Physikalisch-Technische Bundesanstalt
Braunschweig and Berlin
National Metrology Institute

Radiation Protection:
Need for harmonized and applicable Type Test Requirements

Need for a Common European Market

Hayo Zutz, 6.3

Requirement for individual monitoring

COUNCIL DIRECTIVE 2013/59/EURATOM

Basic safety standards for protection against the dangers arising from exposure to ionising radiation

Article 81

Dosimetry services

Member State shall ensure that dosimetry services determine internal or external doses to exposed workers subject to individual monitoring, in order to record the dose in cooperation with the undertaking and in the case of outside workers, the employer, and where relevant the occupational health service

IAEA BSS

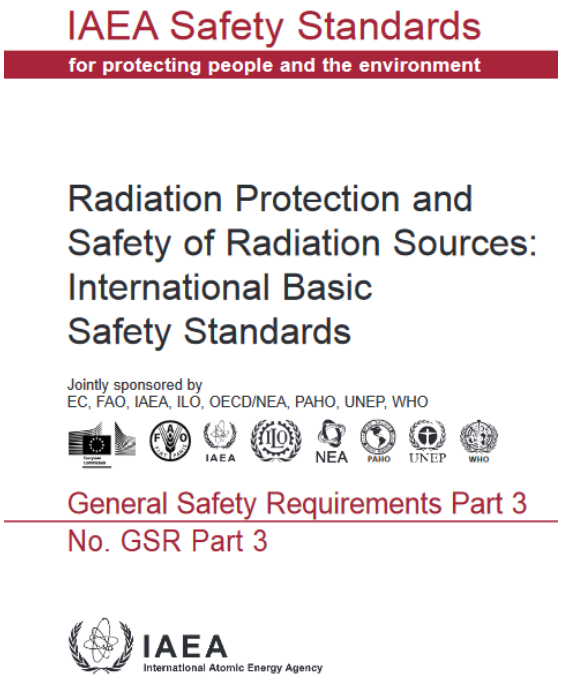
Requirement 14: Monitoring for verification of compliance

3.38. Registrants and licensees and employers shall ensure that:

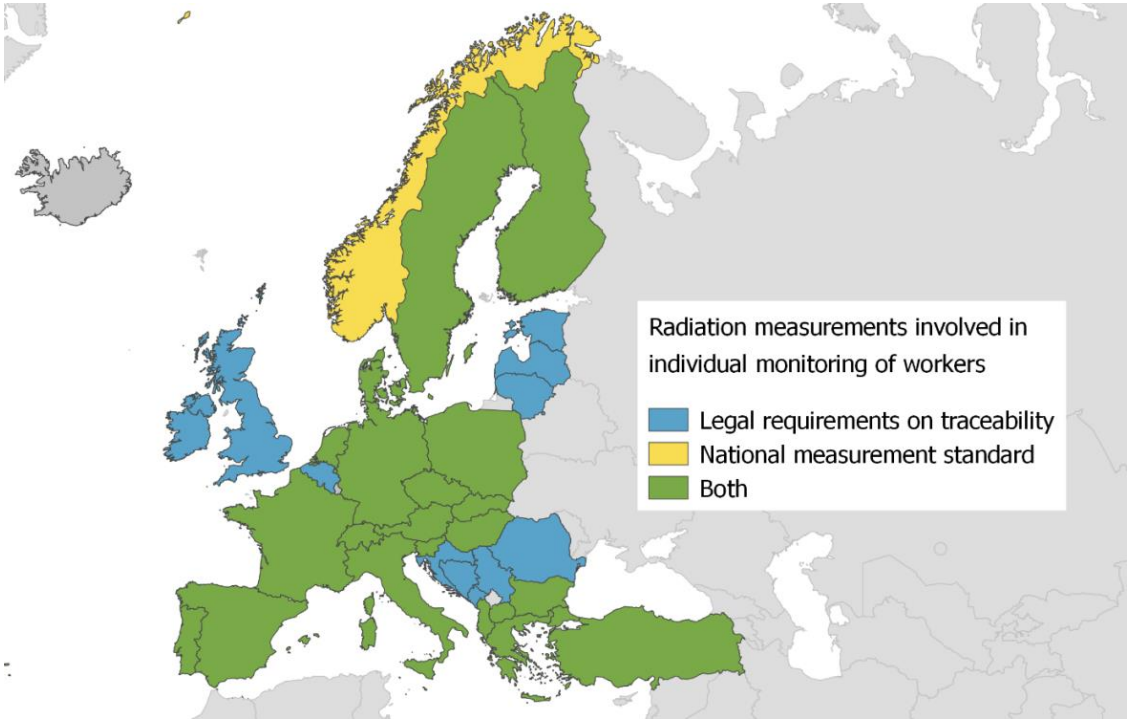
(a) Monitoring and measurements of parameters are performed as necessary for verification of compliance with the requirements of these Standards;

(b) Suitable equipment is provided and procedures for verification are implemented;

(c) Equipment is properly maintained, tested and **calibrated at appropriate intervals with reference to standards traceable to national or international standards**;



The countries with legal regulations (gamma radiation)



From:
Bjerke H, Glavič-Cindro D, Bordy J-M, Cardoso J, Carinou E, Gudelis A, Hupe O, Smyth V. Ionising radiation metrology infrastructure in Europe.
StrålevernRapport 2017:02. Østerås: Statens strålevern, 2017.

The countries with legal regulations (gamma radiation)

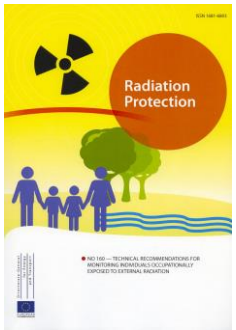
- Most countries have legal requirements for traceability
- Requirements for legal dosimetry are quite different

  ↳ Type testing, traceability, verification

- Requirements for dosimetry services are quite different

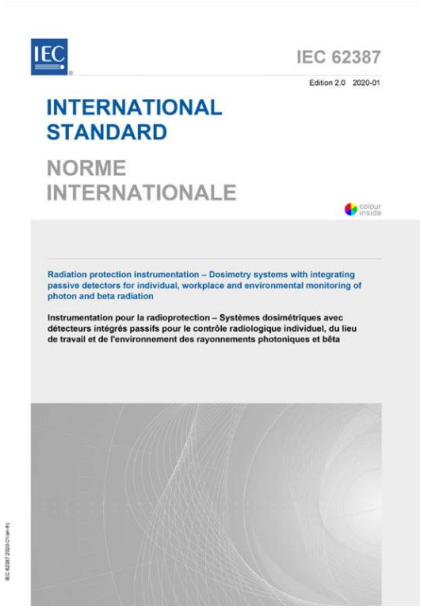
  ↳ Approval criteria are quite different

  ↳ Quality assurance for dosimetry service is quite different



International standards for dosemeters

IEC



IEC 62387

Edition 2.0 2020-01

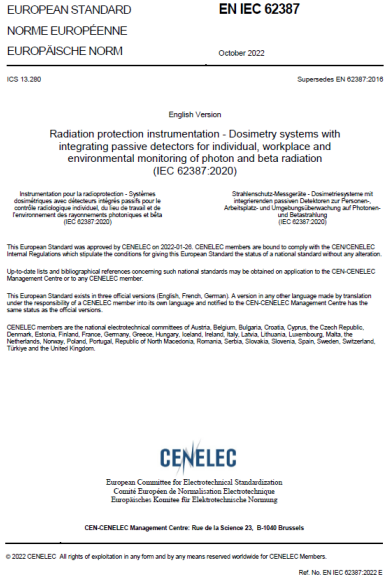
INTERNATIONAL STANDARD

NORME INTERNATIONALE

Radiation protection instrumentation – Dosimetry systems with integrating passive detectors for individual, workplace and environmental monitoring of photon and beta radiation

Instrumentation pour la radioprotection – Systèmes dosimétriques avec détecteurs intégrés passifs pour le contrôle radiologique individuel, du lieu de travail et de l'environnement des rayonnements photoniques et bêta

CENELEC



EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN IEC 62387

October 2022

ICS 13.280

Supersedes EN 62387:2016

English Version

Radiation protection instrumentation - Dosimetry systems with integrating passive detectors for individual, workplace and environmental monitoring of photon and beta radiation (IEC 62387:2020)

Instrumentation pour la radioprotection - Systèmes dosimétriques avec détecteurs intégrés passifs pour le contrôle radiologique individuel, du lieu de travail et de l'environnement des rayonnements photoniques et bêta (IEC 62387:2020)

Strahlenschutz-Messgeräte - Dosimetriesysteme mit integrierenden passiven Detektoren zur Personen-, Arbeitsplatz- und Umgebungsüberwachung auf Photonen- und Betastrahlung (IEC 62387:2020)

This European Standard was approved by CENELEC on 2022-01-26. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CENELEC member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and the United Kingdom.

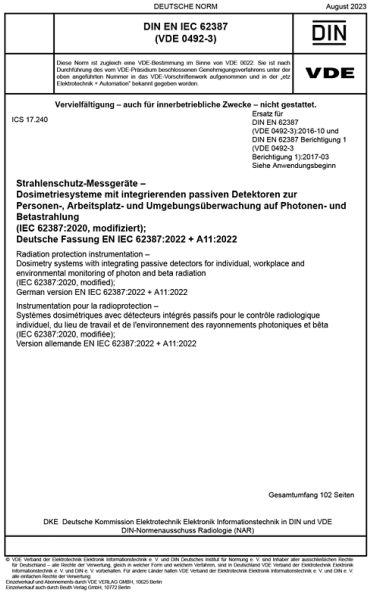
CENELEC

European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

Ref. No. EN IEC 62387:2022 E

national transposition



DEUTSCHE NORM

August 2023

DIN EN IEC 62387 (VDE 0492-3)

DIN

VDE

Diese Norm ist zugleich eine VDE-Bestimmung im Sinne von VDE 0022. Sie ist nach Durchführung des vom VDE-Präsidium beschlossenen Genehmigungsverfahrens unter der oben angeführten Nummer in das VDE-Vorschriftenwerk aufgenommen und in der „etz Elektrotechnik + Automation" bekannt gegeben worden.

Vervielfältigung – auch für innerbetriebliche Zwecke – nicht gestattet.

ICS 17.240

Ersatz für DIN EN 62387 (VDE 0492-3):2016-10 und DIN EN 62387 Berichtigung 1 (VDE 0492-3 Berichtigung 1):2017-03 Siehe Anwendungsbeginn

Strahlenschutz-Messgeräte – Dosimetriesysteme mit integrierenden passiven Detektoren zur Personen-, Arbeitsplatz- und Umgebungsüberwachung auf Photonen- und Betastrahlung (IEC 62387:2020, modifiziert); Deutsche Fassung EN IEC 62387:2022 + A11:2022

Radiation protection instrumentation – Dosimetry systems with integrating passive detectors for individual, workplace and environmental monitoring of photon and beta radiation (IEC 62387:2020, modified); German version EN IEC 62387:2022 + A11:2022

Instrumentation pour la radioprotection – Systèmes dosimétriques avec détecteurs intégrés passifs pour le contrôle radiologique individuel, du lieu de travail et de l'environnement des rayonnements photoniques et bêta (IEC 62387:2020, modifiée); Version allemande EN IEC 62387:2022 + A11:2022

Gesamtumfang 102 Seiten

DKE Deutsche Kommission Elektrotechnik Elektronik Informationstechnik in DIN und VDE
DIN-Normenausschuss Radiologie (NAR)

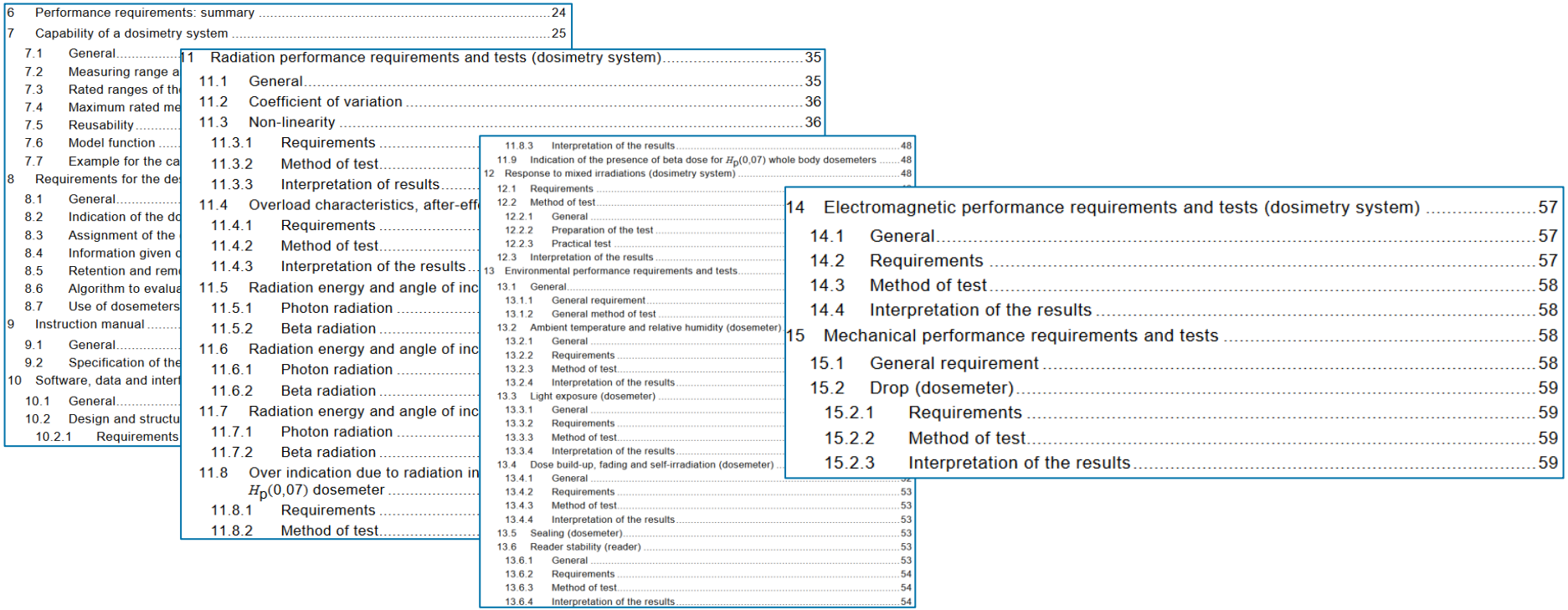
Requirements in the EU?

- What is required for legal relevant measurements in different countries? Compliance with:
  - ➢ IEC or EN or national standards? Full or partially?
  - ➢ National requirements?
  - ➢ ISO 17025 accreditation e.g. for individual monitoring services?
  - ➢ Which version (date) of the standards?
    - ↳ Do updates take affect for existing devices or accreditations?

International standards for dosemeters

- IEC 62387: Radiation protection instrumentation – Dosimetry systems with **integrating passive detectors** for individual, workplace and environmental monitoring of photon and beta radiation
- IEC 61526: Radiation protection instrumentation – Measurement of personal dose equivalents for X, gamma, neutron, and beta radiations - **Active personal dosemeters**
- IEC 60846-1: Radiation protection instrumentation – Ambient and/or directional dose equivalent (rate) meters and/or monitors for beta, X and gamma radiation - Part 1: **Portable workplace and environmental meters** and monitors

Requirements: Example IEC 62387:2020



Requirements: examples

Table 8 – Performance requirements for $H_p(10)$ dosemeters

Line	Characteristic under test	Main characteristics or mandatory measuring range or mandatory range of influence quantity	Performance requirement for the rated range	Clause/ Sub-clause
5	Software, data and interfaces	Authenticity of the software; correctness and integrity of data	To be documented by the manufacturer for the type test and checked during type test	10
6	Coefficient of variation, v	$H < 0{,}1$ mSv $0{,}1$ mSv $\leq H < 1{,}1$ mSv $H \geq 1{,}1$ mSv	15 % $(16 - H / 0{,}1\text{ mSv})$ % 5 %	11.2
7	Relative response due to non-linearity	$0{,}1$ mSv $\leq H \leq 1$ Sv	−13 % to +18 %	11.3
8	Overload, after-effects, and reusability	10 times the upper limit of the measuring range: $10 \cdot H_{up}$, however at maximum 20 Sv. Reused dosemeters shall fulfil the requirements	Perception to be off-scale on the high end side of the measuring range, after-effects may not cause fault measurements and $v(H_{low})$ shall be according to line 6	11.4
9	Relative response due to mean photon radiation energy and angle of incidence	80 keV to 1,25 MeV and 0° to ± 60°	$r_{min} = 0{,}71$ to $r_{max} = 1{,}67$	11.5
10	Relative response due to mean beta radiation energy	0,8 MeV	Indicated value maximal 10 % of $H_p(0{,}07)$ dose equivalent	11.5.2
11	As in lines 9 and 10 but new reference direction opposite to that one used	See lines 9 and 10, if no statement by the manufacturer	See lines 9 and 10, if no statement by the manufacturer	8.4 e)
12	Radiation incidence from the side of the dosemeter	Radiation incidence from α_{max} to $180° - \alpha_{max}$	Indication less than 2 times of indication due to irradiation free in air from the front	11.8
13	Response to mixed irradiations	Irradiation with different radiation qualities	Response within ranges of radiation qualities under test	12
14	Total effect due to environmental performance requirements	Temperature, light, time; for details, see Table 14	See Table 14	13
15	Deviation due to electromagnetic performance requirements	See Table 15	See Table 15	14
16	Deviation due to mechanical performance requirements	Drop; for details, see Table 16	$\pm 0{,}7 \cdot H_{low}$ at a dose of $H = 7\ H_{low}$	15

Table 3 – Angular irradiations for $H_p(10)$ and $H^*(10)$ dosemeters

α	$H_p(10)$ dosemeters (irradiations on phantom, see 5.1.5)	$H^*(10)$ dosemeters (irradiations free in air)
0°	For all radiation qualities whose mean energy fall within the rated range of energy	For all radiation qualities whose mean energy fall within the rated range of energy
± 60°	Three lowest energies in rated range of energy	Three lowest energies in rated range of energy
± 75°	In case $75° \leq \alpha_{max}$: Three lowest energies in rated range of energy, otherwise not mandatory	For workplace dosemeters with $75° \leq \alpha_{max}$ and for environmental dosemeters three lowest energies in rated range of energy
$\pm \alpha_{max}$	Three lowest energies in rated range of energy	For environmental dosemeters three lowest energies in rated range of energy
90°	This test is given in 11.8	For environmental dosemeters three lowest energies in rated range of energy
$\pm (180° - \alpha_{max})$	No test	As for α_{max}, not necessary if the dosemeter is symmetrical
± 105°	No test	As for 75°, not necessary if the dosemeter is symmetrical
± 120°	No test	As for 60°, not necessary if the dosemeter is symmetrical
180°	No test	As for 0° angle of incidence, not necessary if the dosemeter is symmetrical

Requirements: examples

Table 8 – Performance requirements for $H_p(10)$ dosemeters

Line	Characteristic under test	Main characteristics or mandatory measuring range or mandatory range of influence quantity	Performance requirement for the rated range	Clause/ Sub-clause
5	Software, data and interfaces	Authenticity of the software, correctness and integrity of data	To be documented by the manufacturer for the type test and checked during type test	10
6	Coefficient of variation, v	H < 0,1 mSv 0,1 mSv ≤ H < 1,1 mSv H ≥ 1,1 mSv	15 % (16 − H / 0,1 mSv) % 5 %	11.2
7	Relative response due to non-linearity			
8	Overload, after-effects, and reusability			
9	Relative response due to mea... photon radiation energy and angle of incidence			
10	Relative response due to mea... beta radiation energy			
11	As in lines 9 and 10 but new reference direction opposite to that one used	See lines 9 and 10, if no statement by the manufacturer	See lines 9 and 10, if no statement by the manufacturer	6.4 a) c)
12	Radiation incidence from the side of the dosemeter	Radiation incidence from α_{max} to 180° − α_{max}	Indication less than 2 times of indication due to irradiation free in air from the front	11.8
13	Response to mixed irradiations	Irradiation with different radiation qualities	Response within ranges of radiation qualities under test	12
14	Total effect due to environmental performance requirements	Temperature, light, time; for details, see Table 14	See Table 14	13
15	Deviation due to electromagnetic performance requirements	See Table 15	See Table 15	14
16	Deviation due to mechanical performance requirements	Drop; for details, see Table 16	± 0,7 H_{low} at a dose of H = 1 H_{low}	15

Table 3 – Angular irradiations for $H_p(10)$ and $H^*(10)$ dosemeters

α	$H_p(10)$ dosemeters (irradiations on phantom, see 5.1.5)	$H^*(10)$ dosemeters (irradiations free in air)
0°	For all radiation qualities whose mean energy fall within the rated range of energy	For all radiation qualities whose mean energy fall within the rated range of energy
		energies in rated range of
		dosemeters with 75° ≤ α_{max} nmental dosemeters three es in rated range of energy
		ental dosemeters three lowest ted range of energy
		ental dosemeters three lowest ted range of energy
± (180° − α_{max})	No test	As for α_{max}, not necessary if the dosemeter is symmetrical
± 105°	No test	As for 75°, not necessary if the dosemeter is symmetrical
± 120°	No test	As for 60°, not necessary if the dosemeter is symmetrical
180°	No test	As for 0° angle of incidence, not necessary if the dosemeter is symmetrical

Which requirements are tested in every country?
Which requirements are really indispensable?

Requirements on legally relevant software

WELMEC is the European Cooperation in Legal Metrology
It is a regional legal metrology organization with membership composed of the **representative national authorities responsible** for legal metrology in the EU and EFTA countries.

The **Guide 7.2** provides guidance to all those concerned with the application of the Measuring Instruments Directive (MID), especially for software-equipped measuring instruments.
The results are of a general nature and may be applied beyond MID-instruments.

Requirements on legally relevant software


WELMEC Guide 7.2: 2023 Software Guide

Software Guide

(Measuring Instruments Directive 2014/32/EU)

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3

Which requirements and risk levels are needed for radiation protection devices?

Which requirements have to be tested in every country?

Need for harmonized dose monitoring

- The requirements differs from country to country, only the base is the same: the EURATOM treaty
  - ↳ Need: Collection of Status-Quo

- Harder requirements in one country will reduces the availability of dosemeters in that country
  - ➢ Need: Harmonized rules for legally relevant measurements
    - ↳ **Require type testing**

- Type testing requires a large amount of resources but ensures reliable legally relevant measurements
  - ➢ Need: Refined type testing requirements to a common set
    - ↳ **Identify the most relevant requirements**

Ensuring the dose limits

Ensuring the dose limits according the BSS required:

- IMS: Mostly passive dosemeters
- Results are tracked in national dose registers

But: Workers will work in different countries

- ↳ Needs a common dose register
- ↳ Needs electronic dose passport
- ↳ Needs electronic data submission

How to can research and standardization speed up this process?

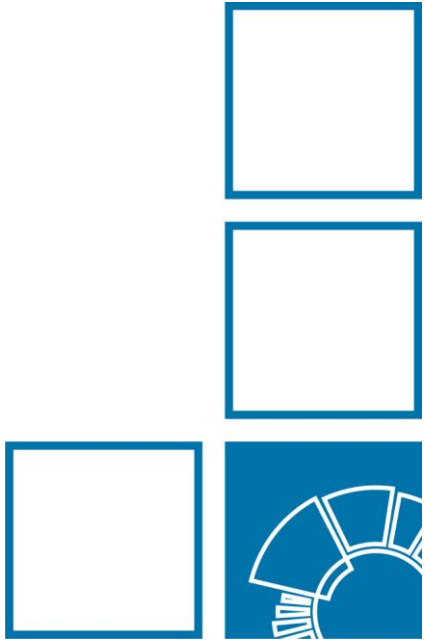
Need for harmonized and applicable Type Test Requirements

Collection of Status-Quo

Harmonized rules for legally relevant measurements

Refined type testing requirements

common dose register
electronic dose passport
electronic data submission



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