Klinikum Augsburg
Akademisches Lehrkrankenhaus der Ludwig-Maximilians-Universität München

German situation on clinical audits

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Background

A system of quality control audits was established in Germany for the use of x-rays in human medicine in 1988. The results of those audits were advices for the users to improve

- technical quality
- quality control
- image quality

Based on Art. 6 (4) of 97/43/Euratom the German X-ray Ordinance (§17a) and Radiation Protection Ordinance (§83) extended the audits in 2002 to nuclear medicine and radiation therapy and to

- individual justification
- observance of reference doses in diagnostic procedures
- documentation of results and aftercare (therapy)

Setting the Scene

The authority for radiation protection enforcement in Germany lies in each federal state.

To harmonize the developments of auditing systems a directive was passed in 2004 that set the framework of organization and described the purpose and goals of the audits.

Ärztliche und zahnärztliche Stellen

Richtlinie zur Strahlenschutzverordnung (StrlSchV) und zur Röntgenverordnung (RöV)

In addition a permanent conference (ZAeS) was initiated to share experiences and discuss common questions arising from the audits.

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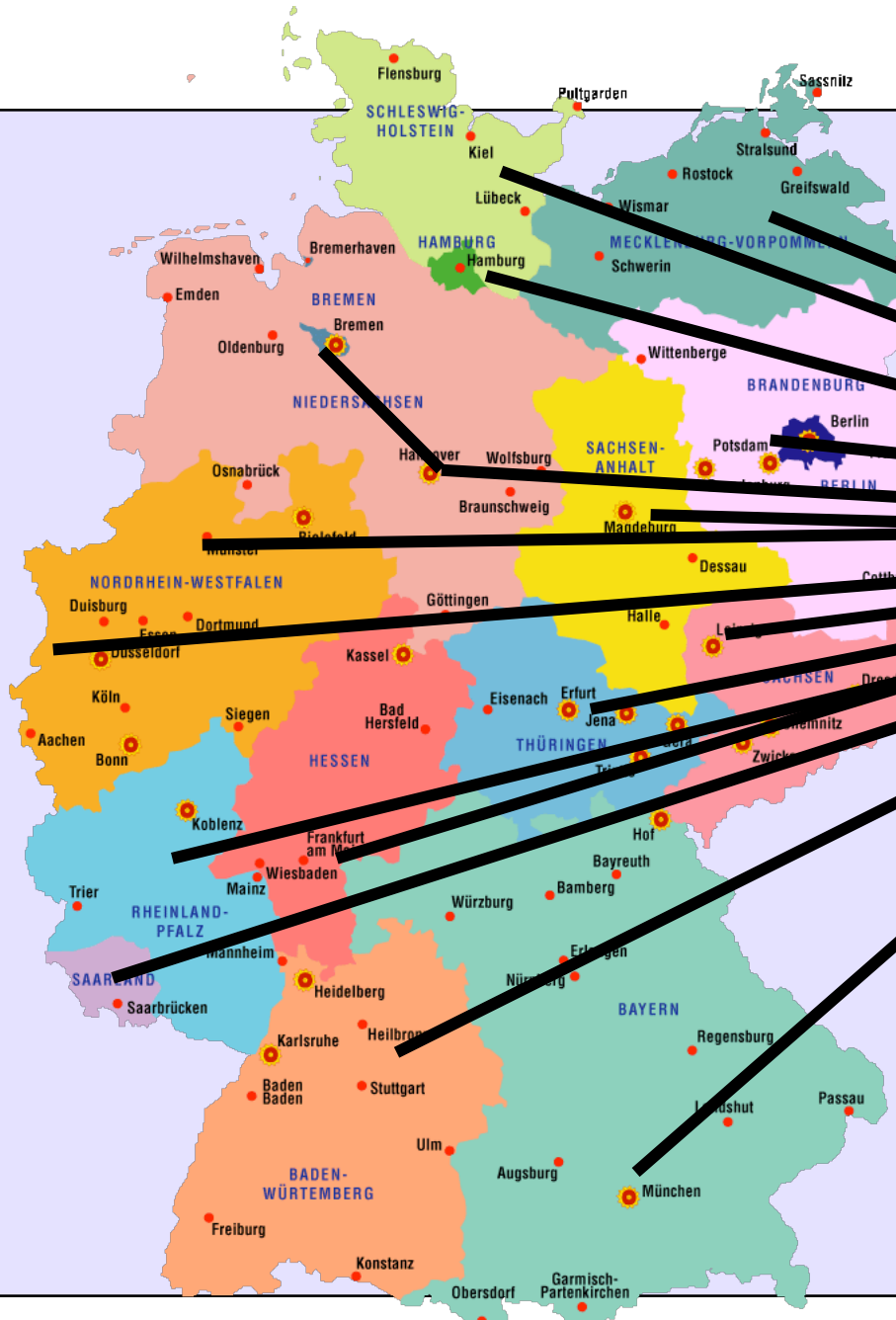
Situation in Germany



Federal Conference of German Department Clinical Audit in Radiation Protection **(ZAeS)**

Integrative Evaluation System

x-ray-diagnostic
radiation therapy
nuclear medicine

Commitment

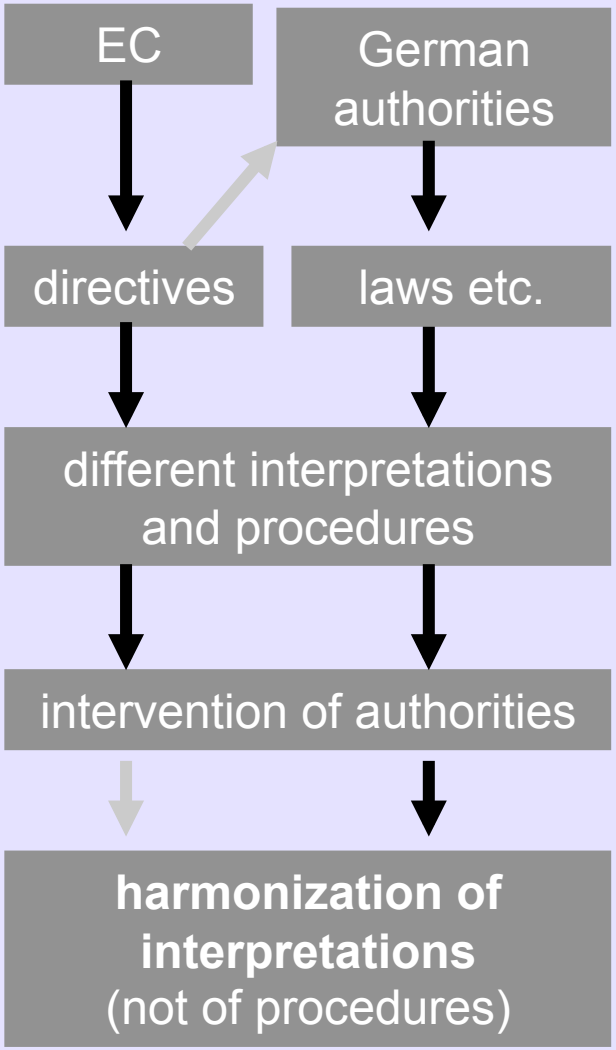
The advantages of federal systems are the chance to try out different strategies which will end up with a comparable outcome

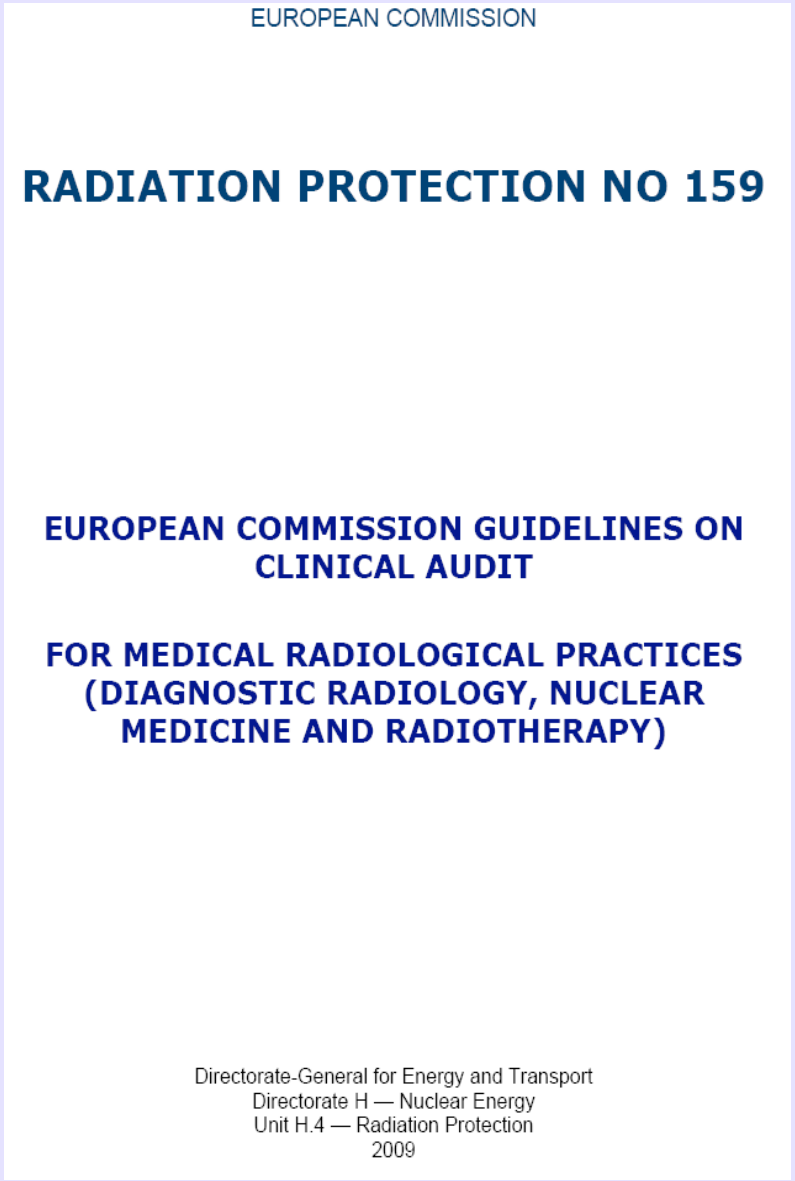
- What have we accomplished in Germany?

Integrative Evaluation System
(adopted 14.11. 2007) √

x-ray-diagnostic	radiation therapy	nuclear medicine
list of deviation	list of deviation	list of deviation

Comparable Structures





The experience of Germany and other European countries that already built a quality control system based on clinical audits was put together in a European Commission Guideline in 2009.

One topic that could be discussed in the workshop is whether and how it is necessary to harmonize and communicate clinical auditing and its tools between the EU countries

Key Philosophy of German Clinical Audits

Advice
- independent
- competent (on eye level)
- collegial
- strictly quality oriented (not financial etc.)

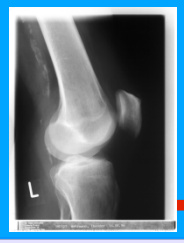
“Aerztliche Stelle”

(X-ray ordinance)

privat practice / hospital

X-ray machine

X-ray pictures.



Dialogue
- bundle the experiences from the frontline
- give assistance to the development of standards and “good practice”
- attend the interests of practical users

Development of Tools

The main tool provided by the central conference is a integrative evaluation (assessment) system. The system undergoes an ongoing refinement and adjustment according to the increase of knowledge and experience.

Einheitliches Bewertungssystem

der Ärztlichen Stellen (ÄSt.en) nach §17a RöV und §83 StrlSchV

Version 3.2b (2009.08.25)

Development of Tools

A clinical audit program is an important factor towards establishing a safety culture and in a process of optimization.

International and National bodies like the SSK and also scientific societies have to contribute to answer open questions and formulate guidelines for problems that arise from a comprehensive quality control system.

Standards, acceptable deviations and variations, tolerance levels, constraints etc. have to be developed and formulated.

Development of Tools cont.

e.g.
On their 243. session at 16./17. September 2010 the SSK passed recommendations for the quality control of nuclear medicine equipment – determination of action levels and limits of tolerance which were adopted by the commission of federal authorities for radiation protection (Fachausschuss Strahlenschutz)

Qualitätskontrolle von nuklearmedizinischen Geräten - Festlegung von Reaktionsschwellen und Toleranzgrenzen
Empfehlung der Strahlenschutzkommission

Tab. 1: Gammakamera planar

Prüfparameter	Bezugswert (BW) Reaktionsschwellen (RS)	Toleranzgrenzen (TG)	Erläuterungen / Bemerkungen
Nulleffekt	BW = Mittelwert aus mindestens 10 Messungen mit > 1000 Impulsen RS = BW ± 20 %	TG = BW ± 50 %	Bei Unterschreiten der RS muss eine Messung der Ausbeute erfolgen.
Energiespektrum	BW = Gammaenergie des verwendeten Nuklids RS = BW ± 5 %	TG = RS	Bei Geräten mit automatischer Korrektur gelten diese Empfehlungen für den Korrekturwert.
Ausbeute/Sensitivität	BW aus Abnahmeprüfung oder letzter Halbjahresprüfung RS = BW ± 5 %	TG = BW ± 10 %	Die Änderung der Ausbeute muss über die Betriebszeit der Kamera dokumentiert und beobachtet werden (Kristall). Durch Homogenitätskorrekturen sollte die Ausbeute um weniger als 20 % reduziert werden
Inhomogenität	BW = extrinsische (mit Kollimator) integrale Inhomogenität im UFOV (useful field of view) aus Abnahmeprüfung oder letzter Halbjahresprüfung RS = BW + 0,5 BW (max. RS = 8 %)	TG = 8 %	Bei Neubestimmung der Parameter (Matrizen) zur Inhomogenitätskorrektur muss immer der Einfluss auf die Ausbeute beachtet werden , ggf. ist eine Neueinstellung der Gammakamera erforderlich. Bei Messungen ohne Kollimator verringert sich TG um den Inhomogenitätsbeitrag des Kollimators.
Ortsauflösung	BW = Bilddokumentation der Abnahmeprüfung RS = TG	4 mm ohne Kollimator 6 mm mit Kollimator	Gilt für visuelle Auswertung eines Bleistreifen- oder Orthogonal-Hole-Phantoms.
Linearität	BW = Bilddokumentation der Abnahmeprüfung RS = TG	Keine sichtbare Verschlechterung zum BW	Ist in der Regel mit Inhomogenitäten verknüpft.
Abbildungsmaßstab	BW = Abstand der Punktquellen oder Pixelgröße bei der Abnahmeprüfung RS = BW ± 5 %	TG = RS	Bei digitalen Kameras erfolgt die Angabe der Pixelgröße.
Ganzkörperzusatz	Abbildungsmaßstab: BW = Abstand der Punktquellen oder Pixelgröße bei der Abnahmeprüfung RS = BW ± 5% Ortsauflösung: BW = Bilddokumentation der Abnahmeprüfung	TG = RS Keine sichtbare Abweichung zum BW	

Facts and Figures for the Workshops

- Clinical audits are important tools for ALARA and the formation of a safety culture
- internal quality assurance programs can assure your quality to a defined standard - but the view over the fence is often missing (you fulfill your own standards, but the world turns around ...)
- no external quality assurance program can improve your quality - You have to go this way yourself
- external quality assurance programs can escort you on your way by providing valuable advice and support
- comprehensive quality assurance programs trigger solutions to yet ignored problems
- the success of every program is mainly dependent from the knowledge and the addiction to quality of the human beings acting as members of the auditing commissions