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	distribution of sealed and non-sealed sources.

Summary: Explanation on how to use the quarterly reports on the import and distribution of sealed and non-sealed sources.

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Document approval

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Document History Log

Revision	Revision date	Description of the modification	Ву
0	2018-10-05	First document	SV]

1. Goal

This guidance is intended for the importers of sealed and non-sealed radioactive substances whose reporting obligation is set forth in the Royal Decree of 24 March regulating the import, transit and export of radioactive substances, and for the supply of radioactive products for which the reporting obligation is set forth in the Royal Decree of 12 July 2015 concerning radioactive products for in vitro or in vivo use in human medicine, veterinary medicine or in clinical studies. The goal is to merge both initial separate reports into one template.

2. Scope

Every importer must report to the FANC all imports of radioactive substances carried out under its registration as importer, and every distributor shall also report each delivery of radioactive products to an end user or facility, that took place under a license for the supply of radioactive products for in vitro or in vivo use in human medicine, veterinary medicine or in clinical studies.

These 'quarterly' reports must be sent **by e-mail only** using the form that can be downloaded from the FANC website, **at the latest 21 days** after the end of each quarter, to the following addresses: trimp@fanc.fgov.be and distinvitroinvivo@fanc.fgov.be.

General principles:

- The subject of the e-mail must be structured as follows: license number(s) –
 company name quarter year
- The structure of the form may not be adapted;
- Only the blank fields of the form may be completed.

The fields must be completed as follows:

- Field 1: Fill in the quarter. Choose Q1, Q2, Q3 or Q4.
- Field 2: Fill in the year in 4 digits (e.g. 2018).
- **Field 3:** Fill in the name and address of the report sender.
- **Field 4:** Fill the customs office where the radioactive substances have been declared. If not applicable, fill in N/A.
- **Field 5 :** Fill in the importer registration number. If not applicable, fill in N/A.
- **Field 6 :** Fill in the radioactive product supply license number. If not applicable, fill in N/A.
- **Field 7:** Fill in the import date by using the following code: **YYYY-MM-DD** (example: 2017-05-22) (ISO standard). The import date means the date on which the goods imported from another EU member state cross the border, or the date on which the goods imported from outside the EU are declared at the customs office.
- **Field 8 :** Fill in the date of delivery to the consignee using the following code : **JJJJ-MM-DD** (e.g. 2017-05-22) (ISO standard).
- **Fields 9 to 15 :** Fill in the name and address of the consignor (country code ISO 3166-1 alpha-2).

Fields 16 to 22 : Fill in the name and address of the consignee (country code ISO 3166-1 alpha-2).

Field 23 : Fill in the product name. This column must be filled only for the supply of radioactive products, for which the reporting obligation is set forth in the Royal Decree of 12 July 2015 concerning radioactive products for in vitro or in vivo use in human medicine, veterinary medicine or in clinical studies. If not applicable, fill in N/A.

Field 24 : Fill in the article code. This column must be filled only for the supply of radioactive products, for which the reporting obligation is set forth in the Royal Decree of 12 July 2015 concerning radioactive products for in vitro or in vivo use in human medicine, veterinary medicine or in clinical studies. If not applicable, fill in N/A.

Field 25 : Fill in the isotope, as mentioned on your license (e.g. I-125, Ir-192).

Field 26 : Fill in the form. Only the following may be used : "**S**" (sealed), "**NS**" (non-sealed) or "**SF**" (special form).

Field 27: For sealed sources, please mention the activity. If not applicable, fill in N/A.

Field 28 : For sealed sources, please fill in the appropriate unit of activity. The unit of activity may only be completed in Bequerel (**TBq**, **GBq**, **MBq**, **kBq**, **Bq**). Please do not use points or commas. If not applicable, fill in N/A.

Field 29: For non-sealed sources, please mention the activity. If not applicable, fill in N/A.

Field 30 : For non-sealed sources, please fill in the appropriate unit of activity. The unit of activity may only be completed in Bequerel (**TBq**, **GBq**, **MBq**, **kBq**, **Bq**). Please do not use points or commas. If not applicable, fill in N/A.

Field 31: Fill in the number of sources per package.

Field 32 : Fill in the number of packages per delivery.

3. Form to be used

The following form is to be used for every quarterly report. It can be downloaded from the FANC website.

