Analysis of the questionnaires on national (regulatory) frameworks for the design of x-ray generators and for the supply of such devices (excluding medical devices)

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CONTEXT

There are no generic design reference standards or recommendations for radiation protection at European or international level for non-medical x-ray generators. IAEA GSR Part 3, EU BSS (2013/59/Euratom) and 2006/42/CE Machinery Directive, Regulation (EU) 2023/1230) only establish general requirements derived from the basic principles of radiation protection.

In addition:

- Not all X-ray emitting devices fall within the scope of the "Machinery" Directive.
- For non-medical devices, the "Machinery" Directive is not well supported by harmonised industrial standards addressing radiation risks in detail.
- There are a wide variety of devices and uses, and consequently of radiation exposure risks.

The EU also wants EU citizens to be able to study, live, shop, work and retire in any EU country and to enjoy products from all over Europe. It does this by ensuring the free movement of goods, services, capital, and people within a single EU market. By removing technical, legal, and bureaucratic barriers, the EU also allows citizens to trade and do business freely. Finally, regulation (EU) 2019/515 defines the rights and obligations in relation to the mutual recognition principle for competent authorities and businesses when selling goods in another EU country.

In this context, France sent a questionnaire in 2021 to collect information from the members of the HERCA Working Group Research and Industrial Sources and Practices (WGRISP) on the design requirements for radiation protection and the regulatory framework for the distribution of different categories of X-ray emitting equipment (X-ray generators, accelerators and equipment containing sealed sources). This initial questionnaire revealed significant differences in approach between the participating countries, particularly for X-ray generators. Some of these devices carry risks of significant radiation exposure and most of these devices are used or could easily be used in several EU countries. Therefore, while national requirements and standards may be adequate to address these risks, they may not be fully compatible with EU legislation, e.g. texts related to the free movement of goods (TFEU).

WGRISP group then drew up a further questionnaire for X-ray generators to exchange practices regarding:

-Regulatory framework for the supply of these devices,
-Design requirements (standards legally binding or not) to ensure radiation protection of the operator of the device and the persons that may be around as well as, more generally, the safe use of the device

QUESTIONNAIRE

The results of this survey are based on a summary of the two questionnaires, the one sent to WGRISP members in 2021 (covering all categories of equipment including x-ray generators) and the other in 2024 (covering x-ray generators only). The two questionnaires were sent to national authorities in 26 European countries. A total of 19 countries responded for X-ray generators, ensuring that the survey is representative (see map below).

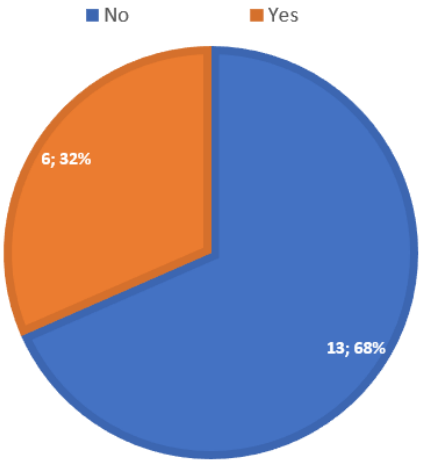
The term X-ray generator refers to any device that emits ionising radiation and typically operates at a voltage of less than 450 kVp, according to the IAEA Specific Safety Guide n°55 (SSG-55). It includes the high-voltage system, the sheath, the tube, and the control panel. By the term "type of X-ray generator" we are referring to various categories of x-ray generator, ranging from the lowest risk to the highest risk (see figure below).

The questionnaire does not cover the premises (casemate, bunker, etc.) in which generators will be installed.

According to the definition in Part 3 of the IAEA GSR, a 'supplier' of a source is defined as a designer, manufacturer, producer, constructor, assembler, installer, distributor, seller, importer or exporter. In this questionnaire, 'supply' refers to any action involving placing an X-ray generator on the market for sale to an end user. This includes the distribution, sale and import of an X-ray generator. Therefore, the possession and/or use of an X-ray generator for manufacturing, production, construction, assembly, installation, maintenance or servicing purposes is not covered by this questionnaire, even if these activities are undertaken by the same company (e.g. maintenance and servicing are mainly carried out by the company that supplies the equipment).

RESULTS

Question 1: Are there any national regulations governing the "supply" of "X-ray generators"?



In response to question 1, 68% of the countries surveyed did not require suppliers of X-ray generators to take any administrative steps to ensure radiation protection when placing such equipment on the market. However, respondents pointed out that European directives and general regulations on radiation protection, which require the application of the optimisation principle, are binding on manufacturers and suppliers of X-ray generators. In Germany, although it is possible to apply for type approval for low dose X-ray generators, the choice is left to the manufacturer or distributor, so there are no regulatory constraints for the distribution or manufacture of these devices. In the Netherlands, the supplier of X-ray generators has administrative obligations to keep a record of the X-ray generators supplied or transferred, but there are no national regulations governing the 'supply' and 'manufacture' of X-ray generators.

Of the 6 countries that replied that their regulations govern the supply and manufacture of X-ray generators, all categories of generators are covered.

Question 2: If so, which regime(s) apply (licence, registration, notification, type approval, exemption), depending on the type of x-ray generator?

The table below shows the different administrative regimes cited by the 6 countries with regulations governing the supply of X-ray generator X.

Regime	Number of countries	Countries concerned
Licence	4	Finland, Norway, Spain, Switzerland
Registration	0	
Notification	2	Italy and Sweden
Type approval	2	Spain

Licence required to supply

Of the 6 countries where the supply of all X-ray generators is regulated, 4 require a licence.

In Norway, the sale and rental (e.g. supply) of all X-ray generators is subject to authorisation. Installation, maintenance or servicing are not subject to licensing as such but are often conducted by the same companies that are licensed to sell/lease.

In Spain, the supply and manufacture of X-ray generators is regulated by Royal Decree, and a licence (authorisation) is required.

In Finland, the use of radiation requires a licence (safety licence). The Radiation Act defines the use of radiation as, among other things, the use and manufacture, trade, installation, maintenance and repair of radiation sources. This means that the trade of X-ray generators requires a safety licence. Suppliers must check the customer's safety licence prior to delivery and keep the list of equipment supplied up to date.

In Switzerland, supply (to the end user), manufacturing, maintenance and servicing as well as the operation (use) of X-ray generators are subject to license. However, in many cases, the authorisation is rather generic and does not contain detailed conditions. The supplier has an obligation to ensure that the end user is duly authorised to hold and use the generator.

Notification required to supply

In Sweden, the supply, e.g. commercial sale, of X-ray equipment is subject to notification. The supplier may only sell an X-ray device to a holder who has a licence/notification for that X-ray device, according to the Swedish regulation.

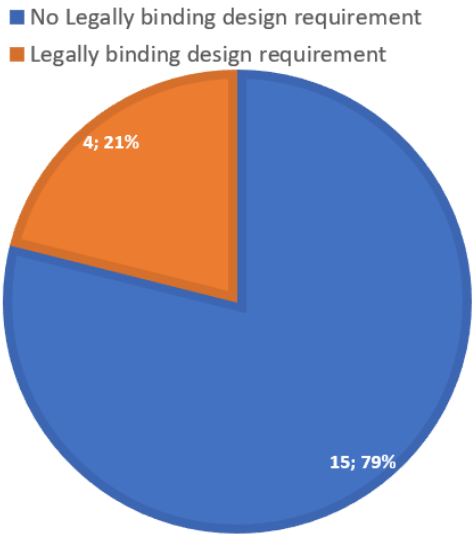
In Italy, the regulatory framework for radiation protection (Legislative Decree No. 101/2020 transposing Directive 2013/59/Euratom BSS) stipulates that the manufacture and supply (specifically import) of ionising radiation equipment for commercial purposes is subject to a notification regime. Notification must be sent to the competent authorities at least 60 days before the start of the aforementioned activities.

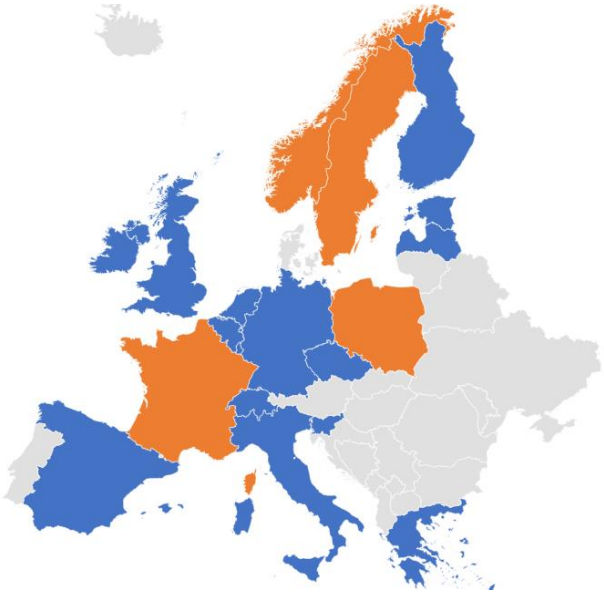
Type approval

Spain have introduced type approval for certain categories of low-risk equipment (dose rate not exceeding 1 µSv/h at a distance of 0.1 m from any accessible surface of the equipment under normal operating conditions). In all cases, type approval is applied for at the initiative of the manufacturer or importer of the equipment. If type approval is granted, the end-user is exempted from applying for an authorisation, registration or notification.

In Spain, the obtaining of the type approval certificate is in compliance with the following criteria:
- the equipment generating ionising radiation must offer sufficient guarantees against leakage of ionising radiation, both under normal conditions of use and under other conditions that may arise accidentally, including possible misuse.
- the equipment must offer advantages justifying its use in view of the potential risk.

Question 3: What are the design requirements for x-ray generators not used for medical purposes set by the regulations, if any, depending on the type of appliance (Please quote the references of the standards/technical document and/or provide a weblink to have access to the regulations in force)?





It is not surprising that many European countries do not impose precise design requirements for X-ray generators, especially given their diversity.

In France, whatever the type of X-ray generator, it must comply with the mandatory standard NF-C 74-100 (or equivalent like CE Medical for veterinary purposes only), which ensures that the generator is designed to be used safely and with good radiation protection. The NF-C 74-100 standard is currently being revised to take account of the latest technical and regulatory developments in radiation protection and may be brought up to European level in the medium term.

Norway, Sweden and Poland impose minimum design rules for low-risk X-ray generators:

- Norway: according to radiation protection Act, section 24, the supplier, during the licence application process, shall ensure that permanently positioned equipment in closed systems for non-medical imaging and technical analyses, including x-ray equipment in process, laboratory equipment containing sealed radiation sources or x-ray tubes, luggage x-ray equipment, body imaging equipment etc., is:
    a) shielded such that the dose rate on the surface does not exceed 5 µSv/h, and
    b) that X-ray equipment has light or sound signals indicating when radiation is generated, and it shall not be possible to generate radiation without the use of a key or code.

-Sweden: cabinet x-ray devices are subjected to notification as long as standard IEC61010-2-091 is applicable, otherwise they are subjected to licensing by authorization.

- Poland: Regulation of the Council of Ministers of 12 July 2006 *on detailed conditions for safe work with ionising radiation sources* set basic requirements for general X-ray generators including maximum dose rates at the beam and maximum dose rates at the 0.1 m from the accessible surface of the housing to define: fully protected, high-protection and exemption X-ray machines.

Question 4: What are the non-legally binding design requirements for x-ray generators not used for medical purposes, recommended by the regulator, or adopted by the industry as a whole?

All responding countries stated that the requirements for compliance with the general principles of radiation protection, as laid down in European Directive EU BSS (2013/59/Euratom), apply to suppliers or manufacturers of X-ray generators. Beyond these general requirements, it is up to the supplier or manufacturer to rely on a recognised standard or other technical document (IAEA guide, etc.) to ensure the safety of X-ray generators, in particular regarding radiation protection.

From a radiation protection point of view, the IEC 61010-2-091 standard on "*special requirements for cabinet X-ray systems"* and the IEC 62523-2010 standard on "*Radiation protection instrumentation - Cargo/vehicle radiographic inspection system*", have been cited by several European countries. Some IAEA Safety Guide such as No. 55 on Radiation Safety of X-Ray Generators and Other Radiation Sources Used for Inspection Purposes and for Non-medical Human Imaging, have also been mentioned.

All of these international documents recommend that X-ray generators used for the aforementioned purposes be equipped with safety features such as :

-collimation of the radiation beam;
-visual indication clearly visible from all possible operator positions when the radiation beam is activated;
-appropriate safety systems to prevent accidental exposure,
-built-in shielding;
-predefined settings for each operating mode;
-a key-operated and/or password-protected control panel;
-appropriate warning labels or signs;
-emergency stop buttons;
-etc.

They also recommend that the supplier provide available information in language that is appropriate and understandable to users, indicate the ambient equivalent dose rate around the source, etc.

The CE medical marking is also often accepted by European countries for the use of X generators for veterinary purposes.

Finally, the analysis of the replies to the questionnaire highlighted the following specific cases:

- Italy, where the Italian Standards Institute (UNI - Ente Italiano di Normazione) has published the standard UNI 8144:1980 entitled " Radiation protection for X-ray diffraction and fluorescence analysis equipment ", which lays down requirements for the design and use of diffractometry and X-ray fluorescence analysis equipment. However, this standard is not mandatory for Italian manufacturers and suppliers.

- Spain, where the regulatory authority imposes internal requirements as part of the approval process for the supply of X-ray generators, such as:
  - Detailed description and drawings of the equipment, including the safety systems incorporated in the equipment and the measures to control access to the source (beam).
  - Isodose curves of the equipment in operation and at rest, if applicable;

- Tests conducted on the prototype to demonstrate its conformity with the specifications for safe operation;
- The quality assurance manual and the organisation envisaged by the applicant to ensure quality in the manufacturing process;
- Applicable regulations used for manufacture.

- Norway, where the requirements on the supplier for the approval process, in terms of competence, procedures, risk assessments, etc., may vary depending on the equipment they sell, with a graduated approach. In addition to the Radiation Protection Act, the Norwegian regulatory authority sets conditions in the licences. For the sale of non-medical X-rays, these conditions are typically:
  1) What type of equipment they are allowed to sell/lease;
  2) Required competence;
  3) Training and information for their customers;
  4) Control of the authorisation and/or registration of the customers to whom they want to sell equipment (All X-ray equipment is also subject to registration - this duty lies with the buyer/user of the equipment, but the supplier must check before installation that they have registered the equipment and/or that they have a valid authorisation if the equipment is subject to this);
  5) Annual report to the Norwegian Regulatory Authority on the sources sold, including proof of registration;
  6) Notification of changes in the company.

-In Germany, type approval for an X-ray device is only granted following an assessment by the Federal Institute of Physics and Metrology (PTB). The PTB requires applicants to provide technical details relating to the device, such as construction plans, and documentation proving compliance with applicable safety requirements, such as automatic shutdown in certain circumstances. The PTB has a document describing the requirements for X-ray equipment, including all relevant international standards.

Question 5: What are the means used by the regulator to ensure that design requirements, either legally binding or recommended by the regulator or the industry, are met?

The analysis of the replies shows that the examination of applications for authorization (mostly by the end holder/user for operation, servicing or maintenance and, to a lesser extent, by the supplier or manufacturer) is the main way in which regulators check the level of safety of the design of X-ray generators with regard to radiation protection. To a lesser extent, the design elements of X-ray generators are checked during inspections in the relevant areas.

However, in the absence of precise standards for certain categories of equipment (recognised standards such as those for X-ray cabinets, standards imposed by regulations, etc.), the means available to European regulators to ensure that the design of X-ray generators is satisfactory from a radiation protection point of view depend on the technical documentation that the applicant is prepared to provide (through the intermediary of a qualified expert known as a radiation protection adviser) and on the analysis carried out by the person in charge of examining the application.

For example, in:

- Belgium, the regulatory authority approves the use of X-ray equipment after a risk analysis; -

- Italy, as there are no legally binding design requirements for X-ray generators and according to Annex IX of the Italian Legislative Decree n.101/2020, the only information required from manufacturers and suppliers of X-ray generators is the type of generator, the maximum acceleration energy of the particles and the power of the generator. Other design features, such

as shielding design, may be required by the regulatory authority to ensure compliance with radiation safety principles and regulatory requirements.

-Finland the Radiation Act:

- Section 56 states that the undertaking which manufactures, imports, places on the market, offers, holds for sale, sells or otherwise transfers radiation sources or accessories and other products related to the safety of a radiation practice (product) must be able to demonstrate that the product is safe;
- Section 58 states that the regulatory authority assesses the radiation safety of a product referred to in section 56 in accordance with the applicable product safety legislation or standards referred to in the Official Journal of the European Union.

-France, in the absence of regulation for x-ray generator supply, proof of compliance of X-ray generators with standard NF C 74-100 (or equivalent standard) is provided by the end user of the equipment as part of the application for authorisation (licence or registration) or in the form of a compliance undertaking for generators subject to the notification regime.

DISCUSSION

The aim of this questionnaire was to take stock of the different approaches to regulate the distribution of x-ray generators and the associated design requirements among the European member countries of the HERCA working group on Research and Industrial Sources and Practices.

Among the main findings, the questionnaire highlighted that only a few countries regulate the supply of x-ray generators. On the other hand, in all responding countries, regulations provide a framework for the use and possession of x-ray generators, including possession for personal use, maintenance, servicing and, where applicable, manufacture. For these countries, suppliers and manufacturers may need to consider EU BSS legislation if their product falls within the scope. For example, designers, manufacturers, and suppliers must ensure that clear and complete information is passed down the supply chain so that users are fully aware of how an x-ray generator (like any other electrical equipment) should be used or installed. The final duty holder must demonstrate to the regulator that all aspects of radiation protection are in place to meet the general requirements of the Ionising Radiation Regulations.

Of all the countries that regulate the supply of x-ray generators, the regulations in Norway, Finland and Spain are the strongest. No X-ray generator, regardless of its risk level, can be placed on the market without authorisation. However, the authorisation is not limited to supply, but also covers possession for installation, maintenance or even manufacture in the case of the manufacturer. Sweden and Italy have opted for an obligation to notify the regulatory authority when an X-ray generator is placed on the market.

In term of design requirement, unlike medical devices, there are no generic design reference standards or guidelines for radiation protection at European or international level. In most European countries, the design requirements in the regulations are deliberately kept very general to cover the diversity of X-ray generators, and do not refer to a specific design standard. Standards are voluntary and enforcement authorities/regulators are concerned with compliance with the essential health and safety requirements set out in the relevant regulations. However, there are some exceptions. Firstly, in Sweden, X-ray cabinets are subject to declaration if evidence of compliance with IEC 61010-2-091 is provided, otherwise an application for approval is required. Secondly, there is the special case of France which imposes a specific French standard (NF C 74-100) on all owners and end-users of X-ray generators. Proof that the X-ray equipment complies with the latter standard (currently issued by a single government laboratory and involving the destruction of the test sample) is generally provided by the manufacturer or supplier, and must be presented by the end user to obtain authorisation to possess or use the equipment.

Regarding non-regulatory design requirements, the situation is more diverse. Some countries rely only on the risk analysis provided by the applicant's radiation protection expert, others have a list of standards applicable to each type of equipment, and others list specific design requirements in internal guidance documents provided to applicants. In terms of harmonised international or European standards, IEC 61010-2-091 and IEC 62523 set out some interesting radiation protection requirements that apply, respectively, to X-ray cabinets and X-ray generators used in cargo/vehicle radiographic inspection systems. At national level, Italy has issued a non-mandatory standard, UNI 8144:1980, which includes design requirements for diffractometer type X-ray generators.

Article 78 of the European Basic Safety Standards Directive imposes the need for the design to meet the ALARA principle. It can be difficult for the end user to assess the design of an X-ray generator for its radiation safety against the different standards required by different countries. For manufacturers or suppliers of equipment, the current situation means that they may have to complete several assessments to meet the different specific requirements of certain countries, which are not required in all countries.

This heterogeneous situation for X-ray generators therefore potentially creates unnecessary obstacles to the free movement of goods and the principle of mutual recognition between the countries of the European Union. Therefore, further improving the harmonisation of legislation and guidance could be an area to consider.

POSSIBLE PERSPECTIVES

The radiation safety of operators using x-ray generators, and of people in the vicinity, depends in the first instance on a well-designed and manufactured device with appropriate safety features, operated by appropriately trained operators. In this respect, there is a clear difference between the way medical devices are regulated (with CE marking and supporting standards) and devices used for other purposes.

The results of this survey could serve as a basis for future discussions and work aimed at further harmonising practices in European countries regarding minimum design requirements for X-ray generators, not only in terms of electrical safety, electromagnetic compatibility etc, but also in terms of radiation protection.