HERCA
Multi-Stakeholders Workshops
on the transposition of the Euratom Basic Safety Standards Directive

Accidental and Unintended Exposures (Paris, 26-28 October 2016)

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Article 63 (a)

- *"Member States shall ensure that all reasonable measures are taken to minimize the probability and magnitude of accidental and unintended exposures of individuals subject to medical exposure"*
  - *Familiar requirements which is implemented in most countries*
  - *What matters is that this is actually implemented by national authorities through supervision*
  - *Radiographers ensure this through their daily contact with the patients, performing procedures, assessment of justification etc.*

Article 63 (b)

- *"Member States shall ensure that for radiotherapeutics practices the quality assurance programme includes a study of the risk of accidental or unintended exposure"*
  - A part of the practice in many countries today
  - The risk assessments should be developed interdisciplinary by medical physicists together with the necessary contribution from radiotherapists/radiographers and oncologists

Article 63 (c)

- *"Member States shall ensure that for all medical exposures the undertaking implements an appropriate system for the record keeping and analysis of events involving or potentially involving accidental or unintended medical exposures, commensurate with the radiological risk posed by the practice"*
  - *Not everyone have singled out events related to ionising radiation*
  - *Reporting potentially serious events is common and also desirable, preferably to the competent authorities*
  - *An advantage to have access to some kind of dose tracking system*
  - *DRL`s will also make this easier to achieve*

Article 63 (d)

- *"Member States shall ensure that arrangements are made to inform the referrer and the practitioner, and the patient, or their representative, about clinically significant unintended or accidental exposures and the results of the analysis"*
  - *Professional bodies should be able to provide guidance on clinically significant events, but are they willing to do so?*
  - *Follow up procedures exists, mainly for deterministic effects/ potential deterministic effects (ICRP recommendations) and unintended exposure of pregnant women*
  - *Main responsibility on the member states through professional bodies together with competent authorities*

Article 63 (e) (i)

- *"Member States shall ensure that the undertaking declares as soon as possible to the competent authority the occurrence of significant events as defined by the competent authority"*
  - The criteria's are mostly events with exceeded limits above normal exposure values and doses to the patients
  - Where there are deterministic effects (also potential)
  - Loss or theft of radiation sources
  - Events that have caused radiation exposure to the public
  - A mandatory set of actions should be established for a defined list with the most relevant incidents

Article 63 (e) (i)

- *"Member States shall ensure that the undertaking declares as soon as possible to the competent authority the occurrence of significant events as defined by the competent authority"*
  - Actions are needed immediately (like closing down a facility)
  - *Uncovers a need for immediate changes in general practice for the specific area within medical exposures*
  - *Soon as possible does not necessary means within 3 days for example*
  - *Reporting total number of events within a specific period can give insight into the safety culture*

Article 63 (e) (i)

- *"Member States shall ensure that the undertaking declares as soon as possible to the competent authority the occurrence of significant events as defined by the competent authority"*
  - *Option 1 → clinically significant events should be reported as soon as possible to the authority*
  - *Option 3 → much like it is today, predefined limits and events leads to a report to the authorities, sometimes combined with some clinical criteria (option 2)*
  - *Actual damages and/or potential damages should be reported as soon as possible*
  - *Also should be focus on preventing unintended or accidental exposures of paediatric patients or the foetus*
  - *In addition to this it should be set margin factors compared to what is expected of common procedures within medical exposure*
  - *We support inclusion of events with large number of individuals as significant events*

Article 63 (e) (ii)

- *"Member States shall ensure that results of the investigation and the corrective measures to avoid such events are reported to the competent authority within the time period specified by the Member State"*
  - these investigations should be performed in a timely fashion regarding the severity of the events in question
  - interdisciplinary teams where there also should be someone with the practical knowledge of the diagnostic and therapeutic procedures (radiographers)

Article 63 (f)

- *"Member States 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"*
  - *Competent authority (national radiation protection agency's)*
  - In general such information should be looked upon as valuable in a medical exposure safety context

EFRS Commitments

- EFRS commit to advocate this new changes to
  - The national authorities
  - Other professional bodies
  - Our member organizations and by this our members throughout Europe

Thank you for your attention