



# **Regulatory framework and inspections in Switzerland**

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# Regulatory body-FOPH

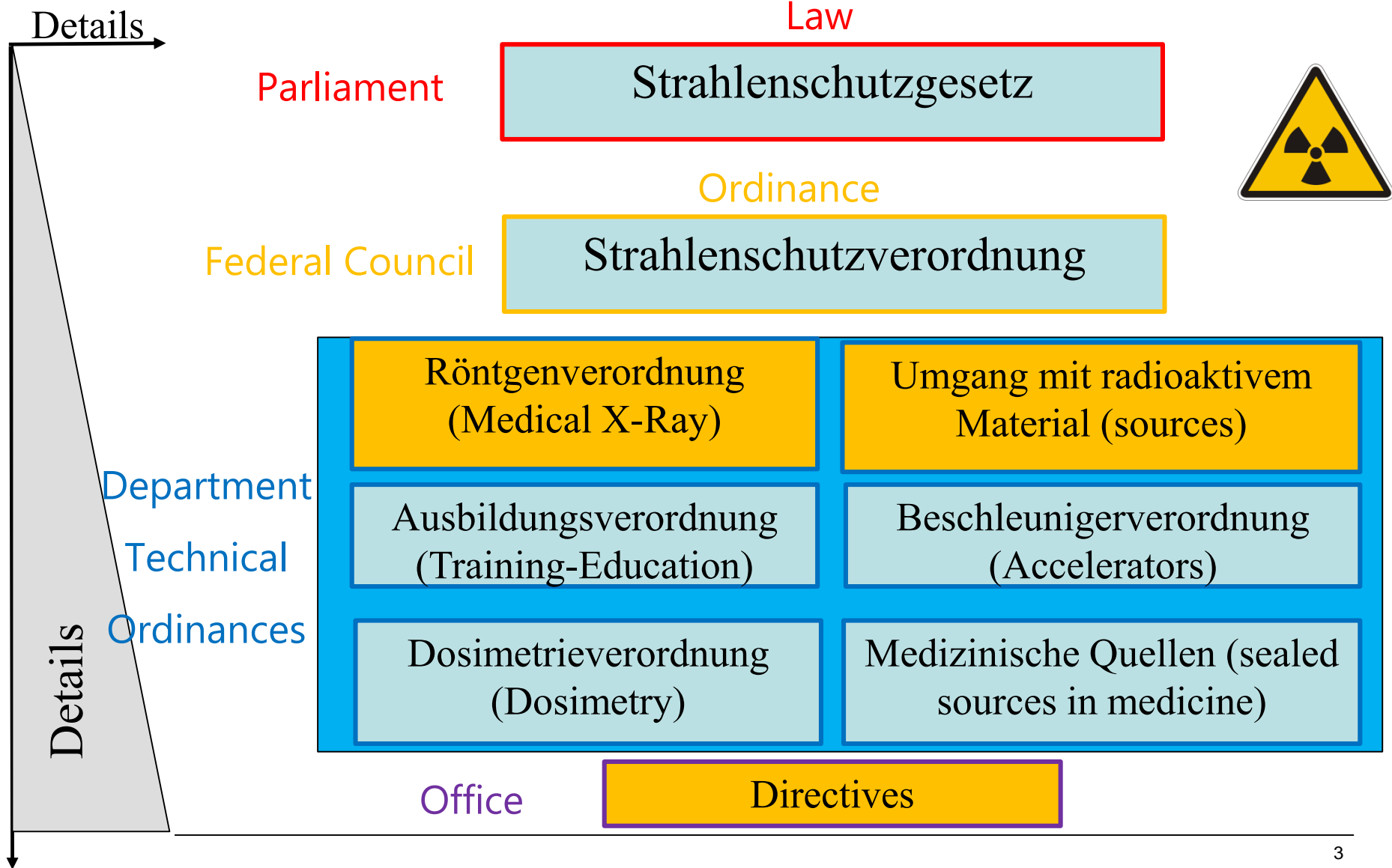
## Duties of the Federal Office of Public Health

- Licensing the use of ionizing radiation (commerce, transport, use)
- Surveillance in
  - Medicine (Patient, Staff)
  - Research (Public, Staff)
  - Education (Public)
  - Environment (Public)

## Advantages

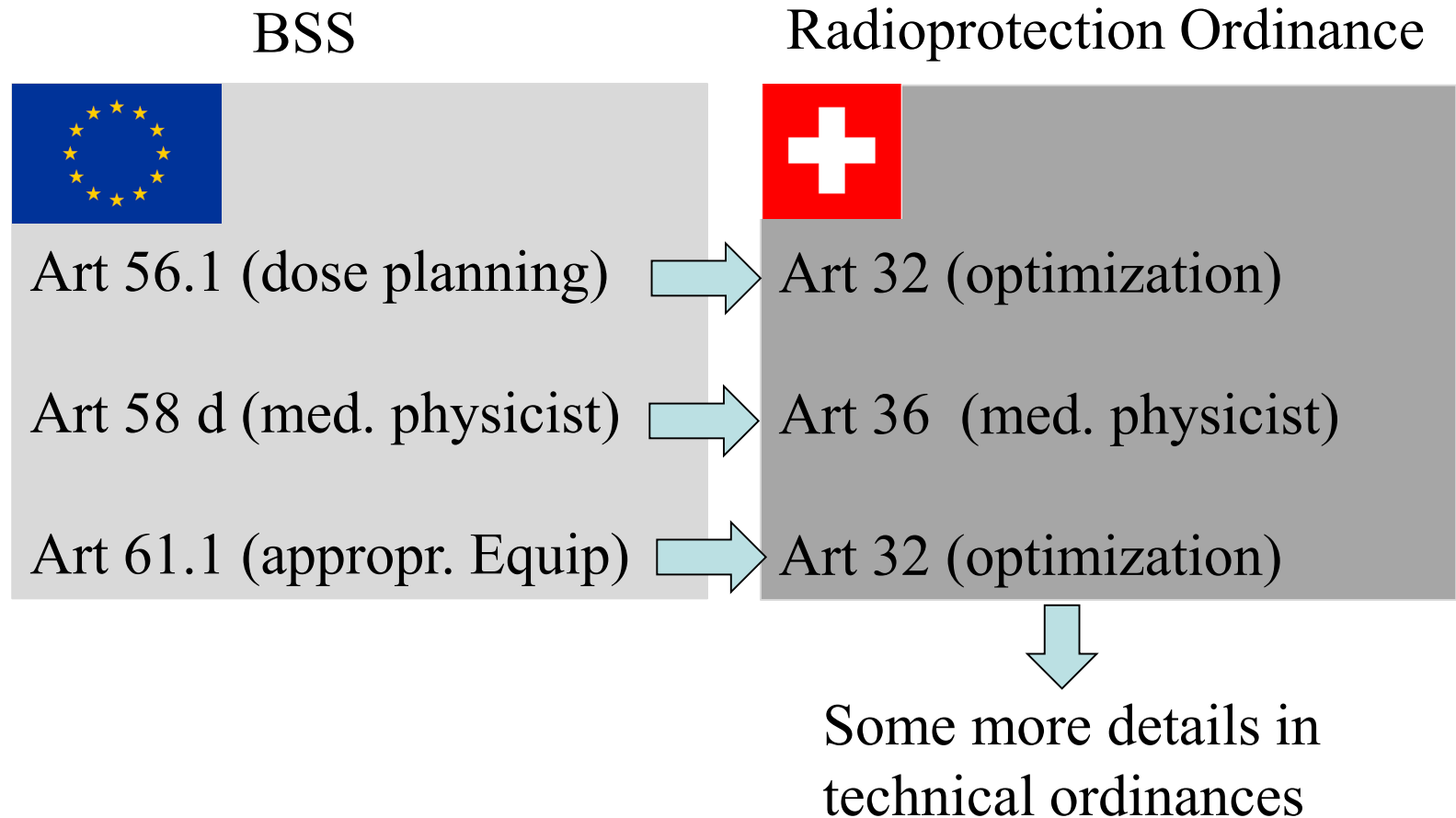
- FOPH oversees the whole process
  - Source from cradle to grave
- Patients
- Workers
- Public
- Environment

# Legal basis: relevant legislation for medical applications





# Transposition of BSS





# Focus of inspections

## Patients

- NRD (nuclide, CT)
- Therapy doses
- QA equipment
  - Activimeter
  - CT
  - Gamma Cam
- QA radiopharmaceuticals

## Occupational

- Training
- Dose  $H_{0.07}$ ,  $H_{10}$
- Work place
- Shielding

## Environment

- Immission limits
  - Water and air
- Waste management

## Public

- Direct exposition in vicinity
- Waste management
- Release criteria of patients



# Key inspections 2010-18

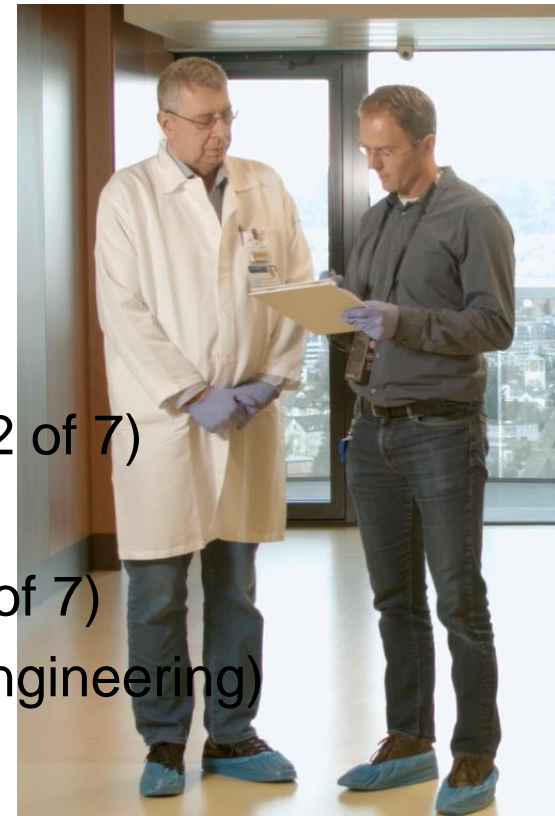
- PET-CT upcoming 2019
- Coaching lab work of small institutes with few patients
- Therapy with Xofigo Ra-223
- Quality of radiopharmaceuticals (Tc-Kits)
- SIRT
- SPECT-CT
- I-131 Therapy
- I-131 wastewater handling
- PET-CT



# Profile of our 7 Inspectors

Group nuclear medicine and research

- Medical physicists (3 of 7)
- Physicist with training in radiopharmacy (2 of 7)
- Environmental engineer (1 of 7)
- Technician with laboratory experience (1 of 7)
- 5 with PhD (4 physics, 1 environmental engineering)
- Accompanied in the beginning
- 2 day education in auditing
- Training in nuclear medicine departments
- We are not ISO/IEC 17020:2012 certified inspectors
- FOPH has certification though





# Inspection Process

- Team defines focus for 1-2 years
  - For example SIRT
- Inspect every department
- Final report
- Training day-workshop to present results





# Type of inspections

- Check every step from patient admission to release
- Questionnaire with open and closed questions
- Verification of legal requirements (ordinance, directives)
- Data analysis e.g. NRD or staff dose
- Measurements
- 2-3 inspections in 10 years in nuclear medicine dep.
- Usually we take half a day on site for an inspection



# Patient protection

- Optimization
  - Checking NRD (Activity, CT DLP and CTDI)
  - Therapy dose calculation (I-131, SIRT)
  - Accuracy of applied activity (Activimeter QA)
  - CT protocols (work of medical physicist)
- Justification
  - Nationwide statistics can identify outliers
- Findings communicated with report or workshop



# New issues

- Lu-177 and Lu-177m in the environment
- I-131 in waste incineration plants
- -> Develop new directives on how to handle these issues
- License for QA companies (activimeter, gamma cam)

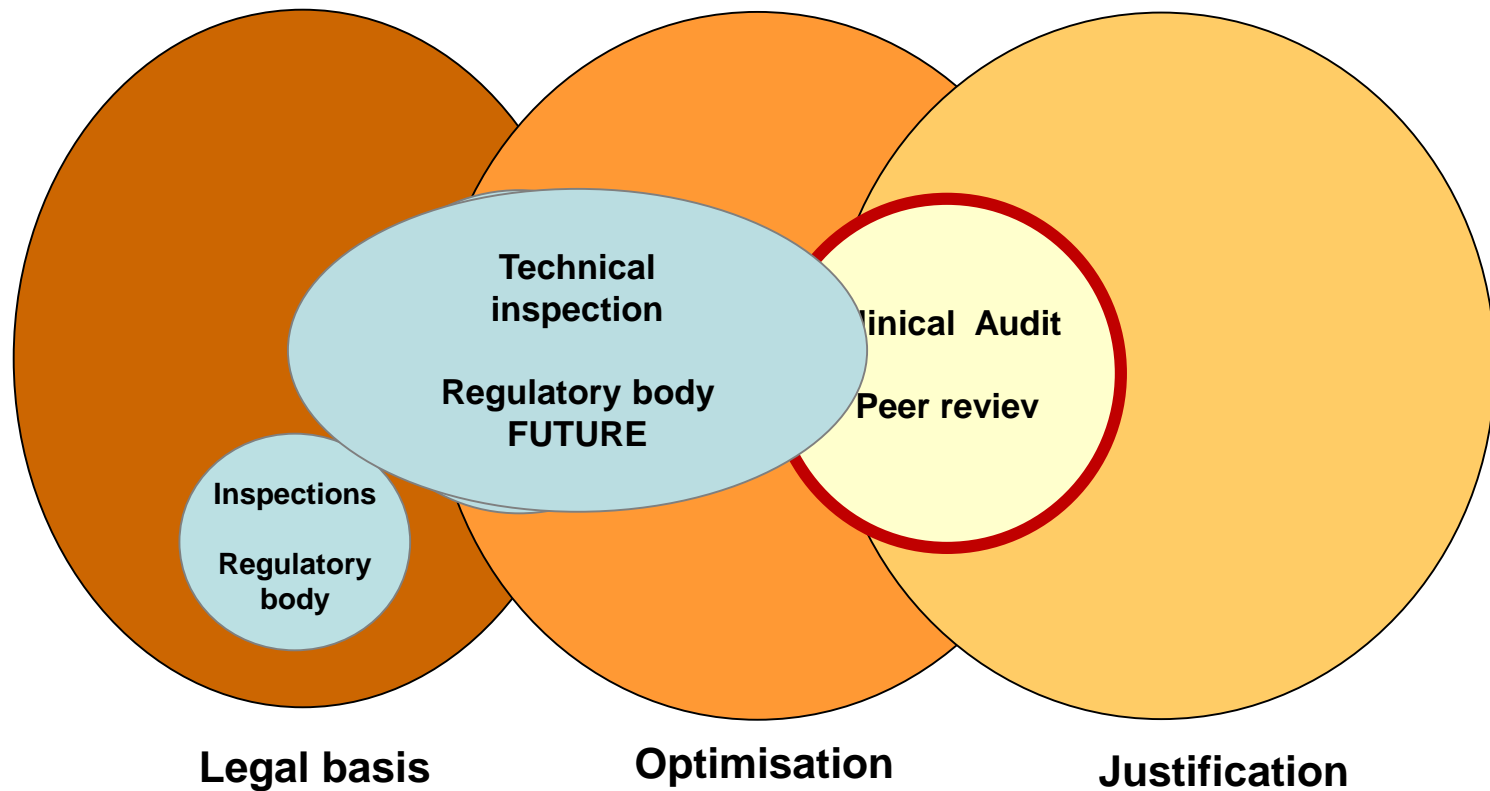


# Justification issue

- Nationwide statistics identify outliers
- Confront the hospital with outliers - > they will change their practice for good (usually😊)
- Regulatory body and physicists are not meant to suggest medical treatments but we can ask questions so that the doctors think about their practice or mandate a third party equipped with the necessary competence
- In the future regular clinical audits will tackle the problem



# Regulatory inspection vs clinical audit



Clinical audits performed by peers are starting



# What is good, what could be better...

...with our method of inspection

## Good

- Inspect all
- Take the best from all
- Final report and training day

## To be improved

- Planning unannounced inspections to see what we usually don't see
- Incidence reporting
- Competence to tackle justification



# Questions



FOPH Bern, Switzerland