HERCA MSW on Reporting Accidental and Unintended Doses

Reporting in Finland

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STUK Guides ST 2.1, 3.3 and 6.3

Significant events in radiology and NM

- Unintended exposure of a member of public)
- Wrong patient in CT, IR and in NM
- Significant exposure of a worker during an abnormal event
- Significant excess exposure of a patient or a fetus in an abnormal event during CT, IR or NM
- Systematic equipment or system failure
- Ssome other event that should be communicated to other responsible parties in order to prevent similar events.

Reporting other than significant events

- Other abnormal events shall be compiled together and reported to STUK by the end of January of the following year (grouped in accordance with ST Guide 3.3 Appendix D).
- Typical cases of imaging failures leading to an extra exposure (due to a projection error, the movement of the patient or a similar reason, for example) do not need to be reported to STUK as abnormal events.

Other events to be reported annually (other than CT, IR or NM) 1/2

Exposed party	Type of abnormal event	Cause or contributing factor	Number of events per year
Abnormal events related to the referral			
Wrong patient	Referral written for the wrong person	Human error	
		Human error, the high likelihood of errors in the referral system*) a contributing factor	
Patient	Incorrect examination or anatomical object in the referral	Human error	
		Human error, the high likelihood of errors in the referral system*) a contributing factor	
	Another type of error in the referral		
Abnormal events related to the performance of the examination			
Wrong patient	Wrong patient examined	The patient's identity was not verified before the examination	
Patient	An incorrect examination was performed or an incorrect anatomical object was imaged	Human error during the performance of the examination	
	Failed examination or an excess exposure related to the examination	Erroneous or deficient instructions	
		Human error during the performance of the examination	

Other events to be reported annually (other than CT, IR or NM) 2/4

Extraordinary exposure, other events			
Patient	Failed examination or an excess exposure related to the examination	Isolated case of equipment failure	
		The high likelihood of errors in equipment, an auxiliary appliance or system*) as a contributing factor	
	Examination repeated unnecessarily	No information available on earlier similar examination, or results from earlier examination not available	
Patient and worker	Worker also exposed due to the abnormal event mentioned above (when the worker's exposure is not significant)		
Worker	Worker exposure (when the exposure is not significant)		
	Other event:		
Unintended exposure of the foetus			
Foetus	Pregnant person exposed	The pregnancy is at such an early stage that it cannot be verified	
		The possibility of a pregnancy was not considered before the procedure	
A near miss that caused actions to be taken at the place of radiation use			
	When a more detailed report to the authorities is not considered purposeful		

*) A high likelihood of errors refers to the poor usability of equipment or a system, allowing extraordinary radiation exposure to be caused by a human error that can occur easily.

Classification of abnormal events in RT

- Abnormal events do not include incidents in which an unexpected consequence for the patient arose solely on account of a medical decision made by a physician, and the matter does not concern a deficiency in the radiotherapy activities quality system or a failure to comply with the said system.
- An abnormal event is an equipment fault, human error or combination thereof that is systematic or incidental and has caused (a factual event) or could have caused (near-miss situation) danger to the health of a patient, a member of staff or an outsider.

Systematic and incidental faults

- An equipment fault is defined very generally to mean faulty equipment operation, a programme error, or an error or deficiency in the instructions for operation and functioning.
- A systematic fault generally concerns more than one patient or person, while an incidental fault generally affects only one patient or person.
- Even a minor systematic fault may be significant when assessing factors that jeopardise safety and when gathering information with a view to preventing new errors.

Magnitude of the harm

- Abnormal events are also divided according to whether the hazardous situation affected the staff, external persons, or a patient.
- When the victim is a patient, hazardous situations are classified according to the size of the real or possible accidental dose and the magnitude of harm caused to the individual patient.
- A faulty dose is an abnormal dose caused by a fault which differs significantly from the radiotherapy plan approved by a physician.
- Four classes of abnormal event: A, B1,B2 and C.

A: Staff or outsider

- Person has sustained a radiation dose that is abnormal or exceeds the dose limit due to an equipment fault or human error.
- When the matter concerns an equipment fault in a radiotherapy appliance or safety system, this class also includes cases that could have resulted in such a situation without exceptionally great caution or good fortune.
- All events have to be reported to STUK.

B1: Patient Event that seriously endangers the patient's health

- The patient has received (a factual event) or could have received (a near-miss situation) an incorrect radiation dose of a kind that can seriously endanger the patient's health.
- Attention must be paid to the overdose applied to the target area or risk organ, on account of which the patient could suffer serious complications.
- The deviation from the planned total dose is more than 25%. If an overdose of less than 25% can cause serious complications, then the abnormal event belongs to this class.
- Reports to STUK in
  - All factual events
  - Near-miss situations caused by a systematic error (an equipment fault or human error) or an incidental equipment fault

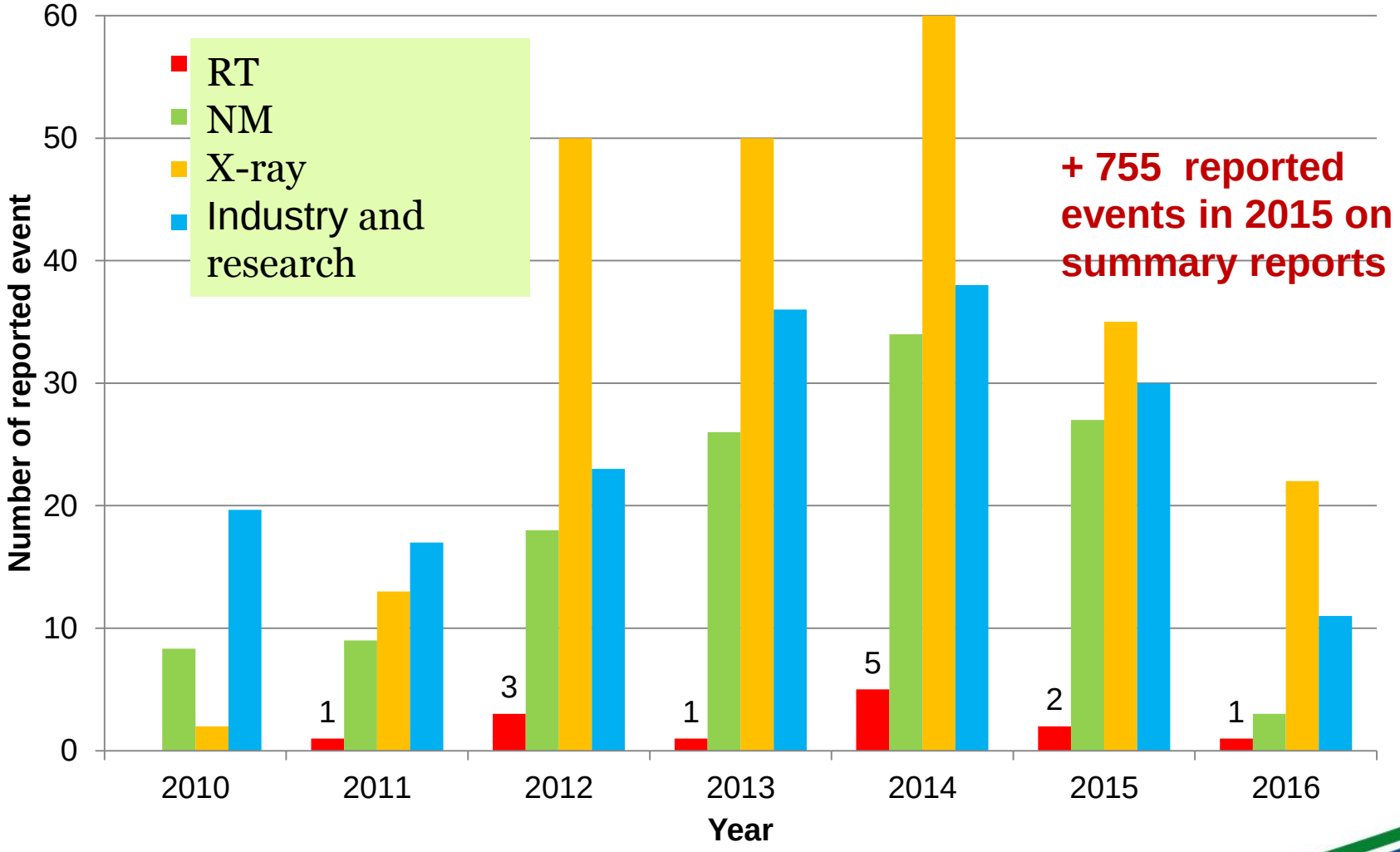
B2: Patient Event that mildly endangers the patient's health

- The patient has received (a factual event) or could have received (a near-miss situation) an incorrect radiation dose of 5–25% to some area.
- The overdose may cause no increase in the risk of serious complications for the patient that differs clearly from general practice.
- Reports to STUK in
  - All factual events caused by a systematic error (an equipment fault or human error)
  - Near-miss situations caused by a systematic equipment fault

C: Patient Abnormal events not pertaining to radiation safety

- Such as hazardous situations arising from the mechanical characteristics or electrical safety of equipment.
- No need to notify STUK.

Number of Reported Events 2010-3.6.2016



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