Type testing of basic protection devices in Germany

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Outline

- Type approvals in Germany
- Type testing of X-ray devices
- The new category “Basic-protection device”
- Conclusions

Ionising Radiation Regulations in Germany

Council Directive 96/29/EURATOM

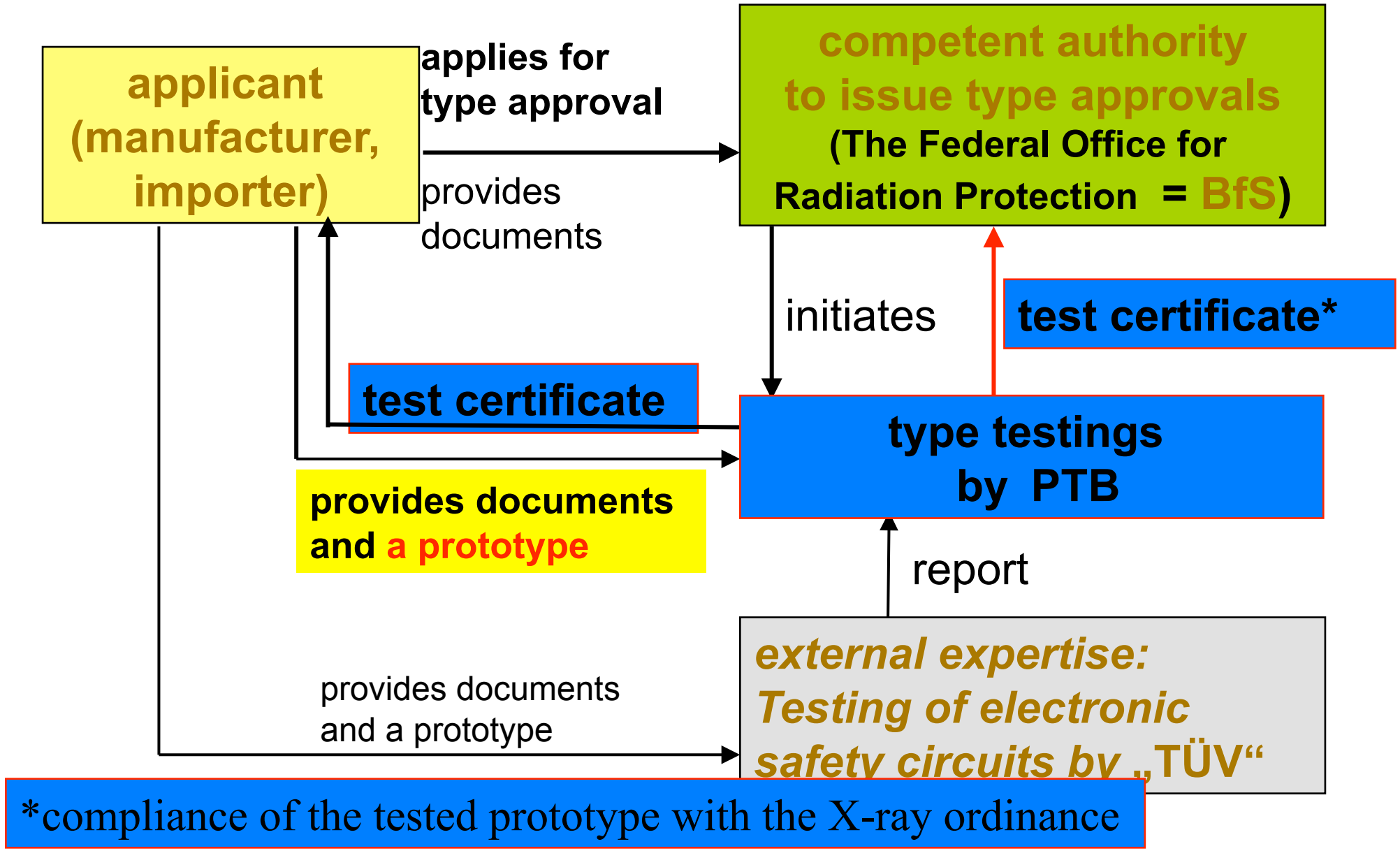
= basic safety standards for the protection of the workers and the general public against the dangers arising from ionizing radiation:

implemented in Germany via:

- **Radiation Protection Ordinance (from 2001)**
  handling, use, storage, transport, disposal….of
  radioactive substances
  operation of accelerators or X-ray devices with HV > 1 MV

- **X-ray Ordinance (from 2002)**
  (Röntgen-Verordnung = "RöV")
  operation of X-ray devices with 5kV < HV < 1 MV
  and stray radiation devices

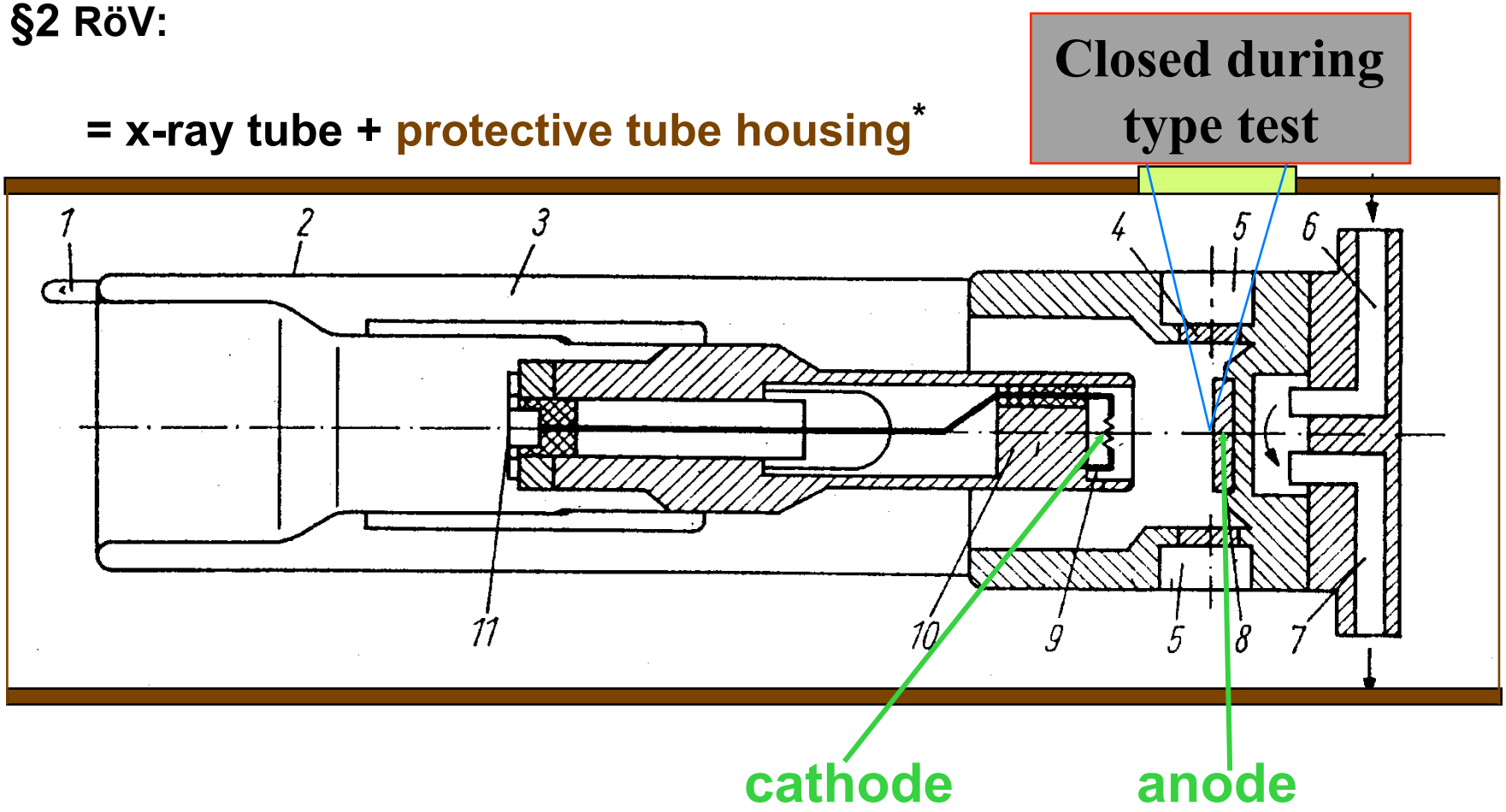
Type approvals in Germany (X-ray ordinance)



X-ray tube assembly

§2 RöV:

= x-ray tube + protective tube housing*



*may include the HV-generator

Requirements on X-ray tube assemblies for a type approval in Germany

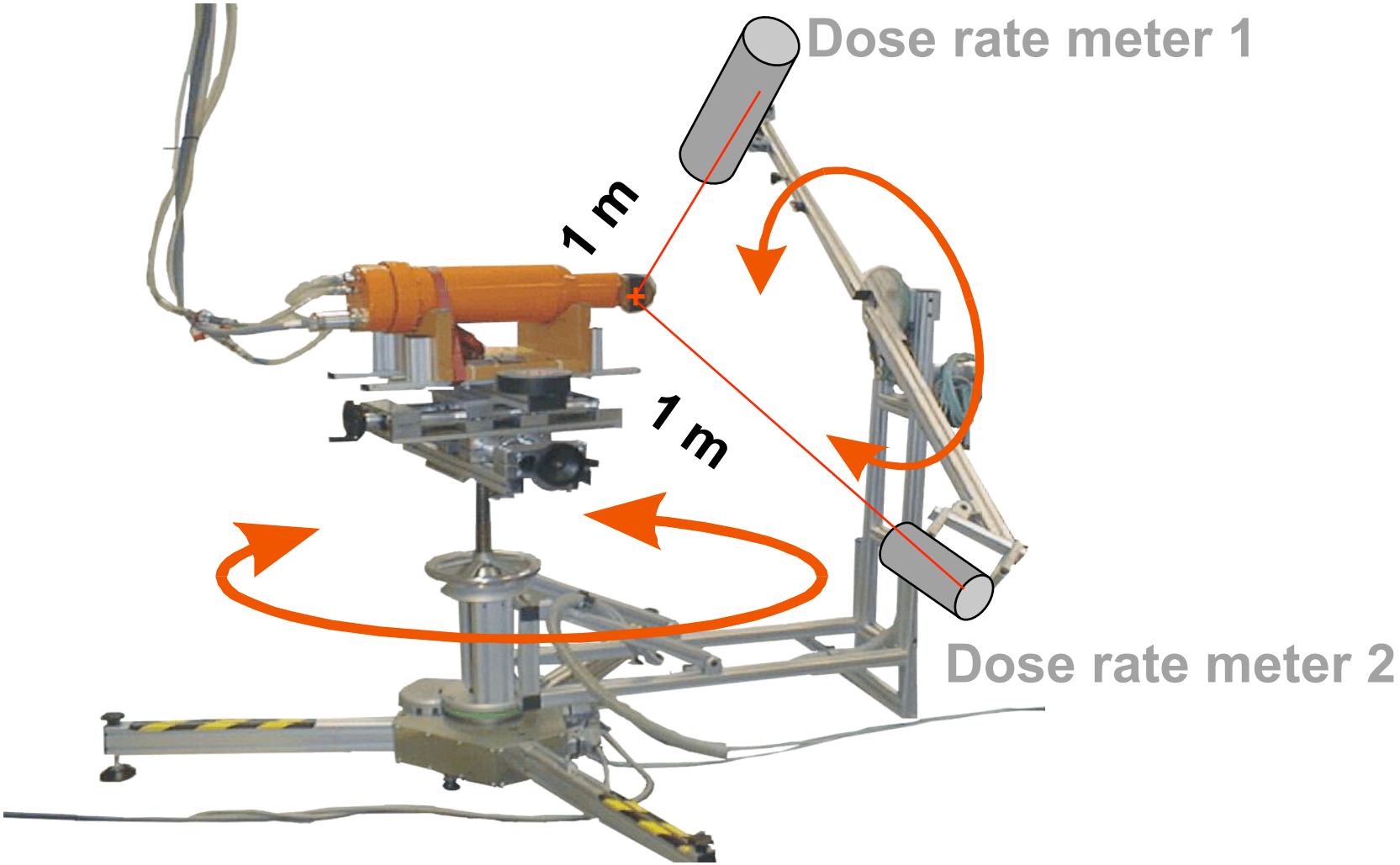
Dose rate limit:*

in 1 m distance from the focal spot*
at maximal operating conditions (maximal HV, maximal current)
with closed X-ray exit window!
(i.e. only the leakage of X-radiation is considered)

≤ 2,5 mSv/h for HV ≤ 200 kV
≤ 10 mSv/h for HV > 200 kV

***ambient dose equivalent rate $\dot{H}^*(10)$:**

„4 Π“ - measurement of „radiation leakage“



Council Directive 96/29/EURATOM

Article 3

Reporting

1. Each Member State shall require the carring out of the practices reffered to in Article 2 (1) to be reported,
(e.g. the **operation of** any **electrical equipment emitting ionizing radiation** and containing components operating at a potential difference of more than 5 kV)
except for in this article

2. No reporting need be required for practices involving the following:

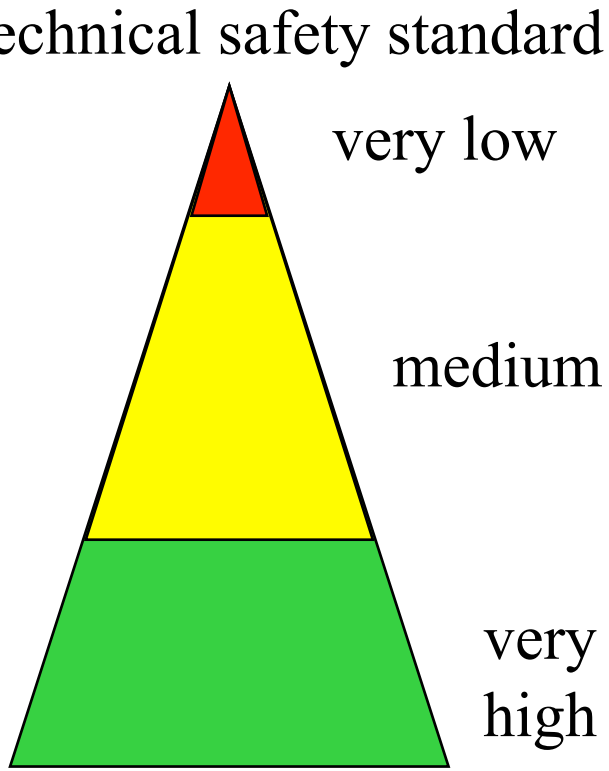
d) operation of any electrical apparatus, provided that:

(i) it is type approved by the competent authorities of the Member State; and

(ii) it does not cause, in normal operating conditions, a dose rate exceeding 1 μSv h^{-1} at a distance of 0,1 m from any accessible surface of the apparatus;

Categories of type approved X-ray devices due to the new German X-ray ordinance (RöV):

X-ray tube assemblies	10 mSvh^{-1} at 1 m
basic protection devices (to be implemented with the new X-ray ordinance)	10 µSv h^{-1} at 0,1m
high protection devices	25 µSv h^{-1} at 0,1 m 10 µSv h^{-1} at 0,1 m
full protection devices	7,5 µSv h^{-1} at 0,1 m 3 µSv h^{-1} at 0,1 m



For the operation of type approved X-ray devices in Germany, in any case prior Reporting is required!

i.e. the "1 µSv h^{-1} (at 0,1 m from surface)"-concept of 96/29/ EURATOM

(valid, when NO Reporting is required) is not applicable in Germany!

Organisational radiation protection regime

RöV §4: No authorization needed but prior Reporting is required!

Category	authorised expert's report	radiation protection officer	technical qualification
type approved X-ray tube assembl.	X	X	X
basic protection devices		X	X
high protection devices		X	X
full protection devices			
type approved stray radiation devices	**Neither authorisation nor Reporting is required!** (according to 96/29/EURATOM Article 3 No.2) dose rate limit: 1 **μSv h^{-1} at 0,1 m**		

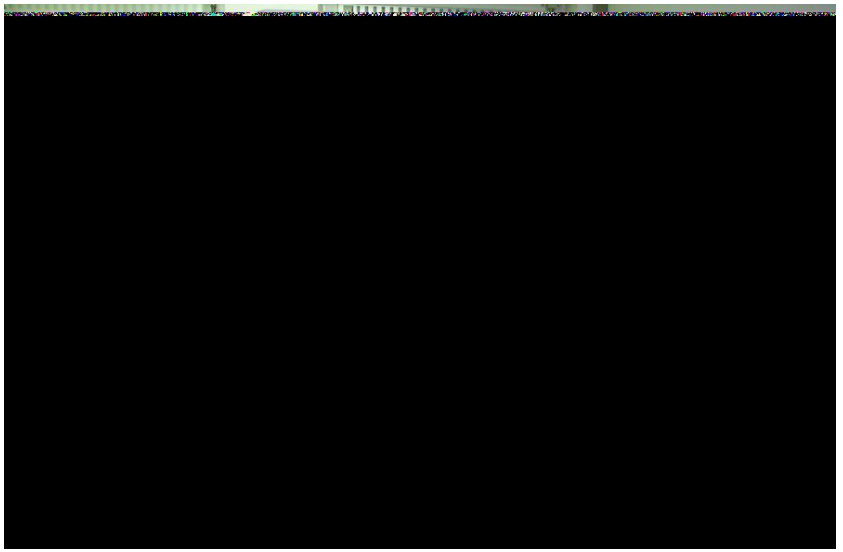
Technical requirements for

full protection devices

vs

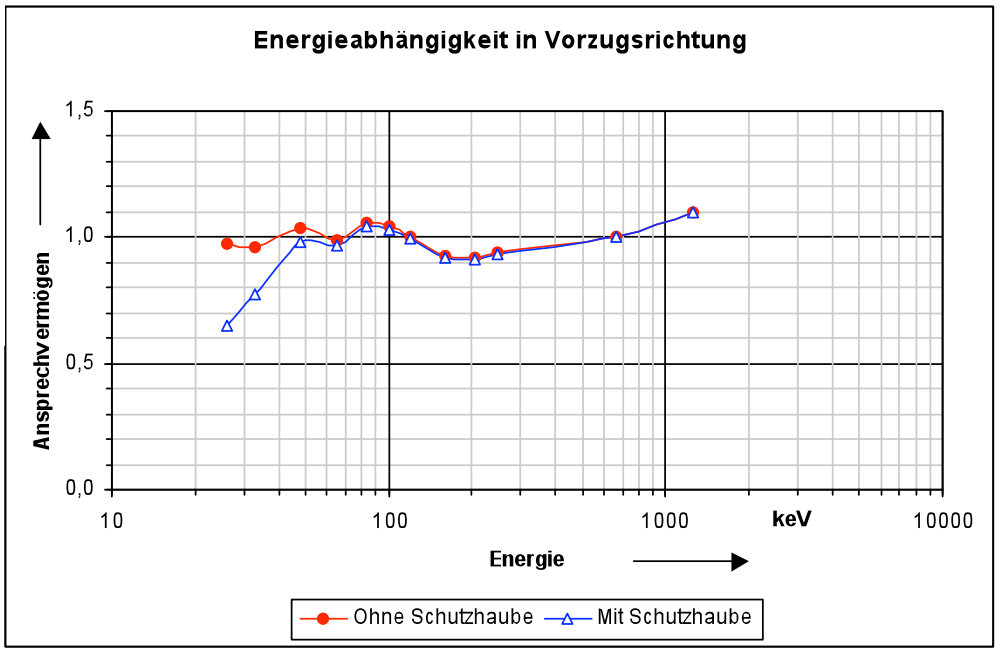
basic protection devices

Work places at „full protection devices“



*H**(10)-Scintillation-dosemeter (Automess)*

*type approved by PTB



Risk of exposures to humans

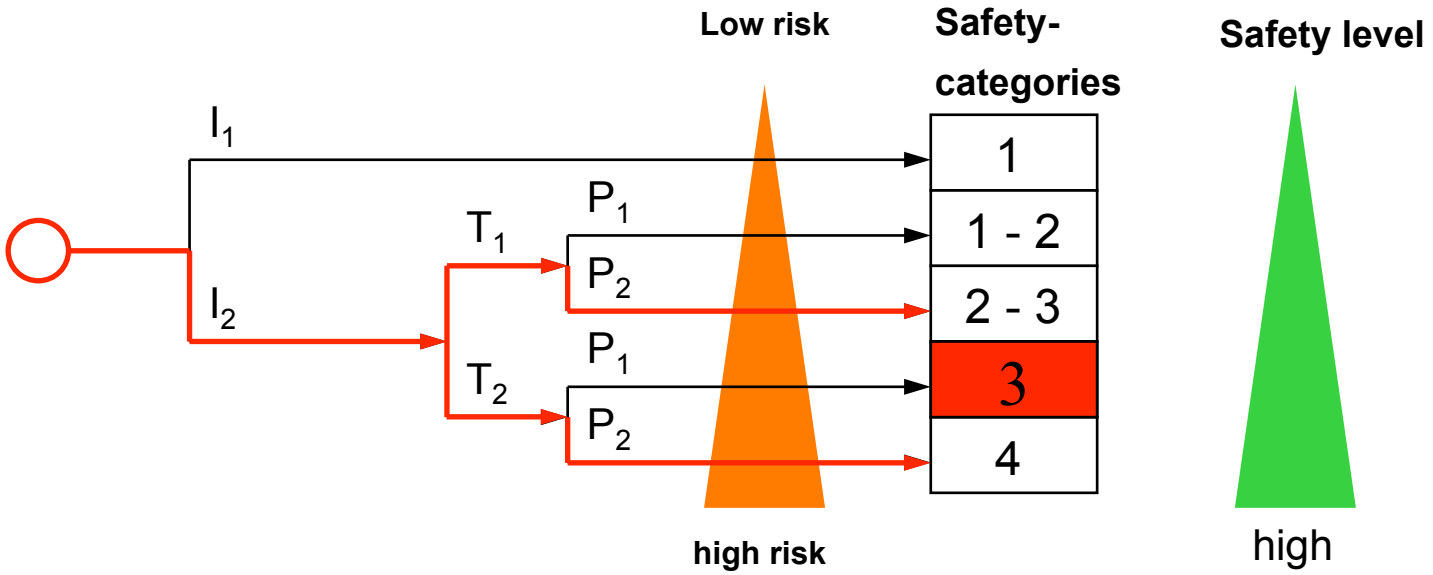
Dose rate in the beam: ≈ 100 Sv/h

⇒ severe injuries of the hands

→ possible violation of effective dose limits due to heavy stray radiation

Requirements on the safety circuits of full protection devices

Risk assesment due to EN 954-1



I = Injury (1= harmless, 2= **severe**)

T = exposure time (1= short, 2= long)

P = Preventability (1= high, 2= **low**)

Safety category 3 due to EN 954-1/PTB

- two independent safety circuits control that all doors (openings) are closed during operation of the x-ray device
- faults at one of the safety circuit are detected with a high probability and cause the shut down of the X-ray device
- simultaneous faults (by common failures) at both safety circuits have to be excluded with a probability extremely close to 1
- a locking mechanism is required which assures, that the doors can be opened only, when the radiation level is below the limits

X-ray devices for baggage scanning …

Foto: Heimann Systems

… do not fit into the existing categories of RöV

X-ray tube assembly? (2,5 $mSvh^{-1)}$	No!
high protection device? (access with hands only)	No!
full protection device? (completely closed casing)	No!
stray radiation device? (X-rays are not used intentionally)	No!

⇒ A new category is required, called:
„basic protection device“!

Potential basic protection devices: Baggage scanners

HI-SCAN 6030di © Smiths Heimann

Operated by qualified personnel

Basic protection devices: Food scanners

Typically part of production lines with sample feedings of appropriate size; Operated by non experts!

Workplace at a food-scanner

- **similar to full protection devices**
  ⇒ same dose rate limit: 10 μSvh^{-1} in 0,1 m from the surface
- **closed casing with only one exception: the sample feeding which has an appropriate size**
  all other openings/doors require "Cat. 3"-safety circuits
- **limited transfer doses (not regulated by RöV):**
  in any case
  < 50 mSv (industry)
  < 1 mSv (baggage scanning)
  but preferably:
  "ALARA"!

Conclusions

- **high safety standards in Germany are achieved by using type tested and type approved X-ray devices:**

  - exposure to humans under normal operation remains as low as reasonably achievable ("ALARA")

  - risk of failures with hazardous exposures remains as low as reasonably achievable ("ALARA")

  - Necessary administrative requirements, especially for "full protection devices" are as low as reasonably achievable
  (Reporting only! **No** expert's report, **no** radiation protection officer, **no** technical qualification of the operators are required!) **("ALARA")**

- **a new category "basic protection devices" will be established with the forthcoming X-ray ordinance in Germany**

- **so far, there are no joint standards for type approved X-ray devices in Europe**

The new category
„basic protection devices“
was proposed in 2005
by a group of experts from

and

Renate Czarwinski (presently IAEA)
Klaus-Heiner Motzkus

and others

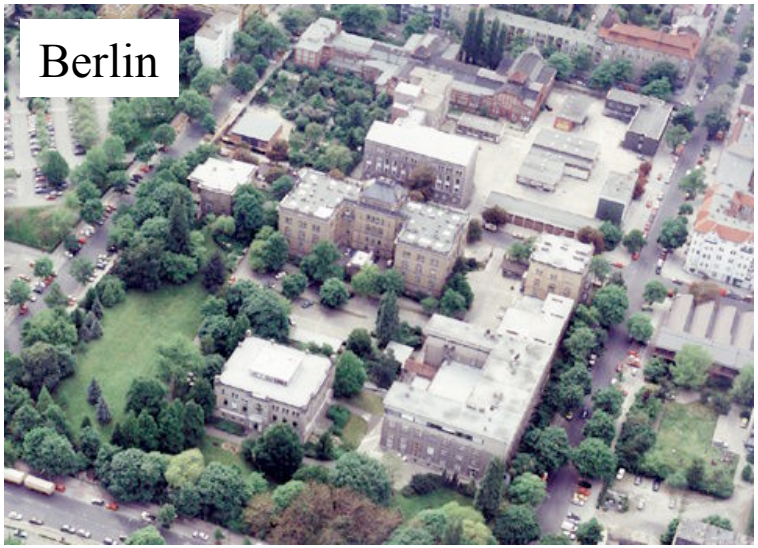
Dr. Stefan Neumaier
Dr. Harald Dombrowski

and others

Thank you for your attention!

Annex

Physikalisch-Technische Bundesanstalt =



- **National Metrology Institute (NMI) in Germany: fundamentals of metrology, metrology for economy and for the society**

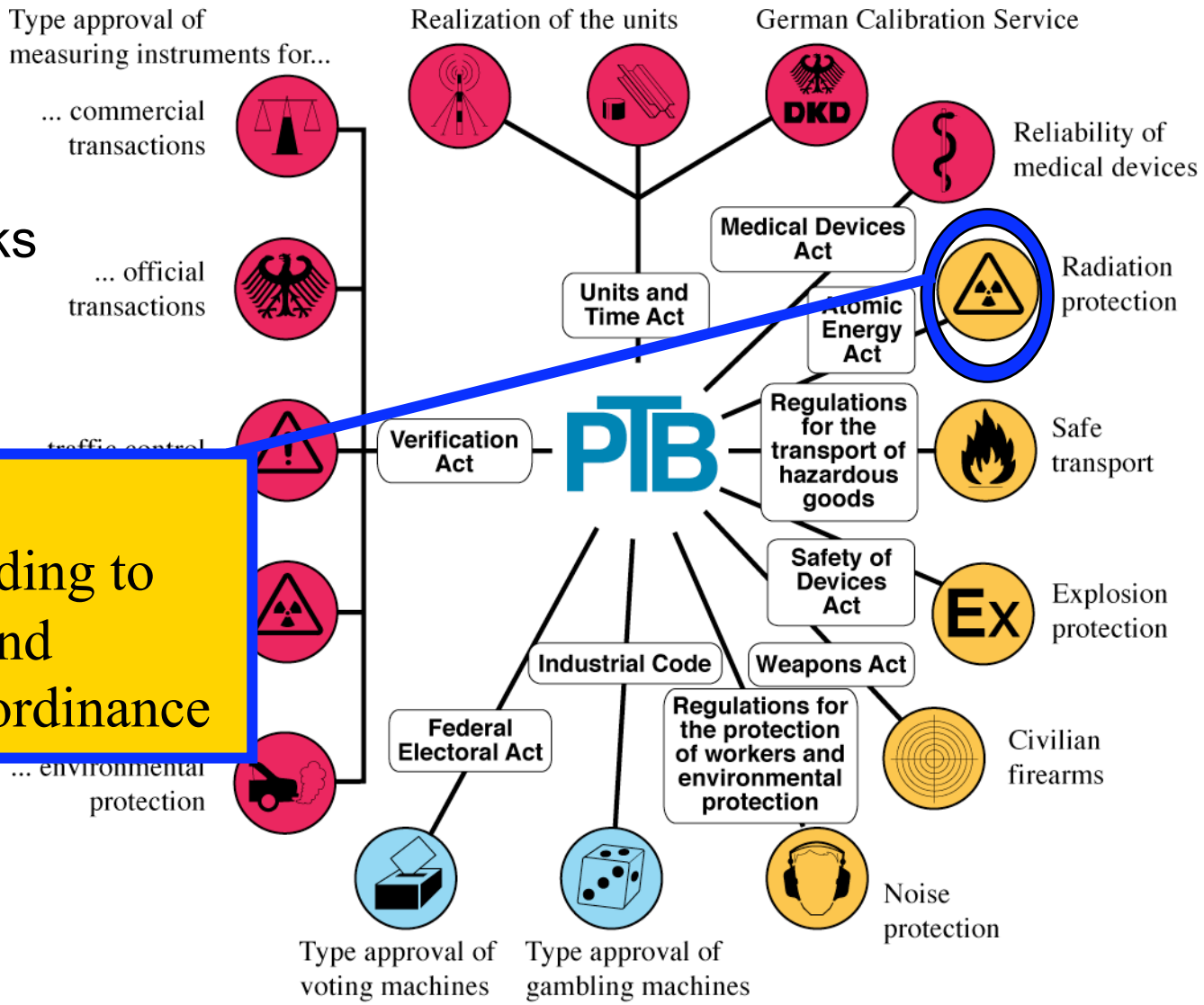
  - under the regime of the Federal Ministry of Economics and Technology

- **Founded 1887 by Werner von Siemens and Hermann von Helmholtz**
  - PTB was the first metrology institute world-wide!
- **1600 staff members**
- **140 Mio. €/a budget**
- **Two sites: Braunschweig and Berlin**

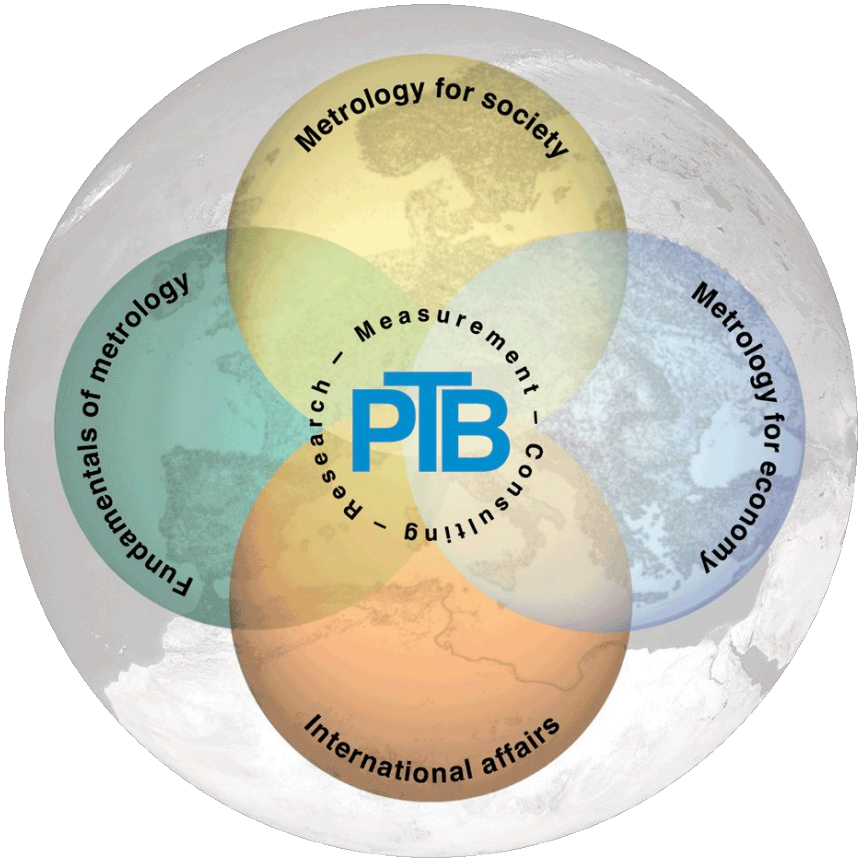
Metrology for society

More than 60 laws and directives assign specific tasks to PTB

Type testing for type approvals according to the German X-ray- and radiation protection ordinance



Fields of activity



Fundamentals of metrology

Realization and dissemination of SI-units

Metrology for economy

Increasing the efficiency of economy, safeguarding of employment

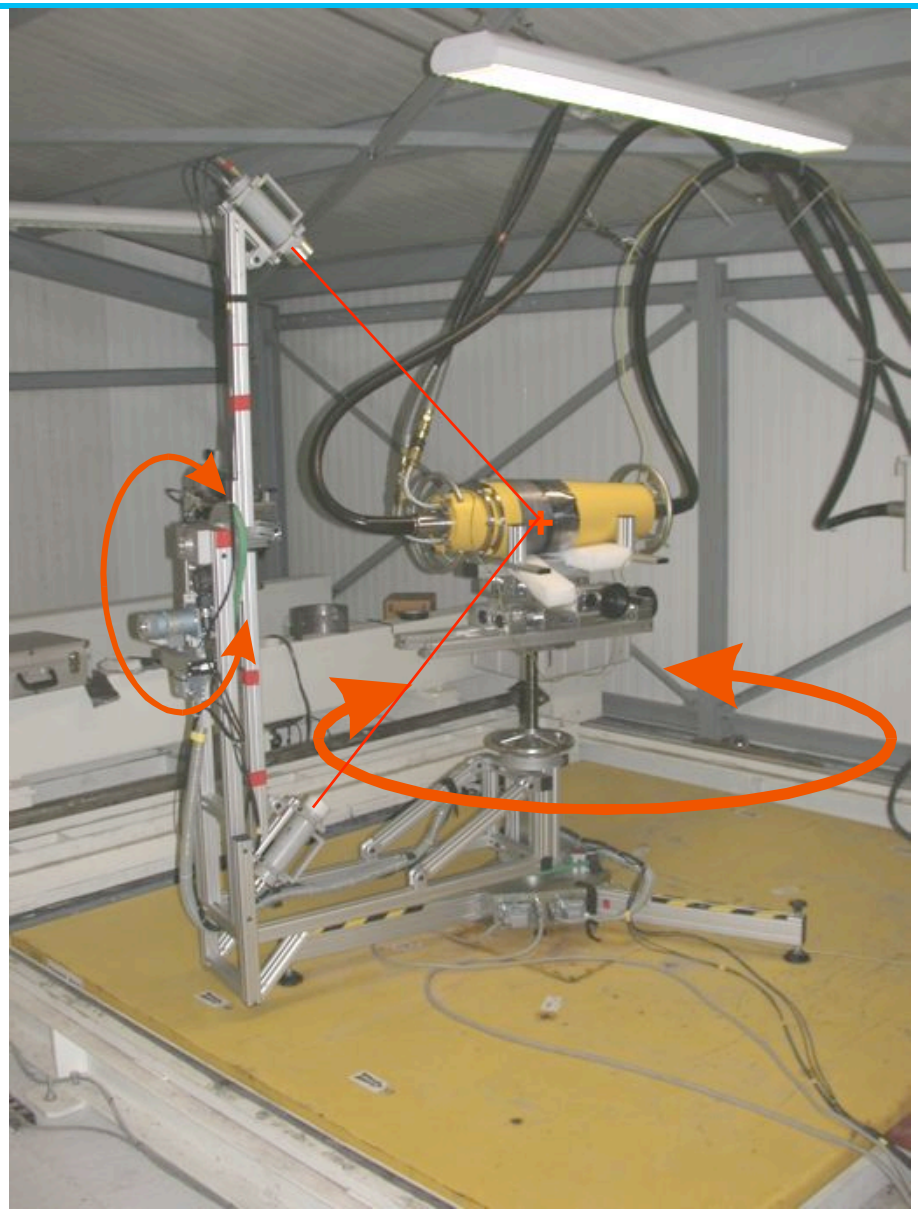
Metrology for society

Promotion of consumer protection, safeguarding of living conditions

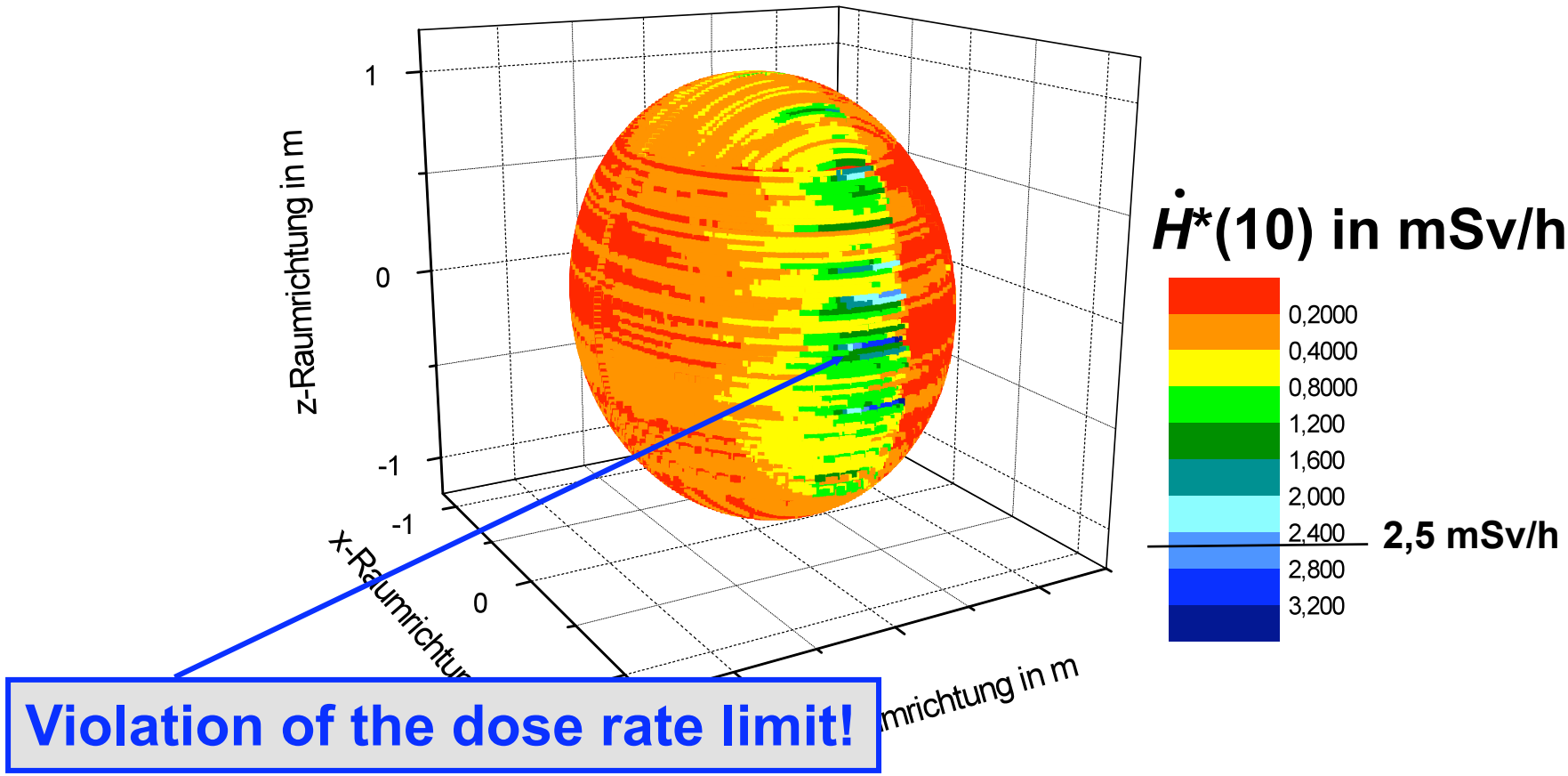
International affairs

Removal of technical barriers to trade, unification of metrology

Messung der ODL bei Röntgenstrahlern

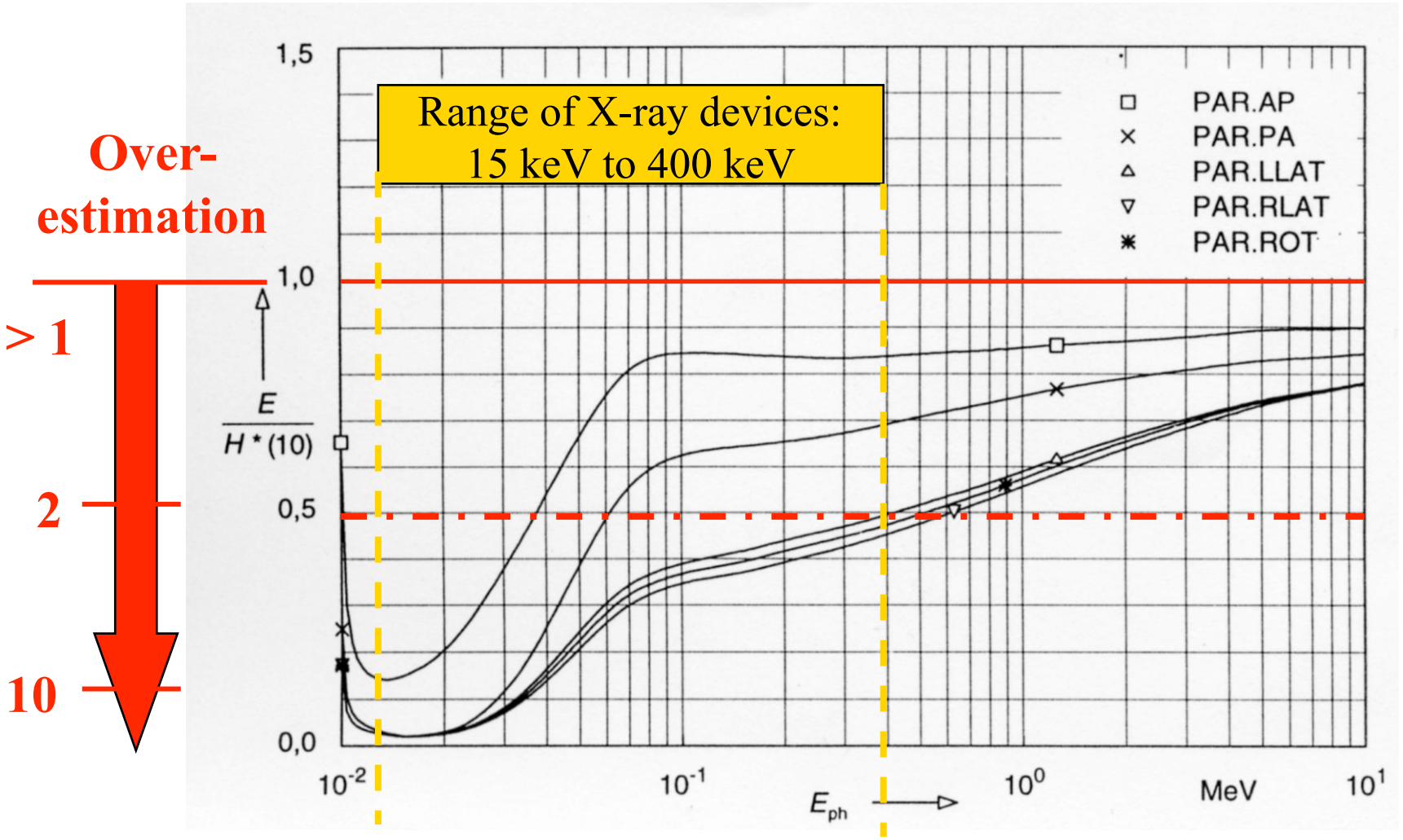


Dose rate distribution of a X-ray tube assembly

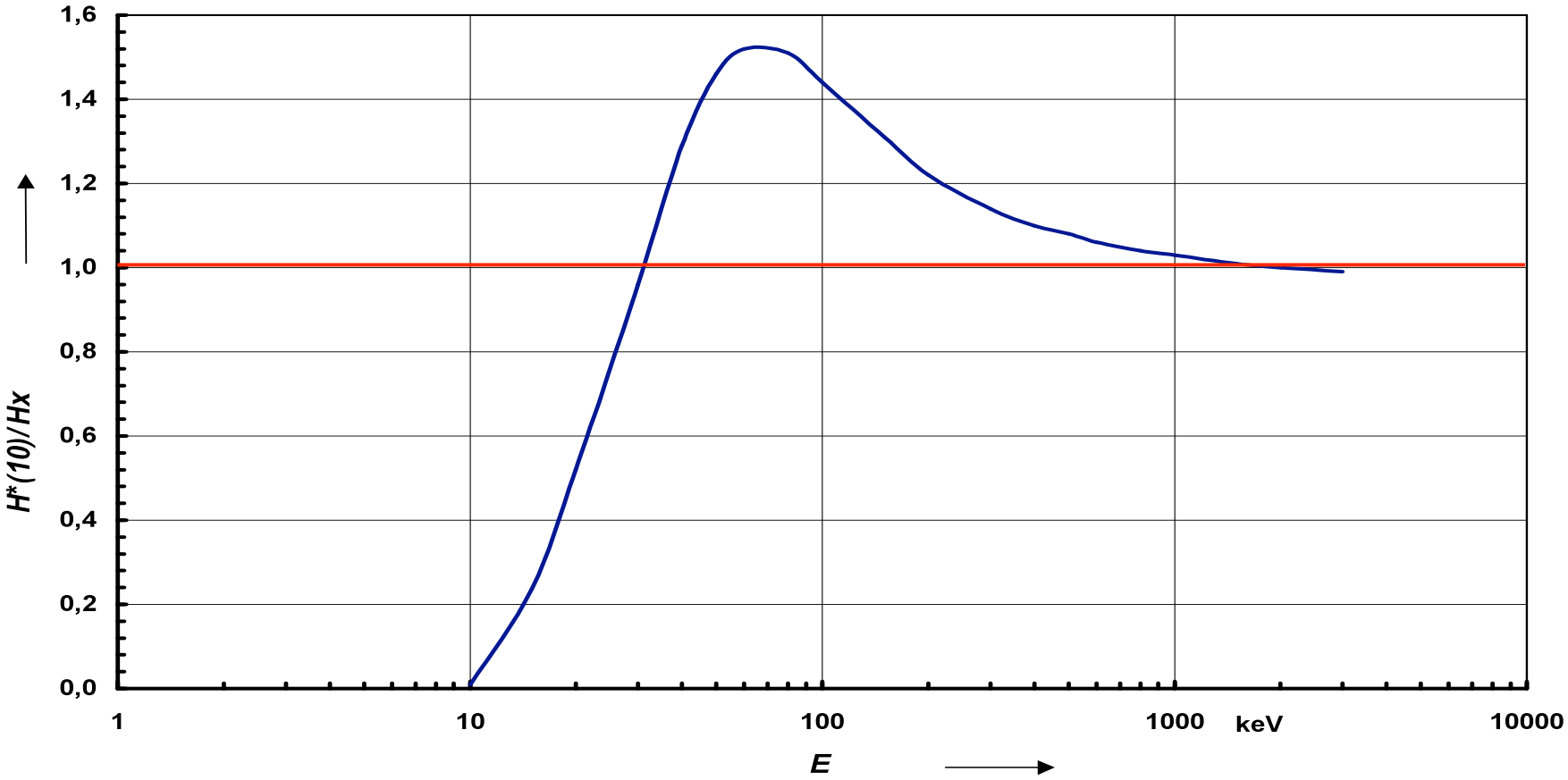


Violation of the dose rate limit!

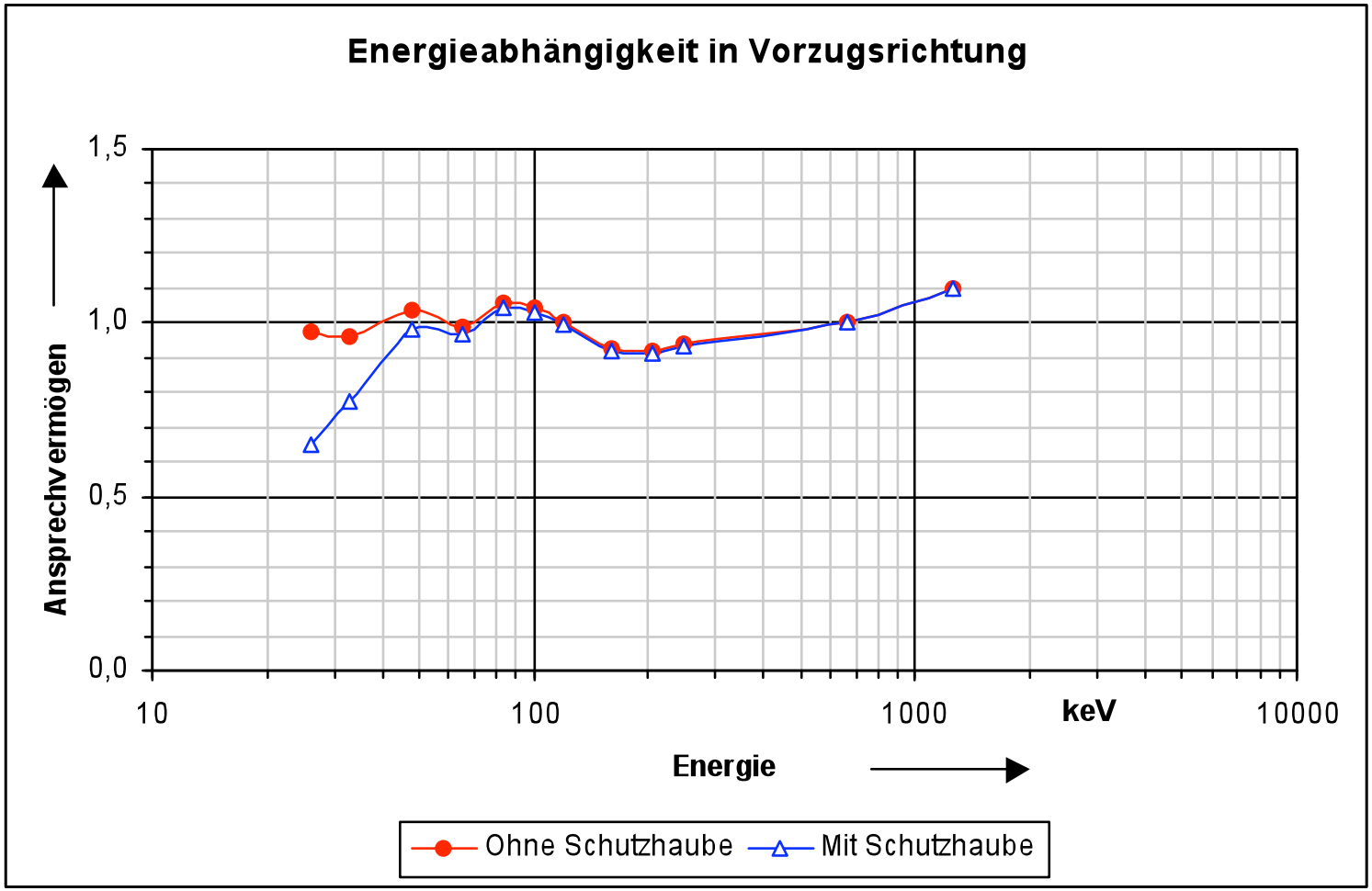
Ambient dose equivalent $H^*(10)$ overestimates the effective dose E



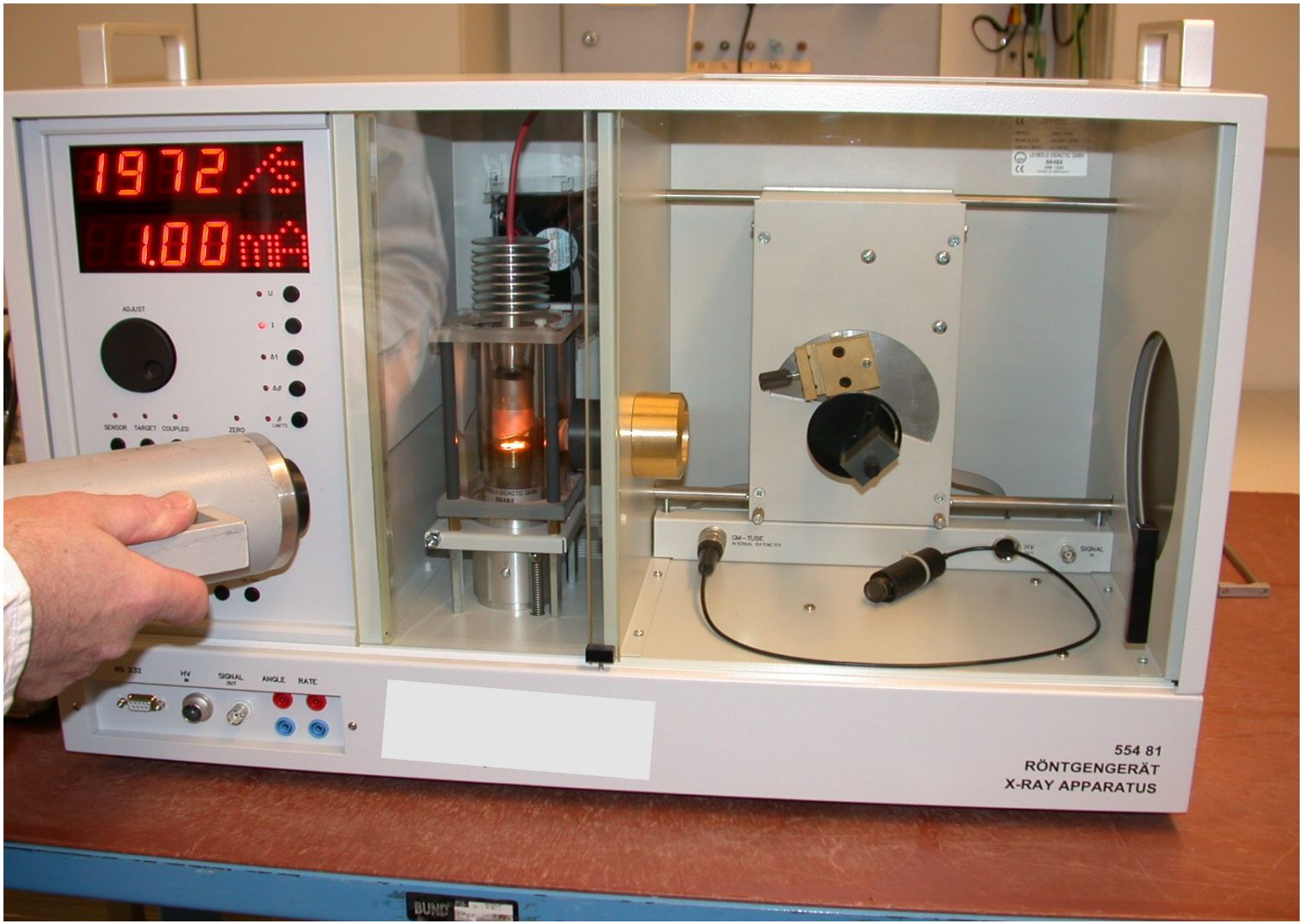
*H**(10) / *H*x



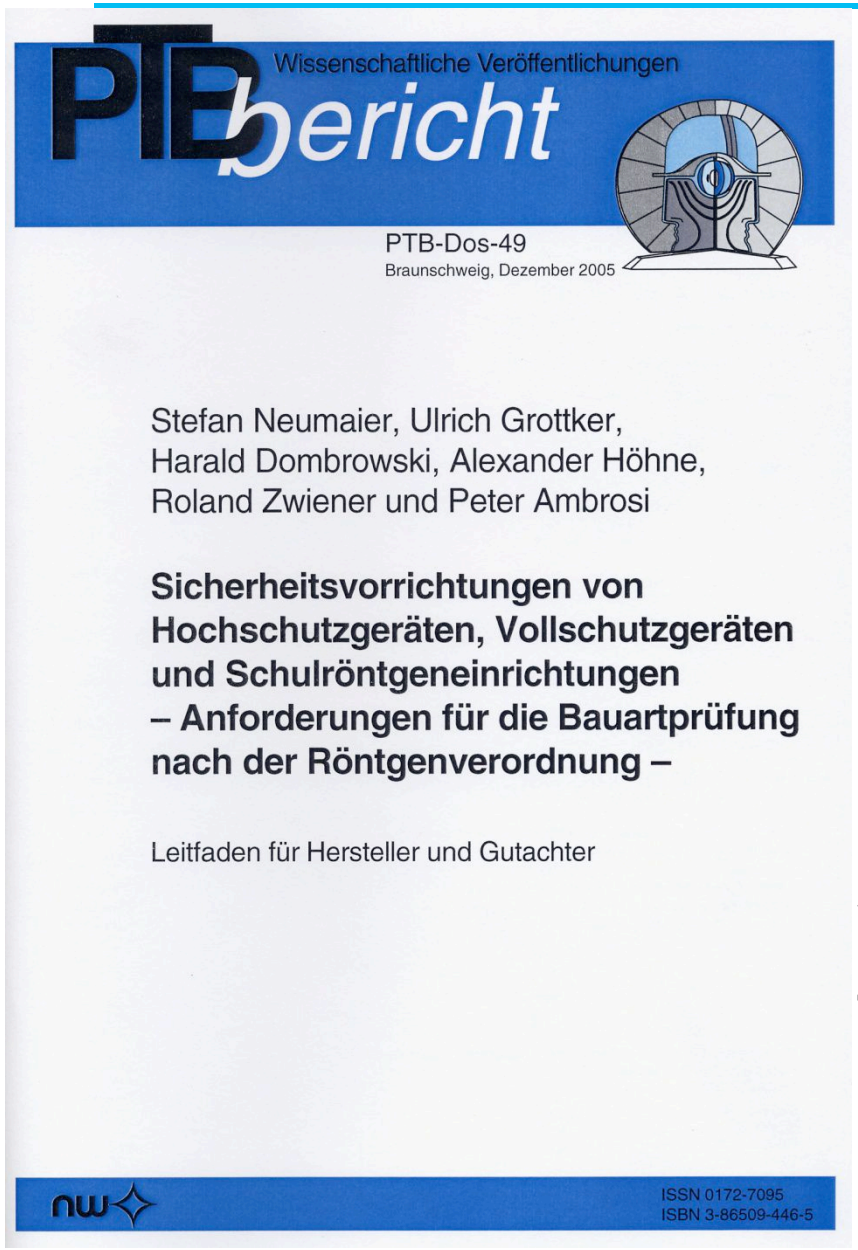
Energy dependence of the response (in terms of *H**(10))



Full protection device used for educational purposes at schools and at universities



Umsetzung des Länderbeschlusses



Leitfaden für Hersteller und Gutachter*

***PTB zieht TÜV-Gutachten zur Sicherheitstechnik bei Bauartprüfungen mit heran**

Neufassung Anlage 2: Basisschutzgeräte

6. Basisschutzgeräte

Bei Basisschutzgeräten muss sichergestellt sein, dass

6.1 das Schutzgehäuse außer der Röntgenröhre oder dem Röntgenstrahler auch den zu behandelnden oder zu untersuchenden Gegenstand so umschließt, dass allein Öffnungen zum Ein- und Ausbringen des Gegenstandes vorhanden sind,

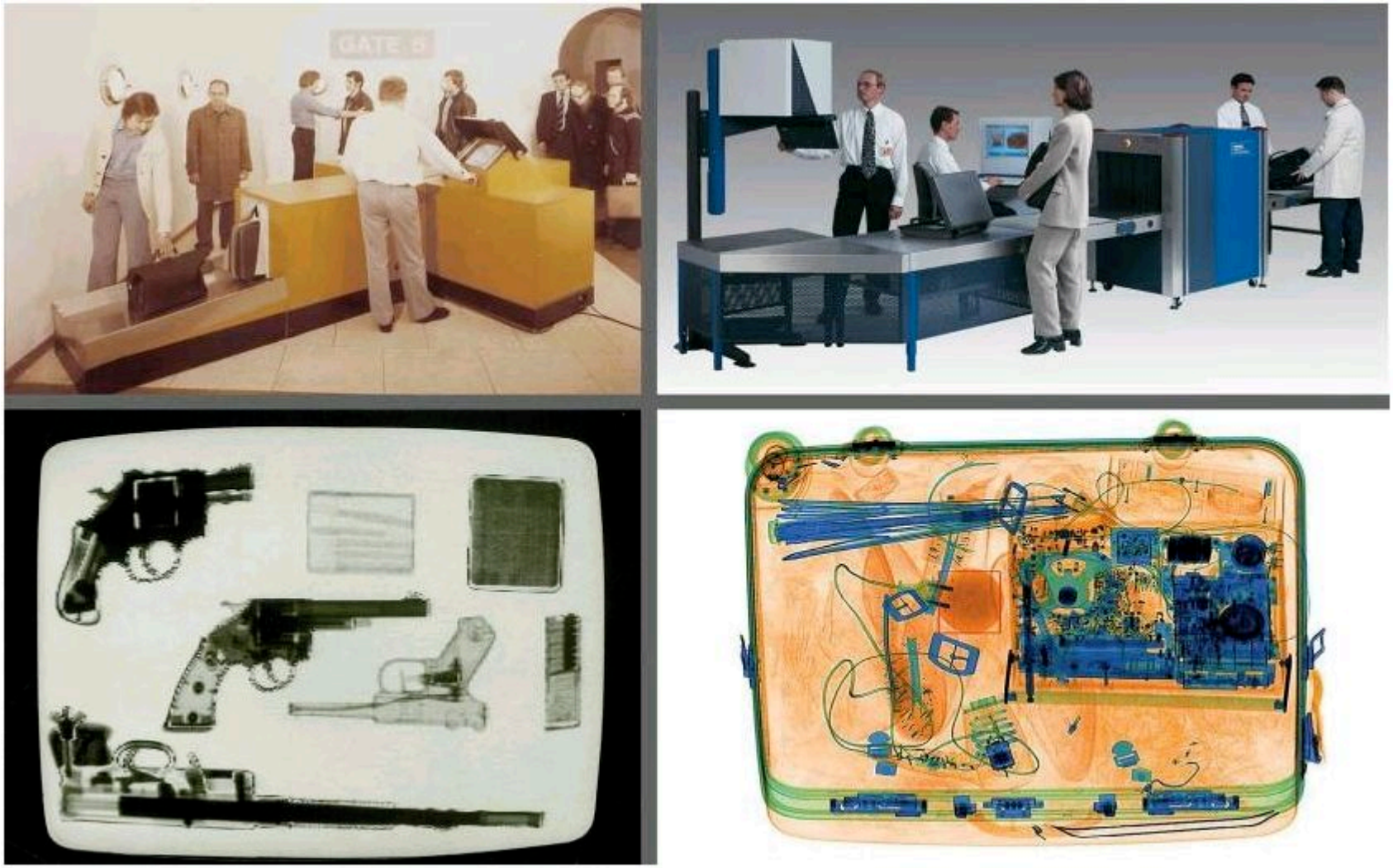
6.2 die Ortsdosisleistung im Abstand von 0,1 Meter von der berührbaren Oberfläche des Schutzgehäuses und im Abstand von 0,1 Meter vor den Öffnungen 10 Mikrosievert durch Stunde bei den vom Hersteller oder Einführer angegebenen maximalen Betriebsbedingungen nicht überschreitet,

6.3 die Röntgenröhre oder der Röntgenstrahler nur bei vollständig geschlossenem Schutzgehäuse betrieben werden kann. Dies gilt nicht für

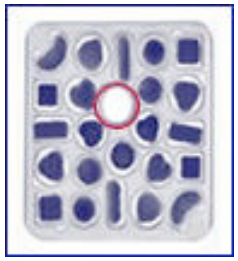
6.3.1 Öffnungen im Schutzgehäuse gemäß Nummer 6.1, wenn das Ein- und Ausbringen des zu behandelnden oder zu untersuchenden Gegenstandes ausschließlich mittels Probenwechsler oder Fördereinrichtung geschieht und die Abmessungen der Öffnungen diesem Zweck angepasst sind, oder

6.3.2 Untersuchungsverfahren, die einen kontinuierlichen Betrieb des Röntgenstrahlers erfordern, wenn die Ortsdosisleistung im Innern des geöffneten Schutzgehäuses 10 Mikrosievert durch Stunde nicht überschreitet.

Basisschutzgerät: Beispiele für applications



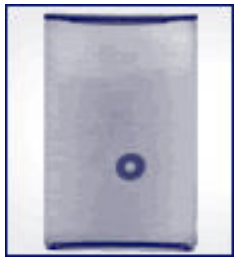
Basisschutzgerät: Beispiele für Anwendungen



Gebäckschachtel

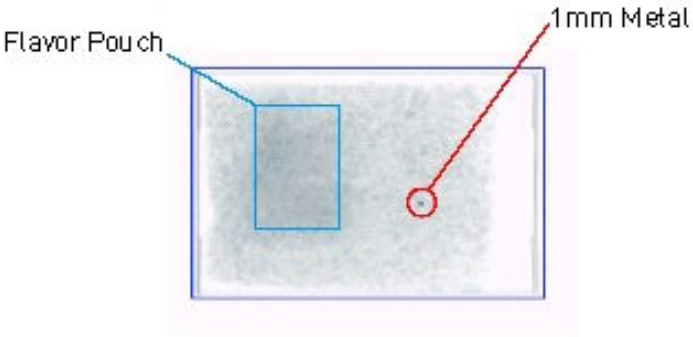
Reisetasche

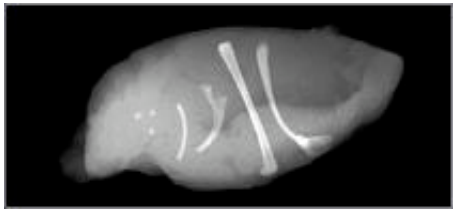
Nudelpackung



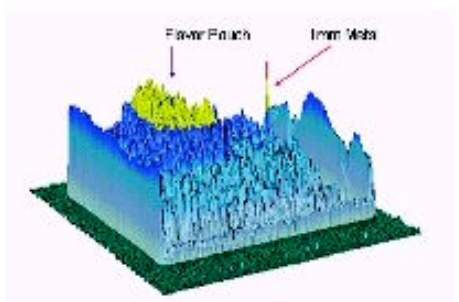
Getränkedose

- Suche nach Fremdkörpern / unerwünschten Gegenst.
- Kontrolle auf korrekte Verpackung
- Bestimmung von Fettgehalt
- Chemische Analyse





Filet-Fleisch



Röntgenstrahler für tiermedizinische Zwecke

Röntgenstrahler für tiermedizinische Zwecke

Ionising smoke detectors

Type testing by PTB and BAM

PTB

ODL im Abstand von 0,1 m
von der berührbaren Oberfläche des
Ionisationsrauchmelders ≤ 1 µSv/h.

Aktivität < 10 FG

Anforderungen nach SSK-Empfehlung

BAM

zu Fragen der Dichtheit (Temperaturprüfung,
Schlagprüfung, Fallprüfung, Brandprüfung)
sowie der Qualitätssicherung.