

# HERCA Working group on Research and Industrial Sources and Practices

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Review of regulatory frameworks for  
undertakings carrying out  
installation, maintenance and  
service of ionising radiation  
equipment used in industry and  
research

## Information Paper

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# Review of regulatory frameworks for undertakings carrying out installation, maintenance and service of ionising radiation equipment used in industry and research

*An information paper from the Heads of the European Radiological Protection Competent Authorities*

## Introduction

The HERCA information paper is to assist European competent authorities in making regulatory decisions on installation, maintenance and service (IMS) of radiation sources, x-ray devices and other devices used in industry and research emitting ionizing radiation.

The term “IMS” in this paper and its use in the context of the protection of the health of workers against ionising radiation means any activity on radiation sources, x-ray devices or other devices emitting ionising radiation. That involves work on the source shielding, the source driving unit or other electronic or mechanical component that could expose the source, reduce the shielding around the source or compromise the radiation safety of the unit or the source or replacement of X-ray tube.

In the Council Directive 2013/59/EURATOM<sup>1</sup> of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, practises of IMS are not directly listed among the activities that must be licensed or registered<sup>2</sup>. In this context, IAEA Basic Safety Standards<sup>3</sup> are more precise and sets out requirements that the registrants and licensees shall ensure that adequate maintenance, testing and servicing are carried out as necessary so that sources remain capable of fulfilling their design requirements for protection and safety throughout their lifetime. This might be a reason why regulatory practices in this area are very different from country to country.

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<sup>1</sup> COUNCIL DIRECTIVE 2013/59/EURATOM of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom.

<sup>2</sup> Council Directive 2013/59/EURATOM, Article 27 and 28.

<sup>3</sup> Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, GSR General Safety Requirements Part 3.

The HERCA WG RISP wanted to know how IMS is implemented in different countries and how stakeholders like companies performing IMS are concerned. This is of interest as there are companies performing IMS both within a country but also in other countries and hence are faced with different legislations and requirements for apparently similar or even same practices. The number of organizations providing IMS across Europe might be relatively limited depending on the type of equipment. However, there are also contractors who perform IMS from third countries because they are suppliers of the equipment. It is therefore essential to find a common solution and a unified approach for this type of practises.

### Challenges in regulating IMS

Some countries apply a graded approach by having licensing or registration which means authorization according Directive 2013/59 Euratom.

In some countries, the source holder needs to have a license for IMS. In addition, the source holder is responsible for radiation safety issues also for installation, maintenance and service activities. This means that the source holder has to agree with the IMS operator. If the IMS operator comes from abroad, the foreign workers are considered as outside workers and foreign companies perform activities under the responsibility of the authorised company.

In other countries, the IMS operator needs a license for IMS and is responsible for all radiation safety issues related to IMS.

### Ideas of a common approach in regulating IMS

Generally, HERCA countries have regulatory provisions for IMS either in the Radiation Protection Law or subsidiary regulations and there is always a company responsible to assure radiation safety and a license or registration for performing IMS is required. Usually, it is either the source holder or the IMS operator who needs to have a license for IMS.

As some countries require licensing or registration, depending on certain criteria, it could be of interest to define what kind of IMS is considered to be due to licensing and what kind of IMS is due to registration.

Considering IMS for different devices emitting ionising radiation, for instance cabinet x-ray versus hand-held x-ray versus industrial radiography x-ray devices, other technical devices emitting radiation, devices containing sealed sources or different activities and practices a graded approach in licensing or registration should be taken into consideration.

Maintenance of a more advanced x-ray equipment for industrial radiography, accelerator, neutron-generators, gamma radiography holder or replacing sealed sources, IAEA category 1-54 in different equipment's however, might require much more radiation protection awareness and thus should be due to licensing. The main criteria for such a division are the radiation protection measures to be implemented during IMS such as personal dosimetry, categorization radiation workers, safety assessment of practices, training, equipment for servicing, etc. to

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<sup>4</sup> IAEA Safety Guide No. RS-G-1.9, Categorization of Radioactive Sources.

perform calibration of beam, different measurements (dose rate, leak test, measurement of contamination).

### The Holder of the source needs to get licensed

The advantage for the holder of a source to be licensed for IMS might be that the source holder becomes aware of the importance of radiation safety aspects concerning IMS, still, the IMS operator is responsible for the performed work and thus should be aware of potential radiation safety issues. Therefore, an agreement between both parts might be necessary to ensure adequate radiation protection of workers and, in certain cases, the regulatory authority must be informed in advance on such agreement. A challenge might be that the source holder has a license for IMS and therefore is responsible for situations despite lack of both radiation protection competence and technical knowledge. In cases where more than one undertaking is involved in IMS, there must be a written cooperation agreement between the involved parties. In complex situation the owner of the equipment and the maintenance company have to discuss and define, who is responsible for which steps of work. It is important that it is clear for all stakeholders who is responsible for which step concerning IMS on order to avoid ambiguous situations when radiation protection issues arise.

### The IMS operator needs to get licensed

The advantage when the IMS operator needs to have a license is that it assures that the IMS operator has the radiation safety competence that is required by legislation. Thus, the IMS operator can serve different clients without special agreements. The results of the questionnaire on IMS (2019) shows that requirements for a license or registration vary substantially between different practices. This implies that safety assessment for the corresponding practices, access to a radiation protection expert (RPE)<sup>5</sup>, radiation protection officer (RPO)<sup>6</sup>, dedicated training from radiation protection and training for performing IMS according to the producer's instruction or manual, individual dose monitoring of workers as well as medical surveillance of workers should be obligatory at least for certain practices. The RPE needs to have relevant competence in the corresponding area where IMS is performed.

### Mutual recognition

Additionally, in case mutual recognition within Europe is applied, IMS operator could relatively easily get a license in different countries and offer their services. In particular, small countries having a limited number or even lack of IMS operators in certain areas could benefit from mutual recognition. Some small countries already recognize foreign licences or registrations if they are obtained in accordance with national legislation.

The questionnaire on IMS (2019) shows that most countries consider that workers from abroad are considered to be covered by the individual monitoring, medical surveillance and professional educational programme of radiation protection of their home country.

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<sup>5</sup> Council Directive 2013/59/Euratom, Article 82.

<sup>6</sup> Council Directive 2013/59/Euratom, Article 84.

## Summary

The regulatory framework for the implementation of the IMS in HERCA countries is well established. There are differences both in terms of authorization (licensing or registration) of IMS practises and sharing responsibilities for the implementation of IMS, including the implementation of radiation protection measures.

Regulatory framework varies substantially between different countries as either the source holder or the IMS operator might be required to have a license for IMS. Independently, what regulation looks like, it should be clear to all stakeholders which part is responsible for which moments.

With regard to that IMS operators may be active in different countries, the exchange of information concerning licencing to engage mutual recognition and facilitate cross border activities should be promoted.