Technical Specifications on the Safe Use of X-ray Generators

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Medical electrical X-ray devices is regulated by an European framework, but not devices intended for industrial, research or veterinary use. This lack of international standards has led the French Nuclear Safety Authority (ASN) to set up a working group tasked with defining a technical radiation protection baseline for stationary and mobile X-ray generators.

Radiation protection issues

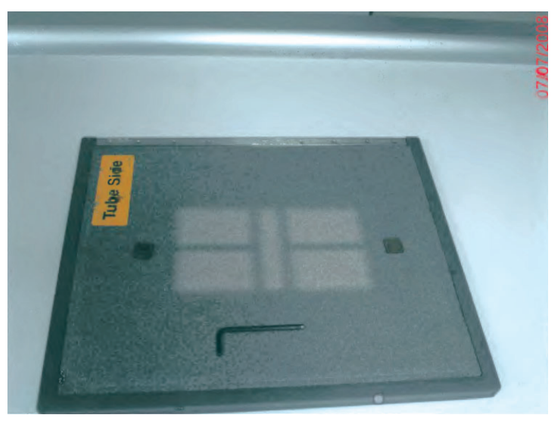
The use of electrical devices emitting ionising radiations is increasing mainly to avoid and replace whenever possible devices containing radioactive sources.
Their advantage: no risk of ionising radiation emissions when not in use. In use though, the exposure levels are quite comparable to those generated by devices containing radioactive sources. The use of X-ray generators involves a number of specific constraints including, in particular, the need to control electrical parameters affecting radiation protection around devices.

Field based observations

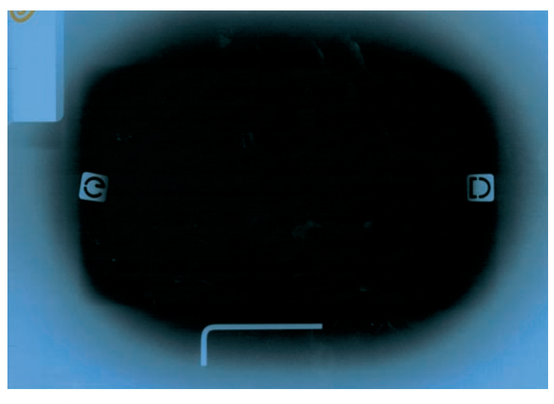
Operators are sometimes subject to unnecessary exposure due to device design problems or operating configurations leading to high level exposures (adjustments, beam alignment, etc.).

Adjustment problem

Veterinary radiodiagnostics: discrepancy between the actual size of the primary X-ray beam and the optical field indicated by the device.



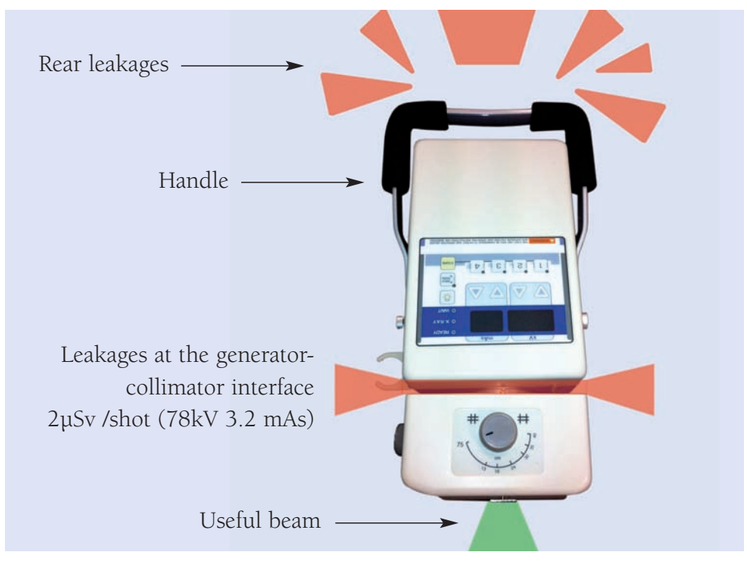
Theoretical target area



Actual target area

Risk of the veterinary surgeon's hands being exposed to the primary beam as he held a small animal in place.

X-ray leakage



Portable X-ray device



X-ray generator in self-shielded enclosure

Radiation leakages from stationary or portable X-ray generators : unexpected operator exposure when the device is in use.

Work already accomplished

The working group set up by ASN with the Institute for Radiation Protection and Nuclear Safety (IRSN), Bureau Veritas and the French Alternative Energies and Atomic Energy Commission (CEA) has defined technical specifications after preliminary studies.

Bibliography

- International Electrotechnical Commission draft standards, which include the latest technological progress regarding X-ray generation (IEC 62-463 & IEC 62-523);
- European regulations concerning electrical medical devices (Directive 93/42/EEC);
- French standard NF C 74-100 (1981) on “Radiology equipment, X-ray apparatus. Construction and tests. Requirements”;
- German, Finnish, American and Canadian regulations, etc.

The existing technical baseline on X-ray generators in France and other countries is neither adequate nor exhaustive.

Classification of radiological risks specific to X-ray generators

1. “Source term” control (useful beam);
2. Radiation leakages from the device (outside the dedicated target area);
3. Unexpected radiation emission (e.g. capacitor discharge from certain devices when they are turned off).

Identification of the main conditions of X-ray generator use

- In self-shielded enclosures;
- In dedicated rooms where no personnel may be present;
- Devices involving emergent radiations in a dedicated room where personnel may be present;
- On site.

Main technical specifications adopted

- Differences between displayed values (high voltage and current) and the actual values applied to the X-ray tube;
- Kerma rate in the useful beam;
- Safety system making it impossible to exceed the reference high voltage;
- Shielding leakages;
- Shutter performance;
- Emergency stop buttons;
- Control system to start the X-ray emission (keys, etc.);
- Access rights to different software levels (use, maintenance, etc.);
- Light indicators (power ON, X-ray emission in progress, etc.);
- Operating parameter display;
- Availability of technical documentation.

The technical specifications identified in this study will be imposed in X-ray generator distribution licences for industrial, research and veterinary applications. These licenses are prescribed by the French regulations following the transposition of EU Directive 96/29/EURATOM.
At the end of this work, ASN intends to present and suggest this technical baseline at the European level.

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