

Impact of the Euratom Directive on the need of follow up and feedback from activities

Ch. Pafilis
S. Economides

Council Directive 2013/59/Euratom



- Basic safety standards for protection against the dangers arising from exposure to ionizing radiation.
- Consolidation of European Legislation: (Directive 96/29/Euratom-Basic Safety Standards, Directive 97/43/Euratom-Medical Exposures, Directive 89/618/Euratom-Public Information, etc.)
- Common approach regarding radiological safety.
- Safety culture
- Optimisation of radiation protection



Council Directive 2013/59/Euratom



- Specific provisions for the optimization of radiological safety.
- Responsibility of the stakeholders: authorities, undertakings, workers, etc.
- **The Directive itself is an optimisation tool.**
- The terms **feedback** and **follow up** do not appear frequently in the text.
- Instead: Information exchange, experience, cooperation, reporting notification, etc.

Whereas...

(6) The Group of Experts appointed by the Scientific and Technical Committee has advised that **the basic safety standards, established according to Articles 30 and 31 of the Euratom Treaty**, should take into account the new recommendations of the International Commission on Radiological Protection (ICRP), in particular those in ICRP Publication 103, and **should be revised in the light of new scientific evidence and operational experience**.



Regulatory control – Graded approach



- MSs shall require practices to be subject to regulatory control for the purpose of radiation protection, by way of notification, authorisation and appropriate inspections, commensurate with the magnitude and likelihood of exposures resulting from the practice, and commensurate with the impact that regulatory control may have in reducing such exposures or improving radiological safety.
- A graded approach is also applied regarding the information required to be provided by the undertakings to the regulatory authority

Regulatory control - Authorisation

- The regulatory decision to submit types of practices to either registration or licensing may be based on regulatory experience, taking into account the magnitude of expected or potential doses, as well as the complexity of the practice.
-National legislation or the specific conditions shall also require, when appropriate, the **formal and documented implementation of the principle of optimisation**.



Regulatory control - Inspections



- MSs shall ensure that mechanisms are in place for the timely dissemination to relevant parties, including manufacturers and suppliers of radiation sources and, where appropriate, international organisations, of protection and safety information concerning significant lessons learned from inspections and from reported incidents and accidents and related findings.

Control of radioactive sources

- MSs shall require each undertaking holding:
 - an unsealed radioactive source to notify the competent authority promptly of any loss, theft, significant spill, or unauthorised use or release.
 - a sealed source to notify the competent authority promptly of any loss, significant leakage, theft or unauthorised use of a sealed source.



Control of radioactive sources - Cooperation



- Each MS shall **promptly share information and cooperate** with other relevant MSs, relevant third countries and relevant international organisations regarding the loss, theft or discovery of high-activity sealed sources, other radioactive sources and radioactive material of concern and regarding **related follow-up** or investigations, without prejudice to relevant confidentiality requirements and relevant national legislation.

Medical exposures – Whereas...



- ...it is the role of the competent authority in radiation protection to address the prevention of accidental and unintended medical exposure and the follow-up in case of their occurrence. In this respect, the role of quality assurance programmes, including a study of risks in radiotherapy, to avoid such incidents should be emphasised, and recording, reporting, analysis and corrective action should be required in such cases.

Medical exposures



"**clinical responsibility**" means responsibility of a practitioner for individual medical exposures, in particular, justification; **optimisation**; clinical evaluation of the outcome; cooperation with other specialists and staff, as appropriate, regarding practical aspects of medical radiological procedures; obtaining information, if appropriate, on previous examinations; providing existing medical radiological information and/or records to other practitioners and/or the referrer, as required; and giving information on the risk of ionising radiation to patients and other individuals involved, as appropriate;.

Medical exposures - Education, information and training



- MSs shall ensure that practitioners and the individuals involved in the practical aspects of medical radiological procedures have adequate education, information and theoretical and practical training for the purpose of medical radiological practices, as well as relevant competence in radiation protection.



Medical exposures - Accidents

- MSs shall ensure that mechanisms are in place for the timely dissemination of information, relevant to radiation protection in medical exposure, regarding lessons learned from significant events.



Emergency – Whereas...



- The efficient management of an emergency with cross- border consequences calls for enhanced cooperation between MSs in emergency planning and response.
- While urgent information exchange between MSs and the Commission in the event of an emergency is established through Council Decision 87/600/Euratom, there is a need to put in place arrangements for information exchange beyond the scope of this Decision to allow cooperation with all other MSs and with third countries which may be involved or are likely to be affected.

Emergency preparedness

- Each MS shall **promptly share information and cooperate** with other relevant MSs, relevant third countries and relevant international organisations regarding the loss, theft or discovery of high-activity sealed sources, other radioactive sources and radioactive material of concern and regarding related **follow-up** or investigations, without prejudice to relevant confidentiality requirements and relevant national legislation.



Emergency preparedness



- MSs shall ensure that emergency response plans are tested, reviewed and, as appropriate, revised at regular intervals, taking into account lessons learned from past emergency exposure situations and taking into account the results of the participation in emergency exercises at national and international level.

Emergency response

- MSs shall require the undertaking to notify the competent authority immediately of any emergency in relation to the practices for which it is responsible and to take all appropriate action to reduce the consequences.



Emergency - Cooperation



- Each MS shall, in the event of an emergency occurring on its territory or likely to have radiological consequences on its territory, promptly **establish contact** with all other MSs and with third countries which may be involved or are likely to be affected with a view to **sharing the assessment** of the exposure situation and coordinating protective measures and public information by using, as appropriate, **bilateral or international information exchange** and coordination systems. These coordination activities shall not prevent or delay any necessary actions to be taken on a national level.

Significant events



MSs shall require the undertaking to:

- implement, as appropriate, a **recording and analysis system** of significant events involving or potentially involving accidental or unintended exposures;
- promptly **notify the competent authority** of the occurrence of any significant event resulting or liable to result in the exposure of an individual beyond the operational limits or conditions of operation specified in authorising requirements with regard to occupational or public exposure or as defined by the competent authority for medical exposure, including the results of the investigation and the corrective measures to avoid such events



Discharges

- MSs shall require:
 - the undertaking responsible for practices where a discharge authorisation is granted to monitor appropriately or where appropriate evaluate the radioactive airborne or liquid discharges into the environment in normal operation and to report the results to the competent authority.
 - any undertaking responsible for a nuclear power reactor or reprocessing plant to monitor radioactive discharges and report them in accordance with standardised information.



Individual monitoring



- MSs shall ensure that arrangements are in place for the appropriate **exchange**, among the undertaking, in the case of an outside worker, the employer, the competent authority, occupational health services, radiation protection experts, or dosimetry services **of all relevant information on the doses previously received by a worker** in order to perform the medical examination prior to employment or classification as a category A worker pursuant to Article 45 and to control the further exposure of workers.

Existing exposure situations

- MSs shall ensure that those responsible for the implementation of a strategy shall regularly:
 - **provide information** to exposed populations on the potential health risks and on the available means for reducing their exposure;
 - with regard to activities that involve naturally occurring radioactive material and are not managed as planned exposure situations, **provide information** on appropriate means for monitoring concentrations and exposures and for taking protective measures.



ANNEXES



- **ANNEX XI:** Emergency management systems and emergency response plans as referred to in Articles 69, 97 and 98
- **ANNEX XV:** Requirements for undertakings responsible for a high-activity sealed source as referred to in Article 91
- **ANNEX XVIII:** List of items to be considered in preparing the national action plan to address long-term risks from radon exposures as referred to in Articles 54, 74 and 103

Thank you!



facebook.com/eeaegr



twitter.com/eeaegr



www.eeae.gr