

# European Radiation Protection Legislation and Initiatives

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**Abstract.** Article 33 of the Euratom Treaty requires that Member States shall lay down appropriate provisions to ensure compliance with the Basic Safety Standards and shall take the necessary measures with regard to the harmonised implementation. This paper will give an overview on the current EU legislation in force, which is relevant to the non-destructive testing sector. Furthermore, it will present trends and developments in the radiological protection situation of workers in this industrial sector and will provide information on initiatives of the European Commission aimed at improving the radiological protection situation of workers and general public. In this respect, a recent survey on occupational radiation exposures to workers carried out for the Commission (ESOREX) indicates significant room for reduction of workers doses in the non-nuclear industry and in particular in the non-destructive testing sector. Summaries and conclusions of several European seminars and workshops dealing with non-destructive testing issue recommended operational instruments to be designed for the exchange of information on regulatory, administrative and operational measures aimed at implementing good practices and dose reduction techniques. The direct interconnection of radiation protection bodies on the one hand and the non-destructive testing sector on the other hand should form an efficient and effective management system for keeping doses to workers and to the general public well below limits. A specific network for exchange of information and experience in the sector of non-destructive testing is currently under development. This network should form the basis for harmonising national radiation protection requirements and promote good practices in the non-destructive testing sector. In addition, the Radiation Protection Unit is currently examining the situation of workers not permanently employed by those who are responsible for interventions involving ionising radiation, the so-called outside workers. The paper will present the ongoing activities with respect to improve their employment and radiological protection situation.

## 1. European Radiation Protection Legislation

### *1.1 Basic Safety Standards*

At a Community level, on the basis of the Euratom Treaty, Title II, Chapter 3, “Health and Safety”, a Community legislative framework has been put in place since 1959 that comprises today more than 20 legal instruments of different nature, including 6 Directives.

The Council Directive 96/29/Euratom from 1996 [1], laying down basic safety standards for the health protection of the general public and workers against the dangers of ionizing radiation sets up a system of notification or authorisation of practices with radioactive sources, according to the degree of concern. As a matter of principle, the production, processing, handling, use, holding storage, transport, import to and export from the Community is part of the regulation. In the context of the Directive, the disposal of

radioactive substances including all types of radioactive sources is subject to notification or authorisation.

The new Directive confirms the three major general principles underlying radiation protection. The principle of justification of practices implies that the detriment from exposure should be justified by the benefit resulting from the class or type of practice and thus requiring that no frivolous applications of ionizing radiation be permitted. The cornerstone of radiation philosophy remarks the principle of optimisation of protection which is translated into the principle that doses should be as low as reasonably achievable (ALARA) taking into account social and economic considerations. Finally, the principle of dose limitation ensures an equitable distribution of individual benefits and detriment.

#### *1.1.1 Control of Exposure of Workers in non destructive testing industries*

Normal common-sense precautions should be taken to avoid all unnecessary exposures to radiation. Beyond this, assessments should be made to estimate the doses to workers. If annual doses for individual workers are less than 1 mSv no special precautions are required. If annual doses exceed 1 mSv the normal scheme for controlling exposures can usually be applied. If doses exceed 6 mSv it is necessary to define controlled areas.

The identification of work activities will in general proceed first on the basis of types of non destructive test, secondly on the basis of the types of used radiation sources or equipment.

In cases where all the information is available, the authorities may identify non destructive testing industries right away and impose appropriate regulatory requirements. In many cases however, the authorities need information to be provided by the undertaking, and thus introduce a reporting requirement.

#### *1.1.2 Control of Exposure of the Public*

Exposures of the public may arise from the non destructive testing activity itself, from transport, storage or handling of the sources or from disposal of the source. The important routes of radiation exposure of the public are external gamma radiation, inhalation and ingestion. The requirements for members of the public are laid down in Title VIII of the Basic Safety Standards. Article 47 stipulates that the undertaking responsible for a practice shall be responsible for achieving and maintaining an optimum level of protection for the population and the environment. There is currently no guidance as to which dose constraints should apply to the exposure of members of the public as a result of non destructive testing activities.

### *1.2 Outside Workers Directive*

In the beginning of the 1980s, the problem of radiological protection of workers belonging to contracted companies (undertakings) was raised. In most of the different work sectors the so-called outside workers received 80% (and even more) of the collective dose, and quite often higher individual doses than workers permanently employed by operators. Since the outside workers' radiation protection issue was not explicitly taken into account by the 1980 European Basic Safety Standards Directive, there was a need for an additional piece of European radiation protection legislation.

In this context, the European Union adopted in 1990 the Council Directive 90/641/Euratom on the radiological protection of outside workers. This Directive shall ensure at European Union level that the radiological protection situation for the outside

workers is equivalent to that offered to workers permanently employed by the undertakings in all work sectors where occupational exposures may arise.

A recent survey showed that at least 100.000 outside workers circulate within Europe mainly working in the nuclear fuel cycle industry. Furthermore, it is assumed that there are, in addition, a few thousand employees working temporarily in the industrial non-destructive testing sector.

The cornerstone of the radiological protection system of the migrant workers is an appropriate radiation dose monitoring and recording system. In this context, the BSS Directive and the outside workers Directive require the establishment of national dose registers and the issuing of radiation passbooks. A single European radiation passbook would be undoubtedly a step forward towards the simplification of procedures and for the improvement of the radiological protection situation of outside workers occupationally exposed to ionising radiation.

Further legislative actions of the EU will provide for the elimination of differences in national approaches to the practical implementation of the Directive 90/641/Euratom, while aiming at the same fundamental objective: ensure that outside workers benefit from the same level of protection as permanently employed workers.

### *1.3 Controls on radioactive sources*

Occasionally, the national competent authorities have to deal with cases in which radiation sources are inadequately managed, or radiation sources are found outside of regulatory control. Both those categories of events could result in serious health consequences for the workers or members of the public involved. The likelihood of such events is increased when the sources are no longer actively used and they are put in storage or simply left unattended for long periods. In fact, there are indications that controls can become weak between the time when the sources are removed from active use and the time they are returned to producers for possible reuse, or declared as waste and placed under systems of radioactive waste management.

The Basic Safety Standards Directive applies to all practices which involve a risk from ionising radiation and it imposes the basic principles for radiation protection and other generic requirements, without however giving detailed rules for the wide variety of existing practices. In the past, it has already been necessary to complement its requirements with measures aimed at specific purposes. This resulted in the adoption of Directive 92/3/Euratom on shipments of radioactive waste [2]. The adoption of Regulation 1493/93/Euratom on shipments of radioactive substances between Member States that resulted from the abolition of controls at the intra-Community borders on 31.12.1992 [3].

Today, the attention of the radiation protection authorities worldwide has been drawn to the issue of the correct management of radiation sources, especially high activity sealed radioactive sources. Maybe due to their mobility and high number, they have been involved in many of the known radiation incidents and accidents.

Over the last decades, there has been a significant increase in the number and utilisation of radiation sources, especially following the relatively wide availability of artificial radionuclides and the many quality and safety assurance controls to be performed in many different areas.

Within the framework of the Community Plan of Action in the field of radioactive waste [4], the European Commission recently published a study on management and disposal of disused sealed radioactive sources in the European Union

The authors of the study arrived at a rough estimation that approximately 500,000 sealed sources have been supplied during the past 50 years to operators in the EU's fifteen Member States. Of these, approximately 110,000 sources are currently in use. Most of the

remaining sources have been sent to central interim storages, returned to manufacturers or have been disposed of. The sources at greatest risk of being lost from regulatory control are disused sources held in local storage at the users' premises. The study estimates that there are about 30,000 such sources throughout the EU.

In this context and in order to improve the regulatory control over radioactive sources different pieces of legislation have been issued by the European Union.

### *1.3.1 Council Regulation (Euratom) n° 1493/93 on shipments of radioactive substances between Member States.*

The regulation provides for a double declaration system (by holder and consignee) for intra-community shipments of radioactive sources:

- Prior to the shipment: The holder has to obtain from the consignee (recipient) of radioactive substances a declaration (stamped by the authorities of the Member State of destination) that all relevant requirements are met.
- After the shipment. The holder has to provide the authorities of the Member State of destination all relevant information on the shipments carried out during the period of a calendar quarter.

It applies to all radioactive sources and substances above the exemption values laid down in the Basic Safety Standards.

### *1.3.2 Council Directive 2003/122/Euratom on the control of high activity sealed radioactive sources (HASS) and orphan sources*

Further to the provisions in Directive 96/29, the directive on the control of high activity sealed sources (so-called HASS Directive) sets up a system that allows for traceability of sealed sources exceeding a certain activity defined in the annex of the directive.

The HASS Directive aims at harmonising the control of sources and the type of available information, having in mind the free movement of sources within the Community. While establishing in first line obligations in connection with the national authorities, a number of its provisions give an international dimension to this system of control:

- Authorisation is requested for any practice involving a source within the scope of the Directive, which includes imports and exports of sources (the supplier is a "holder" for the purposes of the Directive).
- Obligations on record keeping imply that information is recorded both on the circumstances of receipt of the HASS (including name of manufacturer, supplier or another user) and on those of transfer (to a manufacturer, supplier, another user or to a recognised installation). This information is not limited to holders and manufacturers based in the European territory. Records are communicated to the national authorities.
- Holders are obliged to ascertain that, before a transfer is made, the recipient holds appropriate authorisation: this is also applicable to sources being exported outside the Community.
- Identification and marking. For sources imported from outside the Community, the supplier is responsible for the respect of the relevant obligations
- International cooperation. Member States shall promptly exchange information and cooperate with other relevant Member States or third countries and with international organisations as regards loss, removal, theft or discovery of sources and as regards related follow-up or investigations.

The deadline for setting up the legislation and infrastructures necessary to comply with the HASS Directive expired on 31 December 2005. Failure to meet this deadline can have serious consequences for the Member States of the Union, including the possible referral of the case to the European Court of Justice.

In conclusion, the European Union adopted specific legislation, based on the Euratom Treaty, supplementing the Basic Safety Standards Directive and consistent with the Regulation on Shipments of Radioactive Substances with a view both to strengthen the control by the competent national authorities on sealed radiation sources and to emphasise the respective responsibilities of holders and dealers.

A specific regulatory text on the management of sealed sources improves the protection of man and the environment by, on one hand, harmonising to the highest level the most effective regulatory practices applied in the Member States on the basis of the general requirements of the Basic Safety Standards Directive and, on the other hand, by strengthening the European Union legal acquis.

## **2. European Projects**

### *2.1 ESOREX Project - Trends and Developments in Occupational Radiation Exposure in Europe*

In 1998, the Radiation Protection Unit of the European Commission initiated the European Survey on Occupational Radiation Exposure, ESOREX. The Project covers 30 European countries and consists of two parts.

Part I of the project provides information and a comparative overview about the various national regulatory, administrative and operational arrangements for monitoring, reporting and recording of radiation doses to occupationally exposed workers for each country. The evaluation of this survey identifies topics where harmonisation could improve the radiation protection situation from a regulatory point of view.

Part II contains annual data for each country on workforce and the related dosimetric data. This data is provided on the basis of a common questionnaire returned by those national institutions responsible for official dose reporting and recording in each of the countries. The information introduced in the ESOREX database is extracted from the monitoring data available in the national dose registers or the accredited dosimetric services. The dose data is grouped together into different work categories and within each category subdivided into dose bands. Currently, data is assessed for the years 1995 – 2005 and evaluated in such a way that allow a direct analysis and a comparative overview on occupational radiation doses in the nuclear, medical, general industry and other occupational fields and their sub-categories. For the non-destructive testing sector, analysis and statistics of the dosimetric data, in particular the levels and the trends in individual and collective doses, show that there is room for significant improvements.

### *2.2 European Non-Destructive Testing ALARA Network*

Optimisation is a fundamental principle of radiological protection in the position of prime importance. The principle requires that everything reasonable should be done to reduce radiation exposures under the dose limits as low as reasonably achievable (ALARA). The first summary of the before mentioned ESOREX survey specifically identified the non-nuclear industry and particularly industrial radiography as a work sector that has given rise

to some significant occupational exposures. Furthermore, a workshop on the ALARA principle underlined that in the non-destructive testing sector the ALARA principle could be further developed. This formed the focus of the 5<sup>th</sup> European ALARA Network Workshop [5] which recommended in its conclusions improvements in the following key areas:

- analytical techniques to assist in the decision-making process;
- site radiography working procedures, especially the arrangements between the radiography company and the client;
- operational arrangements at management level and in the practical working field;
- training of radiography staff in radiation protection;

With reference to the summary and conclusion of the above mentioned Workshop the radiation protection unit has set up a Joint Working Group on industrial radiography to take forward the recommendations of the participants. The working group consists of representatives from NDT industry associations, NDT industry and clients as well as from radiation protection competent authorities and from the Commission.

The increased emphasis in recent years on optimisation and its practical implementation in the non-nuclear sector have opened new perspectives in the organisation of radiological protection. In this context, the creation of a European ALARA network for the non-destructive testing industry seems to be the most efficient instrument for the initiation of a chain of basic steps towards reduction of workers' doses in this industrial sector.

Therefore, the Radiation Protection Unit of the Directorate General for Energy and Transport initiated the creation of a European non-destructive testing ALARA network. This network will form the basis for harmonising national radiation protection requirements and promote good practices in the non-destructive testing sector.

The objective of the NDT ALARA network is the establishment of a platform for the direct exchange of experience and information on regulatory requirements, administrative and operational procedures aimed at giving effects to the reduction of doses to workers and the general public.

The direct interconnection of companies offering industrial radiography and of clients with the radiological protection bodies shall be used for sharing knowledge on operational and practical measures.

For occupational dose reduction in the non-destructive testing area, the network shall issue guidance for using a structured approach in the application of the ALARA principle. This guidance shall be based on data and information exchange on practical working arrangements between actors in the non-destructive testing industry taking into account legal and regulatory requirements.

### **3. Conclusions**

Through repeated updates of the Basic Safety Standards over more than forty years, the Commission has ensured a continuous improvement of the protection of the health of workers and members of the public against the dangers arising from exposure to ionizing radiation.

The current Directive adopted in 1996 is an important milestone in the process to develop a consistent and complete radiation protection regulation. Current radiation protection requirements have been supplemented by several additional legal instruments aimed at improving radiological protection of workers in specific employment situations. In

addition, more detailed requirements have been introduced in relation to the management of radioactive sources.

It will be very interesting to monitor how the provisions on the management of high active sealed radiation sources will be transposed in national legislation. Some Member States have transposed only part of the Directive; a few have not yet even made any submission of draft legislation under Article 33. It is therefore premature to discuss the different national approaches. The Commission is of course using all available legal procedures to ensure that all Member States will proceed with implementation as a matter of urgency.

## References

- [1] Directive 96/29/Euratom – O.J. No L 159 of 29.6.1996
- [2] OJ No L 35 of 12.2.1992
- [3] OJ No L 148 of 19.6.1993
- [4] OJ No C 158 of 25.06.92
- [5] 5<sup>th</sup> Workshop, "Industrial Radiography: Improvements in Radiation Protection" - Rome, October 2001