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Federal Department of Home Affairs FDHA
**Federal Office of Public Health FOPH**
Consumer Protection Directorate

*KSR Workshop on ethics and justification of Radiation Protection*

# Justification as seen by the Federal Office of Public Health

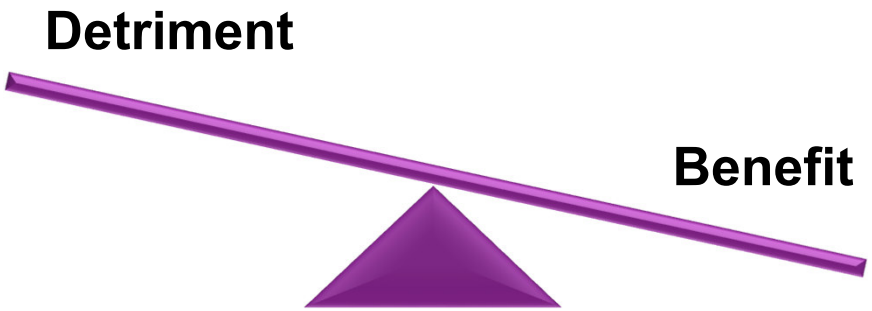
Sébastien Baechler

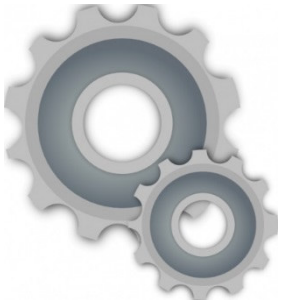
# Main tasks of the FOPH as radiological protection competent authority

- **Licensing authority**
  - Issue licenses for the use of ionizing radiation in medicine, industry (not nuclear industry) and research
- **Supervisory authority**
  - Control and support the regulatory implementation in medicine and research (inspections, guidelines)
  - Monitor radioactivity in the environment
- **Other tasks as competent authority**
  - Develop regulations and prepare decisions for the Federal Council
  - Inform the public about any issue related to radiation protection

# Principle of justification (ICRP 103)

- Any **decision** that alters the radiation exposure situation should do more good than harm.
  - *by introducing a new radiation source*
  - *by reducing the risk of potential exposure*
  - *by reducing existing exposure*

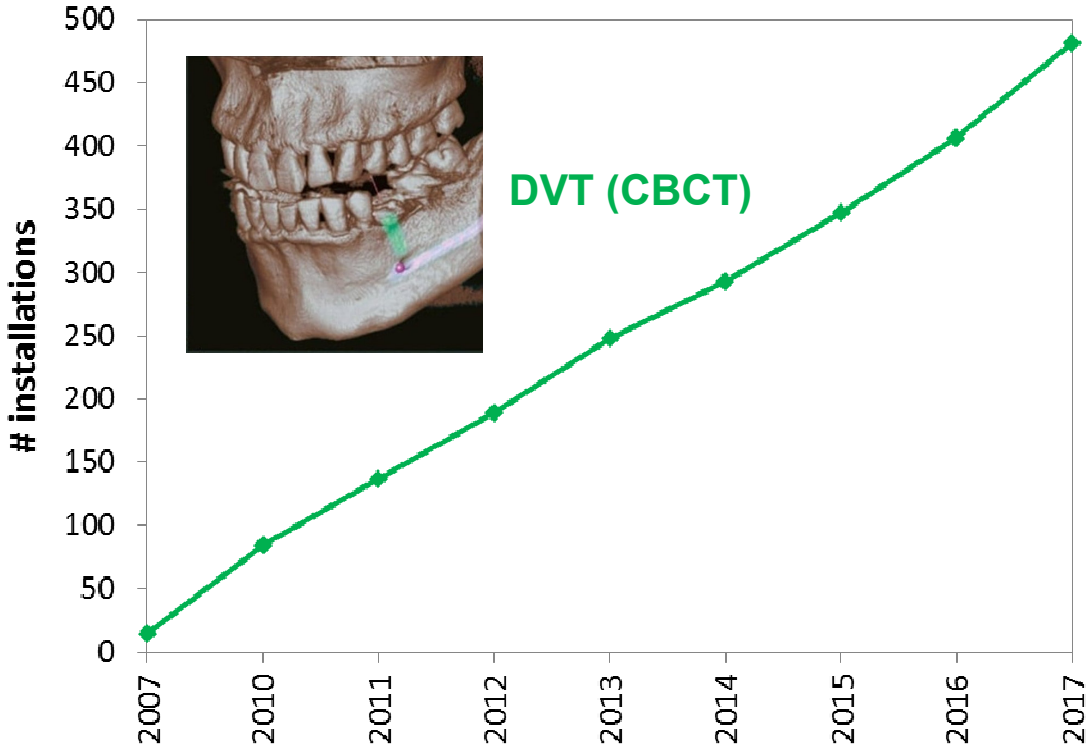




# Process of justification

- The competence to make **justification decisions** lies with the licensing authority (FOPH).
  - **Licensing process** → check conditions for granting a licence - ***Radiological Protection Act (RPA) Art. 31:***
    - Installations are in accordance with the current state of science and technology
    - Radiological protection is assured in accordance with the *RPA*, including *Art. 8 "Justification of radiation exposure"*
    - *…*
- A more detailed approach is needed for patient exposure

# FOPH issues a license for the medical use of a specific installation to a given center



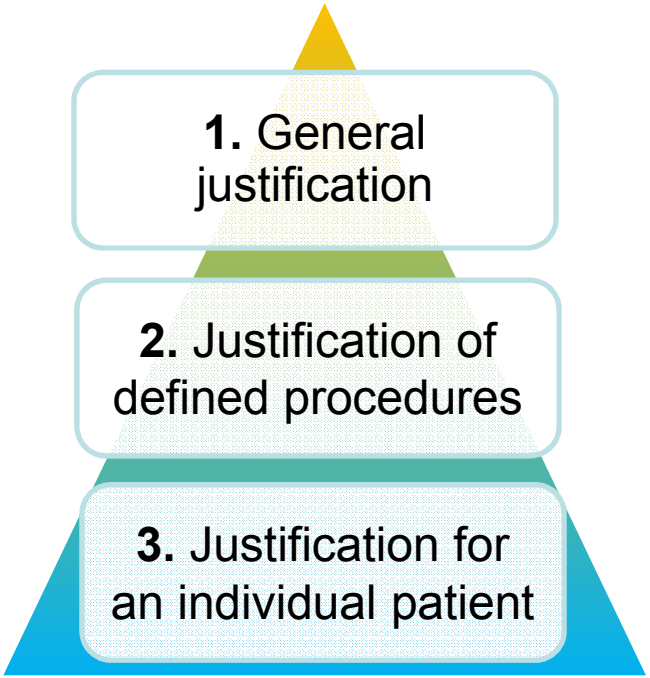

# installations increases

# exams increases

**Justification ?**

# Justification of patient exposure

- The justification lies with the **medical practitioner**
- Framework for justification New! (levels 1, 2, 3)
  - Assignment of responsibilities
  - Referral guidelines
    - Authorities, professional bodies
  - Two roles:
    - Radiological practitioner
    - Referring practitioner




➡ **Implementation in the regulation**

# Justification of medical exposure in the revised RPO* *(Draft - entry into force expected for 1.1.2018)*

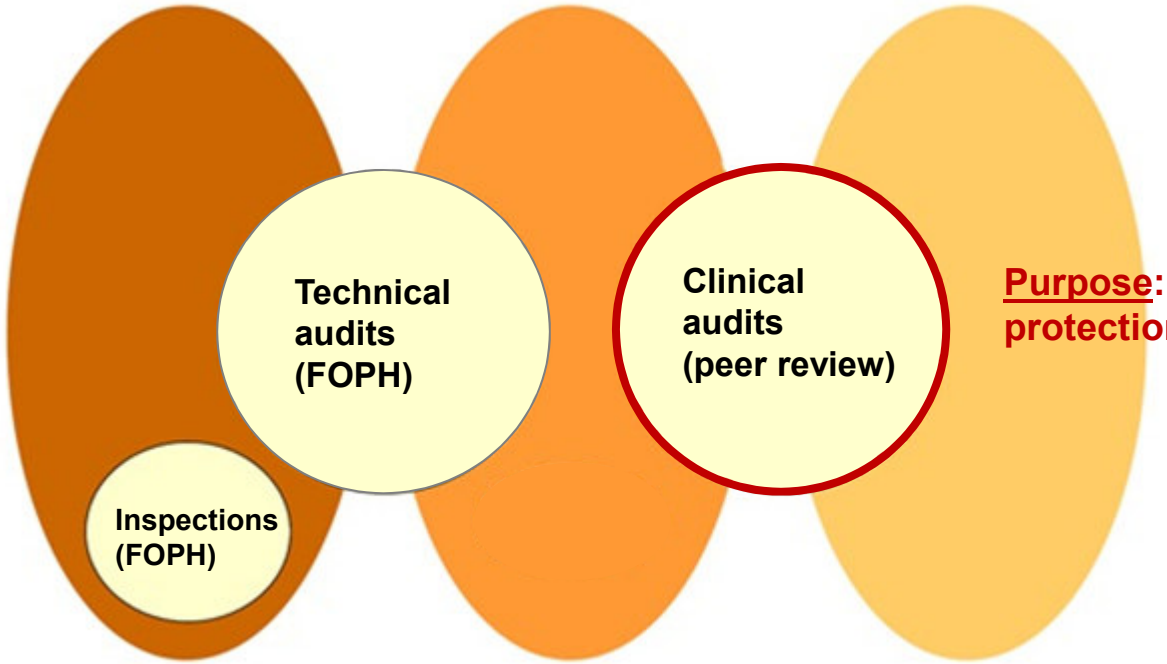
- ***Art. 3*** *Justification (general)*
- **Art. 27, 28, 29** Implementation of levels 1, 2, 3 New!
- **Art. 30** Screening (justification by health authority)
- **Art. 31** Non-medical human Imaging (aptitude test, security reasons) New!
- **Art. 40** Pregnant patient New!
- **Art. 41** Clinical Audits (to guarantee that medical procedures are justified) New!
- **Art. 44-45** Clinical trials, justification by ethics committee New!
- **Art. 198** Federal Commission on radiological protection (level II) New!

(* RPO = Radiological Protection Ordinance)

# Art. 28 Justification of procedures (level II)

- Recommendations of the Commission on Radiation Protection in collaboration with professional bodies
  - New procedures, existing procedures (re-evaluation), existing referral guidelines
- What if a procedure is not justified ?
  - No licence or licence with restriction of use
  - Focus for clinical audits
  - No reimbursement (?)
    - Radiation protection aspects in Health Technology Assessment

# New approach to supervision in medecine



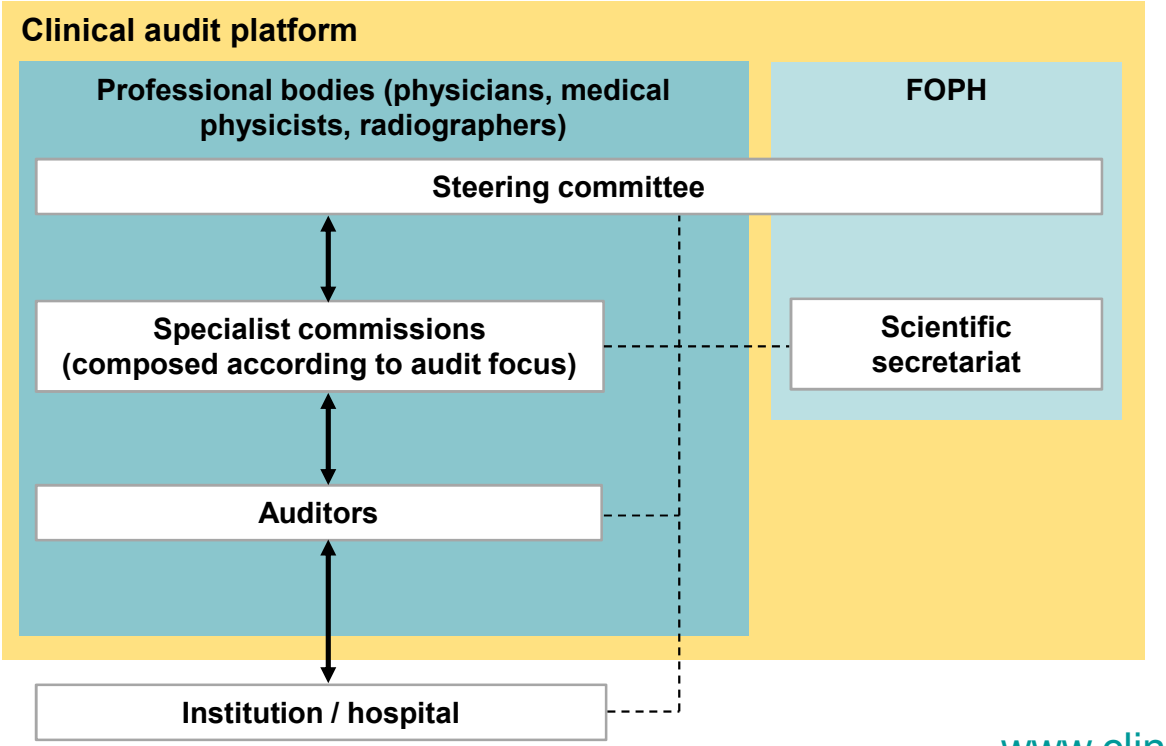

**Purpose: evaluate radiation protection practices**

**Legal basis**
***Technical dispositions***

**Optimisation**
***Patient dose / procedure (DRL)***

**Justification**
***Justification of procedures***

# Clinical audits to improve patient safety and quality of care : stakeholder involvement

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# Decision competences for justification

- **Planned exposure situation**
  - Licensing authority (FOPH)
  - For patients: medical practitioners
- **Emergency exposure situation**
  - Federal Council
    - *Urgent phase: National Emergency Operations Centre*
- **Existing exposure situation (Radon, contaminated area)**
  - Federal Council, FOPH, cantonal authorities

# Conclusions and perspectives

- Justification is a major issue for the FOPH, especially in the medical field.
- The revised RPO will set the regulatory framework to meet this challenge.
- A suitable regulatory framework and a well-accepted competent authority are necessary but not sufficient.
- Involvement of all stakeholders is necessary.

**« Triple A » : Awareness, Appropriateness, Audits**

# Thank you for your attention