



HERCA Position Paper Accidental and Unintended Medical Exposures

May 2017

This document was approved by the Board of HERCA on 11 May 2017

Index

Key Messages	3
1. Introduction and background	5
2. Current Status and Approaches by Competent Authorities	6
3. Inclusion of Underexposures	6
4. Value of analysis and reporting	7
5. Dissemination of information	9
6. Conclusion	9
References	9

HERCA Position Paper

Accidental and Unintended Medical Exposures

While the medical use of radiation is generally safe, the impact of accidental and unintended medical exposures can be considerable. In response the EC Basic Safety Standards Directive (BSSD) 2013/59/Euratom¹ introduces new requirements to address these issues and provides for a graded approach for analysis and reporting, based on radiological risk of the practice being investigated.

Key Messages

1. Article 63(e) places the responsibility for defining significant events on the Competent Authority. HERCA is of the view that it is unlikely that a single descriptive European approach will be possible, particularly in relation to the definition of significant events and reporting levels to Competent Authorities.
2. Regarding “clinically significant”, HERCA is of the view that its definition is not the responsibility of the radiation protection authority, and would support that this is based on foundations provided by a body or bodies with clinical expertise or is based on guidance provided by medical societies.
3. HERCA encourages the competent authority to establish a reporting system commensurate to the radiation risk and its available resources.
4. Regarding underexposures:
 - In radiotherapy, HERCA believes the BSSD requirements for reporting accidental and unintended exposures to the Competent Authority should be interpreted to include underexposures.
 - In diagnostic specialties, HERCA does not advocate that individual events related to exposures less than intended should be defined as significant by the Competent Authority.
5. HERCA believes that dissemination of information regarding lessons learned from :
 - reported significant events might best be undertaken by the Competent Authority, to whom such events are reported,
 - other events, such as near misses, should be run through national initiatives by the Professional Bodies themselves or by bodies other than the Competent Authority.

6. HERCA believes that this information regarding lessons learned will be helpful to undertakings when reviewing their procedures, risk analyses and quality assurance programs.
7. HERCA is of the view that in cases where deliberate actions or gross negligence have contributed to significant events, then enforcement is appropriate, but in all other circumstances the emphasis should be on improved standards and patient safety and future compliance and a “no-blame culture” should prevail.

1. Introduction and background

The use of ionising radiation for the purposes of medical diagnosis, treatment and research has become routine in all healthcare systems throughout Europe. Advances in technology have improved anatomical and physiological imaging across a range of clinical scenarios. Treatment of benign and malignant neoplasms has improved in accuracy and effectiveness. Monitoring in research trials of the impact of new drugs using techniques employing ionising radiation has become a standard methodology.

The use of ionising radiation in medicine is considered justified at the fundamental level, as defined by ICRP as Level I, and is a core assumption of the BSSD. This position is based on an acceptance that in general terms, the potential benefits of using ionising radiation in medicine far exceed any associated detriment, taking into account both possible stochastic and deterministic effects.

The medical use of radiation is generally safe. This is supported by the incident rate data that are available from countries where requirements are already in place for reporting of accidental and unintended exposures. For example, data from England², 3 for 2015 for its National Health Service shows approximately 1100 diagnostic incidents were reported while over 40 million procedures took place. For the same period 68 radiotherapy treatment incidents were reported while 7.5 million treatment exposures were delivered.

Notwithstanding this level of assurance, the impact of accidental and unintended medical exposures can be considerable, on individuals who receive such exposures, on the institutions involved and on the public's confidence in healthcare systems. In response BSSD Article 63 introduces new requirements to address these issues. Previously there was no requirement to do so as part of the radiation protection framework provided by European Council Directive 97/43/Euratom⁴ which addressed medical exposures.

Gathering data on accidental and unintended medical exposures is a key factor in gaining a better understanding of the magnitude of problems and rectifying them and many European Member States have done so for some time. The introduction of a range of requirements within the BSSD will formalise and extend these processes and this has been welcomed by regulators and professional bodies alike. It is consistent with the need for greater organisational transparency and patient rights now required in healthcare systems.

Article 63 places responsibilities on institutions in the event of accidental and unintended exposures, including:

- requirements for analysis of events involving or potentially involving accidental or unintended medical exposures,
- requirements for arrangements for informing the referrer, practitioner and patient, or their representative, of clinically significant accidental or unintended exposures,
- requirements for reporting to the Competent Authority the occurrence of significant events and their subsequent investigation and corrective measures

This document addresses these new requirements. It is informed by a multi-stakeholder workshop (MSW) held during October 2016 in France⁵. Its publication during the transposition

period for the Directive is intended to help clarify the approaches that may be taken by Member States, while acknowledging the national variations which are allowed by the Directive and which might be necessary depending on the healthcare systems in place.

HERCA is aware of other initiatives including the International Basic Safety Standards (GSR Part 3)⁶ and the IAEA/WHO “Bonn Call for Action”⁷ which address this issue. The approach outlined in this document is consistent with these initiatives as much as compliance with Euratom BSSD allows.

2. Current Status and Approaches by Competent Authorities

Between 2012 and 2015, HERCA’s Working Group on Medical Applications (HERCA WGMA) conducted three surveys of radiation protection authorities to clarify arrangements that have been in place based on their national regulations, prior to the introduction and transposition of the latest BSSD. All Member States recognised the need for robust systems that had credibility and were responsive.

The surveys revealed significant differences across Europe, relating to the basis and methodology of reporting processes, guidance values on triggers for reporting incidents to the Competent Authority and intentions for transposition and implementation of the BSSD. In some countries immediate reporting of all incidents is required but in practice few reports are received. For those countries where there are definitions of reportable incidents, criteria varied and do not always follow a strict scientific approach, although risk factors relating to dose play some part in all systems but not always in a consistent manner. For example, an unintended low dose procedure, such as a chest radiograph, given to the wrong individual generally requires reporting. In contrast, this is not always the case for an individual who received an elevated unintended dose from an intended procedure.

Some common themes have emerged. Events involving paediatric patients or the unborn child are often included specifically in reporting criteria, and this demonstrates an awareness of the need to protect vulnerable groups. Some form of graded approach is evident in most countries, but this varies in practice, with some countries restricting reporting to high dose procedures such as radiotherapy and interventional radiology while others require incidents in other specialties to be reported, but respond to each on the basis of risk.

The discussions between HERCA WGMA members and representatives of European professional bodies have also revealed considerable differences in possible approaches and opinions about reporting levels, with some proposing aligning reporting levels to established concepts in medical radiation protection such as diagnostic reference levels and others preferring to follow established concepts from other areas of medicine such as actual and attributable clinical harm.

3. Inclusion of Underexposures

Out with medical applications, radiation protection concepts and frameworks are put in place to guard against the dangers of ionising radiation to humans and previous Basic Safety Standard Directives, which addressed occupational and public exposures only, were framed with this in mind.

The use of ionising radiation in medicine challenges this somewhat, particularly in therapy where the radiation itself is providing direct benefit through its interaction with tissue and consequent cell destruction. While historically emphasis has been placed on overexposures in radiotherapy, the consequences of significant underexposures cannot be ignored. Treatment of malignant conditions, with doses below that intended can result in local tumour recurrence with catastrophic implications for patients. HERCA believes the BSSD requirements for reporting accidental and unintended exposures to the Competent Authority should be interpreted to include underexposures in radiotherapy, as explicitly stated in the International Basic Safety Standards.

Exposures less than intended in diagnostic specialties are more difficult to define as the primary intention of the exposure is not to deliver dose, but to achieve adequate image quality for the diagnostic purpose. It is accepted that delivering doses that are below those required to provide this can have a significant impact on diagnosis. Such events should be investigated internally as part of processes designed to improve quality and optimisation. HERCA does not advocate that individual events of this nature should be defined as significant by the Competent Authority.

There is a view however that where underexposures apply to large groups of patients, particularly those in health screening programmes, then institutions should at least report such events to the Health Ministry or some similar body and to the Competent Authority if required under national legislation.

4. Value of analysis and reporting

Article 63 introduces requirements for analysis and reporting of incidents involving accidental and unintended exposures, but differentiates between the actions required on the bases of actual or potential degree of risk or actual clinical significance and links these with internal and external processes relating to the undertaking and/or the Competent Authority. For some of these, the Competent Authority is required to define a significant event as a basis for external reporting.

Article 63(c) requires an undertaking to investigate and keep records of all events that involve or potentially involve accidental or unintended medical exposures. The Directive does however allow for a graded approach for these activities, based on radiological risk of the practice being investigated. For example, there is scope for processes relating to dental examinations to be less involved than those relating to radiotherapeutic exposures and this is welcomed by the Professional Bodies and HERCA alike.

It is important to note however that the process is linked to the risk associated with the practice and not to the potential or actuality of an incident. This reflects the scale of potential harm rather than the actual harm.

Article 63(d) requires information is provided to the referrer, practitioner and patient, or representative, when unintended or accidental exposures are clinically significant. This is consistent with current approaches to transparency and good medical practice and provides flexibility when vulnerable individuals are involved e.g. children. The term “clinically significant” is not defined in the Directive. Similarly the Directive does not place a responsibility on anybody or authority to define this term. HERCA is of the view that defining such exposures is not a role for the radiation protection authority and this view is shared by representative Professional

Bodies involved in the MSW. Health Ministries may have a view on their own involvement, but it is clear that the medical societies in particular could play a role, either at a national or European level, by providing guidance, taking into account definitions of clinically significant events in other areas of healthcare. Clearly the Directive allows for the undertaking itself to decide on what constitutes a clinically significant accidental or unintended exposure, but HERCA would support that this decision is based on foundations provided by a body or bodies with clinical expertise.

By way of contrast, Article 63(e) does place the responsibility for defining significant events, as a basis for investigation and reporting, on the Competent Authority. This takes the requirements of Article 63(c) to another level.

In defining “significant events”, and bearing in mind all the consequent actions, the Competent Authority will need to consider relevance to:

- individual patient safety/risk
- vulnerable groups
- indicators of safety culture
- potential impact of the lessons learned of the specific events

When considering individual patient safety and/or risk, the concepts of clinically significant exposures and significant events should remain exclusive, but there may be some logic to including clinically significant exposures as part of the definition of significant events. There is widespread support for this among many regulators and professionals.

Risk alone however is not the only basis for defining significant events and a need for external reporting. Many radiation protection authorities have recognised other emotional and political sensitivities including the importance of paying specific attention to vulnerable groups such as children and unborn children. While radiation sensitivity and lifespan impact on risk and safety, this alone may not account for the reporting criteria established for these and other vulnerable groups, nor should it.

While reporting individual events may focus on the safety of the individual exposed, reporting of multiple events of the same or similar nature resulting from a specific fault or error has wider ramifications and potential value. The occurrence of multiple events, whether involving high or low dose and risk to patients, are indicators of the robustness of an organisation’s safety culture, and reporting of these can have a noticeable impact on rectification of failures. Data from existing reporting systems in a range of Member States suggests that when defining reporting levels, or significant events, many radiation protection authorities have included this factor in their guidance and systems.

When deciding on the definition of significant events, the Competent Authority will need to consider how it expects them to be reported. This is provided for by Article 63(e). Where an event is clinically significant, it is likely that reporting and corrective measures should be seen as a priority by the undertaking. Similarly, the occurrence of significant events should be declared to the Competent Authority as soon as possible. While not a requirement of the Directive, other events carrying smaller or no actual radiation risk might also be reported, but with less urgency and even periodically, as advised by the radiation protection authority. This might apply to events where the main reason for reporting is as an indicator of safety culture integrity rather than any patient’s risk. Finally, overall decisions relating to reporting will be influenced by the authority’s resources and ability to respond.

The analysis and subsequent reporting to regulators of accidental and unintended exposures will only succeed if all parties appreciate the value of the processes and act within a framework of positivity and learning. Clearly regulators have statutory duties and enforcement responsibilities but if the maximum benefit is to be realised from incident reporting systems, then such systems need to be conducted appropriately and not in an adversarial manner. HERCA is of the view that in cases where deliberate actions or gross negligence have contributed to significant events, then enforcement is appropriate, but in all other circumstances the emphasis should be on improved standards and patient safety and future compliance and a “no-blame culture” should prevail. It is within this spirit that the role and responsibilities of the Competent Authority are to support the framework of positivity and learning, to ensure and enforce that adequate processes for dealing with events are generally established within an undertaking and that they are actually conducted in the case of an event.

5. Dissemination of information

The Directive introduces requirements for the timely dissemination of information regarding lessons learned. This will be helpful to undertakings when reviewing their procedures, risk analyses and quality assurance programs. This requirement applies only to significant events. This might best be undertaken by the Competent Authority, to whom such events are reported, or by the Health Ministry or some similar body which might have overall responsibility for patient safety. This is an important aspect of Article 63 as part of a proactive approach to radiation safety across the radiation community as a whole and not just within individual institutions.

The dissemination of information from events that are not classed as significant can have as much value as that from significant events. There is some support from Professional Bodies for the extension of requirements for dissemination to this type of event, and there are examples of national and international initiatives where this already takes place and has a valuable impact on patient safety and quality of services. Consideration might be given to addressing this in Regulations or through administrative means. National initiatives could be run by the Professional Bodies themselves or by bodies other than the Competent Authority.

6. Conclusion

Analysis and reporting of accidental and unintended medical exposures and wider dissemination of relevant information, as required by Article 63 of the latest BSSD provides a valuable framework and identifies the important aspects of a national system designed to address accidental or unintended medical exposures. If handled sensitively, addressing accidental and unintended exposures can aid public confidence and improve quality of services.

It is unlikely however that a single descriptive European approach will be possible, particularly in relation to the definition of significant events and reporting levels to Competent Authorities.

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