

TRACKING RADIATION EXPOSURES FROM MEDICAL DIAGNOSTIC PROCEDURES

IAEA Perspective

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IAEA

International Atomic Energy Agency

Atoms for Peace and Development

- ♦ IAEA is the world's central intergovernmental forum for scientific and technical cooperation in the nuclear field
- ♦ 173 Member States
- ♦ Headquarter in Vienna, Austria



NUCLEAR SCIENCE



HUMAN HEALTH



FOOD AND AGRICULTURE



ENVIRONMENT



NUCLEAR ENERGY



SAFETY AND SECURITY



SAFEGUARDS

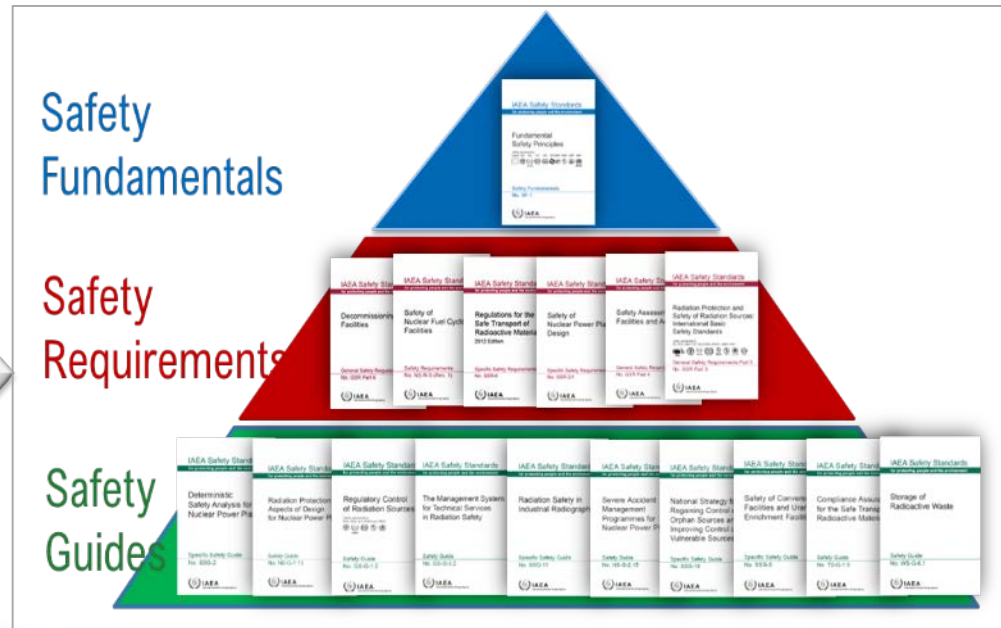
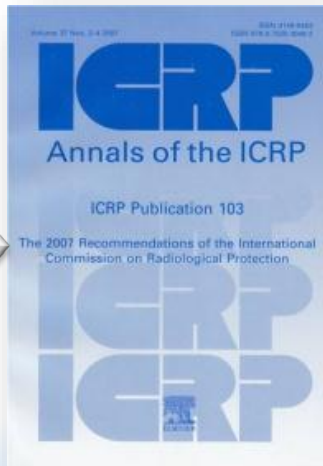
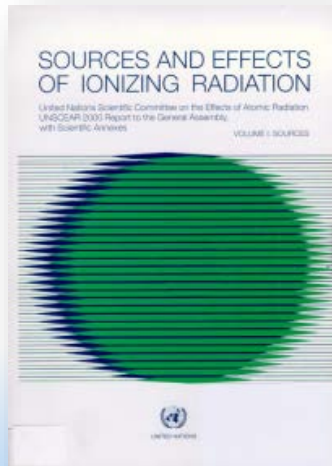
IAEA Statutory role

IAEA establishes standards of safety for protection of health ...,
and provides for the application of these standards

UNSCEAR **studies**
effects of atomic
radiation

ICRP provides
recommendations
for protection

IAEA establishes **safety standards**



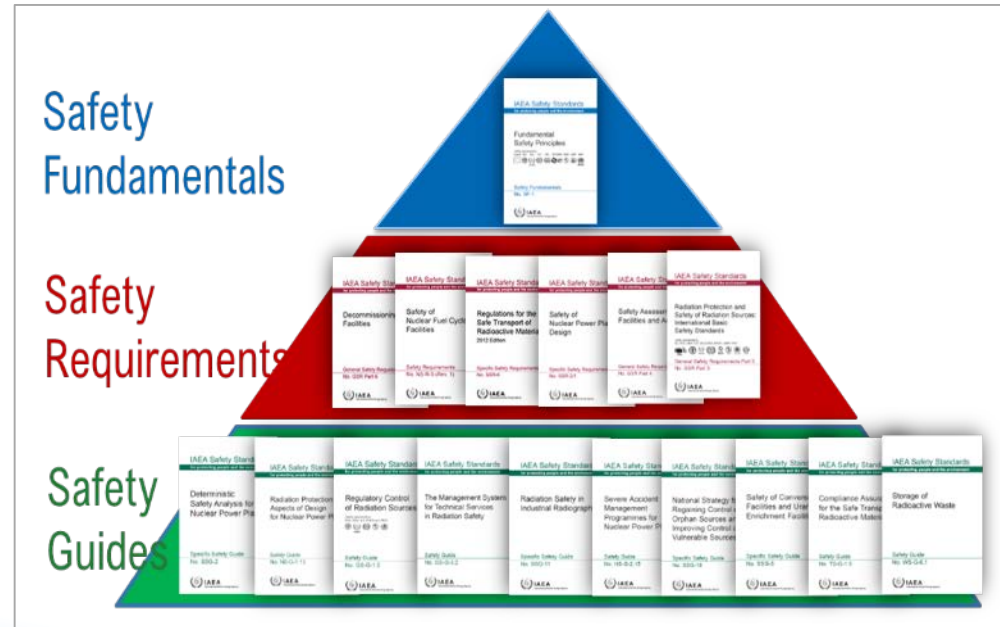
IAEA Statutory role

IAEA establishes standards of safety for protection of health ..., and provides for the application of these standards

- All Safety Standards go through a formal process of Member State comments
- Reflect the international consensus



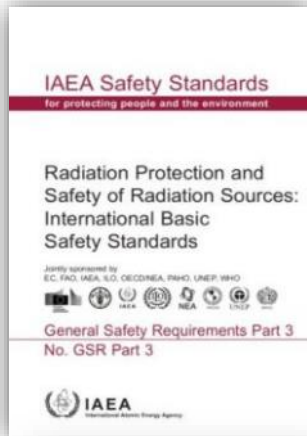
IAEA establishes safety standards



Radiation Protection in Medical Uses

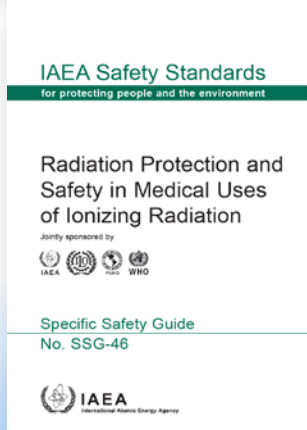
International Basic Safety Standards (GSR Part 3)

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



Safety Guide SSG-46: Medical uses of IR

- Published October 2018
- Jointly sponsored by IAEA, WHO, PAHO, ILO
- Cooperation in developing from international/regional professional organizations: IOMP, ISR, ISRRT, WFNMB, ESTRO



Radiation Protection in Medical Uses



BONN CALL FOR ACTION

10 Actions to Improve Radiation Protection
in Medicine in the Next Decade

Safety Standards

Trainings

Guidance

Knowledge exchange

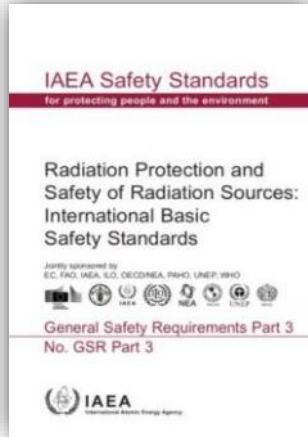
Technical assistance

Building awareness

Technical Meetings and Consultancy Meetings:

- A formal consultation on topics that need further consideration
- Member States and relevant stakeholders invited to nominate representatives
- Perspective of all regions/
Member States considered

Medical exposure of patients

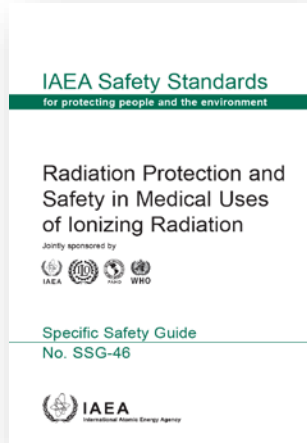


- Dose limit do not apply to medical exposure of patients
- Effort towards improved **justification** and **optimization** of radiation protection for each patient exposure

3.157. The **justification of medical exposure for an individual patient** shall be carried out by means of consultation between the radiological medical practitioner and the referring medical practitioner, as appropriate, with account taken, in particular for patients who are pregnant or breast-feeding or are paediatric, of:

- (a) The appropriateness of the request;
- (b) The urgency of the radiological procedure;
- (c) The characteristics of the medical exposure;
- (d) The characteristics of the individual patient;
- (e) Relevant information from the patient's previous radiological

Medical exposure of patients

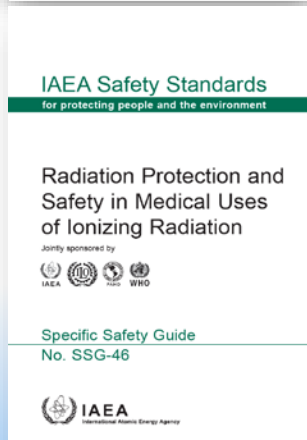
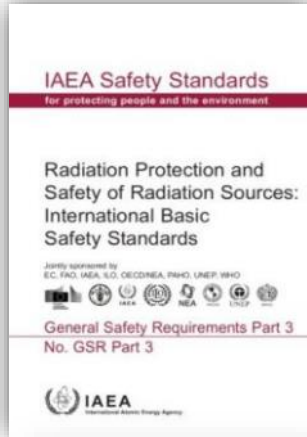


3.144. In determining the appropriateness of the radiological procedure for **an individual patient**, the following questions should be asked by the referring medical practitioner:

- (a) **Has it already been done?** A radiological procedure that has already been performed within a reasonable time period (depending on the procedure and clinical question) should not be repeated (unless the clinical scenario indicates the appropriateness of repeating the procedure). The results (images and reports) of previous examinations should be made available, not only at a given radiology facility but also for consultation at different facilities. **Individual patient exposure records should be used to facilitate the decision making process if available.** Digital imaging modalities and electronic networks should facilitate this process.
- (b) **Is it needed? ...**
- (c) **Is it needed now? ...**
- (d) **Is this the best investigation to answer the clinical question?...**
- (e) **Has the clinical problem been explained to the radiological medical practitioner? ...**

3.142. The patient should be informed about the expected benefits, risks and limitations of the proposed radiological procedure, as well as the consequences of not undergoing the procedure

Medical exposure of patients



Optimization of protection and safety: In diagnostic and interventional medical exposure, keeping the exposure of patients to the minimum necessary to achieve the required diagnostic or interventional objective:

- Appropriate medical radiological equipment and software
- Appropriate techniques and parameters
- Calibration
- Diagnostic reference levels
- Local dose assessments to compare to DRL
- Review to determine whether optimization is adequate

The justification and optimization process can be facilitated through the use of digital hospital information systems and their integration.

New IAEA Safety Report

SAFETY REPORT SERIES No. XX

PATIENT RADIATION EXPOSURE MONITORING IN MEDICAL IMAGING

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Patient radiation exposure monitoring goals:

- Ensuring optimised radiation protection and consistent practice of medical imaging
- Ensuring safe and precise imaging of individual patients
- Supporting the process of justification and appropriateness
- Providing information on collective dose to population and trends

RECORDING

- Electronic recording of exposure data in standard objects (e.g. DICOM objects)
- Recording of single events in a unique object (DICOM Radiation Dose Structured Report, RDSR)
- Manual recording (handwriting when electronic means not available)

Storing

- Dose objects sent to an archive to be permanently stored

COLLECTING

- Collection of data from different dose objects (patients, X ray units/ modalities/ healthcare units/ regions/ countries/... according to specific schemes and templates, reflecting the purpose of data collection)
- Manual collection when electronic means not available

Storing

- A selection of data stored for further purposes

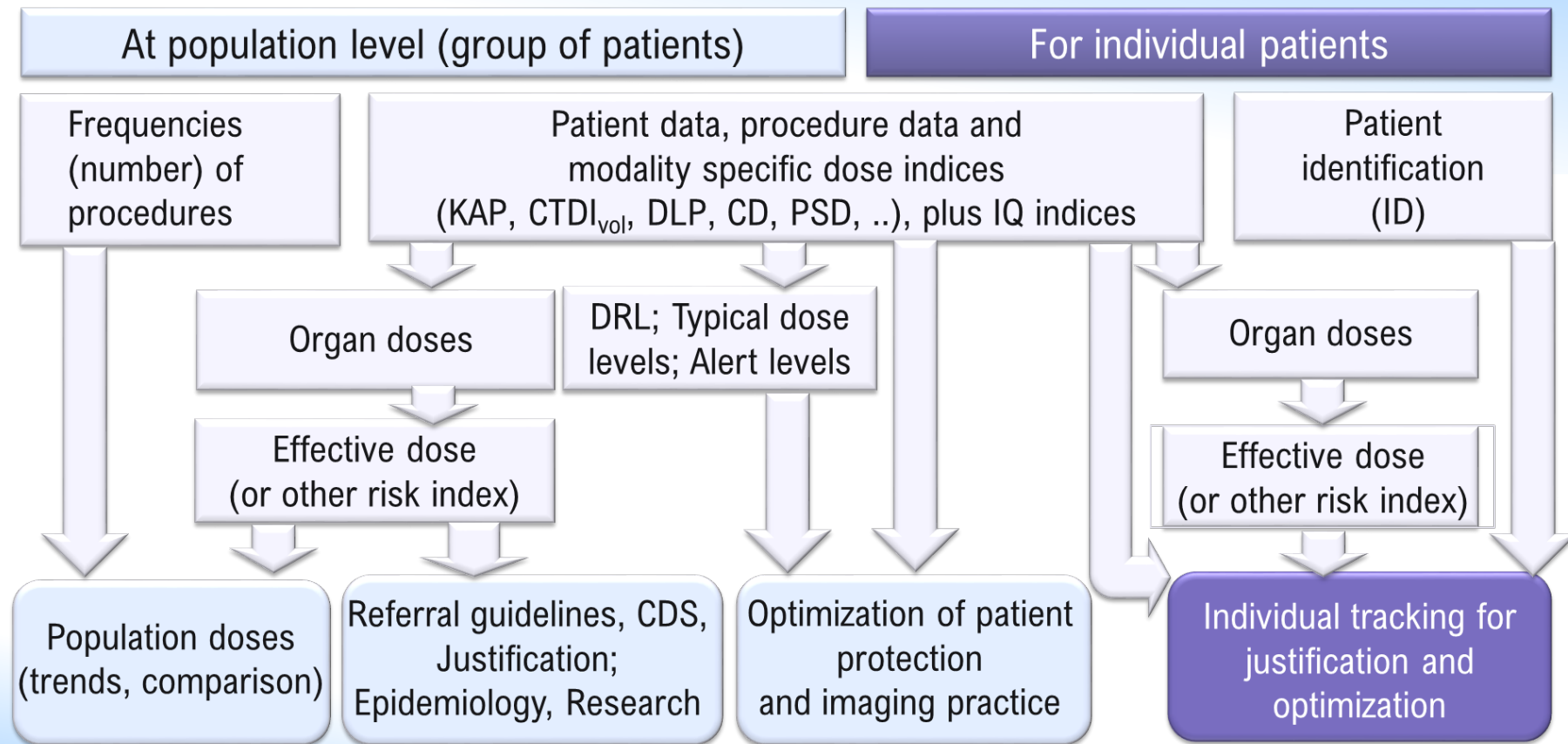
ANALYSING AND REPORTING

- Statistical analysis (mean, median, ranges, quartiles,...)
- Trending analysis (per protocol, per size, per room,...)
- Tracking analysis (temporal changes,...)
- Population analysis (DRLs, collective doses, ...)
- Comparisons
- ...

Storing

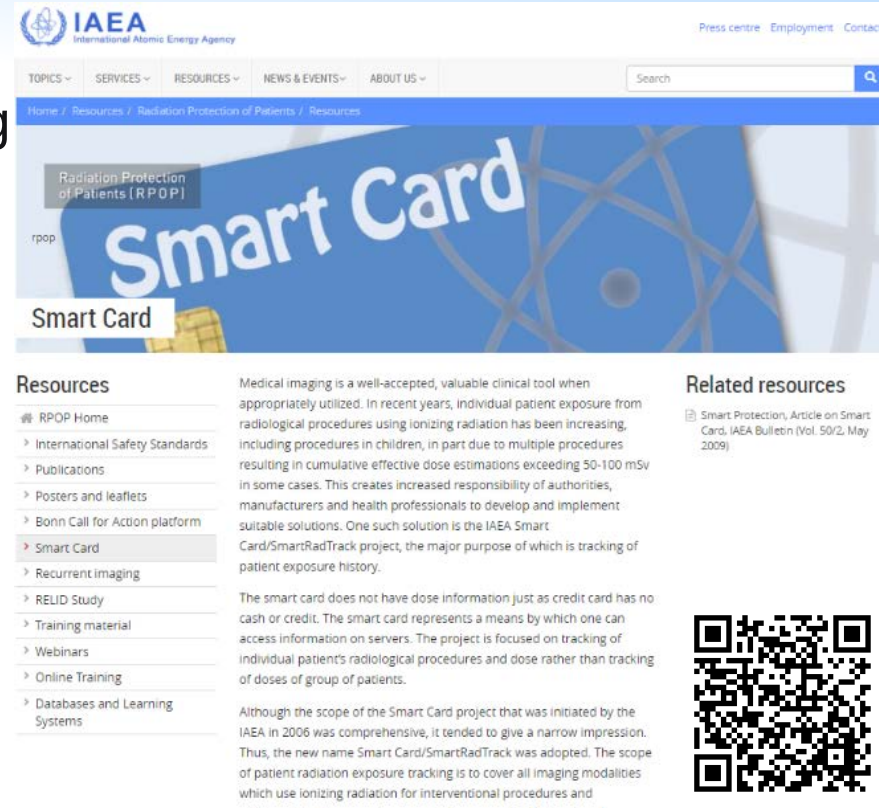
- Results stored if needed
- Standard objects exist (i.e: DICOM Patient RDSR)

Patient exposure monitoring strategy



Patient exposure tracking

- IAEA Smart Card Project launched in 2009
- Aimed to develop a methodology for tracking radiation exposure history of patients
- Developed through series of consultations:
TM 27-29 April 2009; CS 25-27 January 2010;
TM18-21 October 2010; TM 30 Jan–1 Feb 2012;
TM 23-26 September 2013; TM 28-30 April 2015
- Series of actions and publications:
 - survey to assess status of exposure tracking
 - survey on unique patient ID
 - survey with referring physicians
 - templates and models for tracking
 - case reports on use of tracking



The screenshot shows the IAEA website's 'Resources' page for the Smart Card project. The header includes the IAEA logo and navigation links. The main content area features a large image of a Smart Card with the text 'Radiation Protection of Patients (RPOP)' and 'Smart Card'. Below this, there is a 'Resources' sidebar with links to RPOP Home, International Safety Standards, Publications, Posters and leaflets, Bonn Call for Action platform, Smart Card (highlighted), Recurrent imaging, RELID Study, Training material, Webinars, Online Training, and Databases and Learning Systems. The main text area discusses the importance of medical imaging and the Smart Card project's goal of tracking patient exposure history. A 'Related resources' section on the right links to a Smart Protection article. A QR code is located in the bottom right corner.

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Radiation Protection of Patients (RPOP)

rpop

Smart Card

Smart Card

Resources

- RPOP Home
- International Safety Standards
- Publications
- Posters and leaflets
- Bonn Call for Action platform
- Smart Card
- Recurrent imaging
- RELID Study
- Training material
- Webinars
- Online Training
- Databases and Learning Systems

Medical imaging is a well-accepted, valuable clinical tool when appropriately utilized. In recent years, individual patient exposure from radiological procedures using ionizing radiation has been increasing, including procedures in children, in part due to multiple procedures resulting in cumulative effective dose estimations exceeding 50-100 mSv in some cases. This creates increased responsibility of authorities, manufacturers and health professionals to develop and implement suitable solutions. One such solution is the IAEA Smart Card/SmartRadTrack project, the major purpose of which is tracking of patient exposure history.

The smart card does not have dose information just as credit card has no cash or credit. The smart card represents a means by which one can access information on servers. The project is focused on tracking of individual patient's radiological procedures and dose rather than tracking of doses of group of patients.

Although the scope of the Smart Card project that was initiated by the IAEA in 2006 was comprehensive, it tended to give a narrow impression. Thus, the new name Smart Card/SmartRadTrack was adopted. The scope of patient radiation exposure tracking is to cover all imaging modalities which use ionizing radiation for interventional procedures and

Related resources

- Smart Protection, Article on Smart Card, IAEA Bulletin (Vol. 59/2, May 2009)



<https://www.iaea.org/resources/rpop/resources/smart-card>

Patient exposure tracking

- Joint Position Statement by 7 organizations issued in 2012

It is jointly agreed upon that:

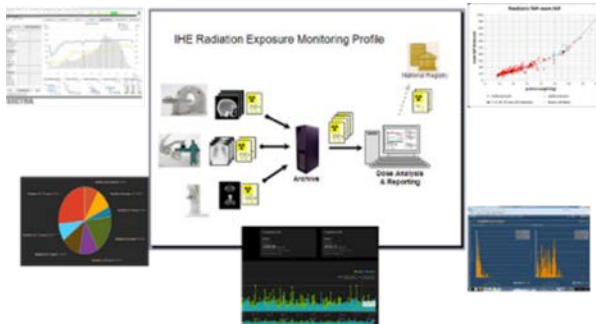
1. Tracking of radiological procedures is useful (Annex).
2. Tracking is of particular interest for CT, interventional procedures and some nuclear medicine examinations that involve relatively higher doses.
3. Countries should consider including necessary provisions in their national requirements for patient radiation exposure tracking. Implementation must comply with relevant national privacy and confidentiality regulations.
4. The advances in picture archiving and communication systems (PACS) and other information technology, availability of radiation dose data in many imaging and image guided procedures in standardized radiation units and internationally harmonized formats, and increased utilization of electronic health records (EHR) provide evolving opportunities to successfully achieve increased coverage of both local and global patient radiation exposure tracking.



<https://www.iaea.org/sites/default/files/documents/rpop/iaea-smart-card-position-statement.pdf>

Improved access to data

- Standardisation of exposure data recording and presentation
- Wider implementation of REM systems:
 - modality-specific metrics
 - procedures/ dose tracking



Vassileva J, Holmberg O. Radiation protection perspective to recurrent medical imaging: what is known and what more is needed? Br J Radiol 2021; 94: 20210477

Author, year	Country/region	Cohort (specific criteria, # patients, age group)	Type of procedures	Period of exposure history
Sodickson et al ⁷⁷	USA	31,462 patients, mean age 56.9 y in an academic medical center	CT	22 years
Fazel et al ⁷⁸	USA	952,420 nonelderly adults, mean age 35.6 y in five health care markets	All	3 years
Dorfman et al ⁷⁹	USA	355,088 children, mean age 9.0 y (0–18) y, in five health care markets	All	3 years
Lutterman et al ⁸⁰	USA	200 consecutive inpatients ≥ 18 y, mean 60.4 y, two academic hospitals	All	Single hospital stay
Bostani et al ⁸¹	USA	34,672 patients, academic hospital	CT	1 year
Lee et al ⁸²	Korea	13,803 children age <15 y In an academic hospital	CT	5 years
Stopsack et al ⁸³	USA	[td]	CT	10 years
Lumbreras et al ⁸⁴	Spain	154,520 (68.8% of all patients) with ≥ 1 exam, 14% children < 15 y	All	12 years
Rehani et al ¹⁴	USA, Europe	2,504,585 patients in 4 institutions with 324 hospitals	CT	1–5 years
Brambilla et al ¹⁵	USA, Europe, Asia, Africa	702,205 patients in 20 hospitals in 20 countries	CT	0.4–6.1 years

Conservative estimate:

Around 1 millions globally = 0.64% of all patients who undergo CT exams cumulate ≥ 100 mSv

Arellano et al ⁸⁹	USA	8,952 who had CED ≥ 100 mSv in an academic hospital	CT	5 years
Li et al ⁹⁰	USA	25,253 patients, mean age 58.2 (≥ 18 y), academic hospital	FGI	109 months
Jeukens et al ⁹¹	Netherlands	49,978 patients, median age 62 (0–103), academic hospital	CT	Maximum 5 years
Frija et al ⁹²	Europe	1,218,429 patients from 18 hospitals in Europe	CT	4 years
Rehani et al ⁹³	USA	3,880,524 patient-days, mean age 57.8 y in 279 USA hospitals	CT	5 years
Brambilla et al ²⁵	Italy	28,870 patients, tertiary care center	CT	2.4 years

IAEA Technical Meetings on recurrent imaging



IAEA TM on Radiation Exposure of Patients from Recurrent Radiological Imaging Procedures,
4-6 March 2019, Vienna

53 participants representing
26 IAEA MSs and 9 international organizations and professional bodies: ICRP, WHO, UNSCEAR, ISR, ISRRT, IOMP, ESR, Image Gently, and DITTA

IAEA TM on the Justification and Optimization of Protection of Patients Requiring Multiple Imaging Procedures,
19-23 October 2020, online

93 participants representing
32 Member States and 13 international organizations and professional bodies: ICRP, WHO, UNSCEAR, EC, HERCA, FDA, ISR, ISRRT, IOMP, ESR, EFOMP, Image Gently, and DITTA.



Reports available from: <https://www.iaea.org/resources/rpop/resources/recurrent-imaging>

IAEA Technical Meetings on recurrent imaging

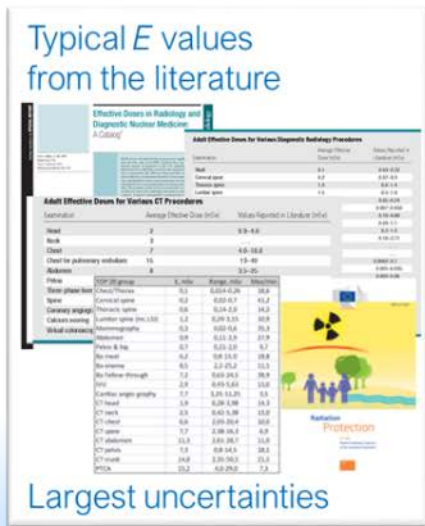
- Represented clinical and radiation protection perspectives
- Reviewed the epidemiological data of cancer risk
- **ICRP**: Radiation dose and risk from a justified and optimized procedure are negligible to low
- If **multiple procedures** are performed to the same individual, cumulative effective dose, as well as equivalent dose to some tissues/organs **may exceed 100 mSv**
- Risk classified as “**moderate**” (ICRP)

ICRP Publication 147, 2021

Effective dose (mSv)	Risk of cancer	Proposed term for dose level	Examples of medical radiation procedures within different dose categories ²
<0.1	Inferred $<10^{-5}$ on LNT model	Negligible	Radiographs of chest, femur, shoulder limbs, neck, and teeth; ^{99m}Tc sentinel node imaging; radionuclide labelling for in-vitro counting with ^{14}C and ^{57}Co .
0.1–1	Inferred 10^{-5} – 10^{-4} on LNT model	Minimal	Radiographs of spine, abdomen, pelvis, head, and cervical spine; radionuclide labelling for in-vitro counting with ^{51}Cr ; ^{99m}Tc for imaging lung ventilation and renal imaging.
1–10	Inferred 10^{-4} – 10^{-3} on LNT model	Very low	Barium meals; CT scans of the head and combinations of chest, abdomen, and pelvis; barium enemas; cardiac angiography; interventional radiology; ^{99m}Tc myocardial imaging; lung perfusion ^{99m}Tc for imaging lung perfusion; ^{99m}Tc imaging of bone lesions; cardiac stress tests; ^{99m}Tc SPECT imaging; imaging with ^{18}F , ^{123}I , and ^{111}In .
10–100	Risk 10^{-3} – 10^{-2} based on LNT model and epidemiology ³	Low	CT scans of chest, abdomen, and pelvis; double CT scans for contrast enhancement; interventional radiology; ^{67}Ga tumour and ^{201}Tl myocardial imaging; multiple procedures to give doses of 10s mSv; endovascular aneurysm repair (10–35 mSv). Renal/visceral angioplasty; iliac angioplasty; follow-up of endovascular aneurysm repair (35–100 mSv).
100s	$>10^{-2}$ based on epidemiology ³	Moderate	Multiple procedures and follow-up studies.

Patient exposure from recurrent imaging

- Data interpretation is complicated by the lack of standardization of the methods for estimation of effective dose and lack of patient-specific organ dose estimation.
- Since different methods do not result in identical estimates, the E values should be compared with caution



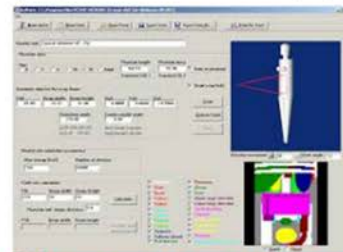
Computed E using modality-specific conversion factors

$$E_k = CF \cdot F$$

F - modality specific metrics (DLP in CT or KAP in radiography/fluoroscopy)
 CF - tabulated factor based on modelling of the patient by reference models

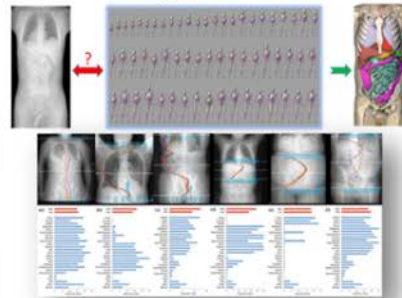
Ignores patient's habitus and irradiation field

Computed E using a generic patient model and Monte Carlo (e.g. PCXMC, CTExpo)



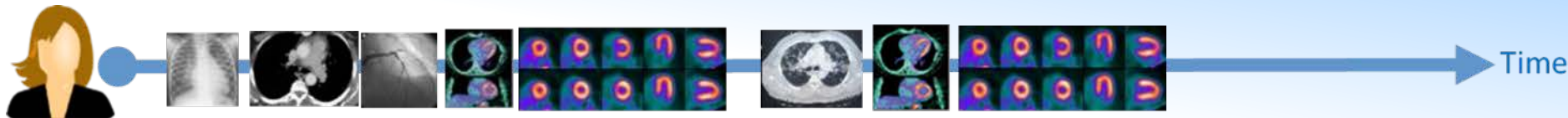
Closer representation of the patient exposure

Computed E using patient-specific organ doses



Most patient-relevant technique

Patient exposure from recurrent imaging



Various studies with over 11 million patients tracked from hospitals in USA, Italy, France, Belgium, UK, Netherlands, Spain, Finland, Slovakia, Bulgaria, Croatia, Lithuania, Korea, Japan, UAE

- From $<0.1\%$ to 15% of patients with $CED > 100$ mSv
- Between 3 and 40 % aged under 50
- Between 9.6 and 69 % with no malignancy or cancer history but no active disease

Although varying due to local specifics or disease prevalence, these studies indicate the general pattern and call for attention

Joint Position Statement

- Published in May 2021 jointly by 9 organizations
- **Purpose:** To guide processes such that patients with medical conditions which prompt more frequent imaging procedures receive needed medical care, without undue exposure to ionizing radiation.

JOINT POSITION STATEMENT AND CALL FOR ACTION FOR STRENGTHENING RADIATION PROTECTION OF PATIENTS UNDERGOING RECURRENT RADIOLOGICAL IMAGING PROCEDURES

This Position Statement was developed by the International Atomic Energy Agency (IAEA) jointly with the European Federation of Organizations for Medical Physics (EFOMP), European Society of Radiology (ESR), Global Diagnostic Imaging, Healthcare IT and Radiation Therapy Trade Association (DITTA), Heads of European Radiological Competent Authorities (HERCA), Image Gently Alliance, International Organization for Medical Physics (IOMP), International Society of Radiology (ISR), International Society of Radiographers and Radiological Technologists (ISRRT), in collaboration with the World Health Organization (WHO).

<https://www.iaea.org/resources/rpop/resources/recurrent-imaging>



Joint Position Statement

It is recognized that **additional actions** are needed to:

- 1 Assess the level of recurrent radiological imaging and associated radiation doses
- 2 Identify clinical conditions where recurrent radiological imaging is likely to lead to relatively high cumulative doses in patients
- 3 Develop strategies for radiological imaging in clinical conditions that require recurrent imaging
- 4 Ensure justification and appropriateness of the entire series of radiological procedures for a patient
- 5 Monitor radiation exposure history of patients
- 6 Further reduce doses through technological developments
- 7 Customize imaging protocols to address each patient clinical problem
- 8 Strengthen radiation protection education and training of health professionals
- 9 Strengthen communication

<https://www.iaea.org/resources/rpop/resources/recurrent-imaging>



Tracking patient exposure history

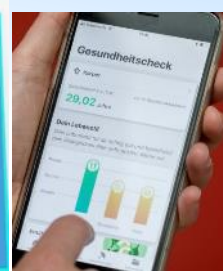
① What to track?

- Procedures (imaging records)
- Patient dose

My Child's Medical Imaging Record

Date	Exam	Where Exam Performed

Date	Exam	Where Exam Performed



Goal

Modality-specific metrics Size-based modality-specific metrics E_k E_0 Organ doses Dose to organ(s) of interest E_H Radiation risk index Patient risk

Further standardisation needed of the methods for these estimates accounting for uncertainties

- For procedures with risk for tissue reaction: cumulative skin dose
- For procedures with risk for stochastic risk: **patient-oriented risk metrics**

Task Group 113

Reference Organ and Effective Dose
Coefficients for Common Diagnostic
X-ray Imaging Examinations

ICRP

Work in Progress

Tracking patient exposure history



② Who will have access to exposure history data?

Radiology staff? Referring physicians? Patients?

👉 Concern about misuse and misinterpretation by referring physicians and patients
(*e.g. Walsh C, et al, Eur Radiol. 2020;30(8):4434-37*)

👉 Resource-constrained, value depending on healthcare and RP systems
(*Martin C, Barnard M, J Radiol Prot. Oct 2021*)

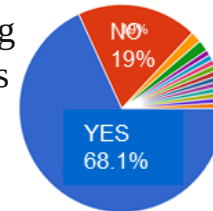
- User groups of REM systems and their access level should be carefully considered to ensure proper use
- Education and training crucial

IAEA Surveys (2020, IAEA)

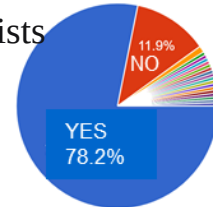
387 physicians from 65 countries

If you know radiation exposure history of patient, will it affect your decision making the next exam?

Refereeing physicians



Radiologists



Graff J, *Patient perspectives on radiation dose.*

RadProtDosimetry 2015 165(1-4):25-9

Survey with 199 replies (USA, UK)

“If patients can be given a good way to track cumulative exposure, they will feel some additional level of control.”

Example: Actions in Europe

European Radiology
<https://doi.org/10.1007/s00330-021-07696-1>

COMPUTED TOMOGRAPHY

Cumulative effective dose from recurrent CT examinations in Europe: proposal for clinical guidance based on an ESR EuroSafe Imaging survey

Guy Frija¹ • John Damilakis² • Graciano Paulo³ • Reinhard Loose⁴ • Eliseo Vano⁵ • European Society of Radiology (ESR)⁶

Table 4 How to reduce the number of recurrent examinations?

Having discussions with the physician requester

- ✓ Highlighting the potential risk/benefit of recurrent examinations
- ✓ Discussing whether decreasing the number of exams and/or replacing CT with MRI or Ultrasound would be possible
- ✓ Informing them that they would be provided with the cumulative dose for each patient having recurrent CT examinations

Developing actions

- ✓ Establish the list of clinical situations where recurrent CT examinations are undertaken in the institution
- ✓ CT Protocol optimisation to perform the procedure at the lowest dose for the clinical indication
- ✓ Involve the radiographers and the medical physicists of the department and increase awareness
- ✓ Set a dose tracking system for these patients, ideally integrated into the electronic health record
- ✓ Provide the physician requester with feedback on the cumulative dose reached for each concerned patient in order to constantly update the benefit-risk estimation
- ✓ Set-up an internal audit focused specifically on patients undergoing recurrent examinations
- ✓ Develop localised guidelines on patient follow-up when the CED $\geq$ 100 mSv



EURAMED
European Alliance for Medical
Radiation Protection Research

ESRF EUROPEAN SOCIETY
OF RADIOLOGY

EFRS
EUROPEAN FEDERATION OF
RADIOGRAPHER SOCIETIES

ESTRO



MEDIRAD»



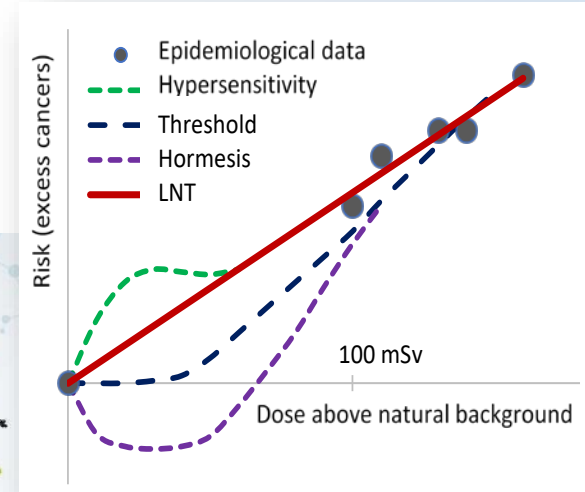
EURAMED
ROCC-N-ROLL
European Medical Application and
Radiation Protection Concept

SINFONIA

Improved access to data

Strengthening research studies of low-dose effects from medical exposure

- Improved epidemiological studies:
 - Improved access to patient-specific organ doses,
 - linked to patients health records,
 - while accounting for reverse causation and confounding factors.



Focus on patient safety

- The Joint Position Statement was intended to prompt greater dialogue
- The risk to benefit analysis must account in holistic for all incidental and long-term benefits and risks for patients, their clinical history and specific needs
- This is a step toward the patient-centric healthcare

