

TRANSLATION. ORIGINAL TEXT IN FINNISH.

Making the sale and possession of X-ray equipment subject to a licence

Exempting the possession of X-ray equipment used in health care and veterinary medicine from a safety licence

Through this decision, the Radiation and Nuclear Safety Authority (STUK) repeals Section 6 of its decision 147/310/95, dated 24 February 1995, concerning the exemption from a safety licence. Therefore, the sale of X-ray equipment and possession of functional X-ray equipment is subject to a safety licence as specified in Section 16 of the Radiation Act (592/1991).

Under Section 17, paragraph 1, point 4 of the Radiation Act, the possession of X-ray equipment used in health care (medical and dental care) and veterinary medicine remains exempt from a safety licence as specified in Section 16 of the Radiation Act.

The X-ray equipment referred to in this decision, whose trade and possession requires a safety licence, includes devices that generate ionising radiation electrically and that contain parts operating with a voltage difference of over 5 kV.

The Radiation and Nuclear Safety Authority grants the safety licence in accordance with the Radiation Act. When the licence is granted for the sale of medical X-ray equipment referred to in the Medical Devices Act (629/2010), the Radiation and Nuclear Safety Authority will not separately assess the conformity to requirements of the X-ray equipment being introduced into the market or sold. The prerequisite for this is that the devices have undergone a conformity assessment that guarantees their safety and performance, and that a CE label in accordance with Section 9 of the Medical Devices Act has been attached to them.

This decision is valid as of 1 January 2016.

Reported according to Directive 98/34/EC (amendment 98/48/EC) of the European Parliament and of the Council.

Director General

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