

CCRI webinar:
X-ray imaging dosimetry challenges
28 May 2024

Regulations on X-ray imaging dosimetry

Jenia Vassileva



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Outline

- Current international safety standards
- Implementation problems and challenges
- Need of changes

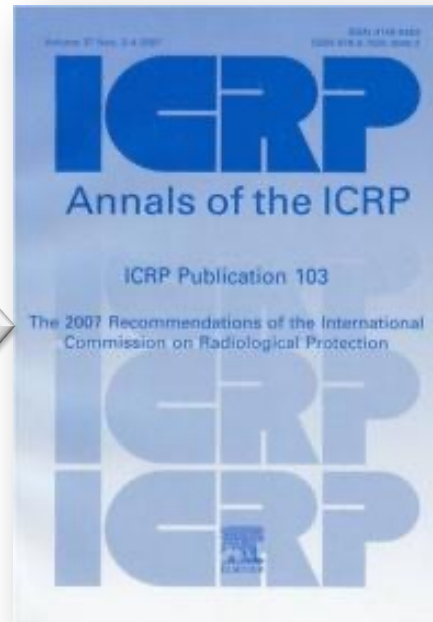
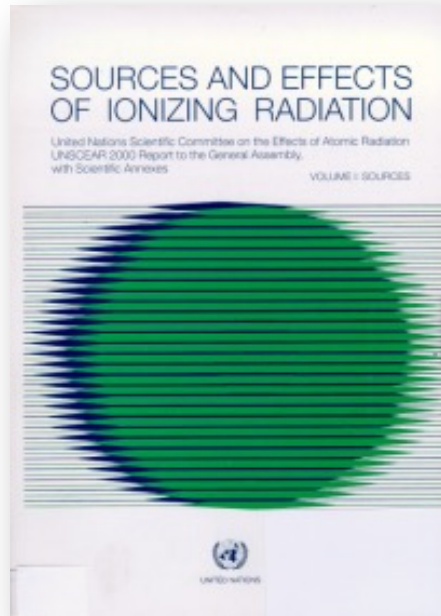


Current international safety standards

UNSCEAR
studies effects
of atomic
radiation

ICRP provides
recommendations
for protection

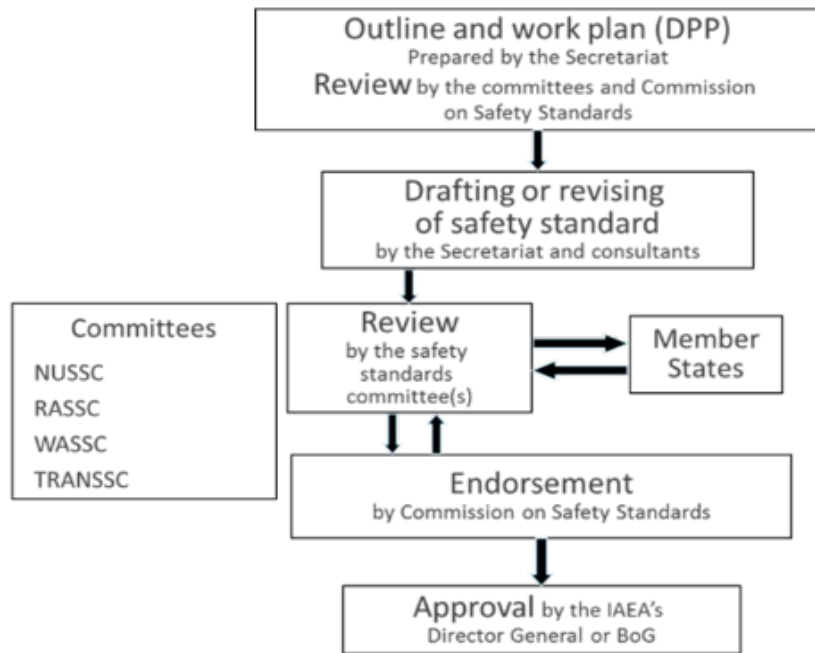
IAEA establishes safety standards



Current international safety standards

- All Safety Standards go through a formal process of Member State comments
- Reflect the international consensus
- Become a basis for the national legislation

IAEA establishes safety standards



Current international safety standards

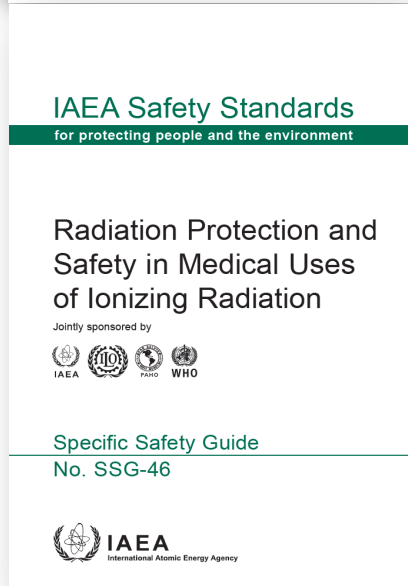
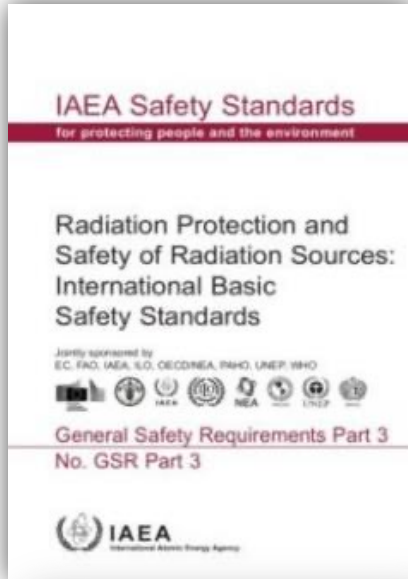
International Basic Safety Standards (GSR Part 3)

- Published 2014
- Set basic requirements for protection and safety
- Co-sponsored by 8 international organizations

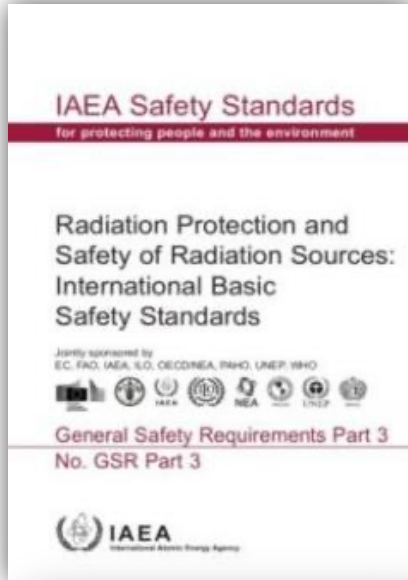


Specific Safety Guide SSG-46

- Published 2018
- Provides recommendations for the implementation of GSR-Part 3 in medical uses of ionizing radiation
- Jointly sponsored by IAEA, WHO, PAHO, ILO
- Developed in cooperation with international/regional professional organizations: IOMP, ISR, ISRRT, WFNMB, ESTRO



Medical exposure (GSR Part 3)



Requirement 34: Responsibilities of the government (paras 3.147–3.149)

Requirement 35: Responsibilities of the regulatory body (3.150)

Requirement 36: Responsibilities of registrants and licensees (3.151–3.154)

Requirement 37: Justification of medical exposures (3.155–3.161)

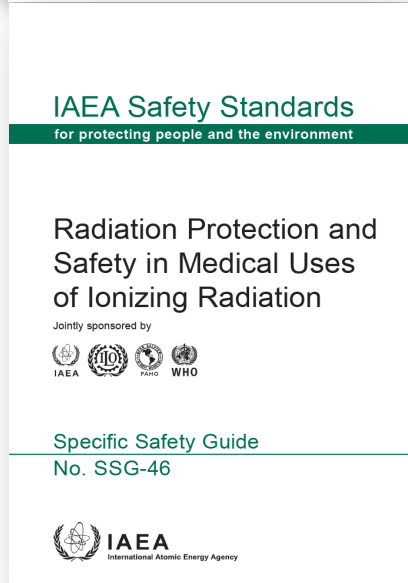
Requirement 38: Optimization of protection and safety (3.162–3.174)

Requirement 39: Pregnant or breast-feeding female patients (3.175–3.177)

Requirement 40: Release of patients after radionuclide therapy (3.178)

Requirement 41: Unintended and accidental medical exposures (3.179–3.181)

Requirement 42: Reviews and records (3.182–3.185)



Optimization of medical exposure (GSR Part 3)

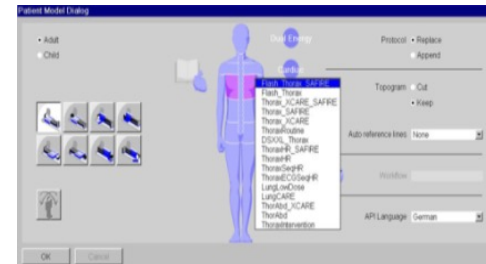
Requirement 38: Optimization of protection and safety (3.162–3.174)

Registrants and licensees and radiological medical practitioners shall ensure that **protection and safety is optimized for each medical exposure**

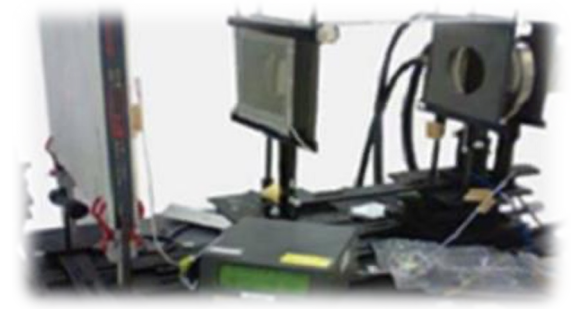
① Equipment design



② Operational considerations



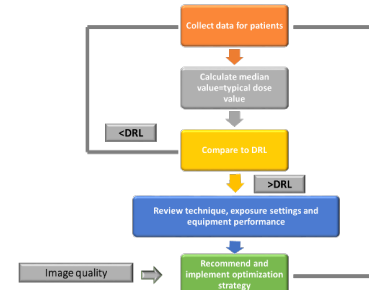
③ Calibration



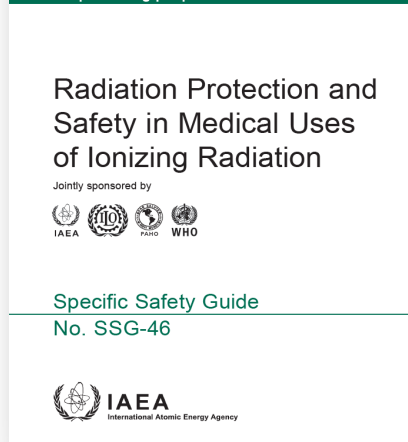
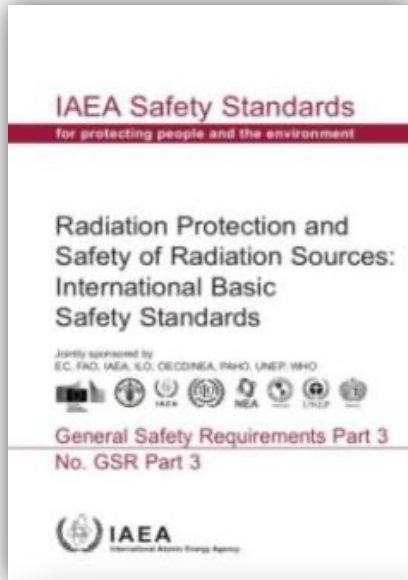
④ Dosimetry of patients



⑤ Diagnostic reference levels



⑥ Quality assurance



Components of optimization (GSR Part 3)

③ Calibration of radiation sources



3.167. The **medical physicist** shall ensure that:

- (a) **All sources** giving rise to medical exposure are **calibrated in terms of appropriate quantities** using internationally accepted or nationally accepted protocols;
- (b) Calibrations are carried out at the time of **commissioning** a unit prior to clinical use, **after any maintenance** procedure that could affect the dosimetry and **at intervals** approved by the regulatory body



SSG-46 (paras 3.201-3.205):

‘Source calibration’ in X ray imaging is to be interpreted as the measurement of **certain dosimetric quantities** (ICRU) that are **modality dependent** and which should be carried out in **reference conditions**.

- Measurements should be made for a range of representative technique factors used clinically, and following recognized protocols.
- After the initial calibration, the **intervals for periodic calibrations might differ**, depending on the complexity of the medical radiological equipment (QC).

Components of optimization (GSR Part 3)

③ Calibration of dosimetry instrumentation



3.167. The **medical physicist** shall ensure that:

(d) **Calibration of all dosimeters** used for dosimetry of patients and for the calibration of sources is **traceable to a standards dosimetry laboratory**.

SSG-46 (paras 3.206-3.209):

- Dosimetry instrumentation used at a radiology facility should be calibrated at appropriate intervals. A period of **not more than two years** is recommended.
- Calibration using **diagnostic radiology spectra and dose rates** representative of clinical practice (or with comparable radiation qualities).
- Calibration should be traceable to a **standards dosimetry laboratory**:
 - ▶ **national PSDL or SSDL** in the State, with access either directly or through a duly accredited calibration facility, or
 - ▶ sent to **another State or region** if there is no national SDL in the State/ region, or
 - ▶ Instrument **manufacturers' calibrations**, provided that the manufacturer operates or uses a calibration facility that is itself traceable to a SDL and appropriate calibration conditions have been used.



Components of optimization (GSR Part 3)

③ Calibration of dosimetry instrumentation



3.167. The **medical physicist** shall ensure that:

(d) **Calibration of all dosimeters** used for dosimetry of patients and for the calibration of sources is **traceable to a standards dosimetry laboratory**.

SSG-46 (paras 3.206-3.209):

- Dosimetry instrumentation used at a radiology facility should be calibrated at appropriate intervals. A period of **not more than two years** is recommended.
- **Cross-calibration of dosimeters**, where the officially calibrated dosimeters of the radiology facility's are used to check or compare with other dosimeters.
- Cross-calibration can be utilized as a **part of periodic quality control tests**.

Examples:

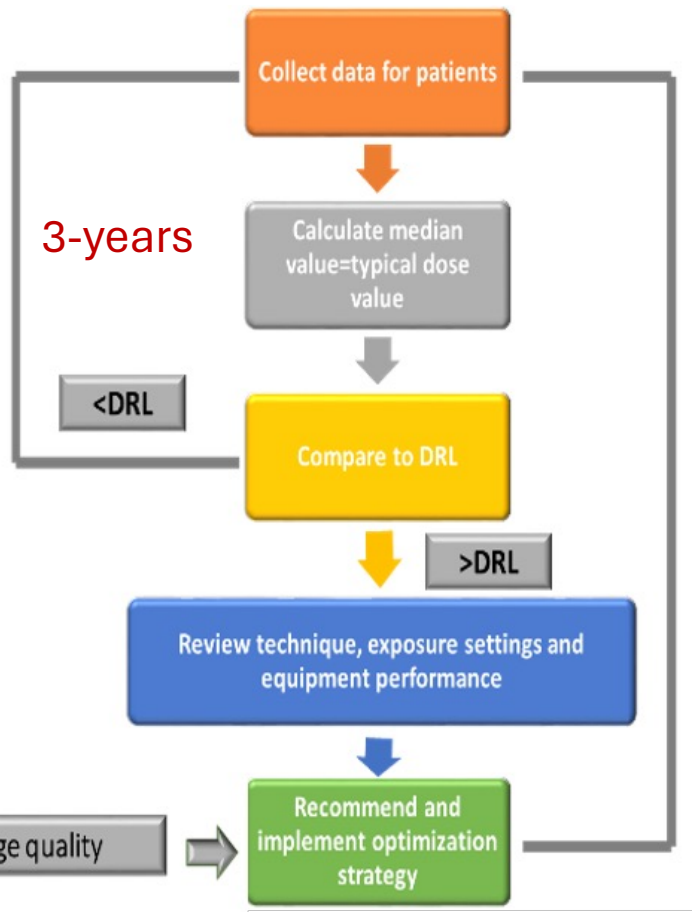
- 1) **Field KAP meters** should be calibrated (or cross-calibrated) against a reference KAP meter or air kerma dosimeter in situ in the clinical environment rather than in a SSDL.
- 2) When a radiology facility has **many dosimeters**, and to calibrate all dosimeters could be too costly.



Components of optimization (GSR Part 3)

④ Dosimetry of patients

⑤ Diagnostic reference levels (DRLs)



3.168. Registrants and licensees shall ensure that dosimetry of patients is performed and documented **by or under the supervision of a medical physicist**, using **calibrated dosimeters** and following internationally accepted or nationally **accepted protocols**, including **dosimetry to determine typical doses** to patients for common diagnostic radiological and image guided interventional procedures.

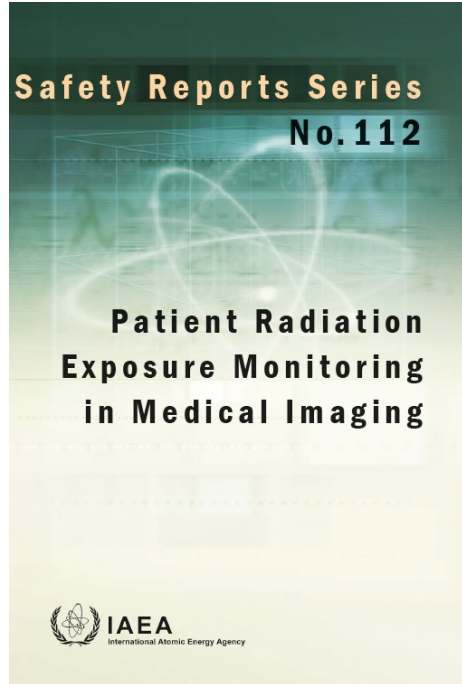
3.169. Registrants and licensees shall ensure that:

(a) **Local assessments** are made at approved intervals ...

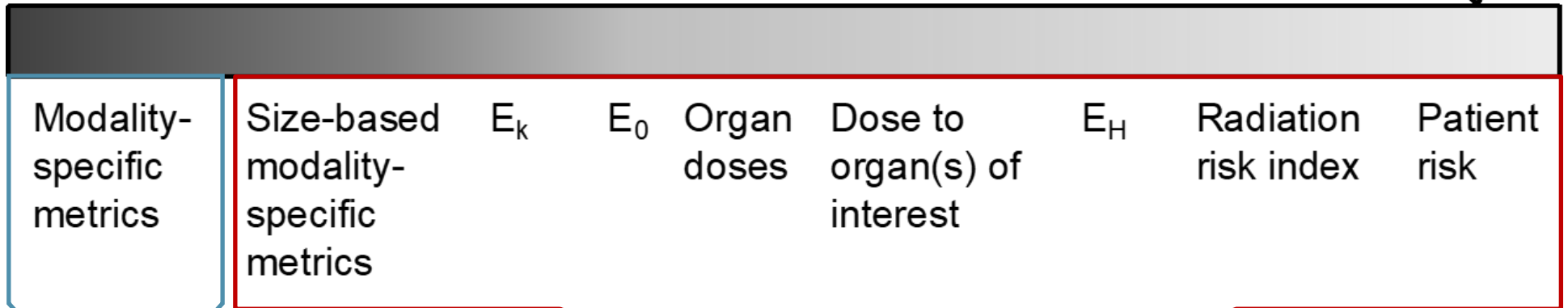
(b) **Review** is conducted to determine whether the optimization is adequate, or whether corrective action is required if, for a procedure: Typical doses ...**exceed** the relevant DRLs; or ...**fall substantially below** the relevant DRL and the exposures do not provide useful diagnostic information or do not yield the expected medical benefit to the patient.

Detailed guidance provided in SSG-46 (paras 3.210-3.231)

Patient radiation exposure monitoring (SRS-112)



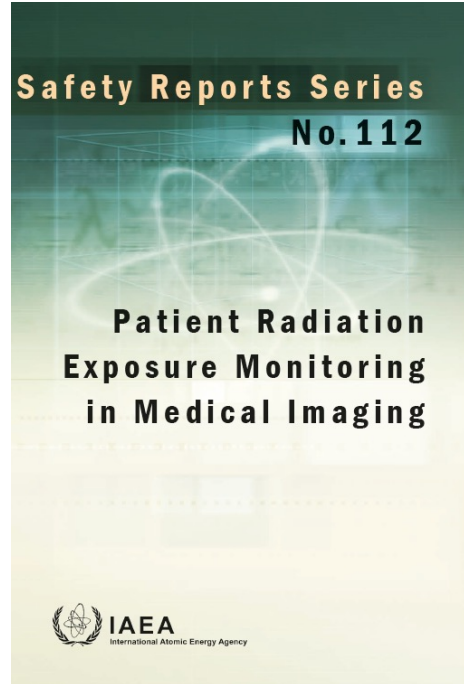
Goal ↓



- ### Measurable quantities
- Benchmarking typical doses to DRLs
 - Optimization of clinical protocols
 - Performance assessment of an imaging system and QC
 - Quality assurance

- ### Calculated dose quantities
- Comparison of risks from different imaging methods and procedures
 - Prevention of skin injuries
 - Estimation of risk to embryo/ fetus
 - Assessment of individual patient risk

Patient radiation exposure monitoring (SRS-112)



- Manually



- Automatically



- Evaluation of the **data accuracy** needs to cover all the steps of patient exposure data monitoring:
 - Measurements and calculations to provide the dose and image quality metrics;
 - Data recording and collection;
 - Data analysis - attention to the uncertainties of the methods of analysis.
- **Medical physicists** play a crucial role

Components of optimization (GSR Part 3, SSG-46)

⑥ Quality assurance for medical exposure



3.170. Registrants and licensees, in applying the requirements of these Standards in respect of management systems, shall establish a **comprehensive QA programme** for medical exposures with the active participation of **medical physicists, radiological medical practitioners, medical radiation technologists** ..., and in conjunction with other health professionals as appropriate. ..

3.171. ...QA programmes include:

- (a) **Measurements of the physical parameters** of medical radiological equipment made by, or under the supervision of, a **medical physicist**:
- ▶ At the time of **acceptance** and **commissioning** of the equipment prior to its clinical use on patients;
 - ▶ **Periodically** thereafter;
 - ▶ After any **major maintenance** procedure that could affect patient protection;
 - ▶ After installation of **new software** or modification of existing software that could affect protection of patients.
- (b) **Corrective actions** if measured values of the physical parameters are outside established tolerance limits.
- (c) **Verification** of the appropriate physical and clinical factors used in procedures.
- (d) Maintaining **records** of relevant procedures and results.
- (e) Periodic **checks of the calibration and conditions of operation** of dosimetry and monitoring equipment.

Components of optimization (GSR Part 3, SSG-46)

⑥ Quality assurance for medical exposure



Detailed guidance provided in SSG-46 (paras 3.232-3.246)

3.244. ...Periodic **checks of the calibration and conditions** of operation of dosimetry equipment and monitoring equipment ...is to ensure that such instrumentation has a **current calibration**, typically conducted within the last two years (para. 3.206), and that it is **functioning correctly**.

- The QA programme should establish a **frequency for calibration** for each instrument and a set of **QC checks on the operation** at set intervals.
- This applies to **stand alone dosimetry equipment** and to **dosimeters integrated into the medical radiological equipment** (such as KAP meters in fluoroscopic systems, and to software of the medical radiological equipment itself that calculates, displays and reports dose metrics such as CTDI and DLP in CT and reference air kerma in image guided interventional procedures.
- **Phantoms** used in QA and dosimetry should fulfil the requirements specified in the corresponding **international standards**.

Implementation problems and challenges

■ Patient dosimetry

- ▶ Verification of calibration of dosimeters integrated into the medical equipment not included in QC;
- ▶ Mandatory calibration/ verification of all instrumentation for patient dosimetry in a SDL, thus not allowing cross-calibration and use of devices/ dose displays integrated in the X-ray equipment;
- ▶ Data collection for DRLs/ typical doses without paying attention for the accuracy of dose displays;
- ▶ Overuse of effective dose without assessment of and attention to the associated uncertainties;
- ▶ Lack of standardization of phantoms/ methods for calculation of organ doses and effective dose.

■ Measurements of physical parameters and QC of medical equipment

- ▶ Not seen as a part of QA programme, but rather as a regulatory activity, or metrology testing;
- ▶ Often performed by external laboratories/ companies/ TSO to the RB;
- ▶ Mandatory accreditation (as the main requirement) following ISO 17025, ISO 17020 or other standard;
- ▶ Involvement of medical physicists qualified in DR not required in the regulations;
- ▶ Complicated requirements and expensive and slow process for inclusion of all QC and dosimetry instrumentation in a national metrology register.

Implementation problems and challenges

- Due to lack of resources

- ▶ Access to appropriate equipment and software
- ▶ Access to calibration services
- ▶ Access to qualified medical physicists
- ▶ Access to competent regulators/ inspectors

- Due to regulatory issues

- ▶ Incomplete/ outdated national radiation protection and metrology legislation
- ▶ Wrong interpretation/ implementation of international standards and recommendations
- ▶ Conflicting requirements of national radiation protection and metrology legislation
- ▶ Lack of cooperation between different authorities and professionals

Conclusions

- Current international safety standards and guidance provide a sufficient basis for establishing a comprehensive programme for X-ray imaging dosimetry
- Further efforts needed to address the identified implementation problems
- Better coherence needed between the metrology and RP regulations and responsible authorities
- Need to strengthen requirements for continuous monitoring of patient radiation exposure data
- Need of standardization of patient dose computational phantoms and methods

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j.n.vassileva@gmail.com