

INSTALLATION, REPAIR AND SERVICING OF RADIATION APPLIANCES

1	GENERAL	3
2	SERVICING WORK REQUIRES A SAFETY LICENCE	3
3	RADIATION SAFETY IS AN ESSENTIAL PART OF SERVICING WORK	3
3.1	The responsible party appoints the responsible persons	4
3.2	Occupational radiation exposure is monitored	4
3.3	The necessary radiation meters are used during the work	4
3.4	Radiation shielding shall be ensured in the work areas	5
3.5	Radiation safety instructions are required for servicing work	6
4	ABNORMAL EVENTS SHALL BE PREPARED FOR	6

APPENDIX DEFINITIONS

This Guide is valid as of 1 November 2015 until further notice.

It replaces Guide ST 5.8, Installation, repair and servicing of radiation appliances, issued on 4 October 2015.

Helsinki 2016

ISSN 0789-4619

ISBN 978-952-309-319-5 (pdf)

ISBN 978-952-309-320-1 (html)

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

Installation, repair and servicing are an essential part of the radiation safety of the use of radiation appliances. Regular and professional servicing helps to ensure that radiation appliances can be used safely throughout their entire life cycle.

This Guide sets out the principal radiation safety aspects to be considered when radiation appliances that generate ionizing radiation (hereinafter referred to as “radiation appliances”) are installed, repaired and serviced (hereinafter referred to as “servicing work”) and a safety licence is required.

The definitions of the terms used in the Guide are presented in the Appendix.

Section 25, paragraph 1 of the Radiation Act (592/1991) contains provisions concerning the radiation safety of servicing work.

The electrical safety requirements concerning electrical work and the repair of electrical equipment are provided in the Electrical Safety Act (410/1996). The Finnish Safety and Chemicals Agency (Tukes) is the competent regulatory authority referred to in the Electrical Safety Act.

2 Servicing work requires a safety licence

A safety licence must be obtained for servicing a radiation appliance whenever use of the appliance requires a safety licence or registration. A safety licence is also required for work done on appliances that generate ionising radiation for use in health care. Licences are issued on written application to the Radiation and Nuclear Safety Authority (STUK) when the prerequisites for granting the licence are met.

The holder of the safety licence shall be a company or a sole trader registered in Finland or some other party falling within Finnish jurisdiction. This means that the holder must have a place of business, address and registered responsible representative in Finland.

If the party running a radiation practice (hereinafter the responsible party) aims to arrange the servicing for a radiation appliance in Finland but to have it performed by a foreign

equipment supplier or service company, the responsible party itself shall apply for a safety licence for the servicing work. In this case, the employees of the foreign equipment supplier or service company are considered outside workers.

No safety licence is required for servicing work that poses no radiation hazard during the servicing and that has no substantial effect on radiation safety in using the equipment. Such work includes the following, for example:

- servicing work for equipment that generates ionizing radiation by means of electricity, when the power to the equipment is not connected and the servicing work does not involve modifying the shields within the equipment or altering the equipment’s radiation output properties
- servicing work for equipment containing radioactive substances when the shield of the radiation source can be kept closed throughout the servicing work and the shields are not modified.

Measurements related to technical quality control performed by the radiation users can be performed subject to the safety licence of the responsible party and under its supervision.

Section 25, paragraph 2 and section 25, paragraph 3 of the Radiation Act (592/1991) contain provisions concerning the licensing requirements for servicing work.

3 Radiation safety is an essential part of servicing work

When servicing radiation appliances, attention shall be paid to the operating instructions of the appliances and the safety precautions presented therein shall be complied with. The radiation safety of the persons in the working environment shall be ensured.

The party responsible for the use of the appliances shall be notified of the servicing work in good time before the work is started.

Immediately after the work ends, the performer of the servicing work for radiation

appliances shall ensure that the appliance is operating perfectly and that its appropriate use shall not cause danger or unnecessary radiation exposure to the operating personnel, patients or other persons.

The performer of the servicing work shall notify the party responsible for the use of the appliances in writing about the completed service procedures.

Guide ST 3.3 discusses the inspection of the operating condition of X-ray equipment used in healthcare after a substantial repair or service.

3.1 The responsible party appoints the responsible persons

The party responsible for the service work shall specify the duties of the radiation safety officer in writing. A deputy may need to be appointed for the radiation safety officer during their absences due to annual holidays or illness, for example.

The requirements of qualification for radiation safety officers are presented in a separate ST Guide. The deputy is subject to the same qualification requirements as the radiation safety officer.

The responsible party shall ensure that the radiation safety officer and the persons performing the servicing work have received the necessary training required for the work, understand the matters related to the use of the appliances and the safety of the servicing work and are able to perform the work safely.

If the radiation safety officer is unable to supervise servicing work in person at each work site, then the responsible party must appoint an on-site radiation safety person or persons to attend to radiation safety during servicing work.

The responsible party shall ensure that the radiation safety officer and other persons involved in the servicing work regularly receive supplementary training in radiation protection.

Guide ST 1.4 contains more detailed instructions for appointing the radiation safety officer as well as a list of their tasks.

The requirements of qualification and supplementary training for radiation safety officers are presented in Guide ST 1.8.

3.2 Occupational radiation exposure is monitored

Due to the nature of the work and the related risk of abnormal events, servicing work shall primarily be classified as work whose performers belong to radiation work category A. In this case, the employer shall arrange for individual monitoring and medical surveillance of the workers. If the exposure during the service work (including abnormal events) cannot exceed 6 mSv per year, the workers can be classified in category B.

Classification into category B shall be justified by assessing the local working conditions and the total radiation exposure of the worker as caused by all work involving radiation exposure, including any possible abnormal events.

If the holder of a safety licence for servicing work has servicing work performed by outside workers, the responsible party shall ensure that monitoring of radiation exposure and medical surveillance has also been arranged for these outside workers.

Guide ST 1.6 provides instructions for the classification of workers engaged in radiation work. Guide ST 7.1 provides instructions for organising individual monitoring. Guide ST 7.5 provides instructions for the medical surveillance of workers. Section 37 of the Radiation Act (592/1991) contains provisions concerning the monitoring of radiation exposure and the medical surveillance of outside workers.

3.3 The necessary radiation meters are used during the work

Category A workers shall carry personal dosimeters.

If entering into the appliance's radiation beam is possible during the servicing work, the person performing the work shall be carrying one of the following during the work:

- an alarming dosimeter with a warning for increased dose rate
- a dose rate meter with an acoustic signal for increased dose rate.

The alarm caused by an increase in the dose rate shall be so clear that it will be definitely observed regardless of the ambient conditions

and protective equipment (such as hearing protection).

In addition to the alarms listed above, a dose rate meter shall always be used when servicing the following equipment:

- radiotherapy equipment
- industrial radiography equipment
- equipment containing high-activity sealed sources
- accelerators used for the production of radionuclides.

A meter that is suited to observing radiation (such as an alarming dosimeter or a meter for measuring beta and gamma radiation) shall be used for the servicing work of other industrial radiation appliances when necessary.

After the servicing is complete, suitable measurements shall be employed in order to ensure that the requirements for the radiation safety of the device are met.

More detailed requirements for radiation meters required for service work are specified in Guide ST 1.9.

3.4 Radiation shielding shall be ensured in the work areas

The structural radiation shielding requirements for premises in which radiation appliances are used are set out in the ST Guides on equipment and premises. The responsible party must explain the radiation safety arrangements for such premises when requesting a safety licence. The adequacy of radiation shielding must be verified by measurements taken at the equipment operating site.

The structural radiation shielding of premises approved for normal operation of radiation appliances generally also suffices for servicing the said appliances if the radiation beam points in the same direction as is customary when the appliance is used, or if the primary radiation beam limiting device or shutters are closed during irradiation. If other premises are used for servicing of radiation appliances, then these premises must also comply with the shielding requirements. In this case, the following aspects shall be considered, among others:

- In those areas of radiotherapy premises (such as the machine room or ventilation room, for example) that are not occupied by treatment personnel or patients when the appliance operates, the structural shielding may have been dimensioned and constructed to be thinner than in areas that are occupied when the appliance operates.
- The sufficiency of the structural shielding of the premises shall be ensured when new facilities are being commissioned or more powerful equipment is being installed in old facilities.
- When accelerator elements may become radioactive, the delay specified in the accelerator operating instructions for a fall in activity must be observed before performing certain servicing work (e.g. work on beam limiting device, light field-indicators and targets).
- A radiation meter must be used before servicing appliances containing radioactive substances, in order to check that the radiation source is properly enclosed within the radiation shield of the appliance.

The radiation exposure of the employees and outside persons shall be minimised in accordance with the principle of optimization during the test run of a radiation appliance. The following matters, among others, shall be verified in a manner that is appropriate for the situation:

- Only persons whose presence is essential for the work may be present in unshielded rooms during test run.
- Access to the test run area or room shall be controlled and radiation hazard signs shall be posted if necessary.
- In order to prepare for contamination, for example, protective equipment shall be available for ensuring the radiation safety of the workers.
- Appropriate radiation meters and alarming dosimeters as required under item 3.3 shall be available.
- The radiation shielding shall be sufficient in the direction of the primary beam.

Guide ST 1.6 provides instructions for the classification of work areas. Guide ST 1.3 provides instructions for the labelling of work areas. Guide ST 1.10 provides instructions for designing of rooms for radiation sources.

3.5 Radiation safety instructions are required for servicing work

Servicing work for radiation appliances requires radiation safety instructions for the workers performing the servicing.

The radiation safety instructions used by the workers shall include the following, at a minimum:

- basic information concerning the use of radiation and the safety factors
- instructions for ensuring radiation safety at the workplace
- a description of the radiation shielding arrangements (operations and equipment) for various duties
- instructions for servicing work involving the removal of shields and shielding elements from appliances containing radioactive substances, such as in the case of wipe tests
- instructions on measures to be taken in case of abnormal events.

The requirements for wipe tests performed on sealed sources are set forth in Guide ST 5.1.

4 Abnormal events shall be prepared for

The possibility of abnormal events arising due to human error or neglected safety precautions shall also be considered while servicing radiation appliances. In particular, it shall be observed that, during the service of particle accelerators and appliances containing high-activity sealed sources, an abnormal event may cause a significant health risk.

The responsible party shall identify in advance any abnormal events that may occur during the servicing and prepare for them. Activities shall be planned and implemented in a manner that keeps the probability of an abnormal event as low as possible.

Written instructions shall be made available for the workers in preparation for abnormal events.

It must also be ensured that the information concerning the abnormal event is relayed within the organization, allowing it to reach the responsible party and the responsible individuals (the radiation safety officer and the on-site radiation safety person, for example).

STUK shall be notified of abnormal events. The necessary actions and instruction revisions shall also be performed in order to prevent the occurrence of similar events.

Abnormal events shall be reviewed together with the licensee of the appliance being serviced, the radiation safety officer as well as the radiation safety officer and personnel of the service company in order to learn from the events and to prevent similar occurrences.

Abnormal events related to medical devices and supplies shall also be reported to Valvira (National Supervisory Authority for Welfare and Health).

Sections 13 a and 17 of the Radiation Decree contain provisions on the reporting of abnormal events that cause exposure to radiation and observations that are significant in terms of safety.

Guide ST 1.6 presents instructions for preparing for abnormal events and reporting thereof, as well as examples of abnormal events.

The Medical Devices Act (629/2010) contains provisions on the obligation of professional users of devices and supplies to report hazardous situations to the National Supervisory Authority for Welfare and Health.

APPENDIX**Definitions****Servicing work**

The installation, repair and servicing work of radiation appliances generating ionizing radiation that requires a safety licence.

On-site radiation safety person

A responsible person appointed by the responsible party for the place of use of radiation; their task is to assist the radiation safety officer in supervising that the operations at the place of use are safe and that the provided radiation safety instructions are being followed.

Abnormal event

An event resulting in a substantial safety hazard at a location where radiation is used or in its vicinity. An abnormal event may also consist of an exceptional observation or a fact concerning the event that is of substantial significance to the radiation safety of workers, the environment or patients.

Radiation appliance

An appliance producing radiation electrically or containing a radioactive substance.

Radiation safety officer

A specific responsible person appointed by the responsible party; their task is to manage the practical activities performed in order to ensure and maintain the safety of radiation use and to correct any shortcomings.

Outside worker

An employee or sole trader who participates in radiation work ordered by the responsible party without being in their employment.