



Strahlenschutz made in Germany and
by EURATOM



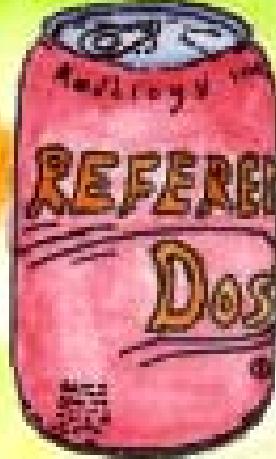
14. Fortbildungsseminar der APT



imprn



Dank an K. Ewen, R. Veit, B. Seidel u.a.!



Zulässigkeitskriterien für medizinischradiologische Geräte – EU Richtlinie?

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Nuclear energy

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Public consultation

Radiation Criteria for Acceptability of Medical Radiological Equipment Used in Diagnostic Radiology, Nuclear Medicine and Radiotherapy, update of European Commission publication Radiation Protection 91, 1997

Consultation period: 25/01/2010 - 20/06/2010

Objectives of the consultation

[Council Directive 97/43/EURATOM on health protection of individuals against the dangers from ionizing radiation in relation to medical exposure](#) stipulates that the EU Member States' competent authorities shall adopt specific criteria of acceptability for equipment in order to indicate when appropriate remedial action is necessary, including, if appropriate, taking the equipment out of service. In order to facilitate the implementation of this requirement in the EU Member States, in 1997 the Commission published Radiation Protection 91: Criteria for acceptability of radiological (including radiotherapy) and nuclear medicine installations (RP 91) [104 KB] . This publication specified minimum criteria for acceptability and has been used to this effect in legislation, codes of practice and by individual professionals throughout the member states and elsewhere in the world.

However, development of new radiological systems and technologies, improvements in traditional technologies and changing clinical/social needs have created circumstances where the criteria of acceptability need to be reviewed to ensure the principles of justification and optimisation are upheld. To give effect to this, in 2007 the Commission initiated a study* aimed at reviewing and updating RP 91, which in due course has led to the development of the present publication.

The final results of the study initiated in 2007 have been presented to the Commission and to the EURATOM Article 31 Group of Experts in mid-2009 and have been judged to be of a very high quality and fully satisfactory to the objectives of the update study. However, following advice from Article 31 Group of Experts, the Commission decided to not proceed with the immediate publication of this document in the Radiation Protection

Richtlinie 97/43/Euratom des Rates vom 30. Juni 1997 über den Gesundheitsschutz von Personen gegen die Gefahren ionisierender Strahlung bei medizinischer Exposition und zur Aufhebung der Richtlinie 84/466/Euratom

Amtsblatt Nr. L 180 vom 09/07/1997 S. 0022 - 0027

CRITERIA FOR ACCEPTABILITY OF RADIOLOGICAL (INCLUDING RADIOTHERAPY) AND NUCLEAR MEDICINE INSTALLATIONS

Radiation Protection No 91

RADIATION CRITERIA FOR ACCEPTABILITY OF MEDICAL RADIOLOGICAL EQUIPMENT USED IN DIAGNOSTIC RADIOLOGY, NUCLEAR MEDICINE AND RADIOTHERAPY

FINAL DRAFT AMENDED-V1.4-091001

To submit your comments, please use the comment form below. Comments should be sent
to TREN-LUX-H4-RADIATION-CRITERIA@ec.europa.eu prior to 30 June 2010.
Consultation period: 25/01/2010 - 30/06/2010

RP91

... Als Ergebnis wurde ein breites Spektrum von Zulässigkeitskriterien für radiologische, strahlentherapeutische und nuklearmedizinische Anlagen entwickelt.

Diese Kriterien sind für die Mitgliedstaaten nicht verbindlich, sollen aber die zuständigen Behörden bei ihrer Aufgabe zur Festlegung bzw. Überprüfung der auch als “Mindestkriterien” bezeichneten Zulässigkeitskriterien unterstützen.

Dabei handelt es sich nicht um

Dieser Bericht wird regelmäßig auf den neuesten wissenschaftlichen und technischen Stand gebracht.

Er gehört zu einer Reihe technischer Anleitungen zu verschiedenen Themen, die die Durchführung der Richtlinie über medizinische Strahlenexpositionen erleichtern sollen.

Objectives of the consultation of RP 162

However, development of new radiological systems and technologies, improvements in traditional technologies and ...

To give effect to this, in 2007 the Commission initiated a study* aimed at reviewing and updating RP 91, which in due course has led to the development of the present publication.

.....but to allow for a public consultation of the draft document, followed by a European workshop. ...

In view of the European Workshop planned for the last quarter of 2010, the Commission is launching this public consultation of the draft publication **Radiation Protection 162: Radiation Criteria for Acceptability of Medical Radiological Equipment Used in Diagnostic Radiology, Nuclear Medicine and Radiotherapy**.

* Dr Keith Faulkner coordinated the overall project and Professor Jim Malone (Introduction and Diagnostic Radiology Lead), Dr Stelios Christofides (Nuclear Medicine Lead) and Professor Stephen Lillicrap (Radiotherapy Lead) coordinated the work in the specialist areas indicated.

Draft RP162

In transposing these European directives into national law, the acceptability criteria required by the MED may be transposed into national law using country specific criteria and approaches.

Zielgruppen

However, the possible audiences for this publication include holders, end users, regulators, industry and standards organizations. It is recognized that each of these has a necessary interest in this publication and its application. It was recognized that the primary audience for the publication is the holders and end-users of the equipment (... **medical physicists,...**).

Definition

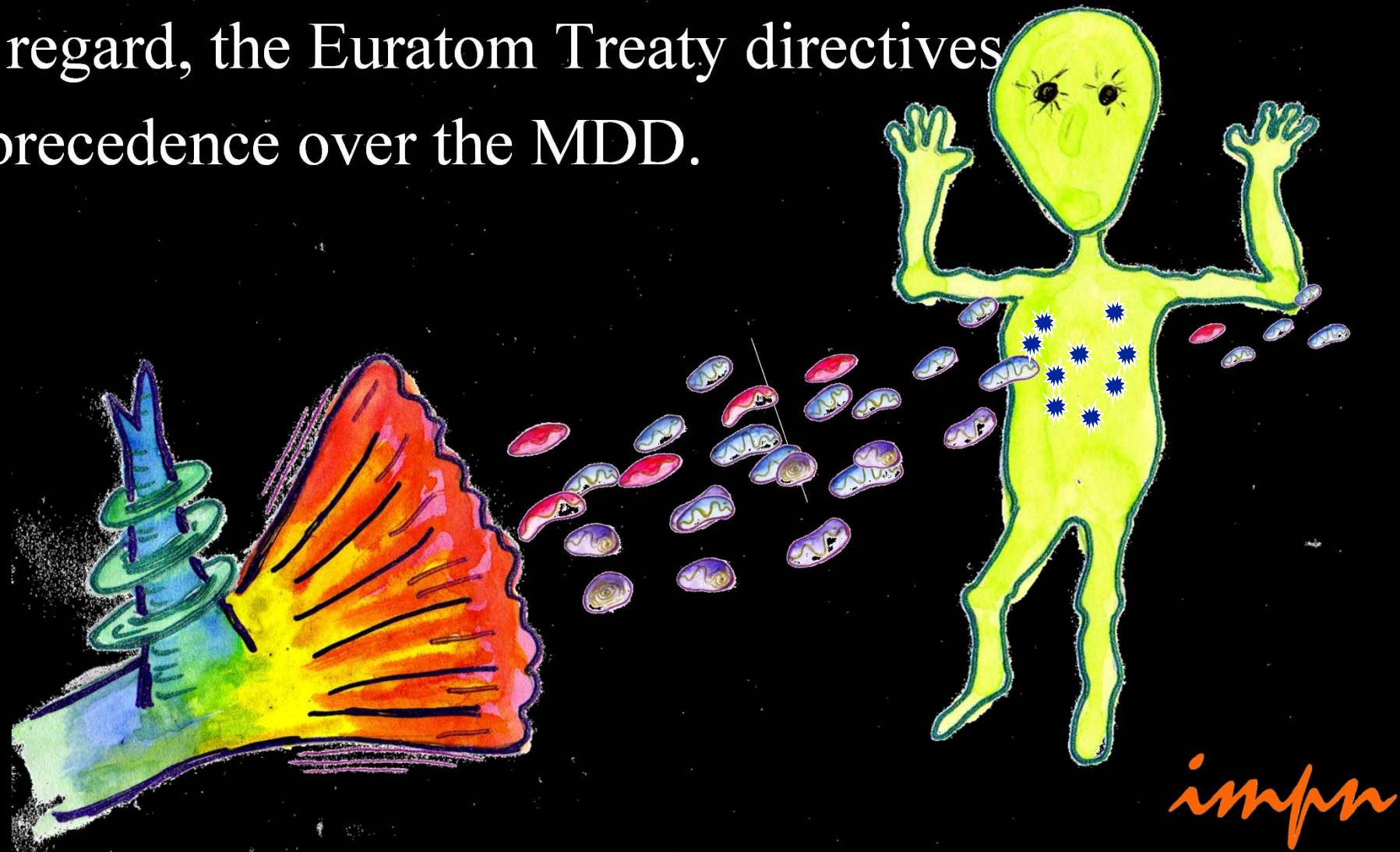
Suspension Levels:

A level of performance that requires the immediate removal of the equipment from use.

Suspension levels are taken as the criteria of acceptability. They must be clearly distinguished from the levels set for acceptance tests.

Draft RP126

In this regard, the Euratom Treaty directives have precedence over the MDD.



impn

SPECIAL CONSIDERATIONS

The directive requires that special consideration be given to equipment in the following categories:

- **Equipment for screening,**
- **Equipment for paediatrics and**
- **High dose equipment, such as that used for CT, interventional radiology, or radiotherapy.**

EXCEPTIONS

... where equipment compliant with safety and performance standards that predate the criteria for acceptability has to be assessed. In such cases, the **MPE** should make a recommendation to the end user or holder, on whether or not this level of compliance is sufficient to meet the intentions of the directive.

DIAGNOSTIC RADIOLOGY

Table 2.9 Criteria of Acceptability for Diagnostic Monitors

Physical Parameter	Suspension Level	Reference	Type
luminance ratio	<200	IPEM (2005a) AAPM (2006a)	B
luminance ratio	Black baseline ±35% White baseline ±30%	IPEM (2005a) AAPM (2006a)	B
Distance and angle calibration – distortion (for CRT)	10%	IPEM (2005a) RCR (2002) SEFM-SEPR (2002)	B
Resolution	Visual inspection low and high contrast resolution different from baseline	IPEM (2005a) AAPM (2006a)	B
DICOM greyscale (GSDF= DICOM Grayscale Standard Display Function)	GSDF ±15%	IPEM (2005a) AAPM (2006a)	B
Uniformity	>40%	IPEM (2005a) AAPM (2006a)	B
Variation between adjacent monitors	>40%	IPEM (2005a) AAPM (2006a) RCR (2002)	B
Room illumination	>25 lux	IPEM (2005a) AAPM (2006a)	B

Art der Kriterien

Type A Criterion

This type of criterion is based on a formal national/international regulation or an international standard.

Type B Criterion

This type of criterion is based on formal recommendations of scientific, medical or professional bodies.

Type C Criterion

This type of criterion is based on material published in well established scientific, medical or professional journals.

Type D Criterion

The Type D situation arises where it has not been possible to make a recommendation.



Table 2.19 Criteria of acceptability for CT Equipment see notes 1-3

Physical Parameter	Suspension Level	Reference	Type	Notes
CTDI, DLP /C _{VOL} , C _w , P _{K,L,CT}	Dose ± 20% of manufacturer's specifications;	IEC (2004a)	A	Accessible protocols ⁴ should be consistent with good practice ⁵ ESPECIALLY for paediatrics.
Accuracy of indicated dose parameters	Dose ± 20% indicated dose		A	
Image noise	Noise ± 25 % of baseline.	IPEM (2005a)	B	
Uniformity	±8 HU	CEC (2006)	B	Value recommended in IEC (2004a) is ±4 HU
CT number accuracy	CT number ± 20 HU (water); ± 30 HU (other material) compared to baseline values	IPEM (2005a)	A	(French standards are ±4 HU nominal or baseline)
Artefact			D	Any artefact likely to impact on clinical diagnosis
Image Display and Printing				See section 2.3
Image slice width	+ 0.5 mm for <1 mm ; ±50% for 1 to 2 mm; ± 1mm above 2 mm.	IEC (2004a)	A	

1 Protocols either programmed in lookup table or in written form.

2 MPE should compare procedure dose levels with appropriate DRLs

3 applicable for equipment manufactured after 2001

CT

IPEM (2005a) Institute of Physicists and Engineers in Medicine. *Recommended Standards for the Routine Performance Testing of Diagnostic X-Ray Imaging Systems, Report 91*. York: Institute of Physicists and Engineers in Medicine.

IEC (2004a) International Electrotechnical Commission. *IEC 61223-3-5 Ed 1.0: Evaluation and Routine Testing in Medical Imaging Departments - Part 3-5: Acceptance Tests - Imaging Performance of Computed Tomography X-ray Equipment*. Geneva: IEC.

Some useful equipment

Radiographic instrumentation

- Calibrated non invasive tube kVp meter (IAEA, 2007a)
- Dosimeter calibrated in terms of air kerma free-in-air with specialized detectors for measurements in different modalities (ICRU, 2005; IAEA, 2007a).
- Indication of current exposure time product (on the x-ray unit or by ancillary equipment).
- Instrument calibrated for measurement of exposure time.

Auxiliary equipment

- Accurate tape measure and steel rule
- Aluminium filters (type 1100, purity > 99%) ranging from 0.25 mm to 2 mm (HDWA, 2000).
- Lead rubber sheet(s).
- Attenuator set and supports
- Radio-opaque grid or equivalent
- Collimation and Alignment tools: **X-ray field mapping device, e.g. radiographic film**, Gafchromic film or equivalent.
- Radio-opaque markers – coins or paper clips.
- Small lead or copper block
- Film Screen Contact Test Tool (Mesh Test Tool).
- Non-mercury thermometer, with a range of 25-40 oC and an accuracy of ± 0.1oC.
- Geometry test object
- High contrast resolution tool (Hüttner 18)

Phantoms

- Standard CT dose phantoms, Body 32-cm PMMA, Head 16 cm PMMA
- CT uniformity (water) phantoms
- Slice thickness phantom; Inclined planes – axial acquisition, Thin disc or bead
- Measurements to assess the performance of DXA units may have to be performed using test equipment, some of which is specifically designed for that purpose
- PMMA phantoms of 10, 12, 15, 18 and 20 cm thickness.
- Standard phantom, e.g.: European Spine Phantom [7, 12], BFP [8]

Tomography

- Test tool (BIR, 2001; IPEM, 1997b).
- Test tool for angle of swing, i.e. a 45° foam pad, pin-hole or other appropriate test tool (IPEM, 1997b)

Instrumentation for light and image display

- Calibrated Photometer for measuring luminance and illuminance.
- Test pattern Image such as SMPTE or T018-QC
- Calibrated Sensitometer with 21 steps or pre-exposed sensitometry strips.
- Calibrated Densitometer, accuracy of 0.01 OD.



Kommentare (DKE/NAR)

Insbesondere im Falle der diagnostischen Radiologie ist es jedoch erforderlich, neben physikalischen Grenzwerten auch die entsprechenden **Messverfahren** anzugeben. Ein reiner Verweis auf Quellen, die oft nicht zugänglich sind, ist nicht ausreichend.

Die Leitlinie sollte generell auf die bestehenden **Europäische Normen** verweisen, in denen die entsprechenden Kenngrößen definiert, ihre Grenzwerte festgelegt und die dazu gehörigen Prüfverfahren beschrieben sind. Das stellt eine klassische Aufgabenstellung für die Normung dar.

Kommentare (BfS)

		2.9	suspension level ">" should precede "GSDF +15%". Comment: Up to now this parameter is not checked in Germany in QA-tests.	line 29-30).
33	35	Table 2.9	For the 2 parameters "Variation between adjacent monitors" and "Room illumination." (rows 8-9 in table 2.9): Comment: according to my knowledge these parameters are not checked in Germany in QA-tests.	
34	36	Table 2.10	For the parameter "Optical density consistency" in the column for suspension level ">" should precede "Baseline". Comment: according to my knowledge this parameter is not checked in Germany in QA-tests.	According to the definition of suspension level (page 13, line 29-30).
35	36	Table 2.11	For all 4 parameters in table 2.11: Comment: according to my knowledge these parameters are not checked in Germany in QA-tests.	
36	37	Table 2.12	For the parameter "Uniformity" in the column for suspension level after "Mammography" "< 30" should be replaced by "> x" (x must be a number < 30)	According to the definition of suspension level (page 13, line 29-30).
37	37	Table 2.12	For the parameter "Variation between adjacent viewing boxes" in the column for suspension level "<" should be replaced by ">". Comment: according to my knowledge this parameter is not checked in Germany in QA-tests.	According to the definition of suspension level (page 13, line 29-30).
38	38	Table 2.13	The minimum specifications for "X-ray tube Nominal Focal Spot" (Bread focus 0,3; Small focus 0,15) and "Compression" (Readout of compression thickness) are not required in Germany.	PAS 1054 requires a nominal focal spot of ≤ 0,4.
39	40	Table 2.15	For the parameter "AEC Thickness Compensation" in the column for suspension level ">" should be replaced by "<" (7x). Comment: this parameter is checked in Germany in QA-tests (PAS 1054) in a different way. Therefore these suspension levels could be too challenging for Germany.	According to the definition of suspension level (page 13, line 29-30).
40	41	8, 12, 13	Comment: up to now tube voltage < 65 kV, non-rectangular collimators and systems without audible exposure indication	



Kommentare (Ewen)

Kommentierung von RP 91 auf der Basis der SV-RL

2. Vergleich zwischen SV-RL und RP 91 (A = Aufnahme, D = Durchleuchtung)

Parameter	Forderung in SV-RL	Stelle in SV-RL	Übereinstimmung mit RP 91
Filterung	$\geq 2,5$ mm Al	01F03	ja (S. 23)
A: kürzeste Schaltzeit	≤ 5 ms	Tab. II, Nr. 6, Anl. I	ja (S. 24)
A: Raster entfernbar in der Pädiatrie	ja	E14 in Anl. I	ja (S. 24)
A: Bildempfängerdosis	5 μGy	Tab. II, Nrn. 5, 6, Anl. I	ja (Tab. 2.2)
A: Zusatzfilter	0,1 mm Cu	Tab. II, Nr. 6, Anl. I	in SV-RL nur für Kinder und nur 0,1 mm Cu (RP 91: Tab. 2.3)
A: Übereinstimmung Licht- und Strahlenfeld	„3/4 %-Regel“	01F10, 03F14	in RP 91 etwas anders formuliert (Tab. 2.3)
A: Übereinstimmung Bildempfänger und Strahlenfeld	„3/4 %-Regel“	01F11, 03F12	nein; RP 91: grundsätzlich keine Überstrahlung (Tab. 2.3)
A: Übereinstimmung Bildempfänger und Strahlenfeld (bei automatischer Einblendung)	„3/4 %-Regel“ (SV-RL unterscheidet nicht zwischen automatischer und nicht-automatischer Einblendung!)	03F11	nein; RP 91: „2 %-Regelung“ (Tab. 2.3)
A: Rastergebrauch möglichst nicht bei Kindern	Raster entfernbar bei Kindern	E14 in Anl. I	ja (Tab. 2.3)
A: Ortsauflösung	$\geq 2,4$ Lp/mm	Tab. II, Nrn. 5, 6, Anl. I	ja ($\geq 1,6$ Lp/mm; Tab. 2.3)
Gehäusedurchlassstrahlung	≤ 1 mSv/h in 1 m (früher nach RöV)	alte RöV	ja (Tab. 2.3)

41. Jahrestagung der Deutschen Gesellschaft für Medizinische Physik



29. Sept. - 2. Okt. 2010 | Freiburg i.Br.

[Impressum]

Heraus Willkommen

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Strahlenschutz / Dosistoptimierung
Zwei-Spektren-CT

MR

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Bildgebungskonzepte: compressed sensing, inverse imaging
MR-Enzephalographie
Molekulare Bildgebung mit hyperpolarisierten Kernen

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2. ANKÜNDIGUNG

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