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GUIDELINE ON AFTERLOADER SOURCE EXCHANGE FORMS (RNXM)

Afterloaders containing small radioactive cobalt or iridium sources are commonly used in radiation oncology. The Ir-192 sources in particular decay fairly rapidly and have to be replaced at frequent intervals. A simple afterloader exchange form - RNXM (GLF-RDN-RN-05A) – was developed to reduce and simplify the paperwork required to regulate these source exchanges.

This guideline assists authority holders as well as distributors of afterloader sources to complete and submit the forms and required supporting documents correctly and efficiently.

Document Amendment History

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Glossary

Abbreviation/ Term	Meaning
HPCSA	Health Professions Council of South Africa
RNXM	Radionuclides Exchange Form – Medical
User	The authority holder who is authorised to possess and use the afterloader and its sources. The term includes the office-bearers (RPO, ARPO, MP and AMP).
RPO, ARPO	Radiation Protection Officer, Acting RPO
MP, AMP	Medical Physicist, Acting MP

1. INTRODUCTION

- 1.1 The main purpose of the afterloader exchange form – RNXM (GLF-RDN-RN-05A) is to reduce and simplify the paperwork required to regulate the many transactions involved in the ongoing exchange of sources for afterloaders.
- 1.2 The User (authority holder) acquires an initial authority to possess and use an afterloader source by submitting a completed form GLF-RDN-RN-07A (old number RN787) to SAHPRA Radiation Control, with relevant supporting documents.
- 1.3 Once the first afterloader source is installed, the User sends in the delivery note and source calibration certificate and receives the initial source exchange form (see Annexure 1 for an example).
- 1.4 The exchange form reflects the details of the current source (called the “old” source, because it will be old/depleted by the time of the next exchange).
- 1.5 After each source change, the User returns the completed exchange form (with required supporting documents) and receives a new form, prepopulated for the next exchange, along with an updated authority. This means that the User does not need to fill in the longer forms to add each new source or to dispose of each depleted source.
- 1.6 Where a hospital has more than one afterloader unit, each unit will have its own series of exchange forms.
- 1.7 Distributors may apply for bulk import and export authorities to cover all the afterloader sources they expect to import and/or export in a year. The decision to grant such a bulk authority to any specific distributor rests with SAHPRA Radiation Control.

2. SCOPE

This guideline is intended for:

- 2.1 Office-bearers on radiation oncology authorities that include Ir-192 and/or Co-60 afterloaders, and
- 2.2 Distributors and source handlers of Ir-192 and/or Co-60 afterloader sources.

The aim of this guideline is to enable all parties to complete the administrative requirements around source changes easily, correctly and with minimal fuss.

3. OVERVIEW OF SOURCE EXCHANGE ADMIN PROCEDURE

- 3.1 The User and Distributor will generally agree on a series of approximate source change dates for the year. The Distributor arranges for delivery of each new source to the User and sets a date for the source change to be done by a qualified source handler.
- 3.2 *Two weeks before* each source change, the User should check that the *correct* exchange form is on file. The number printed next to Old: must be the serial number of the source currently in the unit. Do not recycle exchange forms, as this causes administrative chaos.

- 3.3 If none of the office-bearers (RPO, ARPO, MP and AMP) has received an updated form, contact SAHPRA Radiation Control as soon as possible: radionuclides@sahpra.org.za. Provide the reference number you received with the acknowledgement when you submitted the last exchange form. If you received no acknowledgement, forward the original email in which you sent the form, adding a note that you received no response and indicating the date of your upcoming source change.
- 3.4 Having found or received the form, the User must check, correct/complete and sign section A of the form. Also complete the date line above section A: provide the actual date of the exchange and the estimated date of the next exchange. Then pass the form to the source handler to complete and sign section B at the time of the source change.
- 3.5 Once the sources have been exchanged, the source handler completes section B of the exchange form and gives it back to the User.
- 3.6 The User returns the form to SAHPRA Radiation Control (radionuclides@sahpra.org.za, not to any other member of staff) together with:
- (a) the new source calibration certificate, and
 - (b) proof of delivery of the new source to the User. This document must:
 - i. be signed by the recipient, who must be the source handler, one of the User's office bearers, or another HPCSA-registered radiation worker, who then needs to provide their name, designation and HPCSA registration number.
 - ii. indicate the source type (Ir-192 or Co-60) and serial number.
If this information is not already printed on the delivery note, the person who unpacked the source can add it by hand, along with their name, signature and designation.
- 3.7 If the date of the exchange is significantly different from the estimated date on the form (more than 6 weeks), provide the reason, otherwise Radiation Control will be obliged to ask you, which just wastes time all round. The explanation may be written on the form or included in the covering email.
- 3.8 If you have fallen behind with exchange forms, you will need to report on each exchange in sequence until your forms are up to date, as all sources must be accounted for. (Depleted sources are tracked through to export and destruction.)
- 3.9 On receipt of the correctly completed source exchange form (with attachments), Radiation Control adds the new source to the User's file and issues:
- (a) an updated source change form, ready to for the next exchange, and
 - (b) an updated authority. (The depleted source remains on the authority for the time being.)

- 3.10 Once the depleted source has been exported, the Distributor receives a letter of destruction, which must be forwarded to Radiation Control as proof of export. A customs clearance note (customs release notification) is also acceptable.

The proof of export must:


- (a) be clearly marked with the User's name and/or file number. If not already on the document, this information may be provided in the covering email.
 - (b) include the serial number of the source concerned. If the serial number is not printed on the customs clearance note, the Distributor/exporter can add it by hand, along with their name and signature. A destruction letter will already include the source serial number.
- 3.11 Radiation Control then removes the depleted source from the User's source list and sends the User an updated authority.

4. VALIDITY

This guideline is valid for a period of 5 years from the effective date of revision and replaces the old RNXM Guidelines on Exchange Forms – Afterloaders. It will be reviewed on this timeframe or as and when required.

5. ANNEXURES

5.1 Annexure 1: Example afterloader source exchange form (GLF-RDN-RN-05A)

Doc Number: GLF-RDN-RN-05A	APPLICATION FOR AUTHORITY TO EXCHANGE AFTERLOADER SOURCES (RNXM) in terms of section 3A of the Hazardous Substances Act 15 of 1973	 South African Health Products Regulatory Authority
Revision: 1.0		Effective date: 6-Jun-2022

Printed: 24-JUN-22 **Exchange dates:** **Estimated** ~ 20-SEP-22 Actual:..... Next:.....

Section A: Authority Holder to correct/complete and give to the source handler at next source change to complete Section B. Then send to radionuclides@sahpra.org.za with (a) the calibration certificate of the new source, and (b) proof of delivery of the new source.

Authority Holder: ST NOWHERE'S HOSPITAL File no. **M/0987/6** Authority no. 22/0390 Expiry date: 30-JUN-24
 Department, branch or practice: RADIATION ONCOLOGY: AFTERLOADER RPO: SIMPSON MS M Tel: 012-345 6789
 Street address: FLINTSTONE BUILDING, ST NOWHERE'S HOSPITAL, OTHERVILLE, 6543

Afterloader make & model: FlexiGynTherapy|HDR 22 ZA Afterloader serial no. FT040506

Signed Name (print) Date:

Section B: Distributor/source handler to complete this this section and return the form to the Authority Holder. Distributor to submit proof of export or destruction of the spent source either immediately or with the monthly report.

Distributor: RANDOM DISTRIBUTION CC File no. 9876 Auth no. 22/0119 Expiry date: 28-FEB-23

Depleted sources **sent to** (company & country):

New sources **imported from** (company & country), if different:

Source: Ir-192 X Co-60 (Circle or mark X)				
Source serial #	Initial activity & unit	Delivery note No.	Delivery date	Received by (PRINT NAME)
Old: D85E 7765 Inst Jun22	474.8 <u>GBq</u>	XXXXXXXXXXXXXXXXXX	XXXXXXXXXXXXXXXXXX	XXXXXXXXXXXXXXXXXX
New:				

Signed Name (print) Date: Tel: