KSR-CPR RADIATION PROTECTION WORKSHOP 2017:
Éthique et justification en Radioprotection
Ethik und Rechtfertigung im Strahlenschutz
Ethics and Justification of Radiation Protection
Bern, 7 April 2017

JUSTIFICATION IN MEDICINE AT LEVEL 2: THE NEW KSR/CPR GROUP OF EXPERTS

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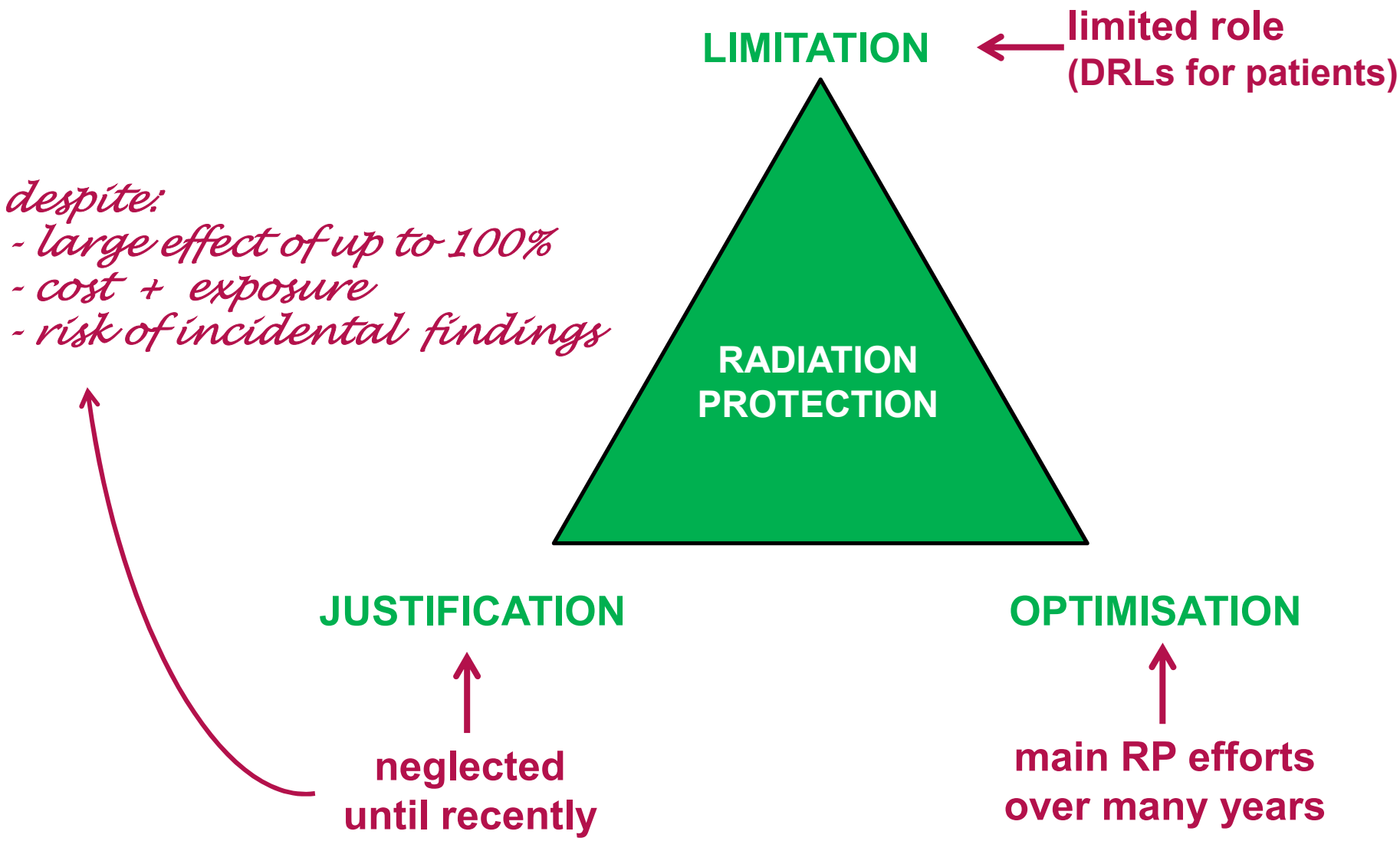
Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

Eidg. Kommission für Strahlenschutz (KSR)
Commission fédérale de radioprotection (CPR)
Commissione di radioprotezione

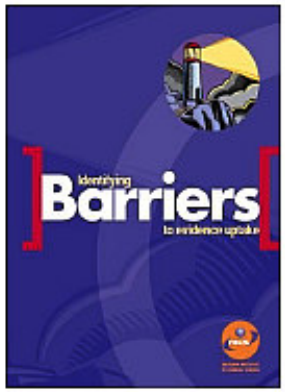
THE PRINCIPLES OF RADIATION PROTECTION
and their role in medicine



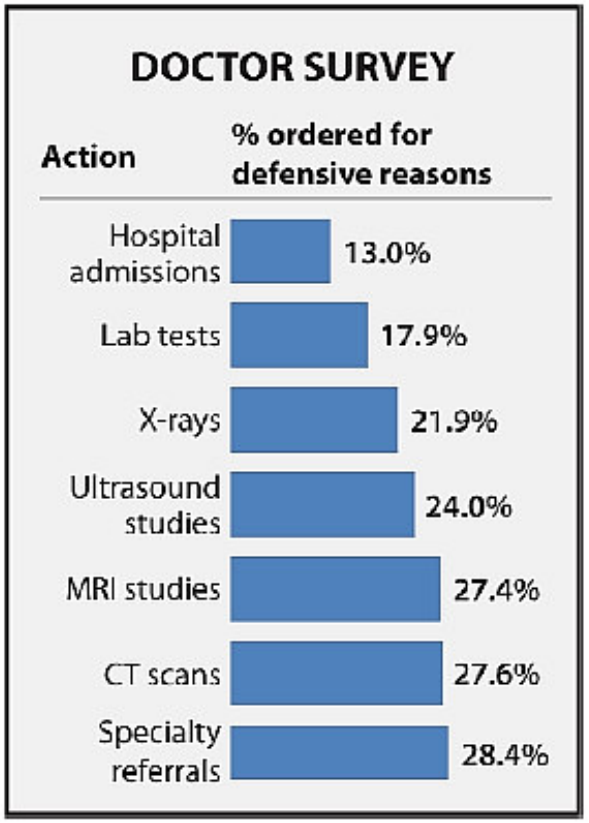
DEFICITS IN JUSTIFICATION EXIST

Some reasons for unnecessary procedures

- *Lack of awareness about radiation doses & associated risks*
- *Insufficient access to referral guidelines at the point of care*
- *Low confidence in clinical diagnosis & over-reliance on imaging*
- *Consumer demand (patient's and/or family's expectations)*
- *Self-referral, opportunistic screening, defensive medicine*
- *Pressure from other specialists e.g. "What does the CT shows?"*
- *Pressure from promotion and marketing of sophisticated technology*
- *Lack of dialogue/consultation between referrers and radiologists*
- *Non-availability of other appropriate imaging modality (e.g. US, MRI)*
- *Fragmentation vs. continuity of health care: unnecessarily repeated examinations*

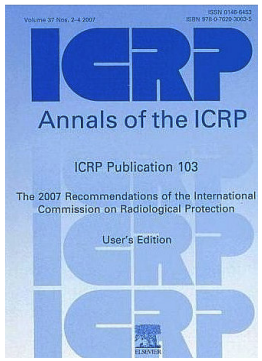


Defensive medicine is a strong driving force

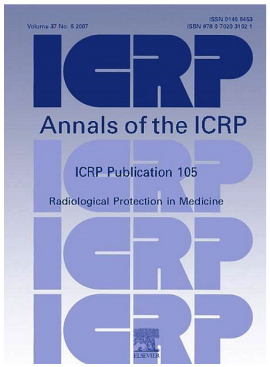


Concerns about malpractice litigation

"…Physicians may respond to the perceived threat of litigation by ordering more referrals and more tests, some of which may be recommended by clinical guidelines and beneficial, but others might be wasteful and harmful"



ICRP RECOMMENDATIONS 103, 105



Justification in radiological protection of patients

is different from justification of other radiation applications, in that generally the very same person enjoys the benefits and suffers the risks associated

There are **three levels of justification** of a radiological practice in medicine.

1. At the first and most general level, the **proper use of radiation in medicine** is accepted as **doing more good than harm to society**.

2. At the second level, a **specified procedure** with a **specified objective** is defined and justified. The aim of the second level of justification is to judge whether the radiological procedure will improve the diagnosis or treatment, or will provide necessary information about the exposed individuals.

3. At the third level, the **application of the procedure to an individual patient** should be justified. Hence **all individual medical exposures** should be **justified in advance**, taking into account the specific objectives of the exposure and the characteristics of the individual involved.

ICRP RECOMMENDATION

IAEA Safety Standards

for protecting people and the environment

Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards

Jointly sponsored by
EC, FAO, IAEA, ILO, OECD/NEA, PAHO, UNEP, WHO

voluntary implementation

EU Directive 2013/59/EURATOM

MEDICAL EXPOSURES

Article 55

Justification

1. Medical exposure shall show a sufficient net benefit, weighing the total potential diagnostic or therapeutic benefits it produces, including the direct benefits to health of an individual and the benefits to society, against the individual detriment that the exposure might cause, taking into account the efficacy, benefits and risks of available alternative techniques having the same objective but involving no or less exposure to ionising radiation.

2. (a) new types of practices involving medical exposure are justified in advance before being generally adopted;

(b) all individual medical exposures are justified in advance taking into account the specific objectives of the exposure and the characteristics of the individual involved.

- obtaining previous information
- including exposure of carers' and comforters' detriment
- research, health screening, asymptomatic individual
- Information of individual

binding for all EU member states

SWITZERLAND: draft Radiological Protection Ordinance (01.01.2018)

Strahlenschutzverordnung, Ordonnance sur la radioprotection, Ordinanza sulla radioprotezione

Art. 39 Justification of diagnostic or therapeutic procedures

1 The general use of diagnostic or therapeutic procedures must be justified **in advance**.

2 The justification of existing diagn. or therap. procedures must be **re-evaluated** when new important facts of their effectiveness or sequelae are available.

3 The Swiss Radioprotection Commission (**KSR**-CPR) will elaborate and publish **recommendations** regarding the justification of these procedures, in **cooperation with** the involved **professional and scientific societies**.
[introduction of formal justification at level 2, according to ICRP 103]

→ new KSR-CPR task, needs a new instrument:

group of experts for justification at level 2

SWITZERLAND: draft
Radiological Protection Ordinance (01.01.2018)

Strahlenschutzverordnung, Ordonnance sur la radioprotection, Ordinanza sulla radioprotezione

Art. 40 Justification of individual application of these procedures

1 Those referring patients or performing these procedures have to **respect existing, diagnostic information and the history** in order to avoid unnecessary exposure.

2 **Referrers** have to define, document and **communicate the indication** to the physician performing the procedure.

3 **Hospitals, radiology departments, and referrers** have to **define and** to **apply referral guidelines**, based on existing national or international referral guidelines.

4 Any application must be **justified in advance** by the performing physician regarding the **aim** of the exposure and the **individual's characteristics**.

5 When a procedure is not justified according to art. 39, it might still sometimes be justified as a **specific, individual application** for a specific patient. This case has to be argued and documented individually by the performing physician.

IMAGING REFERRAL GUIDELINES 1

Comparison for «suspected pulmonary embolism»

Germany (Orientierungshilfe)

Herz und große Gefäße

P: Primäruntersuchung W: Weiterführende Untersuchung S: Spezialverfahren N: Nicht indiziert

Klinische Fragestellung	Bildgebendes Untersuchungs-verfahren	Grad der Empfehlung	Kommentar
E1			
Thoraxschmerz	Rö Thorax	P	Ausschluss Pneumothorax, Infiltrate, Beurteilung der Herz-größe und Lungengefäße
	Echokardio-graphie	P	Nachweis kardialer oder aortaler Ursachen
	Rö Skelett	W	V.a. Knochenläsionen
	CT / CTA	W	Frage dissezierendes Aortenaneurysma, Lungenembolie
	MRT	W	Frage dissezierendes Aortenaneurysma bei CT-Kontraindikation (Schilddrüse, Niere, KM-Unverträglichkeit), Ortsauflösung schlechter als CT. **Nicht bei instabilem Patienten**
	Nuk	W	Lungenperfusions-Szintigraphie oder Myokard-Szintigraphie: Lungenembolie, KHK
	US	W	Bei gut lokalisierbaren Schmerzen: Nachweis von Pleuraerguss, Thoraxwandprozessen, pulmonalen Infiltraten

IMAGING REFERRAL GUIDELINES 2

Comparison for suspected pulmonary embolism

France (Guide du bon usage)

Radiographie du thorax (*Indiqué*)

Scanner du thorax (*Indiqué*)

Recommandation: Indiqué

Grade: A B C AE

Dose: 0 I II III IV

L'angioscanner est, parmi les modalités radiologiques, l'examen de première intention en cas de suspicion d'embolie pulmonaire. Le scanner n'est pas indiqué dans le suivi.

Scintigraphie de ventilation et de perfusion pulmonaire (*Indiqué*)

Echographie cardiaque (*Indiqué seulement dans des cas particuliers*)

Echographie veineuse des membres inférieurs (*Indiqué seulement dans des cas particuliers*)

IMAGING REFERRAL GUIDELINES 3

Comparison for suspected pulmonary embolism

Canada (referral guidelines)

E05. Pulmonary embolism **(See also E13)**	Risk Assessment using Wells Criteria and D-dimer	Indicated [A]	0	The Wells criteria for clinical likelihood of PE is extensively validated and triages patients into three pre-test probability groups: low, intermediate and high. A PE can be safely excluded in patients with a low or moderate pre-test probability and a negative ELISA D-dimer.
	CXR	Indicated [B]	☢	CXR is the best initial imaging modality to demonstrate consolidation and pleural effusion. A CXR might suggest a pulmonary embolus, but does not exclude a pulmonary embolus.
	CT Pulmonary Angiography (CTPA)	Indicated [A]	☢☢–☢☢☢*	CTPA is the best imaging modality for the detection of pulmonary emboli,. It is the best modality for patients with COPD or an abnormal CXR, and may be used following a non-diagnostic V: Q scintigram.
	NM (ventilation / perfusion scintigraphy)	Indicated [B]	☢☢	Planar and SPECT Ventilation / perfusion (V:Q) scintigraphy is diagnostic if used selectively in patients without COPD or consolidation on CXR (Normal CXR) A normal perfusion scintigram excludes clinically significant pulmonary emboli. Can be used when CTPA is contraindicated such as contrast allergy or elevated serum creatinine. Should be used for follow up assessment of pulmonary embolism.
	MRA	Specialized investigation [B]	0	May be considered when there is a contraindication to CTPA and abnormal CXR making ventilation / perfusion scintigraphy unlikely to be diagnostic.

United Kingdom (i refer) longstanding leader, online, free to NHS, very similar to CA

IMAGING REFERRAL GUIDELINES 4

Comparison for suspected pulmonary embolism

USA (ACR appropriateness criteria)

Clinical Condition: Acute Chest Pain — Suspected Pulmonary Embolism

Variant 1: Intermediate probability with a negative D-dimer or low pretest probability.

Radiologic Procedure	Rating	Comments	RRL*
X-ray chest	9		☢
CTA chest with IV contrast	5	This procedure should be optimized for pulmonary arterial enhancement. This procedure may be appropriate but there was disagreement among panel members on the appropriateness rating as defined by the panel's median rating.	☢☢☢
CT chest with IV contrast	3	This procedure should be optimized for pulmonary arterial enhancement.	☢☢☢
US duplex Doppler lower extremity	3	This procedure has a low yield in the absence of symptoms of DVT.	O

Clinical Condition: Acute Chest Pain — Suspected Pulmonary Embolism

Variant 2: Intermediate probability with a positive D-dimer or high pretest probability.

Radiologic Procedure	Rating	Comments	RRL*
X-ray chest	9		☢
CTA chest with IV contrast	9	This procedure should be optimized for pulmonary circulation.	☢☢☢
CT chest with IV contrast	9	This procedure should be optimized for pulmonary circulation. This procedure may be an alternative to CTA, but both should not be performed.	☢☢☢
Tc-99m V/Q scan lung	7	This procedure may be an alternative to CTA, but both should not be performed.	☢☢☢
US duplex Doppler lower extremity	7	This procedure may be an initial study prior to CTA.	O

IMAGING REFERRAL GUIDELINES 4

Comparison for suspected pulmonary embolism

USA (ACR appropriateness criteria)

Clinical Condition: Acute Chest Pain — Suspected Pulmonary Embolism

Variant 1: Intermediate probability with a negative D-dimer or low pretest probability.

Radiologic Procedure	Rating	Comments	RRL*
X-ray chest	9	This procedure should be optimized for	☢

Clinical Condition: Acute Chest Pain — Suspected Pulmonary Embolism

Variant 2: Intermediate probability with a positive D-dimer or high pretest probability.

Radiologic Procedure	Rating	Comments	RRL*
X-ray chest	9		☢
CTA chest with IV contrast	9	This procedure should be optimized for pulmonary circulation.	☢☢☢
CT chest with IV contrast	9	This procedure should be optimized for pulmonary circulation. This procedure may be an alternative to CTA, but both should not be performed.	☢☢☢
Tc-99m V/Q scan lung	7	This procedure may be an alternative to CTA, but both should not be performed.	☢☢☢

Clinical Condition: Acute Chest Pain — Suspected Pulmonary Embolism

Variant 3: Pregnant patient.

Radiologic Procedure	Rating	Comments	RRL*
X-ray chest	9		☢
US duplex Doppler lower extremity	8	This procedure may be an initial examination prior to CTA, which may prevent the need for ionizing radiation in the appropriate clinical setting	O

IMAGING REFERRAL GUIDELINES 5

Methodological requirements:

- Specific clinical question: **indication**
- **Consensus** among stakeholders (Delphi procedure) based on
- **Scientific evidence**: high quality – moderate quality – review – expert opinion ….
- Information on **typical effective dose** (e.g. 0, <1, 1-<5, 5-10, >10 mGy)
- **Recommendation**: indicated, specialised investigation, not indicated initially, indicated only in specific circumstances, not indicated, or alternatively: gradings: 9-7 usually appropriate, 6-4 may be appropriate,3-1 usually inappropriate
- **Specific advice** for pregnant women, unboern children, children
- **Re-evaluation** period
- **Comments**

Insights Imaging (2014) 5:15–23
DOI 10.1007/s13244-013-0300-6

REPORT

European survey on imaging referral guidelines

Denis Remedios · Monika Hierath · Nick Ashford · Peter Cavanagh · Philippe A. Grenier · Catherine M. Lloyd · Georgi Simeonov · Julien-Aymeric Simonnet · Valérie Vilgrain

- Availability?
- Differences?
- Good practice
- Frequency of use?
- Preferences

IMAGING REFERRAL GUIDELINES 6

European survey on imaging referral guidelines

Denis Remedios · Monika Hierath · Nick Ashford · Peter Cavanagh · Philippe A. Grenier · Catherine M. Lloyd · Georgi Simeonov · Julien-Aymeric Simonnet · Valérie Vilgrain

Insights Imaging (2014) 5:15–23
DOI 10.1007/s13244-013-0300-6

- *Survey respondents in 21/30 countries were aware of legal requirements for Guidelines*
- *Survey respondents in 18/30 countries were aware of the availability of Guidelines in their country.*
- *The majority of responders support the development of European Guidelines. These may either be from a combination of multiple national Guidelines with consensus or Pan-European Guidelines developed centrally.*
- *Methodological requirements fulfilled only in 2 countries*
- *Low use of RGLs even in case of availability*

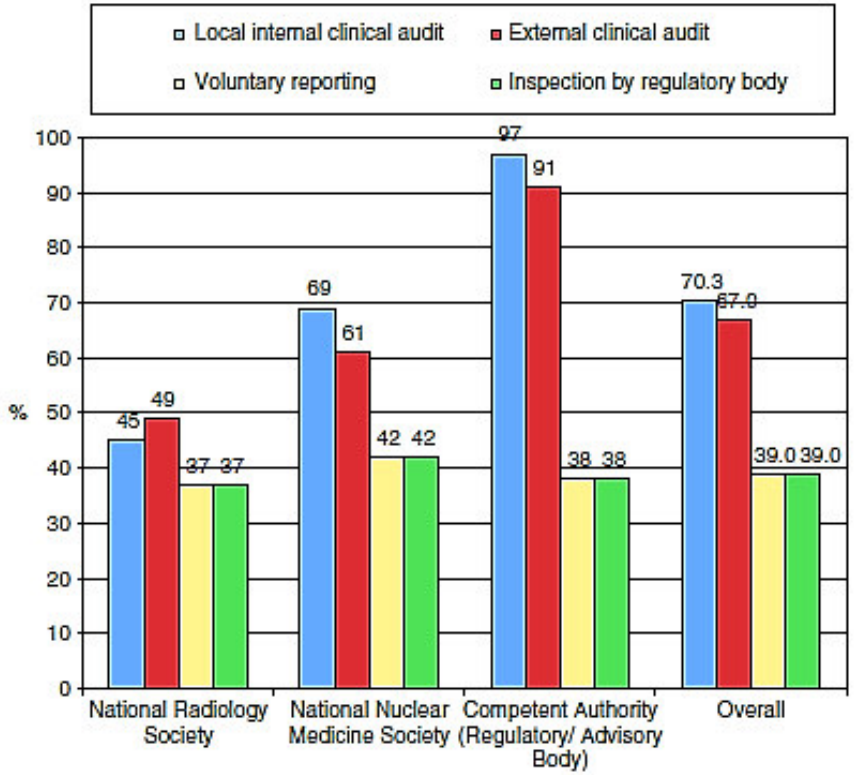


Fig. 9 Preferred methods for monitoring use of imaging guidelines. Clinical audit, both internal and external, is favoured, particularly by competent authorities

Difficulties in fusing different European RGLs

New efforts: European GL + clinical decision support (CDS) system derived from ACR approach [ESR iGuide]

KSR-CPR
Group of Experts for Justification at Level 2

(according to new Radiation Protection Ordinance, 01.01.2018)

TASKS

1 to **comment on the existing international referral guidelines** for specific indications regarding their applicability in Switzerland

2 to observe and comment on the **development of medical justification at level 2**

3 to study the **scientific basis and technical development of procedures** using ionising radiation in medicine

4 to prepare **drafts of Swiss recommendations for justification at level 2** in cooperation **with involved professional and scientific societies**

5 to prepare **statements** regarding the **re-evaluation** of medical justification at level 2 for existing techniques in case of new important facts of their effectiveness or sequelae

6 to prepare **statements** regarding questions in medical justification at level 2 for **new** techniques, technical advances and new indications of existing procedures

KSR-CPR
Group of Experts for Justification at Level 2

(according to new Radiation Protection Ordinance, 01.01.2018)

COMPOSITION and DECISIONS

1 The group of experts is composed of **members of KSR-CPR** and of **experts**. KSR-CPR will nominate the chair of the group. Permanent expert members represent the **specialties dealing primarily with justification of radiological procedures**; experts of other specialties will be invited on demand.

2 **Experts of the regulatory authority** can be nominated as members

3 The group works by mail exchange, online meetings and face-to-face meetings. Its secretary is provided by the FOPH (BAG)

4 The members of the KSR-CPR receive the agenda and the minutes of the group Activities of the group of experts are reported at the meetings of KSR-CPR

6 Decisions of the group of experts require the majority of votes; every member has a right of vote

7 The group reports to the KSR-CPR (activity reports, statements, recommendations)

KSR-CPR
Group of Experts for Justification at Level 2

(according to new Radiation Protection Ordinance, 01.01.2018)

PREPARATORY ACTIVITIES IN 2017

1 Building the core group of experts and getting in cooperation with important additional experts.

2 Building the ways of communication within the Goup of Experts and with the KSR-CPR as well as the FOPH

3 Defining the temporal priorities
(radiology, nuclear medicine first, radiation oncology in a second phase)

4 Defining working rules

CONCLUSIONS FOR JUSTIFICATION IN MEDICINE AT LEVEL 2 IN SWITZERLAND

1 As in other countries, justification in medicine at level 2 has to be enforced

2 The new radiation protection ordinance will set the boundaries

3 The group of experts for justification at level 2, as a body of the KSR-CPR, will face the challenge of finding a consensus among the experts and propose solutions in the special situations defined by the new legislation