HERCA
HEADS OF THE EUROPEAN RADIOLOGICAL PROTECTION COMPETENT AUTHORITIES

Working Group
Medical Applications

Case Study: Czech Republic

Petr Papírník
The Czech Republic
State Office for Nuclear Safety

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Czech situation with BSSD

- Some requirements were transposed in 2011 - 2012
  - Mostly the „clinical“ articles from the medical exposures (justification, optimization, responsibilities) and education and training of health professionals
  - In the health law
- The rest will be transposed on 1st January 2017
  - When the new atomic law comes into force
  - We have already finished and published the new Atomic Act
  - and the new Regulation on Radiation protection is currently being finished

AUE in the new CZ atomic law

- Atomic Act (n. 263/2016) section 87 (Radiological events):
  - License holder or registrant must perform the medical exposures so he minimizes the probability of radiological event *BSSD art. 63 (a)*
  - In case of radiotherapy he must perform an analysis of risk of occurrence of an event *BSSD art. 63 (b)*

Q5.2.1 **To what degree is the risk assessment already undertaken as part of good medical practice?**

In CZ only partly, with the new atomic law, it will be more sufficient

Q5.2.2 **Would such a requirement cause difficulties for stakeholders (eg. introduce delay in making new techniques available)?**

I don‘t think so

Q5.2.3 **In whose competence should be making of these studies of risks?**

Mainly medical physicist, in participation with the radiological oncologist

- If an event occurs, the license holder or registrant must act commensurately with the adversity of the event to minimize the consequences
- The license holder or registrant must inform the RP authority, the patient (or his representative), the referrer and the practitioner about the serious events

AUE in the new CZ atomic law

- Atomic Act (n. 263/2016) section 87 (Radiological events):
  - The license holder or registrant must investigate the event (*BSSD art. 63 (c)*) and near miss and must take actions against their occurrence. The course of actions must be commensurate with the risk connected with the event. They must keep records from investigation and about the taken measures.

Q5.3.1 **In practice, what systems are already in place for record keeping and analysis of all incidents involving diagnostic and therapeutic radiological services?**

In CZ for radiotherapy it is well established, for NM, IR and DG not yet

Q5.3.2 **Where these systems are in place, do they separate out accident and unintended exposures or do they mix them together with other adverse events that can occur in medical care and that aren't related to ionizing radiation?**

In CZ it is in RT strictly only about the ionizing radiation

Q5.3.3 **Do these systems include events potentially involving accidental or unintended exposures (ie near misses – see below)?**

In CZ yes

- The regulation specifies:
  - Categorization of the events and which events are considered to be serious
  - Course of actions that should be taken in case of event or near miss
  - Content of the documents about the events and time of archiving them
  - When, about what and who should be informed about the serious events

AUE in new CZ atomic law

- New Regulation of the Radiation Protection
  - The events are categorized:
    - Most adverse cat A (= BSSD significant event)
    - Middle cat B
    - Less adverse cat C
    - Cats A+B = serious events
    - CZ serious events ≠ BSSD significant events
  - The categorization is explicitly written in the regulation
  - First there is categorization of a single event
    - It depends on the modality
    - It is connected to the health effects
    - It gives relative criteria – percentage deviation from the intended dose in RT and NM
    - And absolute criteria – trigger levels of the dose quantities in DG and IR
  - Than there is re-categorization of the repeated events
    - One category higher or two categories higher
    - Depends on the modality
    - Depends on if it repeats to a single patient or to a number of patients

Categorization of events – single event

- Category A (= BSSD significant events)
  - Radiotherapy
    - Event when the patient has or can have a serious clinical consequences that can lead to permanent injury or death.
    - Event when it is highly expectable occurrence of late effects of the ionizing radiation that are connected with the overexposure of the tissue.
    - Teletherapy and brachytherapy: the applied dose differs (up or down) more than 20 % from the prescribed total dose.
    - Stereotaxy: the applied dose differs (up or down) more than 10 % from the prescribed dose.
  - Interventional radiology, radio diagnostics:
    - CT: C_{VOL} > 10 Gy
    - Interventional radiology: Kerma in entrance reference point > 15 Gy or

$$P_{KA} > 1500\ Gy \times cm^2$$

Categorization of events – single event

- Category B
  - Radiotherapy
    - Event when occurs or can occur a serious clinical consequences that don‘t threaten life but increases the probability of undesirable result, especially complications of the cure or insufficient control of the tumor.
    - Event when it is highly expectable occurrence of late effects of the ionizing radiation that are connected with the overexposure of the tissue.
    - Teletherapy and brachytherapy: the applied dose differs (up or down) within 10 - 20 % from the prescribed total dose.
    - Stereotaxy: the applied dose differs (up or down) within 5 - 10 % from the prescribed dose.
  - Nuclear medicine
    - Therapy: Total applied activity differs more than 100 % from the prescribed activity.
    - Diagnostics: Applied activity is more than 20 times bigger than the prescribed value.
  - Interventional radiology, radio diagnostics:
    - CT: C_{VOL} > 3 Gy if an eye wasn‘t in the primary beam
      C_{VOL} > 0,5 Gy if an eye was in the primary beam
    - Interventional radiology: Kerma in entrance reference point > 5 Gy or
      $P_{KA} > 500\ Gy \times cm^2$

Categorization of events – single event

- Category C
  - Radiotherapy
    - All the other events when the probability of clinical effect is small.
    - Especially: wrong cure conditions (e.g. wedge, modulation of field for one fraction), wrong side or localization for one fraction or cure without written prescription or daily report for one fraction.
  - Nuclear medicine
    - Therapy: applied activity differs from the prescribed value more than 20 %
    - Diagnostics: Applied activity differs from the prescribed value more than 40 %.
  - Interventional radiology, radio diagnostics:
    - All the other events
    - Especially: wrong patient, wrong localization, exposure repetition

Categorization – repetition, one patient

- One category higher
  - Once repeated
    - Radiotherapy
    - Nuclear medicine
    - Interventional radiology
    - CT, fluoroscopy, dental CT
  - 3 times repeated
    - Other radio diagnostics

Two categories higher

- Twice repeated
  - Radiotherapy
  - Nuclear medicine
  - Interventional radiology
  - CT
- 3 times repeated
  - fluoroscopy, dental CT
- 9 times repeated
  - Other radio diagnostics

Categorization – repeated, more patients

- One category higher
  - 3 patients in 1 month: brachytherapy, stereotaxy
  - 10 patients in 1 month: teletherapy, NM therapy, interventional radiology, CT
  - 20 patients in 1 month: NM diagnostics, fluoroscopy, dental CT
  - 100 patients in 1 year: mammography
  - 200 patients in 1 year: other radio diagnostics
- Two categories higher
  - 6 patients in 1 month: brachytherapy, stereotaxy
  - 20 patients in 1 month: teletherapy, NM therapy, interventional radiology, CT
  - 100 patients in 1 year: NM diagnostics, fluoroscopy, dental CT
  - 500 patients in 1 year: mammography
  - 1000 patients in 1 year: other radio diagnostics

It means number of patients that were wrongly exposed due to the same mistake or to the same group of mistakes

Q5.16 **What are stakeholders' views on the value of defining events including large numbers (or potential numbers) of individuals as significant events and therefore to be reported as soon as possible?**

In CZ we use these criteria, but not for potential numbers, because the legislation was finished before we got through HERCA this suggestion (but we will try to put it into a guide)

Informing and reporting

- RP authority must be informed
  - In case of event cat A (= BSSD significant event) *BSSD art. 63 (e) i), ii)*
    - Immediately after finding that there was an event cat A about all the known information about it
    - Immediately after all new information found during investigation of them and after any measures taken related to event (mitigating the effects of the event or preventive) cat A about them
    - 1 month after finding event cat A in radiotherapy by sending protocol about it

Q5.8.2 **What is the purpose of reporting significant events as soon as possible to the competent authority? What should the competent authority do with such immediate reports?**

Such events are so bad that it might be necessary that the RP authority would have to step into the measures taken by the undertaking and change them directly by some commands to avert some terrible consequences either related with the one exposed patient or with some other patients that could be exposed in future.

The information about such events must immediately and directly go to some relevantly competent inspector, he must evaluate it and if the nature of the event shows the necessity of some immediate actions of the RP authority, they must be done without delay (by phone or directly on place)

In the new CZ law we have a special tool when the inspector can command anybody to do or stop doing anything to avoid some terrible consequences and the commanded person must obey

Informing and reporting

- RP authority must be informed
  - In case of event cat B
    - 1 month after finding event cat B in radiotherapy by sending protocol about it
    - 3 month after finding other event cat B by sending protocol about it
  - Once a year must every license holder send a report about radiation protection to the RP authority
    - It must contain (with many other things) a list and analysis (*BSSD art. 63 (c)*) of all the events and near misses

Q5.8.3 **Should events, which the competent authority should know about but they don't need any quick intervention of the authority, be reported later? (i.e. they wouldn't be significant events for reporting as soon as possible and the duty to report them later would go beyond the requirements of BSSD)?**

Yes

Q5.3.4 **While outside the direct requirements of the BSSD, do stakeholders believe reporting of potential accidental or unintended medical exposures is desirable and if so, should this be to the competent authority or to another body (eg. professional organization)?**

Yes – to the RP authority

Q5.10 **What are stakeholders' views on the value of reporting total numbers of events (with some description graded with the risks) within a specified period, which could later be used as part of inspection processes etc. when considering local safety culture?**

In CZ we require this for all the events

Informing and reporting

- Patient (or his representative), referrer, practitioner must be informed if the event could negatively influence patient's health or the cure must be changed (= BSSD clinically significant event) *BSSD art. 63 (d)*
  - In case of event cat A
    - Immediately after finding that there was an event cat A about all the known information about it
    - Immediately after all new information found during investigation of them about them
    - Immediately after any measures (mitigating the effects of the event) taken related to event cat A about them
    - 1 month after finding event cat A in radiotherapy by sending protocol about it
  - In case of event cat B
    - 3 month after finding that there was an event cat B by sending protocol about it

Q5.7.1 **Are the professional bodies best placed to provide guidance on clinically significant events and are they willing to do so?**

I think that they are best placed and I hope that they might be willing to do so

Q5.7.2 **To what degree is such guidance already available – for diagnostic exposures, for interventional procedures, for radiotherapy?**

In CZ for RT partly, for others not at all

Q5.7.3 **Can this be provided at European level or should this be left to be solved out within each Member State (for example by professional bodies themselves or in cooperation with the competent authority)?**

I think that both would be ideal – at European level setting some basic approaches and finalizing them nationally

Questions from the discussion paper

Q5.13 **What are stakeholders' views on options 1 – 6, and in particular on the value of defining significant events as including all clinically significant events and requiring these to be reported?**

1. whether the clinically significant events should be automatically counted as significant events (and therefore reportable as soon as possible to the authority),

    In CZ we don't think that an automatic categorization of clinically significant events as significant is the right approach

2. or if the categorization of the significant events should be independent on categorization of the clinically significant events but it should use some clinical criteria,

3. or if the criteria of significant events should be completely independent on the clinical significance (eg by some number values describing the difference from the prescribed values, geographical miss or absolute dose values for diagnostics),

4. or the criteria of these two categories should be loosely connected with some general statement (eg when the clinically significant event could cause the patient's death or severely and permanently harm him/her, than it should be also significant, other clinically significant events which can influence the patient's health or the cure but they aren't so severe don't need to be significant),

5. or it may also be dependent on whether the clinically significant event in radiotherapy is over- or underexposure.

6. It may be also a solution to set the rules in some combination of these possibilities having a different approach for palliative and curative radiotherapy, for interventional radiology, diagnostic and therapeutically nuclear medicine and for diagnostics.

    In CZ we used combination of options 2 - 6

Other requirements

- Details about what must be part of
  - Immediate informing to the RP authority in case of event cat A
  - Informing about an event cat B to the RP authority
  - Protocol about an event cat A, or B to the RP authority
  - Immediate informing to the patient and doctors in case of clinically significant event cat A
  - Informing about a clinically significant event cat B to the patient and doctors
  - Protocol about a clinically significant event cat A, or B to the patient and doctors
- Archiving times of documents relating to the events or potential events *BSSD art. 63 (c)*
  - 30 years for cat A; 10 years for cat B, C
  - 5 years for potential events
- Course of actions for events and near misses
  - Commensurately with the risk, category and modality

Questions from the discussion paper

Q5.1.2: **Is sufficient attention given to diagnostic exposures as well as therapeutic exposures?**

Yes

Q5.8.1 **Do stakeholders have experience of criteria which have been developed that have credibility within their communities that could be used as part of requirements for reporting of significant events?**

In CZ we had had criteria only in RT, the other criteria were developed newly for the new law and only time will show their credibility

Q5.15 **What are stakeholders' views on the value of these (pregnancy, children, screening in DG, or geographical miss depended on cured region in RT) criteria to be used when defining significant events and therefore to be reported as soon as possible?**

In CZ we didn't explicitly use pregnancy, children or screening in DG criteria for significant events, because we didn't have time to make a proper study that would help us to set these criteria. My opinion is that these facts are usable only for influencing the number of repeated events when they are re-categorized as significant events, not for categorization of single event as significant.

The different approach for categorization of significant events in RT using geographical miss on different cured body regions is in fact present in CZ system by the main sentence of categorization of significant events in RT: „Event when the patient has or can have a serious clinical consequences that can lead to permanent injury or death."

Questions from the discussion paper

Q5.18.1 **Should a maximum time period for investigations of significant events be stipulated within Regulations?**

In CZ we didn‘t put there such a requirement, but in the guide there will be some recommendation

Q5.18.2 **Should a specific time period for each investigation be determined and agreed on a case-by-case basis?**

It might be a good solution because of wide range of possible events

Q5.18.3 **In competence of which employee of the undertaking should be making of these investigations and summarizing of them?**

I think that mainly medical physicist and in RT in cooperation with the radiological oncologist

Q5.19.1 **Is dissemination of information a responsibility of the competent authority, the health Ministry (or similar) or individual undertakings that have experienced significant events?**

In CZ the RP authority with the support of the supporting institution will do this

Q5.19.2 **What experience do stakeholders have of the value of dissemination of this type of information?**

In CZ we have a minimal experience with this

Q5.19.3 **How practical is it to produce valuable but anonymized information that meets the needs of the wider radiological community while respecting the wishes of individual patients involved in significant events?**

Very valuable – it helps to prevent occurrence of such event elsewhere