



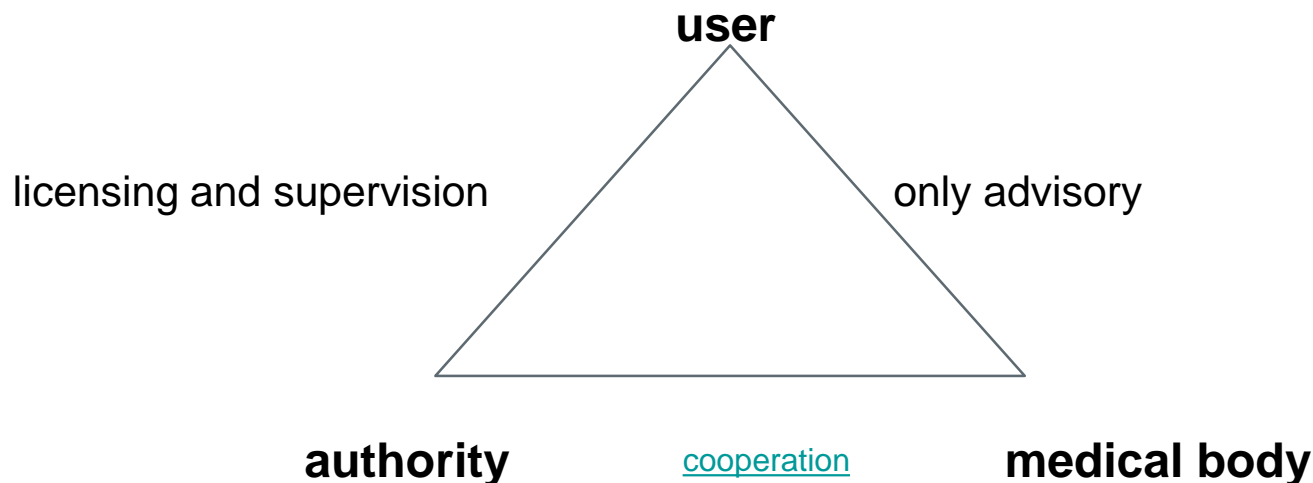
Regulatory framework and inspections in Germany

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In Germany we have 2 kinds of inspections:

- Inspections performed by the radiation protection authorities
- Audits by the medical bodies (Ärztliche Stellen)



History and Transposition of the BSS

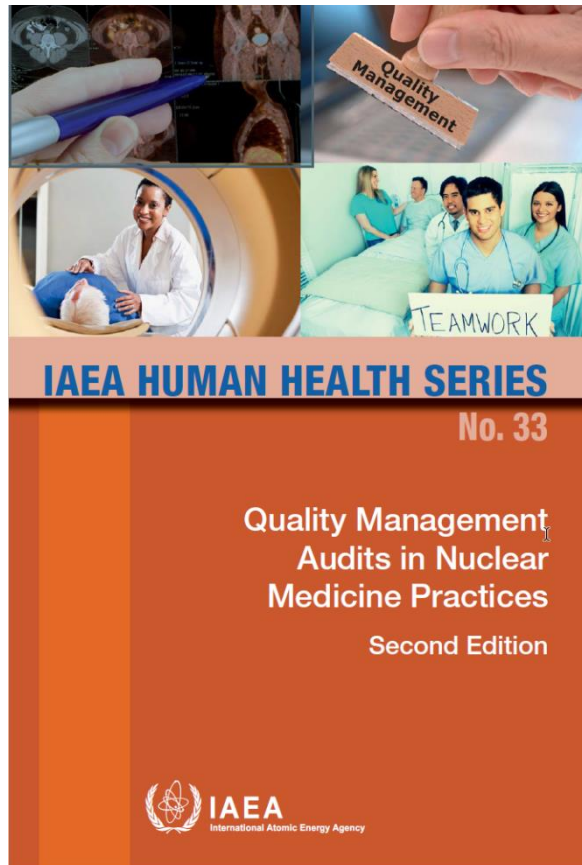
Since 2001 German ordinances on use of radiation (radiation protection ordinance „Strahlenschutzverordnung“ and x-ray ordinance „Röntgenverordnung“) require quality assessment in the fields of nuclear medicine, radiology and radiotherapy. Inspections of both kinds are also an important part of the new radiation protection legislative.

Organization

For quality control there were medical bodies („**Ärztliche Stellen**“) established by the Radiation Supervisory Authority in 2003.

In Bavaria and in many other German federal states the medical body is located at the State Medical Associations.

Basis of the quality control work are e.g.



Bundesministerium für Umwelt, Naturschutz, Bau und Reaktorsicherheit

Az. RS II 4 – 11432/6

**Qualitätssicherung durch
ärztliche und zahnärztliche Stellen**

**Richtlinie
zur Röntgenverordnung
und
zur Strahlenschutzverordnung**

vom 23. Juni 2015

Members of medical body

The medical body in Nuclear Medicine consists of

- Physicians with requisite qualification and experience in Nuclear Medicine and Radiology (optimization and justification)**
- Physicists qualified in Nuclear Medicine and Radiology**
- One each per visit (optimization)**

The medical body in Nuclear Medicine has also responsibility for hybrid modalities in the combined imaging systems.

Quality control - procedure

The controls from the medical point of view focus on

- .Written procedure manuals for the different studies**
- .Indication of the study**
- .Amount of administered activity**
- .Acquisition**
- .Processing**
- .Reporting with the correct diagnosis**
- .Archiving**

Grading of each study and method

•**grade 1 - no complaint**

Results in:

regular inspection period (2-3 years)

•**grade 2 - moderate faults**

regular inspection period

•**grade 3 - clear faults**

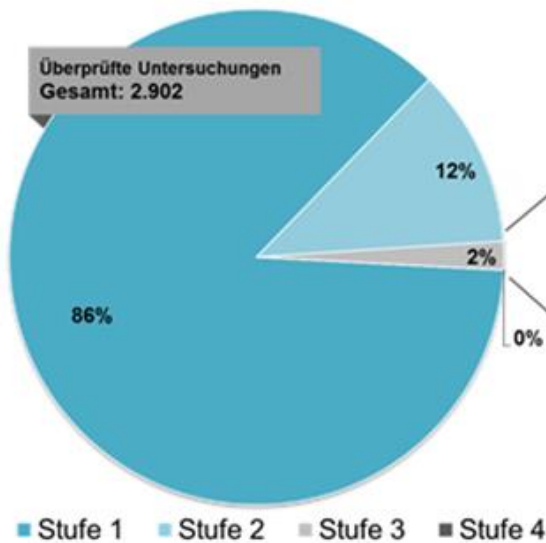
inspection after appr. 6 months

•**grade 4 - severe faults**

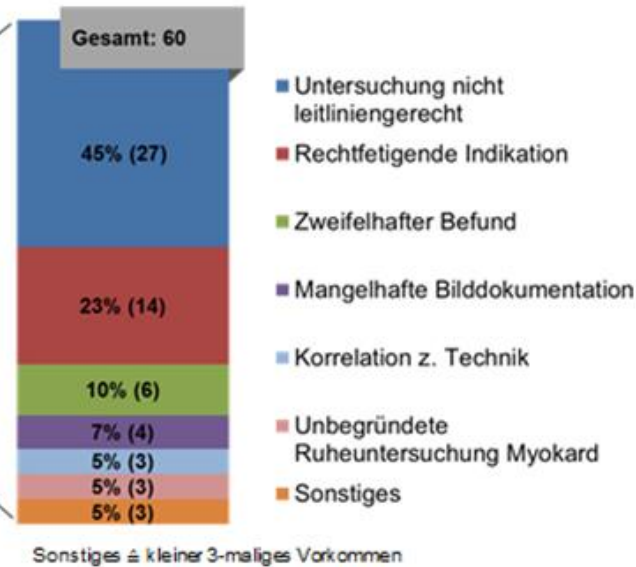
inspection after appr. 3 months

(if patient harm is suspected >> immediate report to the authorities)

Prozentuale Verteilung aller Beurteilungsstufen:



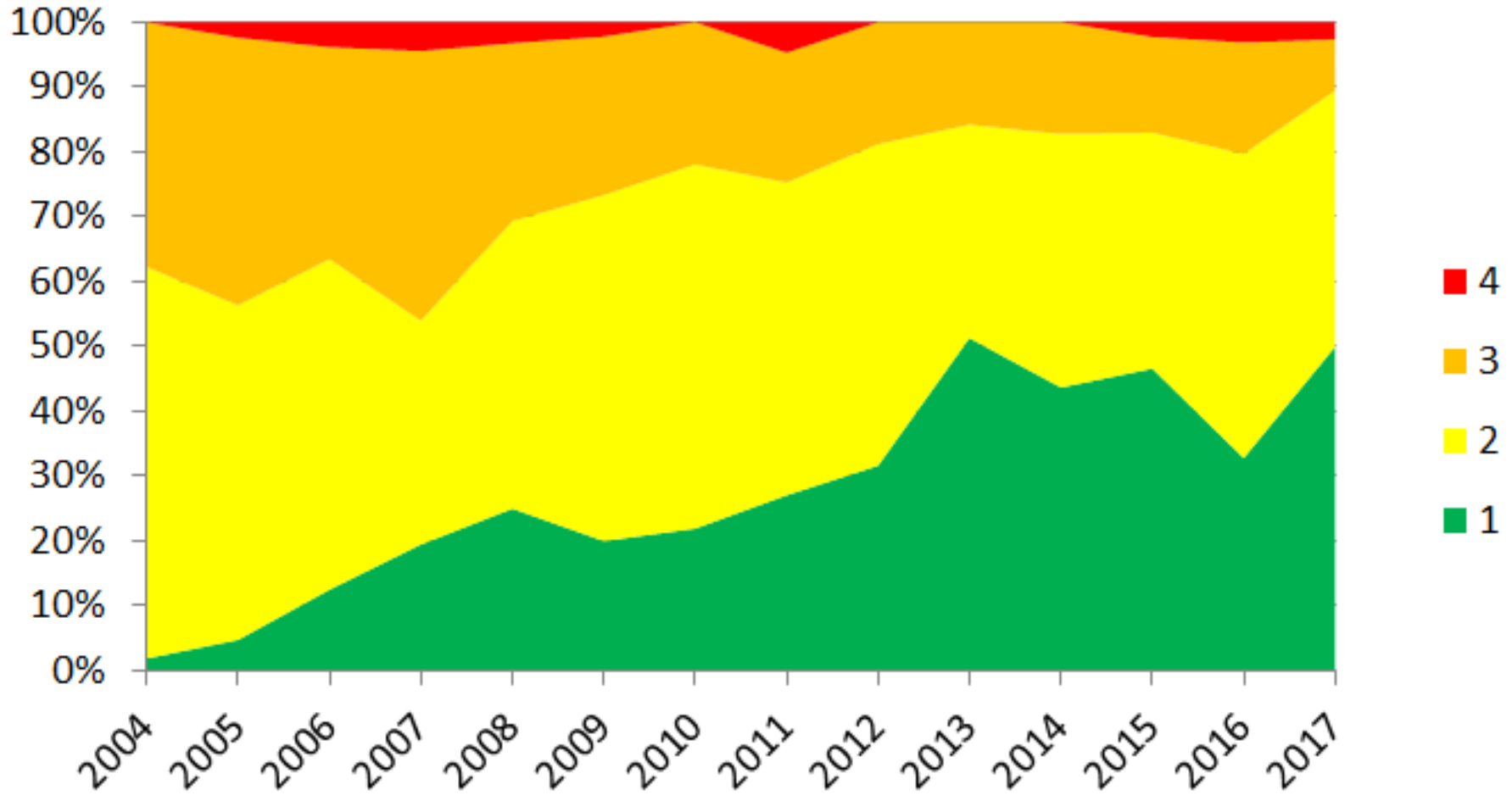
Mängel Beurteilungsstufe „3“:



Im Jahr 2017 wurden in den überprüften Untersuchungen bzw. Behandlungen der Nuklearmedizin 60 „erhebliche Beanstandungen“ („3“) festgestellt. Dies entspricht einem Anteil von ca. 2% an den Gesamtprüfungen (2.902).

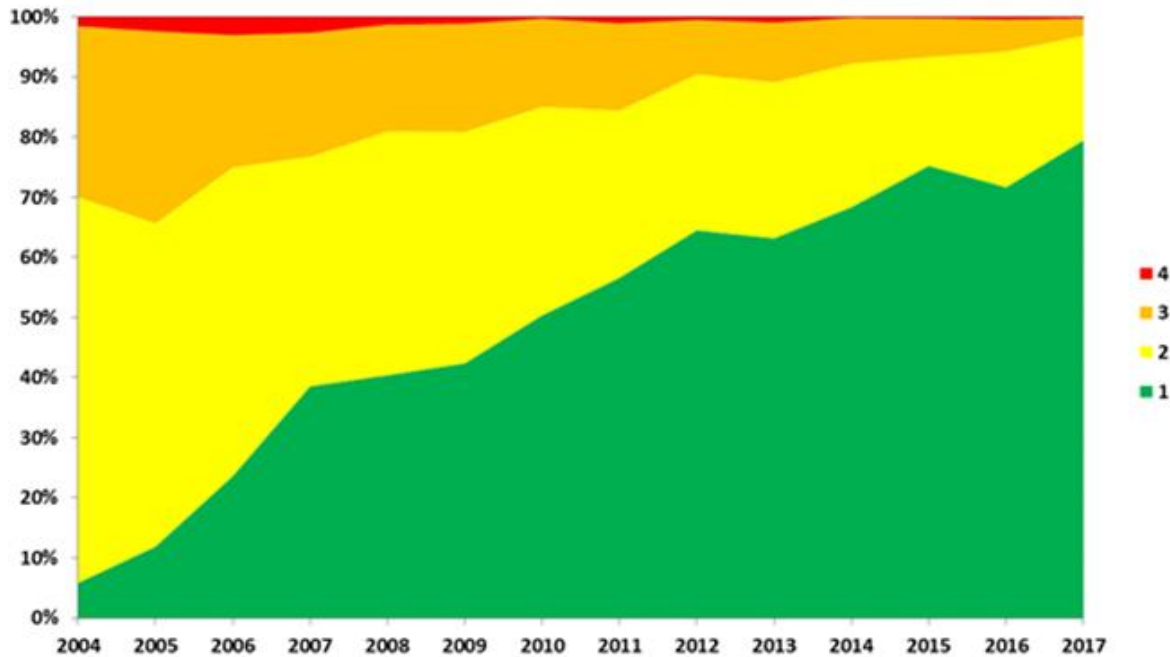
Es wurden keine „schwerwiegenden Beanstandungen“ („4“) festgestellt.

Results - Physics



Adopted from annual report 2017 to the medical body of bavaria

Results - All



Die Beratungsfunktion, die die Ärztliche Stelle gem. § 83 StrlSchV – Nuklearmedizin - wahrnimmt, führt zu Nachbesserungen der Betreiber bei den Mängeln der Stufe „3“ und „4“, die deutlich abnehmen bzw. wegfallen. Die Beurteilungsstufe „1“ zeigt einen steten Zuwachs.

Conclusions

- **The 2 kinds of inspections have proven to be efficient.**
- **The authorities are the only ones with legal power, the medical bodies are only accepted as partner if they have knowledge and give advice only**
- **Documentation and reports are important information for the user**
- **After 15 years of work of the medical body of Bavaria the quality of nuclear medicine studies has increased**
- **The radiation protection of the patients has improved (e.g. decrease of exposition)**
- **The number of faults which can be found by the medical body board is now very low**