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

Inspector Elina Hallinen, STUK
Contents

• Legislative base
• 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
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
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

- Equipment malfunction: 28%
- Systematic equipment malfunction: 13%
- Unintended exposure to patient due to human error during examination: 6%
- Examination of wrong patient due to failed identification: 11%
- Examination of wrong patient due to false referral: 10%
- Unintended occupational exposure: 9%
- Unintended exposure to fetus: 3%
- Other: 3%
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 µSv

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

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)

- Equipment malfunctions (minor consequences) 46%
- Unintended minor exposure to patient due to human error during examination 14%
- Unintended minor exposure to wrong patient 6%
- Unintended minor exposure to patient due to false referrals 28%
- Other 5%

Minor radiation safety deviations in 2018, exposed party

- Unintended exposure to patient 907
- Exposure to wrong patient 56
- Unintended occupational exposure, minor 15
- Unintended exposure to fetus, minor 1

Elina Hallinen
12.6.2019
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.