

TRADE IN RADIATION SOURCES

1	GENERAL	3
2	GENERAL TERMS AND CONDITIONS OF TRADING	3
3	OBLIGATIONS OF SELLER AND TRANSFEROR	3
3.1	Duty to obtain information	3
3.2	Obligation to provide information	4
3.3	Obligation to keep records	4
4	STORAGE OF RADIOACTIVE SUBSTANCES AND WASTE MANAGEMENT	5
5	THE SHIPMENT, IMPORTATION AND EXPORTATION OF RADIOACTIVE SUBSTANCES	5
5.1	Prior declaration of consignee in a Member State of the European Union	5
5.2	Shipment notification to a Member State of the European Union	6
5.3	Imports from outside the European Union and exports outside the territory of the European Union	6
5.4	The shipment, importation and exportation of high-activity sealed sources	6
5.5	Securities deposited for high-activity sealed sources	7
5.6	Customs supervision and customs declaration	7
6	TRANSPORT OF RADIOACTIVE SUBSTANCES	7
6.1	Preparation and receipt of transportation	7
6.2	Transport by road	8
7	ABNORMAL EVENTS	8
7.1	Preparing for abnormal events	8
7.2	Procedure in the case of an abnormal event	8
7.3	Reporting an abnormal event	9

APPENDIX DEFINITIONS

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Authorization

The Radiation Act stipulates that the party running a radiation practice is responsible for the safety of the operations. The responsible party is obliged to ensure that the level of safety specified in the ST Guides is attained and maintained.

Under section 70, paragraph 2, of the Radiation Act (592/1991), STUK – Radiation and Nuclear Safety Authority (Finland) issues general instructions, known as Radiation Safety Guides (ST Guides), concerning the use of radiation and operations involving radiation.

Translation. In the event of any differences in interpretation of this guide, the Finnish and Swedish versions shall take precedence over this translation.

1 General

The life cycles of radiation sources are monitored from manufacturing to decommissioning and the treatment of waste. Regulatory control of trade in radiation sources constitutes a material part of the life cycle monitoring.

This Guide concerns trade in radiation sources that generate ionising radiation and the obligations applicable to the associated practices. The Guide applies to trade in radioactive substances, appliances that contain such substances and X-ray equipment. It also applies, where relevant, to trade in accelerators.

The export of some radioactive substances (including tritium and certain alpha radiation sources) is furthermore subject to the regulations applicable to the dual-use items of the nuclear industry.

This Guide does not concern naturally occurring radioactive substances, nuclear material (plutonium, uranium and thorium) or nuclear waste.

Council Regulation (Euratom) No. 1493/93 specifies the requirements applicable to shipments of radioactive substances between Member States.

The requirements applicable to trade in X-ray equipment employed in healthcare are provided in the Medical Devices Act (629/2010) and in the statutes given pursuant to it. These statutes also contain requirements applicable to the radiopharmaceuticals used in healthcare. Compliance with the aforementioned requirements is supervised by the National Supervisory Authority for Welfare and Health (Valvira).

Dual-use items are provided for in Council Regulation (EC) No. 1334/2000 on setting up a Community regime for the control of exports of dual-use items and technology as well as in the Act on the Control of Exports of Dual-Use Goods (562/1996) and in the Government Decree on Export Control (924/2000) issued pursuant to it.

The regulations applicable to nuclear materials and nuclear waste can be found in the Nuclear Energy Act (990/1987) and the statutes and rules issued by virtue of it. Shipments of radioactive waste between States and the transit of waste are discussed in Guide ST 5.7.

2 General terms and conditions of trading

Trade in radiation sources and associated practices, such as importing and exporting, are generally subject to a safety licence as referred to in section 16 of the Radiation Act (592/1991).

The safety licence is not required for shipping radioactive substances intended for own use from a Member State of the European Union to Finland or for shipping radioactive substances that have been in own use from Finland to another Member State of the European Union. However, in such cases, one must nevertheless have a safety licence for the use of radioactive substances. Shipments of radioactive substances and the related obligations are discussed in more detail in chapter 5 of this Guide.

The import and export of some products is prohibited when a radioactive substance has intentionally been added to the products. Such products include food, cosmetics, jewelry, toys and corresponding consumer goods.

Anyone who imports, trades in, transfers to another party or otherwise places on the market radiation appliances, radioactive substances or materials containing radioactive substances must be able to demonstrate that said products meet the safety requirements pertaining to them.

Section 17 of the Radiation Act provides for exemptions from the safety licence and on the grounds thereof. Activities exempt from the requirement of a safety licence are discussed in more detail in Guide ST 1.5. Section 27 of the Radiation Act provides for the usage restrictions of radioactive substances in consumer goods. Section 21 of the Radiation Act provides for demonstrating products' compliance with requirements.

3 Obligations of seller and transferor

3.1 Duty to obtain information

When transferring radioactive substances the use of which is not exempt from the safety licence, the transferor is obligated to ensure

that the consignee has a safety licence which entitles it to possess radioactive substances. This duty to obtain information does not apply if the radioactive substance's activity or activity concentration does not exceed the exemption value.

The following activities nevertheless always require a safety licence, and the transferor of the radioactive substance has a duty to obtain information regardless of the amount of the radioactive substance transferred:

- the medical use of radiation as referred to in section 38 of the Radiation Act
- the manufacturing or sale of radiopharmaceuticals
- the manufacturing of consumer goods which contain radioactive substances
- the administration of radioactive substances to animals for purposes of diagnosis, treatment or research.

Item 5.1 discusses the duty to obtain information relating to the shipment of sealed sources whose activity exceeds the exemption value or appliances that contain such sealed sources to a Member State of the European Union. When transferring radioactive substances to countries outside the European Union, the transferor must comply with the duty-to-obtain-information and other regulations of the destination country. The exportation of high-activity sealed sources may furthermore involve prior declarations, discussed in more detail under item 5.4.

Section 28 of the Radiation Act provides for the duty to obtain information when transferring radioactive substances.

3.2 Obligation to provide information

The transferor of the radiation source is obligated to provide the consignee with information relevant with regard to safety. Such information includes:

- restrictions pertaining to the radiation source's use and conditions of use
- information on the radiation source and the dose rate of radiation in the vicinity of the appliance
- an account of the safety equipment, maintenance, etc.

The information can be provided in, for instance, manuals, product specifications, test certificates and equivalent documents.

When transferring X-ray equipment the possession or use of which is not exempt from the safety licence, it is appropriate to inform the consignee of its obligation to apply for a safety licence pertaining to the equipment's possession and use in connection with the transfer.

Sealed sources or appliances containing sealed sources must be accompanied with detailed written information on their structure and the properties that have an impact on safety. A sealed source must be delivered together with a certificate that indicates the source's leak-tightness and compliance with standards. The source must furthermore be accompanied with a Special Form Certificate pursuant to transportation regulations, if such a certificate has been issued to the source.

The transferor must ensure that the radiation sources or their shields are furnished with the appropriate signs indicating ionising radiation or radiation hazard. Appliances which contain radioactive substances must be furnished with a marking which indicates the radionuclide, activity and the activity's detection date as well as the serial number and manufacturer of the source.

When transferring sealed sources, the importer or seller must provide the user of the sealed source with information on whether the decommissioned sealed source can be returned to the importer or seller.

Section 15 of the Radiation Act provides for the obligation to provide information when transferring radiation sources. The Medical Devices Act (629/2010) provide more detailed requirements on the markings of X-ray equipment used in healthcare. The requirements applicable to other X-ray equipment are specified in Guide ST 5.2.

3.3 Obligation to keep records

The importer, seller or other transferor must keep records of the receptions and transfers of radiation sources.

The records must include at least the following information on radioactive substances and any appliances that contain them:

- information on whether the source is sealed or unsealed
- the radionuclide or radionuclides
- the activity and its determination date
- the consignee of the radiation source
- the manufacturer of the radiation source and the type of the source
- the unique serial number of the radiation source, if it is a sealed source.

The records must include at least the following information on X-ray equipment:

- the consignee of the equipment
- the manufacturer of the equipment and the name of the model (type)
- the equipment's tube voltage and tube current
- the equipment's unique serial number.

The information kept on radioactive substances and X-ray equipment must be submitted to the Radiation and Nuclear Safety Authority annually, by the end of January the following year. Regarding radioactive substances, the information to be submitted consists of import and export data, transfers and receipts as well as the storage situation at the end of the year. Regarding X-ray equipment, the information to be submitted consists of any X-ray equipment transferred and their new holders.

Section 14 b of the Radiation Act provides on the duty of accounting and notification.

4 Storage of radioactive substances and waste management

Trade in radioactive substances can also entail storage and the treatment of waste. Radioactive substances and any appliances which contain such substances as well as radioactive waste must be stored in such a way that they do not pose a danger to the environment and do not fall into the hands of unauthorised parties.

Decommissioned sealed sources must primarily be returned to their manufacturer.

The holder of the safety licence is obligated to ensure that the radioactive waste generated

in its operations is treated safely and rendered harmless. The license-holder is also responsible for any costs arising from cleaning up the environment.

If the radioactive waste generated by the operations is of the kind that cannot be rendered harmless without considerable expense, the Radiation and Nuclear Safety Authority may request a financial security from the party running a radiation practice (hereinafter the responsible party).

The requirements concerning the storage of radioactive substances are specified in Guide ST 5.1 and Guide ST 6.1. A radiation source storage is also subject to the requirements applicable to security arrangements, specified in Guide ST 1.11.

The decommissioning of sealed sources is discussed in more detail in Guide ST 5.1. The requirements concerning the treatment of radioactive waste originating from the use of unsealed sources are specified in Guide ST 6.2. Shipments of radioactive waste between States and the transit of waste are discussed in more detail in Guide ST 5.7.

Section 19 of the Radiation Act and section 15 of the Radiation Decree provide for the deposit of a financial security.

5 The shipment, importation and exportation of radioactive substances

5.1 Prior declaration of consignee in a Member State of the European Union

The shipment of radioactive substances from one Member State of the European Union to another does not require a safety licence. Trade in radioactive substances, however, does require a safety licence.

When radioactive substances are shipped from one Member State of the European Union to another, the consignee must provide the holder of the radioactive substance with a prior declaration confirmed by a competent authority of the destination country on the consignee fulfilling the statutory requirements applicable in the European Union and the national legislation for the possession, use and waste management of

radioactive substances.

The prior declaration is required when the shipment concerns a radiation source in which the radioactive substance is permanently attached to solid matter or enclosed in a durable shield that prevents the substance's dispersion (sealed source) and when the activity exceeds the exemption value specified in Guide ST 1.5.

The prior declaration must be completed on a standard form available, for instance, on the website of the Radiation and Nuclear Safety Authority. The prior declaration may be made to concern more than one shipment, in which case its maximum period of validity is three years. The prior declaration is not necessary when shipping unsealed sources, for which the shipment notification referred to below is sufficient.

Council Regulation (Euratom) No. 1493/93 provides for the shipment of radioactive substances.

5.2 Shipment notification to a Member State of the European Union

If the activity and activity concentration of a shipped radioactive substance exceed the exemption value specified in Guide ST 1.5, the consignor must provide the destination country's authorities with the following information on the shipped radioactive substances (both sealed and unsealed sources) within 21 days of the end of each three-month period:

- the names and addresses of the consignees
- the radionuclides delivered to each consignee, their activity in total and the number of the consignments
- the maximum radionuclide-specific activities delivered on any one occasion to each consignee
- information on whether the source is sealed or unsealed.

5.3 Imports from outside the European Union and exports outside the territory of the European Union

The import of radioactive substances from outside the European Union and the export of them beyond the borders of the European Union requires a safety licence. Imports and exports such as this are not subject to the practice of

a prior declaration or shipment notification as referred to in items 5.1 and 5.2, respectively. Export operations must comply with the regulations of the country of destination.

5.4 The shipment, importation and exportation of high-activity sealed sources

Shipments of high-activity sealed sources (HASS) are subject to the requirements specified under items 5.1 and 5.2.

The import and export of high-activity sealed sources is subject to the following special requirements:

- The importer must ensure that the high-activity sealed source is furnished with a unique number code.
- The importation of a source that has not been identified is forbidden.
- Information on each export or import must be submitted for the prior approval of the Radiation and Nuclear Safety Authority.
- A financial security must be deposited, prior to importation, for sealed sources whose activity exceeds the HASS limit by at least a hundredfold (see item 5.5).

In addition, the import and export of high-activity sources is subject to the International Atomic Energy Agency's (IAEA) "Code of Conduct on the Safety and Security of Radioactive Sources" and "Guidance on the Import and Export of Radioactive Sources", which Finland has undertaken to abide by. According to the code and guidance, the import and export of certain high-activity sources requires the approval of the authorities of the country of origin and country of destination, as well as prior declarations and notification between the countries.

When seeking approval for the import or export of a high-activity source, the Radiation and Nuclear Safety Authority carries out the necessary enquiries and submits the declarations and notifications to the relevant foreign authorities. When necessary, the approval decision specifies requirements on any special notifications and other measures that the party seeking the approval must complete.

When applying for a safety licence for the use of a high-activity sealed source, the applicant must find out, among other things, the

procedure for returning decommissioned sources to their manufacturer or supplier or for their conveyance to a recognised installation (a facility that manages radioactive waste). Therefore, the importer, seller or other transferor must find out, as early as during the procurement phase, whether a decommissioned source can be returned to the manufacturer or other supplier, and provide this information to the source's user.

Chapter 8 a of the Radiation Act and Chapter 5 a of the Radiation Decree provide for high-activity sealed sources. The radionuclide-specific activity levels (HASS limits) of these sources are specified in Guide ST 5.1.

5.5 Securities deposited for high-activity sealed sources

The responsible party for whose use the radiation source is intended must deposit a financial security for the high-activity sealed source prior to its import or shipment to Finland when the sealed source's activity exceeds the HASS limit by a hundredfold or more. (HASS limit = the activity level as referred to in Annex I of Council Directive 2003/122/Euratom on the control of high-activity sealed radioactive sources and orphan sources) [4].

The amount of the security comprises a fixed standard charge and a source-specific surcharge. The amount of the surcharge is based on what are referred to as charge units, the number of which is arrived at by dividing the sealed source's activity with a figure that is equal to the HASS limit by a hundredfold. If the number of the charge units is more than a hundred, the Radiation and Nuclear Safety Authority may evaluate and determine a lower surcharge.

The furnishing of a security is provided for in sections 19, 31 b and 31 f of the Radiation Act. The determination of the amount of the security is provided for in section 22 d of the Radiation Decree.

5.6 Customs supervision and customs declaration

Customs authorities supervise, for their part, the import and export of radioactive substances as well as compliance with the prohibition concerning prohibited products provided in

section 27 of the Radiation Act (see chapter 2).

When radioactive substances or appliances containing such substances are imported to Finland from outside the European Union or exported from Finland outside the European Union, their quality and quantity as well as the fact that they are subject to a licence must be clearly indicated on the customs declaration or an account appended thereto. Customs also requires the customs declaration to indicate the number of the safety licence entitling the relevant party to import or export and a code pursuant to Customs' instructions.

Section 31 a of the Radiation Decree contains provisions on the customs declaration.

6 Transport of radioactive substances

The transportation of radioactive substances is exempt from a safety licence. However, the Radiation Act contains general obligations imposed on the holder of the safety licence if the holder transports radioactive substances or has them transported or imports radioactive substances. The transportation of radioactive substances is subject to legislation applicable to the transportation of dangerous goods.

6.1 Preparation and receipt of transportation

The consignor of a radioactive substance is responsible for the appropriate preparation of the transportation. The consignor can be the holder of the safety licence or a party authorised by the holder. When consigning radioactive substances for transport, the consignor is responsible for ensuring, e.g. the following:

- The radioactive substance is correctly classified (UN number and title).
- The transport package and its markings meet the set requirements.
- The mode of transportation is appropriate with regard to safety.
- The carrier has all the documents and instructions required by the regulations at its disposal (consignment note and any possible further instructions).

If radioactive substances are transported by air, the consignor and packer must always hold qualifications approved by the Finnish Transport Safety Agency (Trafi).

The responsible party must ensure that the employees receiving radioactive substances have adequate training and instructions for the job. Transport packaging containing radioactive substances may not be stored in reception premises unnecessarily.

6.2 Transport by road

The holder of the safety licence may transport radioactive substances in its possession (to be delivered to a customer, received from a customer or substances covered by its own safety licence) by road. In such cases, the licence holder must meet the obligations of the carrier and driver, including the following:

- The driver has the necessary qualifications for the transport of dangerous goods (a valid ADR certificate or awareness training, if necessary).
- The vehicle has the markings for the transport of radioactive substances, if necessary.
- The vehicle has the equipment and safety instructions required by the regulations.
- The shipments have been loaded safely.
- The damage, loss and unauthorized seizure of radioactive substances has been effectively prevented throughout the transport.

For more information about the transport of radioactive substances, see the guides Radioaktiivisten aineiden kuljetus (Transport of radioactive materials) [10] and Turvajärjestelyt radioaktiivisten aineiden tiekuljetuksissa (Security arrangements in the road transport of radioactive materials) [11], published by STUK.

The transport of dangerous substances is regulated by the Act on the Transport of Dangerous Goods (719/1994) and regulations issued by virtue of the Act. Detailed requirements for transport by road are specified in the Finnish Transport Safety Agency's regulation TRAFI/4541/03.04.03.00/2015. By virtue of Section 11 of the Radiation Act, the transport of radioactive substances constitutes use of radiation. The transport of radioactive substances has been exempted

from the need for a safety licence by virtue of Section 17 of the Radiation Act. The safety licence holder's liability for transport and damage in transport are regulated by Sections 29–30 of the Radiation Act. The ADR certificate is regulated by the Government Decree on the Driving Authorization of the Drivers of Dangerous Goods (401/2011). Awareness training is regulated by a Finnish Transport Safety Agency's order, Annex A, Special regulation S12.

7 Abnormal events

7.1 Preparing for abnormal events

The responsible party must identify, in advance, any possible abnormal events related to trade in radiation sources that may compromise safety. Such events include the disappearance of the radiation source or the suspected or confirmed exposure of an employee. The abnormal event may also be malicious damage to or the theft of the radiation source.

The responsible party must plan and implement operations in such a way that the probability of an abnormal event remains as low as possible. It must furthermore ensure that information about an abnormal event is passed on within its organisation and reaches the responsible party and those responsible.

Any possible abnormal events must also be prepared for by, among other things, providing employees who deal with radiation sources with written instructions on how to operate in the event of abnormal events and reserving sufficient resources for the containment of an area.

7.2 Procedure in the case of an abnormal event

When an abnormal event occurs, the responsible party must carry out the measures necessary to contain the radiation exposure and bring the situation under conditions that are safe in terms of radiation. The reasons for the abnormal event must be investigated, and measures to prevent a reoccurrence must be undertaken.

If a close call involves a significant potential risk, the reasons for the event must be investigated and any possible corrective measures must be taken under consideration.

7.3 Reporting an abnormal event

Any abnormal events must be reported to the Radiation and Nuclear Safety Authority immediately. The report must include the following details:

- the responsible party (holder of the safety licence) and the radiation safety officer
- the name and contact details of the person who submits the report
- the time and place of the event
- a description of the event
- information on the people whose safety may have been at risk and an estimate on any exposure to radiation
- an assessment of any possible radioactive substances released to the environment
- any immediate measures undertaken because of the event.

If necessary, the Radiation and Nuclear Safety Authority must be provided with a written report of the event. In addition to the aforementioned information, the report must detail the reasons for and consequences of the event (particularly any possible radiation exposure) and the measures aiming to prevent the occurrence of similar events.

Section 17 of the Radiation Decree (1512/1991) provides for the reporting of any abnormal events that result in radiation exposure. Guide ST 1.6 discusses operations in abnormal events and the reports to be submitted to the Radiation and Nuclear Safety Authority on abnormal events in more detail. Furthermore, Guide ST 1.11 discusses malicious damage to and the theft of a radiation source and the report to be submitted thereof.

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APPENDIX

DEFINITIONS

Trade in radiation sources

The sale of radiation sources and associated practices, such as possession, import, export, transportation and storage. Trade-associated practices may also include installing and testing radiation sources and rendering radioactive waste harmless.

Import

The physical importation or arrival of a radiation source into Finland from a place outside of the territory of the European Union.

Export

The physical removal or departure of a radiation source from Finland to a place outside of the territory of the European Union.

Shipment of a radioactive substance

The transit of a radioactive substance between Member States of the European Union from a point of departure to a destination, including loading and unloading.

Radiation source

A radiation appliance or a radioactive substance.

Radiation appliance

An appliance that generates radiation electrically or contains any radioactive substance.

Sealed source

A radioactive source wherein the radioactive substance is permanently enclosed inside a capsule or in a solid form; the purpose is to prevent the spreading of radioactive material under normal conditions of use.

Unsealed source

A radioactive substance that is not a sealed source.

High-activity sealed source (HASS)

A sealed source containing a radionuclide of activity that was equal to or exceeded the activity level set per nuclide when the source was manufactured or, if the activity at this time is not known, at the time when the source was first placed on the market. Activity levels for different radionuclides are presented in the Appendix of Guide ST 5.1.

Special Form Certificate

A certificate granted by a competent authority to the manufacturer of a radioactive substance which entitles the manufacturer to transport radioactive substances in a special form in an A type package in larger quantities than a substance that is not in a special form. A radioactive substance in special form refers to either a solid radioactive substance, which cannot disperse, or a sealed capsule which contains the radioactive substance.