

TECHNICAL SUITABILITY STATEMENT ON THE USE OF LEAD-GLAZED MEKS RTG WINDOW FOR X-RAY PROTECTION

Requested by	Hatrick Oy Sakari Kinnunen Pajatie 33 FI – 85500 NIVALA
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Contact person	Eurofins Expert Services Oy Mika Lojander mika.lojander@cpt.eurofinseu.com Huhtimontie 10-12 FI – 04200 KERAVALA
Assignment	On behalf of the client, Eurofins Expert Services Oy carried out a survey and statement regarding the usability of Hatrick Oy's windows in the wall structures of hospitals, medical centers and professional X-ray radiation monitoring, observation and other areas that have conventional X-ray equipment, mammography equipment, conventional dental X-ray equipment, or other conventional radiation sources.
Introduction	The use of radiation in medical imaging and treatment must always be justified, so that personnel and bystanders must always be protected from possible radiation. Lead or various other materials with a defined lead equivalent of mmPb are generally used as radiation shielding The need for protection varies greatly depending on the power of the radiation source, the duration of use and the frequency of use. Mammography equipment below 35 kV generally requires 0.25 mm of lead shielding [1], while 150 kV CT equipment may require 3 mm of lead shielding. In some cases, the need for protection may be even greater due to the duration and intensity of the treatment. Different countries have different laws and regulations regarding the amount of radiation allowed for bystanders and staff. However, the need for protection in structures is very commonly reported as lead thickness or lead equivalent (mmPb). The design of rooms containing radiation sources must always comply with the requirements and regulations of local authorities. Radiation rooms and protection measures almost always require special design and expertise. The statement has been prepared based on the material delivered to Eurofins Expert Services Oy (Appendices 1–8). The statement mainly examines the structure of the window, manufacturing, quality control and the material delivered to the end user. The statement does not take a more detailed position on the special design of X-ray facilities or their structures.
Manufacturer	Hatrick Oy (Pajatie 33, 085500 Nivala) started manufacturing windows in 1987. The company has valid operating system certificates for quality management and environmental systems issued by Eurofins Expert Services Oy, which cover the windows reviewed in this statement and which state that the quality and environmental systems for these products meet the standards ISO 9001:2015 and ISO 14001:2015 requirements (Appendix 7).

Window and frame structure

Hatrick Oy manufactures lead-glazed fixed windows under the MEKS RTG brand name. The lead equivalent in the windows and glazing is 1–6 mm (Pb1-Pb6).

In terms of the window's radiation safety, it is essential that the glass used meets the required radiation protection properties, because its surface area is usually the largest in the window. Corning Med-X Glass is used as glazing, whose radiation protection properties and equivalent lead thicknesses for the different acceleration voltages of X-ray equipment have been presented by the glass manufacturer in its own product brochures and compliance documents. Examples of these are given in Appendix 5.

In addition to the choice of glass, the frame structure is also a critical factor in terms of radiation protection. Because of this, the windows are manufactured using wooden frames with lead protection. The frame of the windows (wood-lead-wood) already has a layer of lead through the thickness of the frame attached during the assembly stage of the frame, which in thickness corresponds to the lead equivalent of the glass used. The glass is installed with glazing bead to the 19 mm rebate so that the lead from the frame overlaps with the glass (5 mm clearance) by at least 14 mm. It can be estimated that the amount of radiation entering through the glass and frame junction is insignificant when it comes to scattered radiation. A lead layer is installed in the groove on the outer side of the frame, which can be safely connected to the other radiation shielding of the surrounding structure in accordance with the special instructions given by the designer. The basic structure of the window is presented in Appendix 1

For premises where better sound insulation is required, Hatrick Oy manufactures MEKS SP RTG windows (Appendix 4). The MEKS SP RTG window has fixed glazing and openable glazed sash. The fixed glazing is completely identical in structure and protection to MEKS RTG, so it can be used in radiation protection in the same way.

Quality control and customer information

In accordance with the principles of the quality certificate, the manufacturer has ensured the correct cutting and assembly of the lead frames of MEKS RTG radiation protection windows with work instructions (Appendix 6). As a quality assurance measure, each manufactured window is checked and a final inspection is performed on one window per production batch, the report of which records, among other the following:

- lead equivalent marking on the window
- lead thickness of the frame

All detected deviations and subsequent measures are recorded in the report (Appendix 6).

The manufacturer has instructions for transportation, storage and for the end-user, which prevent, for example, oxidation of window glass due to incorrect storage and window cleaning (Appendix 5). The glass manufacturer sandblasts a permanent conformity mark onto each glass ordered in specific dimensions. In addition, the manufacturer provides the customer with a glass manufacturer's verification certificate of the properties of the glass used.

Radiation measurement

The material provided by the customer (Appendix 8) contains the results of the radiation measurements of the imaging facilities (4 pieces) carried out by the radiation protection authority (STUK). In the measurements, one measurement point has been behind the radiation protection window supplied by Hatrick Oy, where the imaging personnel typically observe the imaging event during the radiation. The observed radiation dose rates in the measurements were at most 1 µSv/h, and in some measurements no radiation was detected outside the radiation room at all. At the dose rate in question, with the actual exposure amounts, the annual dose amounts that

persons working in the premises are exposed to can be estimated to remain low in relation to the defined dose limits.

Usability statement

Based on the qualifications, training, quality assurance system, instructions and structural description of the window, Hatrick Oy's personnel have sufficient capabilities to manufacture X-ray protective windows in a way that they meet the separately specified customer requirements regarding radiation safety.

MEKS RTG and MEKS SP RTG Pb1 – Pb6 radiation protection windows manufactured in accordance with the quality system can be used safely as part of the structural radiation protection of facilities containing normal medical X-ray equipment.

This requires that the design and implementation of the structures surrounding the windows (including connection detail plans) have been carried out with sufficient competence and care to achieve the required radiation protection.

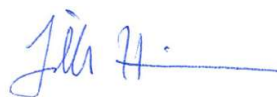
With consideration, windows with different lead equivalents may be used in other radiation protection sites and structures of similar types, considering any special requirements for the facilities/equipment in question.

Kerava, 9.4.2026



Mika Lojander

Senior Expert



Jero Heinonen

Business Unit Manager

The report is electronically signed

Eurofins Expert Services Oy. is notified body No. NB 0809.

References

[1] *Application of dose constraints for shielding of rooms for x-ray imaging- Nordic Radiation and Nuclear Safety Series, Number 01:2023 Technical report, Nordic Working Group on Medical Applications*

[2] <https://stuk.fi/en/radiation-shielding-of-x-ray-rooms> (17.2.2026)

Appendices

- Appendix 1. MEKS RTG cross-section
- Appendix 2. MEKS RTG product card
- Appendix 3. MEKS RTG frame cross-section
- Appendix 4. MEKS SP RTG cross-section
- Appendix 5. Corning SAS technical data of radiation protection glasses
- Appendix 6. MEKS RTG work instructions, inspection report, instructions for end user
- Appendix 7. ISO 9001 and ISO 14001 certificate
- Appendix 8. Radiation measurement results

Distribution

Customer, electronically approved