



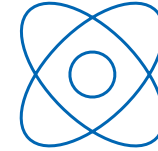
Reporting on Radiation Safety Deviations of Medical X-ray Practices in Finland

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- The number of reported cases
 - Significant
 - Minor
- Structured form for reporting minor cases
- Statistics

Legislative base



Radiation Law 859/2018

Definition of radiation safety deviation

”A radiation safety deviation is an event that causes or threatens to compromise radiation safety, as well as non-planned medical exposure”

- Radiation safety authority shall be notified of these radiation safety deviations
 - Significant cases are to be reported without delay
 - Afterwards a full report and account of corrective actions
 - Summaries of less significant cases of radiation safety deviations of medical exposure

Legislative base

During previous legislation (valid until 15.12.2018) the requirements for notification of radiation safety deviations were similar

- Data presented in this presentation was subject to the previous legislation

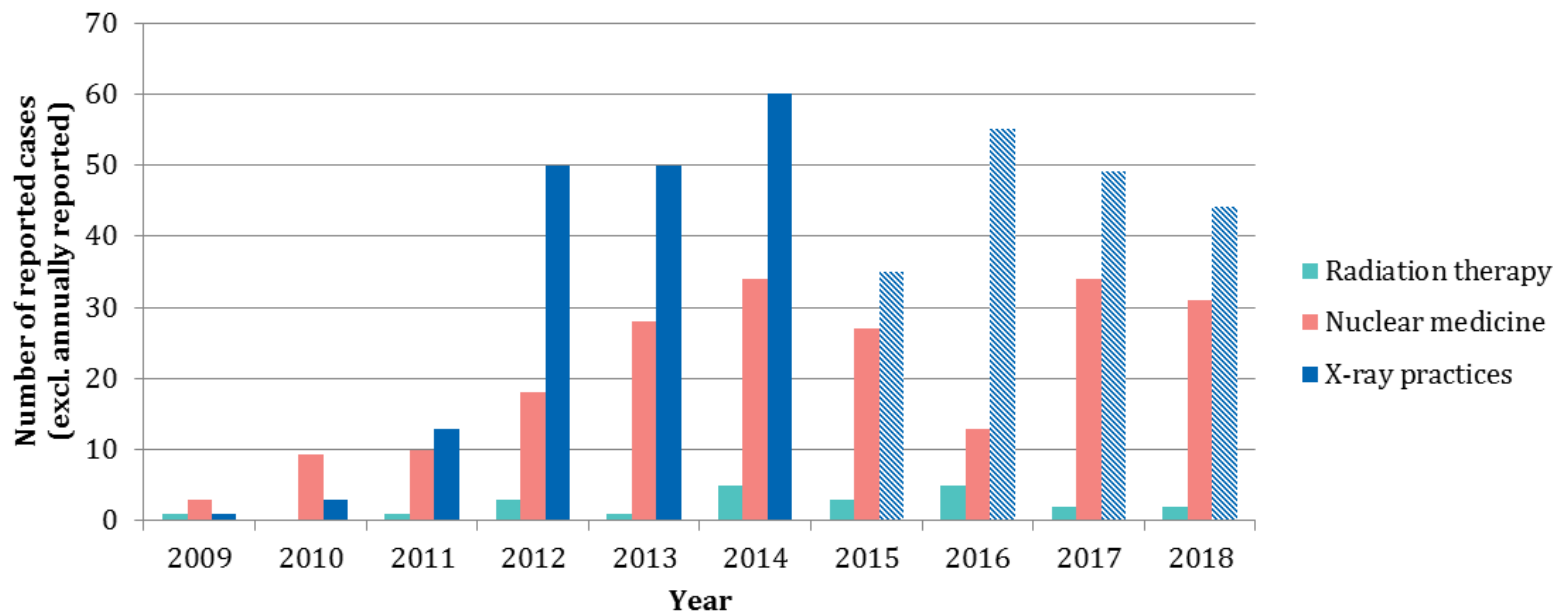
New requirements in legislation

- Radiation safety deviations are to be recognised, prepared for and acted upon beforehand
 - Documentation needed for authorisation, to be included in application for a license
 - STUK Order S/2/2018 "Planning for and handling of radiation safety deviations"

Reported radiation safety deviations in healthcare

- Reporting activity on radiation safety deviations has improved during last 10 years

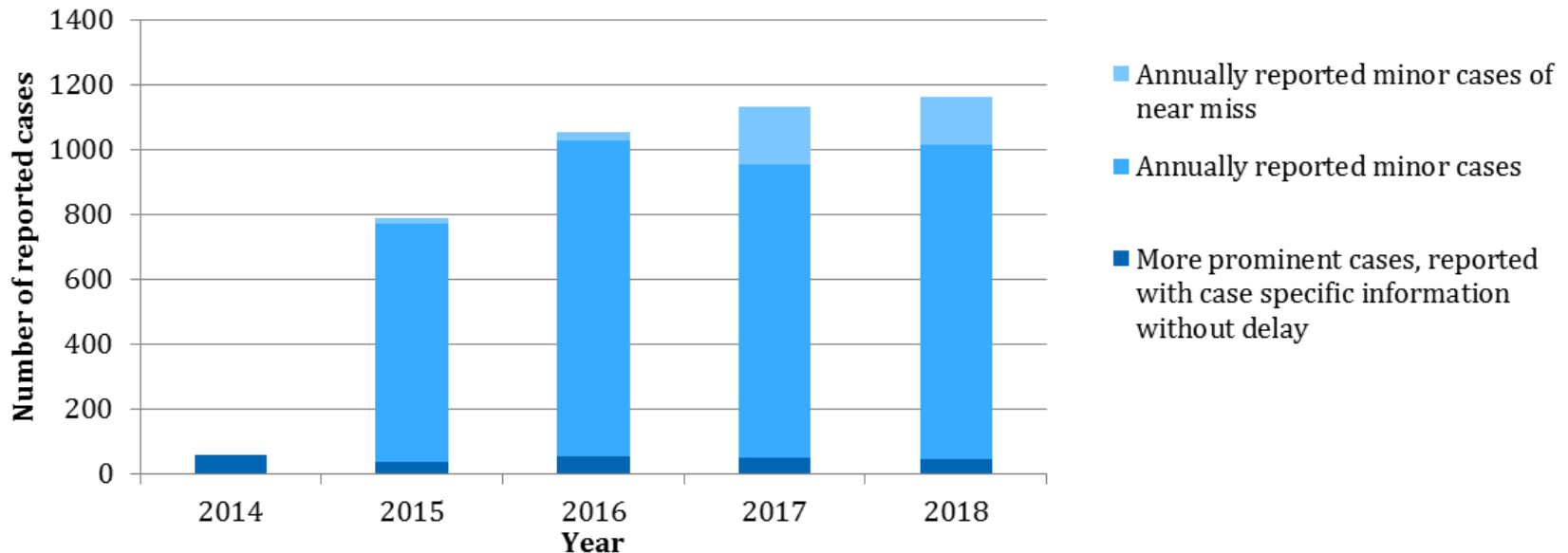
Reported radiation safety deviations in healthcare
cases reported without delay



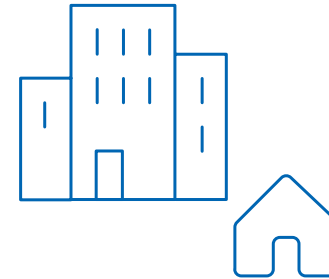
Summary reports of minor cases

- Minor cases in (only) X-ray practices have been reported annually on a structured form since 2015
 - 1 reported case for every 4000-5000 x-ray examinations or procedures
 - Corresponding ratio for significant/prominent cases is 1 for every 80 000-100 000

All reported radiation safety deviations in x-ray practices



Reporting activity



For year 2018 reports came from:

- 100 % of university hospitals
- > 70 % of major hospitals
- ~ 50 % of other hospitals
- ~ 30 % of health clinics with radiological department.
- In addition, reports were send by a significant portion of private health clinics and some dental clinics.
- Interpretation of what is to be considered a radiation safety deviation varies between different hospitals and clinics.

The significant cases with full case descriptions are recorded in STUK's licensing registry.

Structured form for reporting minor cases (only x-ray practices until 2019)

- Categorising cases (years 2015-2018), total 18 categories

1. Incident related to

- Referral process / X-ray examination process
- Other incidents of excess exposure / Near miss -incidents

2. Who is exposed

- Patient / Wrong patient / Fetus / Radiation worker

3. Type of the radiation safety deviation

- for example: Failed examination or excessive exposure related to an examination

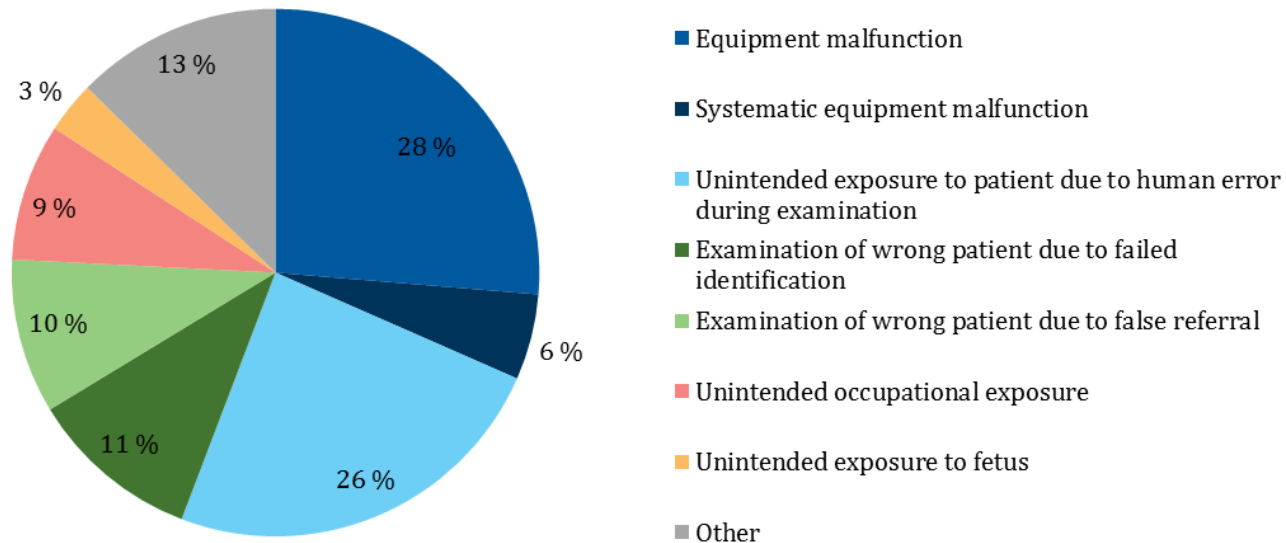
4. Cause or contributing factor

- for example: Equipment malfunction

Statistics (prominent cases)

- Cases considered prominent (previous legislation), examples
 - Exposure of member of the population
 - Involving abnormal exposure of radiation worker
 - Involving excessive exposure in CT or angiography / cardioangiography
 - Systematic equipment malfunctions

Reported radiation safety deviation 2017-18
108 cases in total, excluding annually reported minor cases

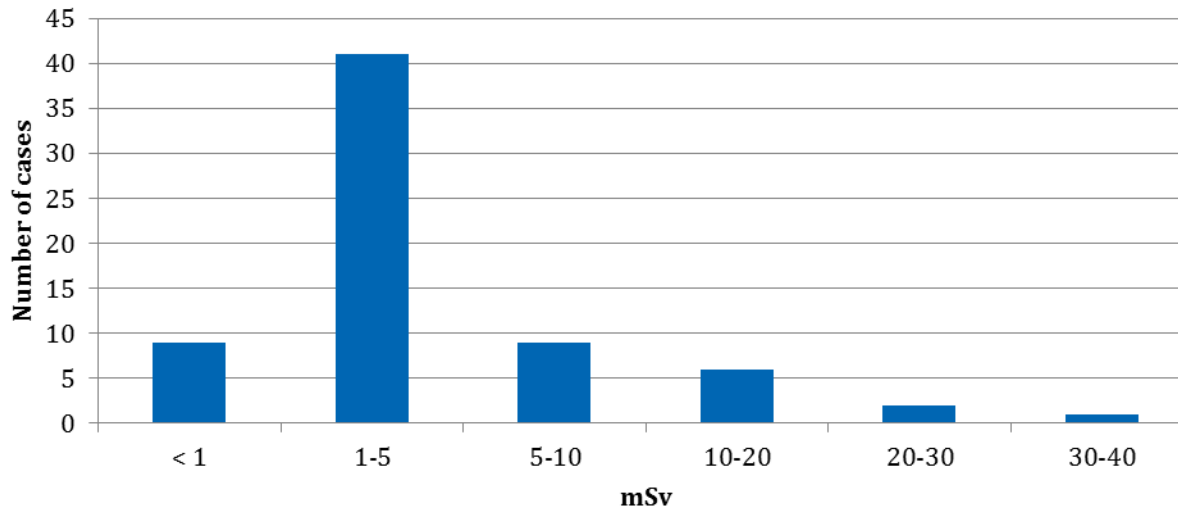


Excessive doses related to prominent cases

Highest doses ever reported have been

- For patient and wrong patient approx. 40 mSv, for fetus 34 mSv, occupational exposure 80 μ Sv

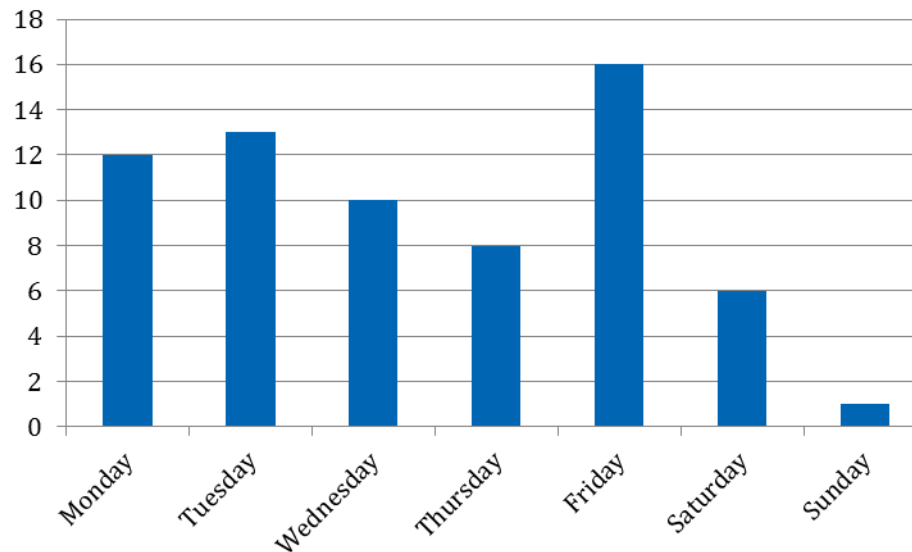
Excess effective dose for patient or wrong patient due to radiation safety deviation, 2017-18



Temporal distribution of radiation safety deviations in healthcare ¹⁾

- Plotting reported cases (excl. annually reported minor cases) on weekdays in which they happened
 - Not only human errors are distributed unevenly during the week

The temporal distribution of non-human errors

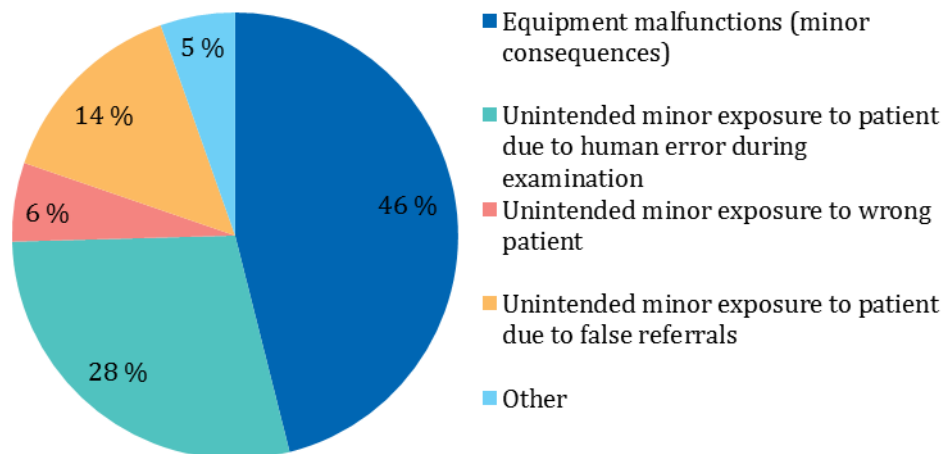


1) Temporal distribution of Abnormal Events, J. Liukkonen, S. Kaijaluoto, STUK, 2017, IAEA-CN-123/45

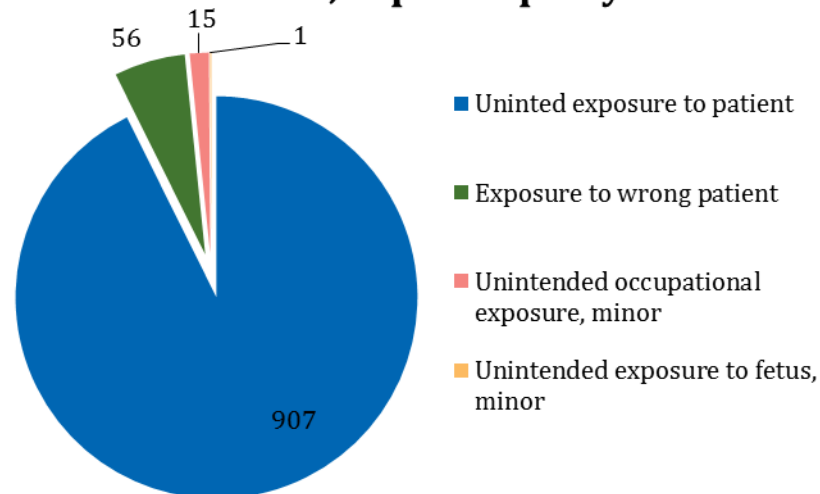
Statistics (minor cases)

- Reported annually, early next year
- Number of cases categorised in the given form
 - Additional information of the cases can be included in the report
- So far no significant trends of any case type can be interpreted from annual reports

Minor radiation safety deviations, reported in 2018 (979 cases)



Minor radiation safety deviations in 2018, exposed party



Now and in the future

New legislation

- The definition of which cases are significant and are to be reported without delay is changed
 - For example patient involving cases only with over 10 mSv excess exposure
- Annual summaries of less significant cases
 - 28 categories (prev. 18)
 - Only cases of medical exposure
 - Cases involving radiation workers not included
 - Nuclear medicine is included

Knowledge of reporting activity and report data can be utilized in regulatory control / inspections in the future.

