DESIGN OF DEVICES EMITTING IONISING RADIATIONS (EXCLUDING MEDICAL DEVICES)

A need for an enhanced European framework?

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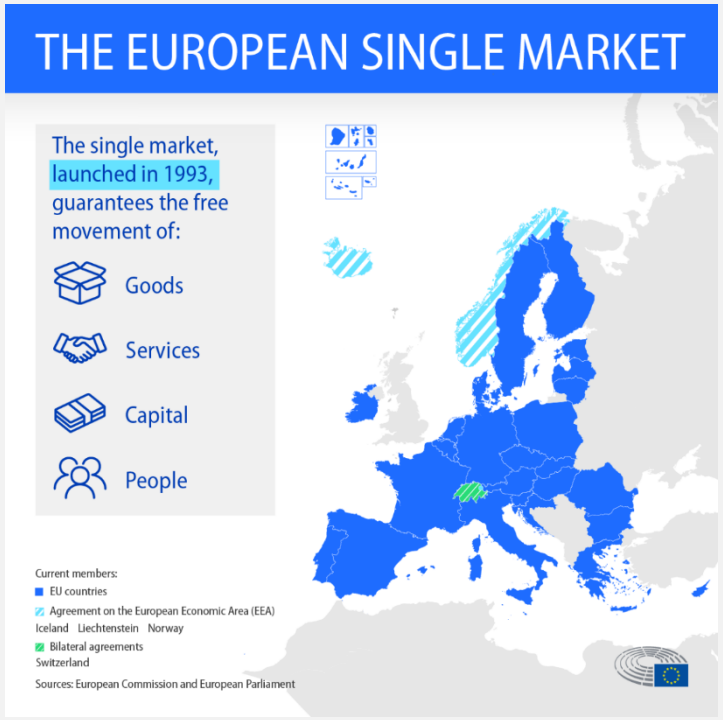
RELEVANT EXISTING REGULATIONS

EUROPEAN UNION GOAL
A SINGLE INTERNAL MARKET WITHOUT BORDERS

The EU aims to enable EU citizens to study, live, shop, work and retire in any EU country and enjoy products from all over Europe.

- To do this, it ensures free movement of goods, services, capital and persons in a single EU internal market.
- By removing technical, legal and bureaucratic barriers, the EU also allows citizens to trade and do business freely.



DIRECTIVE 2013/59/EURATOM

Article 29 - Authorisation procedure

For authorisation purposes, Member States shall require the provision of **information relevant to radiation protection** that is commensurate with the nature of the practice and the radiological risks involved.

In the case of **licensing** and when **determining what information must be provided**, Member States shall take into account the indicative list in Annex IX, which contains in particular:

- **design features** of radiation sources,
- **safety assessment of the activities** in order to assess the quality and extent of protection and safety provisions, including engineering features, as well as administrative procedures.

Article 78 - Information on equipment

Member States shall ensure that any undertaking acquiring equipment containing radioactive sources or a radiation generator is provided a demonstration that the design permits to **restrict exposures to a level which is as low as reasonably achievable**.

Article 88 - Specific requirements for licensing of high-activity sealed sources

In addition to the general licensing requirements, Member States shall ensure that the license **includes minimum performance criteria** for the source, **source container and additional equipment**.

OTHER EUROPEAN REGULATIONS AND DIRECTIVES

Regulation (EU) 2023/988 *(Directive 2001/95/EC)* on general product safety

- Applies to products that are placed or made available on the market **insofar as there are no specific provisions with the same objective** under Union law which regulate the safety of the products concerned.

Regulation (EU) 2023/1230 *(Directive 2006/42/EC)* on machinery (when relevant)

- Applies to machinery, related products and partly completed machinery.

Directive 2014/35/UE on electrical equipment designed for use within certain voltage limits (when relevant)

- Applies to electrical equipment designed for use with a voltage rating of between 50 and 1 000 V for alternating current and between 75 and 1 500 V for direct current.

OTHER EUROPEAN REGULATIONS AND DIRECTIVES

Goals

- Set **general** safety requirement to be respected by economic operators (manufacturer, importer, distributor…) to make available only **safe products** by design and construction/manufacturing.
  - Expectations related to ionising radiation are only mentioned in regulation on machinery and in a very general way:

    "*Any functional ionising radiation emissions shall be limited to the lowest level, which is sufficient for the proper functioning of the machinery or related product during setting, operation and cleaning. Where a risk exists, the necessary protective measures shall be taken*."

- Establish a **conformity assessment procedure** to be carried out (for machinery and electrical equipment).

- List the possible presumptions of conformity with the general safety requirement in case of conformity with:
  - Harmonized European standards (standards the references of which have been published in the Official Journal of the EU),
  - Non-harmonized European standards,
  - International standards,
  - National standards,
  - Requirements of the national law (if in compliance with Union law).

OTHER EUROPEAN REGULATIONS AND DIRECTIVES

Mutual recognition of goods:

The mutual recognition principle ensures market access for goods that are not, or are only partly subject to EU harmonisation legislation.

It guarantees that any good lawfully sold in one EU country can be sold in another. This is possible even if the good does not fully comply with the technical rules of the other country (although there may be exceptions where public safety, health or the environment are concerned).

The principle stems from Articles 34-36 of the Treaty on the Functioning of the European Union and is further defined in Regulation (EU) 2019/515 on the mutual recognition of goods lawfully marketed in another country.

- Regulation 2019/515 applies from 19 April 2020 and replaces Regulation (EC) 764/2008. It defines the rights and obligations in relation to the mutual recognition principle for competent authorities and businesses when selling goods in another EU country.

IAEA SAFETY STANDARDS: RADIATION PROTECTION AND SAFETY OF RADIATION SOURCES (No. GSR PART 3)

Planned exposure situations

Requirement 17: radiation generators and radioactive sources

Registrants and licensees who are **manufacturers** or other **suppliers** shall ensure that radiation generator or radioactive source (and device in which it is used) are:

- well **designed**, well manufactured and well constructed by providing protection and safety
- **tested** to demonstrate **compliance** with the relevant specifications
- well **protected** by an optimized shielding (and other protective devices)

They shall also make **information available** to users on the proper installation and use of the radiation generator, including instructions for maintenance, protection and safety.

DIVERSITY OF DEVICES EMITTING IONISING RADIATIONS AND EXISTING STANDARDS GOVERNING THEIR DESIGN

SOME EXAMPLES OF X-RAY DEVICES

Cabinet X-ray systems

- radiography
- crystallography
- baggage scanning
- irradiation activities

Mobile X-ray devices with an emerging beam

- radiography
- car/truck scanning
- veterinarian radiodiagnosis

Portable X-ray devices with an emerging beam

- baggage scanning
- fluorescence analysis
- real-time radiography

SOME EXAMPLES OF DEVICES CONTAINING RADIOACTIVE SOURCES

Gamma radiography devices

Gamma irradiators

Gamma gauges

Gamma radiography devices (France)

Miscellaneous devices

EXISTING STANDARDS DEALING WITH DESIGN OF DEVICES EMITTING IONISING RADIATIONS (RADIATION PROTECTION)

Harmonised European standards

- Regulation (EU) 2023/1230 (machinery):
  - EN 12198-1 / 12198-2 / 12198-3 (2008): assessment and reduction of risks arising from radiation emitted by machinery ➔ deals with the emission of all types of electromagnetic **non-ionising** radiation
- Directive 2014/35/UE (electrical equipment):
  - EN IEC 61010-2-091 (2021): safety requirements for electrical equipment for measurement, control and laboratory use - particular requirements for **cabinet X-ray systems**

Non-harmonised European standards identified in results of 2021 survey sent by ASN at HERCA/WG RISP

- EN 62598 (2013): nuclear instrumentation – constructional requirements and classification of radiometric gauges

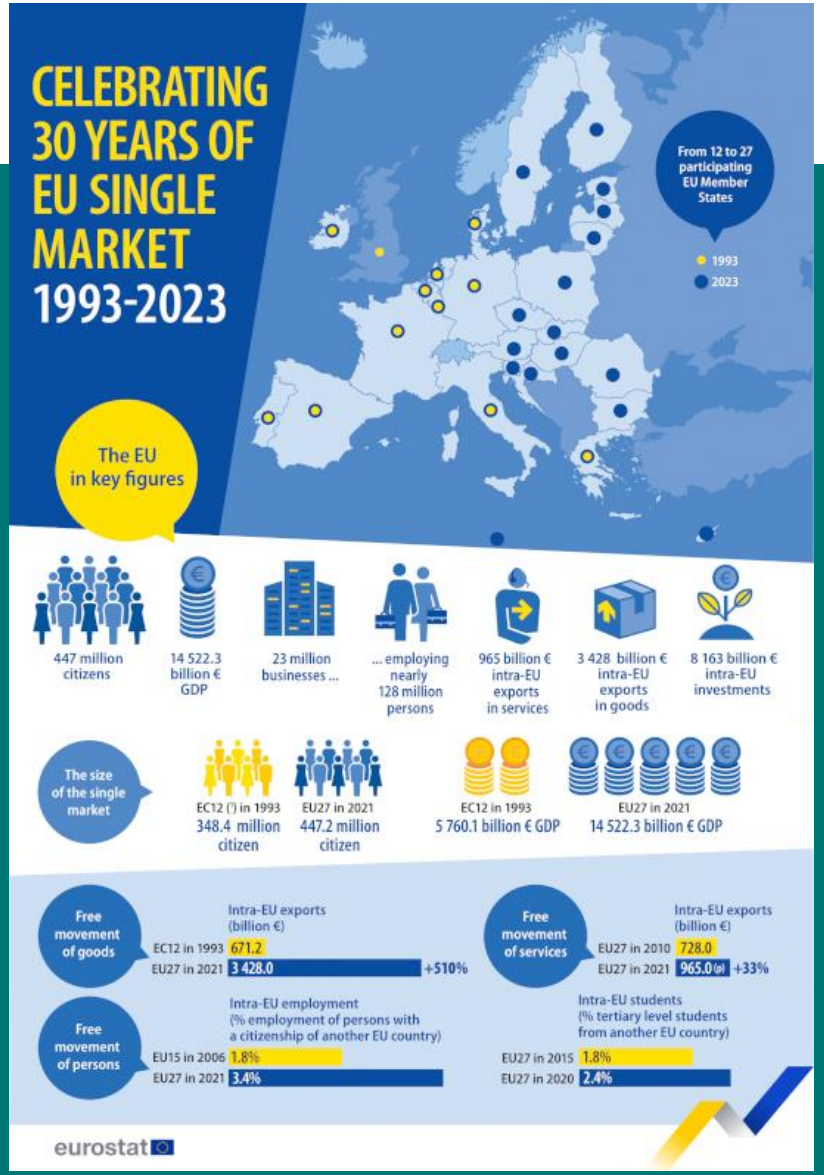
EXISTING STANDARDS DEALING WITH DESIGN OF DEVICES EMITTING IONISING RADIATIONS (RADIATION PROTECTION)

International standards

- ISO 3999 (2004): radiation protection - apparatus for **industrial gamma radiography** - specifications for performance, design and tests
- IEC 62523 (2010): radiation protection instrumentation - **cargo/vehicle radiographic inspection system**

French standards

- NF M 60-551 (1983): radiation protection - **gamma radiography apparatus**
- NF C 74-100 (1981): radiology equipment - **X-ray apparatus** - construction and tests - requirements



FREE MOVEMENT OF GOODS IN EU: AN ENHANCED FRAMEWORK FOR DESIGN OF DEVICES EMITTING IONISING RADIATIONS?

FREE MOVEMENT OF GOODS IN EUROPEAN UNION

❶ The free movement of goods within the European internal market is a **fundamental principle** of the Treaty on the functioning of the EU.

It is assured by:

- the **harmonisation of legislation** at European level (product-specific directive or regulation);
- otherwise by the **harmonisation of technical regulations** (harmonised standards);
- if not by the principle of "**mutual recognition**".

❷ ASN believes that the **radiation safety of operators using a radiation emitting device and of nearby people relies first on a well designed and manufactured device**, with appropriate safety features, the device being operated by appropriately trained operators.

- There is a clear difference in how medical devices are regulated (with CE marking and supporting standards) and devices used for other purposes

❸ Taking into account the principles summarized in ❶, the (lack of) controls implemented in one European country can have consequences in other European countries

PRACTICES IN EU REGARDING DESIGN REQUIREMENTS APPLICABLE TO DEVICES EMITTING IONISING RADIATIONS

The results of the 2021 survey sent by ASN to the HERCA/WG RISP on the design requirements applicable to devices emitting ionising radiation show, in practice, **great diversity of approaches** among EU countries.

The use of **standards** specific to a country, or based on national, European or international standards are sometimes required, either by regulation or by recommendation, or used spontaneously by suppliers/manufacturers.

The existing standards are either **too specific** or **do not address radiation safety** sufficiently. The current EU directives/regulations are **not detailed enough** in terms of design requirements addressing radiation protection.

Unlike medical devices, there are **no generic design reference standard or recommendation**, regarding radiation protection for non-medical devices, either at European or international level.

A NEED OF AN ENHANCED EU FRAMEWORK FOR DESIGN REQUIREMENTS?

Why?

- Some devices emitting ionising radiations carry **risks** of significant radiation exposure
- Most of these devices are **used or could easily be used** in several EU countries
- National requirements/standards or non-harmonised European standards or international standards **may be adequate to address these risks**…
- … but they may **not be fully compatible** with EU regulation (free movement of goods)
- There is a **significant difference** between EU approach on medical devices emitting ionising radiations and industrial devices

How?

Since HERCA/WG RISP members did not support, overall, the initiation of an EU binding text, on design requirements, **the next step could be** to publish an **HERCA general guidelines** (becoming an implicit standard over time?).

Recent work conducted in France (by ASN and IRSN, French-TSO), could be **used as a basis** to develop general technical guidelines for the safe (ionising radiation safety) design of these devices under the aegis of HERCA.

- See ASN and IRSN presentations during the 14th meeting of HERCA/WG RISP regarding X-ray devices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