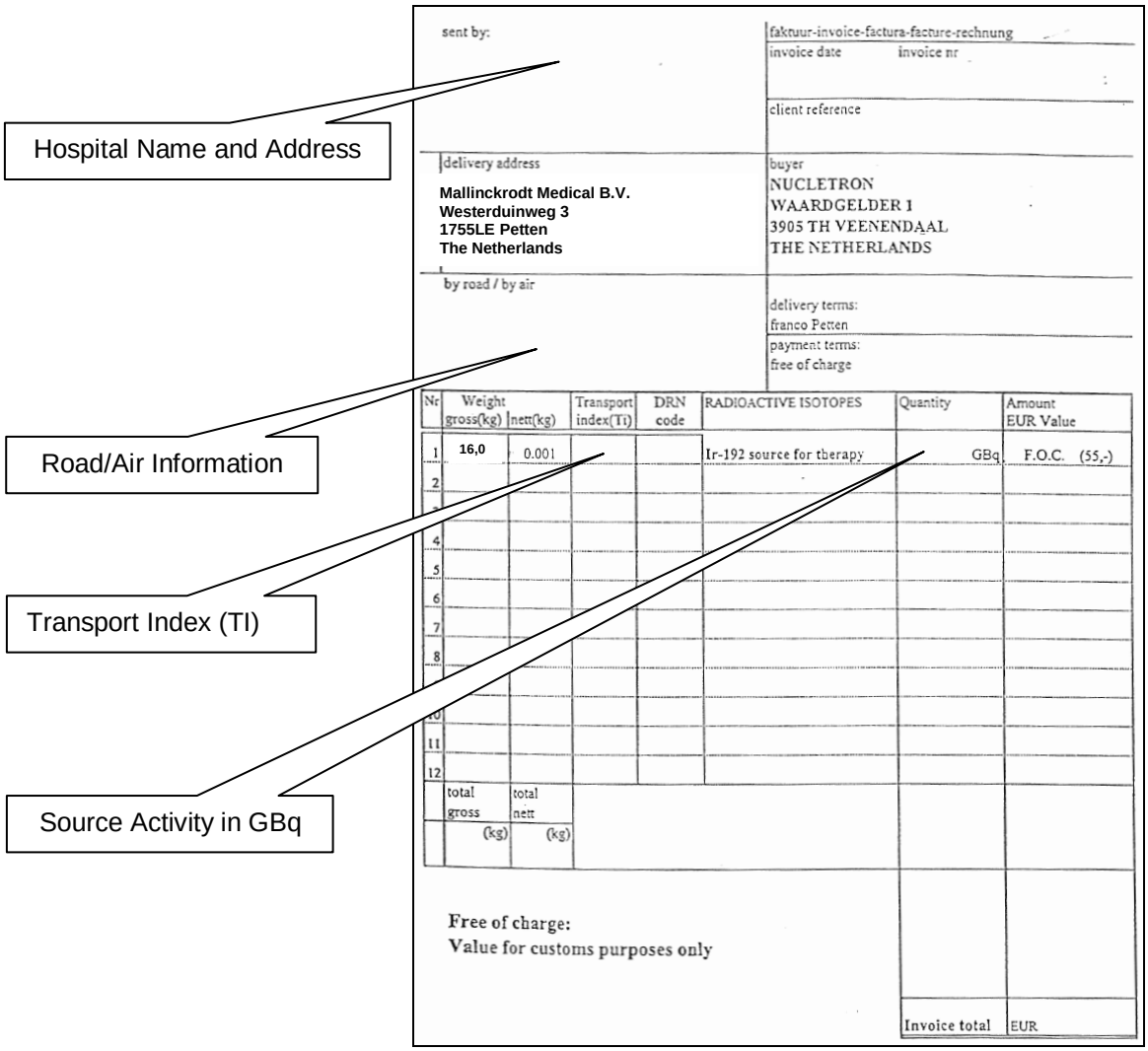

Figure 7: Invoice for Return Shipment

20. **Transport company shipping documents.** A local transport company may use their own transport documents. When completing those documents ensure that the date of shipment, source activity, Transport Index (TI), address of the consignee (Nucletron) and the delivery address (Mallinckrodt) are correctly entered on the documents (see **Figure 7**).
21. **SRD Item 13: Shipping documents.** Check if all shipping documents are correctly completed and signed.
22. **SRD Item 14: Reporting quality problems.** If you have any complaint (e.g. about a source, container, packaging or labeling) then describe the complaint at the bottom of the SRD form.
23. **SRD Item 15: QA label.** In case at step 22 a complaint was reported, **only then** attach one orange QA label N4-10762 B (part number 599.028, see **Figure 8**) to the container and one to the transport bucket before shipping back the consignment. Contact your local Nucletron office or Nucletron representative. The orange QA labels can be obtained from your local Nucletron office or Nucletron representative.

Figure 8: Orange QA Label N4-10762 B (Nucletron Part No. 599.028)

24. **SRD signing and distribution.** If applicable, print the completed SRD. The correctness and completeness of the SRD and shipping documents must be checked and the SRD must be signed by a person who is trained and authorized by Nucletron. Distribute the SRD as follows:
    - Insert the **white original** in the transport bucket.
    - Keep the **white carbon copy** for the service files.
    - Insert the **yellow carbon copy** in the logbook for the hospital/clinic.
    - Fax or E-mail the SRD to Nucletron to indicate that the source is to be returned. **Fax Number: (31) 318 557 168**, **E-mail traffic@nl.nucletron.com**.

WARNING

Do not send a source back to the Netherlands without having received back the approved Source Return Document (SRD) from Nucletron.

25. **SRD Item 16: Closing the transport bucket.** Complete the SRD by marking Item 16 and filling in your name and signature. Insert (the white original of) the SRD in the transport bucket. Screw on the lid and place the sealing plug.
26. **Envelope marked "Return Documents".** Insert the following in the envelope: the Shipper's Declaration For Dangerous Goods form (if needed), the yellow shipping document (if needed), the shipping documents for local transportation to the IATA airline operator (if needed) and the invoice. The envelope contains the documents used by the carrier of the shipment and needs to be kept with the transport bucket (not attached to it).

WARNING

Do not place the transport bucket in a box, crate or any other type of package. The bucket is designed as a package that is suitable for any means of transport.

27. **SRD Approval.** The SRD that was faxed or mailed to Nucletron will be checked for correctness and after approval will be faxed or mailed back to you. Nucletron may request additional documents (such as an Air Way Bill, Shippers Declaration or export license) before granting approval for the return shipment.

WARNING

Do not send a source back to the Netherlands without having received back the approved Source Return Document (SRD) from Nucletron.

28. Transfer the consignment to the carrier or contact your local Nucletron office or Nucletron representative to arrange the transport.
29. **Airway bill** (not provided) and issued by the (cargo) agent at the airport. The transporter/shipper must clearly instruct the (cargo) agent to mention the following information on the airway bill:
    - Handling Info: “Dangerous Goods as per attached Shipper’s Declaration”.
    - Nature and Quantity of Goods: “Radioactive Material”.
    - Address the AWB to: SDV Nederland
      Breguetlaan 67
      1438 BD Oude Meer
      The Netherlands

      For: Nucletron, Veenendaal

2. Returning an empty container

If a container and transport bucket have to be returned without a radioactive source, then proceed as follows. Use the Empty Container Return Document (ECRD) (document number 190.041). Do not use the standard return documents supplied by Mallinckrodt, except for the Invoice for Return Shipment.

1. **Remove labels.** Remove the labels of the previous transported source from the outside of the container and transport bucket.
2. **Empty Container Return Document (ECRD):**
   Note: please write clearly and use enough pressure to ensure the copies are readable.
   - Fill in the hospital name and address.
   - Fill in the container number. You can find this number on the side of the container.
   - Fill in the serial number of the afterloader (if applicable).
3. **ECRD Item 1: Nucletron-certified source handler.** The correctness and completeness of the ECRD and shipping documents must be checked and the ECRD must be signed by a person who is trained and authorized by Nucletron.
4. **ECRD Item 2: Empty check.** Check that there is no radioactive source inside the container and transport bucket.
5. **ECRD Item 3: Source lock closed.** Verify if the source lock is closed.
6. **ECRD Item 4: Transport bucket contamination.** Use a dry filter paper or wad of dry cotton wool to wipe an area of 300 cm^2 on the surface of the transport bucket. Use moderate pressure while wiping the bucket. Determine the activity level per cm^2 of wiped area (non-fixed radioactive contamination). This must be ≤ 0.4 Bq/cm^2.
7. **ECRD Item 5: Transport bucket labels.** Remove the old address label and any labels with a “radioactive” symbol from the bucket. Attach the new labels:
   - **Address label.** The new label is addressed to Mallinckrodt Medical B.V., the consignee for the return shipment. The label should have preprinted sender information. If not, fill in the hospital/clinic name and address next to "By order of:" (see **Figure 4**). Attach the label to the transport bucket.
   - **“Excepted package” label.** Attach this red hatched label marked “UN2908” on the side of the transport bucket (**Figure 9**). On the label, the text: “UN 2908” must be present. This label can be obtained from your local Nucletron office or Nucletron representative.

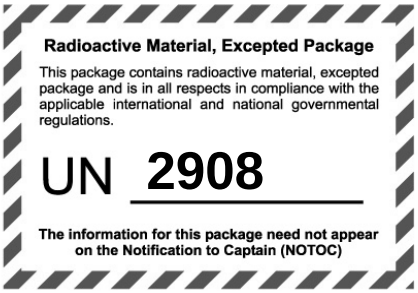

Figure 9: Label Marked “Excepted Package”

WARNING

Return the container only to Mallinckrodt Medical B.V.! Do not send the container to Nucletron in Veenendaal.

8. **Shipper's Declaration For Dangerous Goods form.** This form is not needed.
9. **Local transport forms.** If needed, complete and sign the shipping documents for local transport to the IATA airline operator who will provide the international transport. On the form, mention the text: "Radioactive Material, Excepted Package, Empty Package, UN 2908".
10. **"CMR" shipping document**. The document is used exclusively for ground transport within Europe (not for transport by air or sea). On the document, mention the text: "Radioactive Material, Excepted Package, Empty Package, UN 2908". Complete and sign the document.
11. **Invoice.** Complete the invoice for return shipment (see **Figure 10**). This is needed for customs clearance.

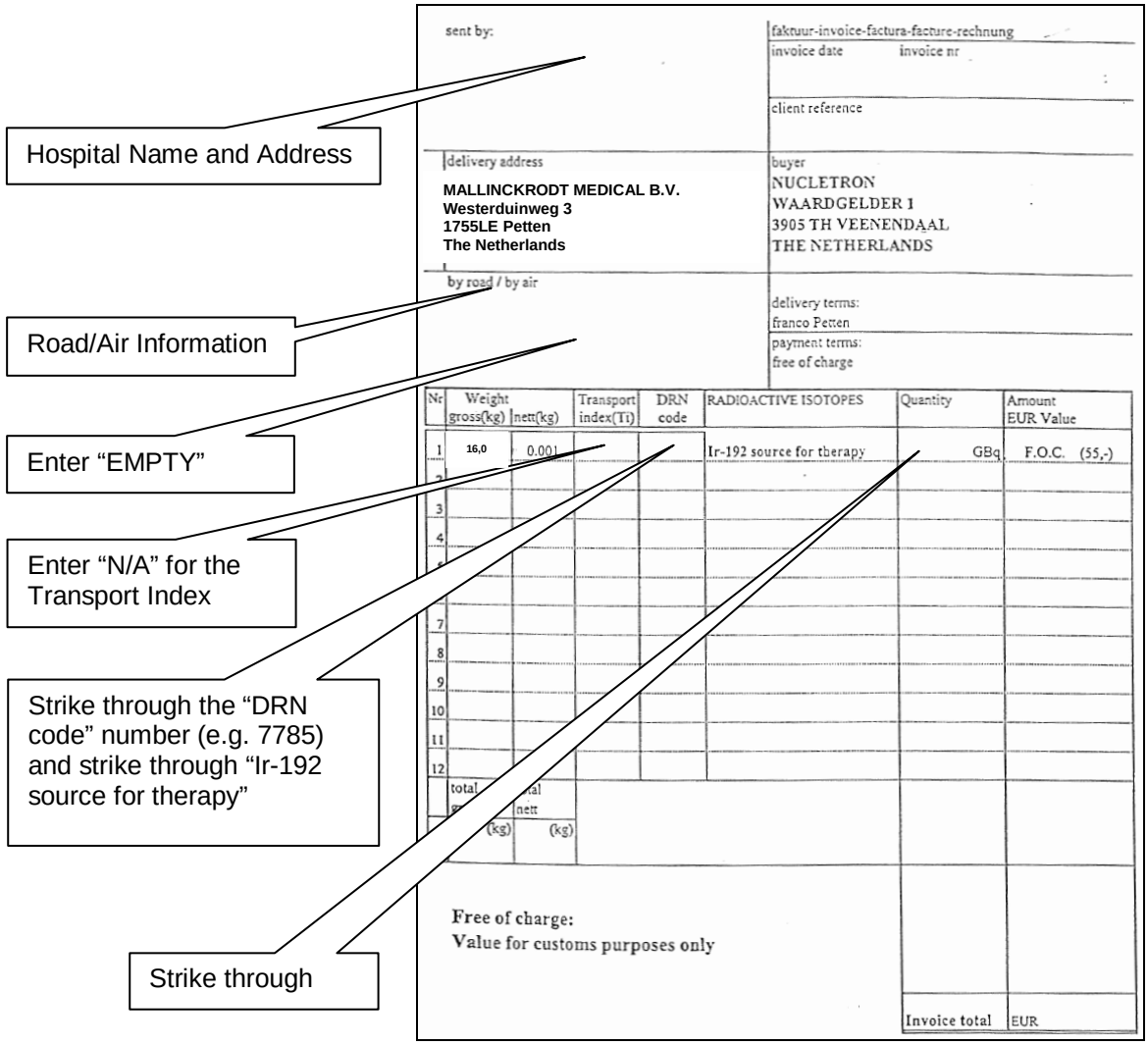

Figure 10: Invoice for Return Shipment

12. **Transport company shipping documents**. It is possible that a local transport company uses its own transport documents. When completing those documents ensure that the date of shipment, source activity, Transport Index (TI), address of the consignee (Nucletron) and the delivery address (Mallinckrodt) are correctly entered on the documents (see **Figure 10**).
13. **Envelope marked "Return Documents".** Insert the following in the envelope: the CMR shipping document (if needed), the shipping documents for local transportation to the IATA airline operator (if needed) and the invoice. The envelope contains the documents used by the carrier of the shipment and needs to be kept with the transport bucket (not attached to it).
14. **ECRD Item 6: Shipping documents.** Check if all shipping documents are correctly completed and signed.
15. **ECRD Item 7: Reporting quality problems.** If you have any complaint (e.g. about the container, packaging or labeling) **only then** attach one orange QA label N4-10762 B (part number 599.028, see **Figure 8**) to the container and one to the transport bucket before shipping back the consignment. Contact your local Nucletron office or Nucletron representative. The orange QA labels can be obtained from your local Nucletron office or Nucletron representative.
16. **ECRD signing and distribution.** The correctness and completeness of the ECRD and shipping documents must be checked and the ECRD must be signed by a person who is trained and authorized by Nucletron. Distribute the Source Return Document as follows:
    - Insert the **white original** in the transport bucket.
    - Insert the **yellow carbon copy** in the logbook for the hospital/clinic.
    - Fax or E-mail the Empty Container Return Document to the Nucletron Head Office to indicate that the container is being returned. **Fax Number: (31) 318 557 168**, **E-mail traffic@nl.nucletron.com**
17. **ECRD Item 8: Closing the transport bucket.** Complete the ECRD by marking Item 8 and filling in your name and signature. Insert the white original of the Empty Container Return Document in the transport bucket.
    Screw on the lid and insert the sealing plug.

WARNING

Do not place the transport bucket in a box, crate or any other type of package. The bucket is designed as a package that is suitable for any means of transport.

18. **ECRD Approval.** The Empty Container Return Document that was faxed or mailed to Nucletron will be checked for correctness. After approval, the document will be faxed or mailed back to you. Nucletron may request additional documents (such as an Air Way Bill, Shippers Declaration or export license) before granting approval for the return shipment.

WARNING

Do not send an empty container back to the Netherlands without having received back the approved Empty Container Return Document from Nucletron.

19. Transfer the consignment to the carrier or contact your local Nucletron office or Nucletron representative to arrange the transport.

20. **Airway bill** (not provided) and issued by the (cargo) agent at the airport. The transporter/shipper must clearly instruct the (cargo) agent to mention the following information on the airway bill:

- "Radioactive Material, Excepted Package, Empty Package, UN 2908".
- Address the AWB to: SDV Nederland
  Breguetlaan 67
  1438 BD Oude Meer
  The Netherlands

  For: Nucletron, Veenendaal

3. Source photograph for HASS Directive

In compliance with the High Activity Sealed Radioactive Sources (HASS), the manufacturer of radioactive sources is obliged per 01-01-2008 to provide a photograph of the source in a shipment.

The HASS directive is a European set of rules based on IAEA recommendations and has been implemented by the European Commission. The purpose of the HASS directive is to prevent exposure of workers and public to radiation arising from inadequate control of high activity sealed radioactive sources and sources that are lost from regulatory and management controls ('orphan sources') and to harmonize controls in place in the (EU) Member States by setting out specific requirements ensuring that each such source is kept under control.

In Nucletron's Flexitron HDR and Flexitron PDR afterloaders, a solid Iridium-192 source is used (ø 0.86mm x 4.5mm). **Figure 11** is an illustrative picture of the Flexisource.

Figure 11: Illustrative picture of the Flexisource

The source is shipped in a transport bucket. Inside the bucket, the source is stored in the source container. The transport bucket has a label with source information. **Figure 1** shows the transport bucket and the source container that is stored in the transport bucket.

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