SAMIRA Study on criteria for acceptability of medical radiological equipment

CARE

(Criteria for Acceptability of Medical Radiological Equipment)

D4.3: Workshop Proceedings

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List of Abbreviations

AAPM	American Association of Physicists in Medicine
BSSD	Basic Safety Standards Directive (Council Directive 2013/59/Euratom)
CBCT	Cone-beam computed tomography
CENELEC	European Committee for Electrotechnical Standardization
COCIR	European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry
EANM	European Association of Nuclear Medicine
EC	European Community
EIBIR	European Institute for Biomedical Imaging Research
EFOMP	European Federation of Organisations for Medical Physics
EFRS	European Federation of Radiographer Societies
ESR	European Society of Radiology
ESTRO	European Society for Radiotherapy and Oncology
EU	European Union
HERCA	Heads of the European Radiological Protection Competent Authorities
IAEA	International Atomic Energy Agency
IEC	International Electrotechnical Commission
IVDR	In Vitro Diagnostic Medical Devices Regulation (Regulation (EU) 2017/746)
MDR	Medical Devices Regulation (Regulation (EU) 2017/745)
MPE	Medical physics expert
PET	Positron-emission tomography
PSQA	Patient-specific quality assurance
RP	EC Radiation Protection Series
SAMIRA	Strategic Agenda for Medical Ionising Radiation Applications
SGQS	SAMIRA Steering Group on Quality and Safety of Medical Applications of Ionising Radiation
SPECT	Single-photon-emission computed tomography
TPS	Treatment planning system

1. Introduction

Since the publication of Radiation Protection (RP) N° 162 in 2012, significant technological and regulatory changes for medical equipment have affected the criteria for acceptability of medical radiological equipment. Given changes in X-ray diagnostic radiology, nuclear medicine, hybrid imaging, radiotherapy and proton therapy, among other fields, an update to this publication is necessary to ensure it aligns with current standards and innovations. An update would be consistent with Council Directive 2013/59/Euratom (Basic Safety Standards Directive, or BSSD), which in Article 60, paragraph 2, mandates that Member States establish criteria for the acceptability of medical radiological equipment, indicating when intervention is required, including the removal of equipment from service. This consortium, combining experts from the European Institute of Biomedical Imaging Research (EIBIR), European Federation of Organisations for Medical Physics (EFOMP), European Association of Nuclear Medicine (EANM), and European Society of Radiology (ESR), will yield an updated publication to ensure that the criteria reflect the latest technological capabilities and regulatory requirements, maintaining high standards of safety and effectiveness in medical radiological practices.

To achieve its specific objectives, the project includes the following elements.

- A study of RP 162, review of relevant literature and survey of national standards regarding acceptability criteria of medical radiological equipment
- A proposal for an updated and extended list of acceptability criteria in line with the current state of technical and equipment standards, methods for assessing relevant technical parameters, and the applicable Euratom and European Union (EU) legal provisions
- A consultation with Member States and other stakeholders on the proposed updated and extended list of acceptability criteria
- A project workshop

The deliverable describes in detail the programme, presentations, discussions and conclusions from the project workshop held on 1–2 June 2026 at the Hotel Parc Belle-Vue in Luxembourg. The consortium presented its research used to draft a document to supersede RP 162 and received vital feedback from stakeholders onsite and online as a final step before preparation of the final report. The consortium was gratified to host approximately 55 onsite and 70 online, representing all EU Member States and many others. The conclusions included below initiated a second round of consultation and will be integrated in the final report.

Workshop date: 1–2 June 2026

Workshop format: in-person meeting, 1.5 days

Venue: Hotel Parc Belle-Vue, Luxembourg

Participating countries: EU27, Norway, Switzerland, Ukraine, Moldova, Serbia, North Macedonia, Türkiye, Israel, Ethiopia, Pakistan, India and representatives of the International Atomic Energy Agency (IAEA)

2. Methodology

2.1 Organizational Aspects

The workshop aimed to present the proposal for an updated and extended list of acceptability criteria developed under WP2 and further consulting Member States and other stakeholders on the same proposal.

The participation of 80–100 persons onsite, including speakers and panellists, was expected, and joining remotely via an EIBIR Zoom webinar was offered to those who were unable to attend in Luxembourg. After a search in late 2025, the Hotel Parc Belle-Vue was selected as host, and it proved an excellent cost-effective venue with state-of-the art equipment for remote participation. The language of the workshop was English.

Budget was allocated for the reimbursement of travel and accommodation expenses for the speakers, panellists and Advisory Board members as well as to cover the costs of the venue and coffee/tea break catering. The workshop costs did not exceed 10% of the total price for all services under the contract. Speakers, aside from the consortium members, were sought at the beginning of the year by formal invitation to the members of the Advisory Board but also the European professional societies where their practice aligns with the session topic. A separate invitation was devoted to participants of the CARE project survey on the use of RP 162 and new national legislation and guidelines involving acceptability criteria, who were asked to share best practices in adopting and implementing acceptability criteria from their Member State.

The exact target groups were aligned with the European Commission (EC) at the beginning of the project and during the first two progress meetings. An online registration form was created in January 2026 to collect registrations of the interested target groups. Participation was only considered accepted following confirmation by the project office. This allowed the consortium to review interested participants in alignment with the EC before confirming their onsite registration to ensure a balanced participation of the desired target groups.

As regards the hybrid format, we followed the strategy that proved effective in prior workshops organised by EIBIR, i.e., to first announce the event as in-person meeting and once the room capacity had been reached allow additional registrants to participate remotely via Zoom webinar. As mentioned above, all registrations were reviewed by the consortium and the EC ahead of confirming onsite participation, so in case of overrepresentation of a country/target group/organisation, excess participants could also be directed to online participation. The envisaged workshop venue’s equipment allowed speakers to give their presentation remotely and interact with the audience in the room. Remote participants, other than those with an active role in the workshop, were muted by default but could interact via the Q&A function of the Zoom webinar, which was monitored by the session rapporteurs and moderators to ensure feedback was addressed.

2.2 Target Groups and Dissemination

The programme of the workshop addressed the following target groups.

- National competent authorities and regulatory authorities
- European and national professional societies
- European and international bodies
- European and international experts in the field
- Standardisation bodies
- Industry (medical device manufacturers)

Workshop-related information was announced to relevant stakeholders through a project webpage on the EIBIR website. Furthermore, specific invitations to the target groups were prepared and specific communication and dissemination activities planned to reach the targeted audience. The following specific outreach to the target groups was envisaged, with regular follow-ups, including through personal contacts to ensure balanced representation of the target groups. Of note, the CARE Advisory Board members as well as the SAMIRA Steering Group on Quality and Safety (SGQS) and Article 31 Working Party on Medical Exposures were invited to join the workshop in alignment with the EC. A save-the-date message was distributed in January 2026 after agreement with the EC and

reviewers regarding the essential details. The EIBIR office confirmed all registrations received and followed up with venue and programme details.

- National competent authorities were reached via the SGQS and Heads of the European Radiological Competent Authorities (HERCA)
- European and national professional societies were reached via the consortium and Advisory Board organisations and their networks of national member societies
- European and international bodies were reached via the Advisory Board
- European and international experts in the field were reached via the networks of EIBIR, EFOMP, EANM, ESR and European Society for Radiotherapy and Oncology (ESTRO) and directly in the case of the IAEA
- Standardisation bodies were reached through the International Electrotechnical Commission (IEC)
- Industry was reached via the European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR) (Advisory Board) and their members

3. Workshop Programme

The workshop programme included presentations by Member States, standardisation bodies and stakeholders as well as discussion panels and sessions allowing for formulating clear and concise workshop conclusions and follow-up. The workshop programme included the results of the work conducted under WPs 1–3.

The workshop programme and presenters were proposed to the EC for approval. Presenters included consortium members, Advisory Board members, member-state representatives, standardisation bodies and other stakeholders as needed.

Confirmed workshop participants received a copy of the draft WP2 document in the latest version available ahead of the workshop following the third progress meeting in May 2026.

The programme is outlined below and notably included opportunities for Member States to exchange experiences and best practices.

Time	Section	Speakers	Rapporteurs
Session 1 – Welcome and Background		**Moderator: Eduard Gershkevitsh**	
13:00–13:30	**1. Opening** • Project objectives • Criteria for acceptability	F. Maksan (EC) M. Brambilla (EFOMP)	N. Peld (EIBIR)
13:30–14:00	**2. Perspectives of invited external bodies** • IEC/CENELEC • HERCA • DG SANTE • COCIR • IAEA	P. Toroi A. Lajunen M. Gabrielli Cossellu C. Drexler V. Gershan	
14:00–15:00	**3. Member State experiences/good practice examples** • Germany • Belgium • Netherlands • Estonia	M. Fiebich F. Dupont J. van de Kamer J. Kepler	

Session 2 – Acceptability Criteria for X Ray Imaging		**Moderator: Laetitia Imbert**	
15:00–15:15	**4. X ray imaging** **– General, digital detectors, dynamic imaging and display systems** • Introduction • Proposed suspension levels • Q&A	M. Brambilla (EFOMP)	R. Pauwels (EFOMP)
15:15–15.30	**5. X ray imaging** **– Mammography** • Introduction • Proposed suspension levels • Q&A	I. Sechopoulos (ESR)	
15:30–16:00	*Coffee/Tea Break*		
16:00–16:15	**6. Dental imaging** • Introduction • Proposed suspension levels • Q&A	R. Pauwels (EFOMP)	I. Sechopoulos (ESR)
16:15–16:30	**7. X ray imaging** **– CT and dual-energy X ray absorptiometry** • Introduction • Proposed suspension levels • Q&A	J. Damilakis (ESR)	
16:30–17.00	**8. Stakeholder views** • ESR • EFRS • COCIR • HERCA • IAEA • IEC	M. Kortesniemi A. England C. Drexler A. Lajunen V. Gershan P. Toroi	
17:00–17:15	**9. Member State experiences/good practice examples** • Ireland/EFOMP	P. Gilligan	J. Damilakis (ESR)
17:15–17:45	**10. Member State/stakeholder perspectives on proposed acceptability criteria for diagnostic & interventional radiology** (open discussion)	All	
17:45–18:00	**11. Summary and conclusions**	M. Brambilla (EFOMP)	

Day 2

Time	Section	Speakers	Rapporteurs
Session 3 – Acceptability Criteria for Nuclear Medicine		**Moderator: John Damilakis**	
9:00–9:15	**12. Nuclear medicine** **– Radionuclide calibrators, well counters and probes** • Introduction • Proposed suspension levels • Q&A	L. Imbert (EANM)	M. Koole (EANM)
9:15–9:30	**13. Nuclear medicine** **– Gamma cameras, SPECT** • Introduction • Proposed suspension levels • Q&A		
9:30–9:45	**14. Nuclear medicine** **– PET** • Introduction • Proposed suspension levels • Q&A	M. Koole (EANM)	L. Imbert (EANM)
9:45–10:15	**15. Stakeholder views** • EANM • EFOMP • COCIR • HERCA • IAEA	K. Bacher L. Brualla González C. Brusasco A. Lajunen M. Carrara	
10:15-10:30	**16. Member State experiences/good practice examples** • Belgium	K. Bacher	
10:30–11:00	*Coffee/Tea Break*		
11:00–11:30	**17. Member State/stakeholder perspectives on proposed acceptability criteria for nuclear medicine** (open discussion)	All	L. Imbert (EANM)
Session 4 – Acceptability Criteria for Radiotherapy		**Moderator: Eduard Gershkevitsh**	
11:30–11:45	**18. Radiotherapy** **– LINACs, CT simulators, megavoltage imaging** • Introduction • Proposed suspension levels • Q&A	O. Blanck (EFOMP)	FA Siebert (ESTRO)
11:45–12:00	**19. Radiotherapy** **– Particle therapy** • Introduction • Proposed suspension levels • Q&A	S. Lorentini (EFOMP)	

12:00–12:15	**20. Radiotherapy** **– Brachytherapy** • Introduction • Proposed suspension levels • Q&A	FA Siebert (ESTRO)	S. Lorentini (EFOMP)
12:15–12:30	**21. Radiotherapy** **– TPSs and dosimetry** • Introduction • Proposed suspension levels • Q&A	E. Gershkevitsh (ESTRO)	
12:30–13:30	*Lunch Break*		
13.30–14.00	**22. Stakeholder views** • ESTRO • EFOMP • COCIR • HERCA • IAEA • IEC	C. Hurkmans L. Brualla González C. Drexler A. Lajunen M. Carrara W. Baus/J. Allen	O. Blanck (EFOMP)
14:00–14:15	**23. Member State experiences/good practice examples** • Spain	P. Almendral	
14:15–14:45	**24. Member State/stakeholder perspectives on proposed acceptability criteria for radiotherapy (open discussion**	All	
Session 5 – Conclusion			**Moderator: M. Brambilla**
14:45–15:45	**25. Open discussion (all topics)**	All	J. Damilakis (ESR)
15:45–16:00	**26. Summary, conclusions, closing**	M. Brambilla (EFOMP) F. Maksan (EC)	

4. Session Summaries

4.1 Session 1: Welcome and Background

E. Gershkevitsh greets the audience onsite and online. M. Brambilla is introduced as the first speaker.

M. Brambilla summarises the CARE methodology, the literature review to scrutinize if new acceptability criteria have been published since the date of RP 162. The organisations who served as sources for literature are displayed. The consortium also conducted a survey of the EFOMP national member organisations to discover how RP 162 has been used and the current guidelines and legislation now in force for medical radiological equipment. The survey showed that RP 162 is widely used and in some countries is used as the sole basis for national legislation. The difference among acceptability criteria, suspension levels and remedial levels in addition to the importance of the BSSD are explained. The consortium also tried to clarify that exceeding a suspension level does not mean the equipment should immediately be taken out of service, but rather a medical physics expert (MPE), the practitioners and undertaking can determine how the equipment can be operated by a risk

assessment or a qualified maintenance service can be asked to restore the equipment. The consortium's preference for deviation absolute levels rather than baselines to express a suspension level and the criteria for the four categories of standards are explained. Exceptions regarding old, for which criteria predate those in the draft publication, and rapidly developing equipment, for which no consensus on suspension levels could be agreed, for inclusion in the draft publication are listed. The methodology to establish conformity with the given suspension levels and the role of the MPE are described. Of importance, a recommended periodicity for testing compliance with suspension levels is not included in the draft publication due to the different requirements for acceptance criteria and remedial levels in a quality control programme. The two phases of consultation and their contribution to the draft publication are explained.

F. Maksan gives context to the project's objectives and its role in the SAMIRA action plan. The legal background of the Euratom Treaty, BSSD and guidance of the RP Series, with an important point on the flexibility of Member States in implementing guidance according to national circumstances and role of the Working Party on Medical Exposures, is explained. The role of various EC directorate-generals and standardisation organisations is explained. The CARE study's role along with other projects under the SAMIRA action plan and the implementation of their results under the AURORad joint action are explained.

P. Toroi presents the perspective of the European Committee for Electrotechnical Standardization (CENELEC) and IEC. The IEC procedure for creating standards is illustrated. The subcommittees authoring guidelines and those relevant to the CARE study are described. The relationship with CE markings is explained in addition to that between CENELEC and the IEC. The IEC serves as an important source for the suspension levels included in the CARE draft publication, and the project's value to the IEC is explained.

A question from online comes from a leader of IEC SC62C/WG1, which is updating the IEC performance standard IEC60976. In the new edition they plan to move away from recommended values for performance, which would oppose the CARE approach. P. Toroi replies she is unfamiliar with this standard but recognises the different approaches by the various IEC committees regarding acceptance criteria and other values. For instance, radiotherapy and dosimetry equipment standards use acceptance criteria and achievable levels. O. Blanck adds the consortium is aware of this work and will take the recommendations into account in the final publication.

A. Lajunen describes the role of HERCA in the drafting of the CARE project publication. Several important points such as the use of a graded approach so that suspension of the device is not regarded as the only option when a suspension level is met. Parameters for testing were requested by several members for inclusion, but the consortium has explained that potential copyright issues and excessive length of the publication are arguments against this approach.

M. Gabrielli Cossellu presents the perspective of DG SANTE as a legal and policy officer in the medical device sector at DG SANTE. Primarily Regulation (EU) 2017/745 (MDR) and 2017/746 (IVDR), covering medical devices and in vitro diagnostic medical devices respectively, govern manufacturing and entry to market. Harmonised standards for medical devices are developed by standardisation requests to CEN and CENELEC, a practice that has been proposed to extend until 2028. The CARE publication should conform with the requirements for protection against ionising radiation contained in the MDR.

C. Drexler presents the perspective of COCIR as another Advisory Board organisation. The industrial members of COCIR welcome the work of the study and an update of RP 162- The leadership of the European professional societies who have contributed experts to the consortium is applauded, and strong collaboration is anticipated until the project's conclusion. It is noted that medical systems are becoming more complex and software-

driven to open new opportunities in care, and new standards and harmonised procedures are essential to integrate new technologies. One recommendation is to increase the length of the introductory texts to ease implementation. The differences in terminology must also be clear, which has been addressed in the latest draft.

V. Gershan finishes the panel of organisations with the perspective of the IAEA. The IEC's acceptability criteria are recommended for adoption, which befits its use as a prominent source by the CARE consortium. Three examples of accidents involving various medical radiological equipment are given to illustrate the importance of acceptability criteria. Each is discussed in detail in IAEA publications.

M. Fiebich gives an overview of acceptability criteria in Germany, beginning with the use of the ALARA principle and the components of the national quality management system, including regular examination and inspection. Acceptance test requirements are listed, and the role of the authorised expert inspection and basis in international and national standards is described. Medical office oversight, legal conditions and IEC standards are also a part of this framework. Mostly international standards are used for test procedures, but if no tolerances are stated in international standards, they are supplied by federal quality assurance guidelines and national standards.

F. Dupont describes the situation in Belgium, where the expertise of MPEs is separated according to the three CARE study clinical areas, although all are represented by the Belgian Hospital Physicists Association. The Belgian Federal Agency for Nuclear Control provides the regulatory authority and technical regulations. MPEs may waive a test or accept a failed criterion when justified, which is essential for novel systems not yet covered by regulation. The Belgian Hospital Physicists Association can suggest changes and is regularly consulted in new regulations. In radiotherapy, very few legally defined acceptability criteria are enforced; thus, the MPE is fully responsible for ensuring fitness for purpose based on international guidelines from, e.g., IEC, American Association of Physicists in Medicine (AAPM) and Netherlands Commission on Radiation Dosimetry.

J. van de Kamer gives an overview of the Dutch quality assurance process, beginning with the strict licensing of MPEs, with formally requiring renewal every five years in preparation. The Dutch Association of Clinical Physics and Federation of Medical Specialists defines field standards and enjoy strong relations with the Ministry of Health, Ministry of Labour and Authority for Nuclear Safety and Radiation Protection for legal enforcement. Flexibility and trust are seen as components for hospital-driven innovation. The Netherlands Committee on Radiation Dosimetry is a Dutch/Belgium consortium with representatives of MPEs, physics assistants, radiation therapists, the Dutch metrology lab VSL, and specialists in radiotherapy, radiology, nuclear medicine, radiation safety, radiobiology and hospital pharmacy with a strong role in developing radiotherapy protocols, befitting the strong MPE in radiotherapy with broad access to linacs and other equipment. Subcommittees and risk analysis, respectively, are begun to address new technologies and procedures. A comparison of Netherlands Commission on Radiation Dosimetry and RP 162/CARE criteria demonstrates compliance with many examples of stricter national limits. A question remains that the variation of stricter demands may lead to quality differences between hospitals, and it is recommended to the describe the responsibility of the MPE and medical doctor.

J. Kepler gives the regulatory background in Estonia, where the national regulation requires compliance with national standards or, in their absence, the guidelines of the EC RP Series. A working group of nuclear medicine practitioners has started to develop national standards, but RP 162 is largely used as the reference document for equipment acceptability criteria. Only three positron-emission tomography (PET) systems are installed, and no currently accredited testing laboratories operate in Estonia, e.g., so an international common standard is welcome. The national medical physics society certifies

MPEs, who participate in acceptance testing and quality management. A license specifies a 2-year interval for periodic performance testing for radiation equipment and 3 years for dental inter-oral. Some RP 162 tests have been adopted for the national situation, and several standards for image quality are in effect, but the harmonisation, traceability, clarity and support for safety culture of the publication are appreciated. An update should consider the evolution of technology as well as the practical feasibility within the clinical workflow by more explicit minimum requirements, expert interpretation of measurements and the need for proportionality among large and small facilities and new and old equipment.

4.2 Session 2: Acceptability Criteria for X Ray Imaging

Aims of the session

The aim of this session was to present and discuss the current draft of the document for general radiography, digital detectors, display systems, mammography and computed tomography.

Summary of presentations

2.4 "X ray imaging – General, digital detectors and display systems" - M. Brambilla

For general radiography, film/screen systems were removed from the updated document, where for computed radiography, levels from RP 162 were unchanged. Other changes were presented in a general sense, e.g., 'what is new' or 'what has changed,' as it is not feasible to show and discuss each value. Focal spot-based levels were removed. Leakage radiation was removed from the current draft, as it was found that the measurement of this metric could potentially cause damage to the system. A new level for dose–area product linearity was introduced, as this was found to be important to ensure patient safety. Several other levels were either updated or left unchanged.

Criteria for automatic exposure control were updated to reflect recent IEC, AAPM and Australasian College of Physical Scientists and Engineers in Medicine documents.

For digital imaging receptors, several image quality parameters were removed, as it was found that it was not feasible to define common criteria sustained by evidence.

Criteria for medical imaging displays were introduced for the first time; these are type A/B levels from IEC and AAPM, respectively.

For dynamic systems, all criteria for general radiography apply, but specific criteria apply as well. Image receptor air kerma was removed due to a lack in consensus on how to implement this.

A new section with criteria for dosimeters used in X-ray imaging was introduced. In RP 162, this was only included for radiation therapy.

The discussion focused mostly on dosimetry, highlighting certain challenges on how to implement dosimeter tests, harmonisation of dose–area product units, and discrepancies between reference radiation qualities and actual X-ray beams. A question was also raised regarding the overall level of suspension in Europe, and perceived differences between law and practice, although it is not possible to provide a specific answer on this.

A general clarification was made regarding the status of the document: comments can still be received until the end of June and are likely to lead to further changes. Beyond that point, only minor changes will be possible.

2.5 "X ray imaging – Mammography" - I. Sechopoulos

For mammography, similar to general radiography, screen-film systems were removed from the document, whereas computed radiography is discouraged with reference to RP 162 for specific suspension levels. Stereotactic biopsy tables were removed, as their assessment would fall outside of the responsibilities of the medical physicist.

For digital breast tomosynthesis, a separate table was added, superseding other criteria.

It was found to be too early to add contrast-enhanced mammography, considering the variety in approaches used, despite the modality being established. Breast computed tomography was not added due to its rarity.

In terms of suspension levels, molybdenum-tube criteria were removed, as there are a few still in use. Similar to general radiography, focal spot criteria and leakage radiation were removed.

IQ was removed due to a lack of consensus, but due to feedback will be restored with an alternative method that does not depend on a specific phantom.

Several suspension levels were added, with reference to IEC, EFOMP and IAEA documents.

During the discussion, a question was raised about the lack of specific criteria for dose in digital breast tomosynthesis. This criterion should be the same as in mammography, citing the EFOMP protocol, which will be clarified in the next iteration of the document.

A question was raised regarding the removal of leakage radiation. It was decided after consultation that this should only be done at acceptance due to potential damage during the measurement.

2.6 "Dental imaging" – R. Pauwels

The text relevant to dental systems will refer, outside of the dental section, only on half-value layer; all other text and levels relevant to dental are contained in the dental section. Changes were made after the consultation period to list of unacceptable equipment, including moving text about handheld intraoral equipment from the suspension level table to this section.

Main sources for suspension levels were recent IEC documents specific to dental systems. The levels that were removed, added, updated, and unchanged were reviewed.

Handheld equipment use was clarified in addition. Changes for intra-oral equipment and cone-beam computed tomography (CBCT) were reviewed. Leakage radiation measurement may be revisited based on internal discussion. For dental imaging, there are several areas in which DRLs have been published but not suspension levels. Image quality levels were removed due to, e.g., qualitative or variability reasons.

Q&A:

- Czech regulatory authority representative comment: tried to forbid intra-oral devices with circular collimation but gave up after a decade of attempting this. This was inserted in legislation and controlled, but the dentists still used it, having a rectangular collimation only for quality control. It is hence practically impossible to regulate out circular collimation. This regulation makes the collaboration with the users difficult for this and all other regulations.
    - Answer: This is a common experience; the only way to achieve this is for IEC to introduce this, then the manufacturers would have to remove this option. This is a justified change, since circular collimation is substantially higher dose. Better education for the next generation would be better.

- Paula Toroi, IEC: The IEC standard states that rectangular collimation "should" be used, not "shall".
- Dutch Association of Clinical Physics representative: The customers need to ask for rectangular collimation. That is, set in the tender specifications that the systems need to have rectangular collimation.
    - Answer: That would be good, but the dentists, who are the clients, don't ask for it.

- Moldovan representative: The suspension levels should be set for the manufacturers not for the users. Shouldn't film-based dental be excluded completely?
    - Answer: Some sites still use film, even in the European Union.

After the meeting, R. Pauwels, A. Lajunen, P. Gilligan and representatives from Czechia and Moldova met and determined the following.

- The complete exclusion of circular collimation will be reverted, likely kept the way it was stated in RP 162, since it is not realistic to ban it altogether; the responsibility for enforcing this is elsewhere.
- Complete exclusion of film is still up for debate. P. Gilligan shared that he still encounters film, albeit rarely, and film is in fact still sold on the market. The report may follow the example of general radiography, i.e., explain in the introductory text that dental suspension levels for film are no longer reported, but not explicitly mention it in the box as an obsolete equipment.
- Removal of dose display: Based on discussion with A. Lajunen and representative from IEC, we will most likely revert this, although we cannot overrule the very lenient suspension level that IEC has unless we find a reference that is at least Type B (the best we can do is add a comment pointing to general radiography and computed tomography).
- Removal of dosimetry, especially for intra-oral: Unless a reference is found for a lower level than the 'classic' 4 mGy, we will likely reintroduce the level of 4 mGy, with a comment that lower levels may be feasible, so basically the same it was in RP 162. P. Gilligan shared a document showing that the 95th dose percentile in the UK is 2.2 mGy, but this is very unlikely to reflect the rest of Europe.

<u>2.7 "X-ray imaging" – J. Damilakis</u>

For computed tomography, a dual approach is taken for computed tomography dose index to ensure that deviations are clinically relevant. Notes have been added on levels that have not changed, only for clarification. Computed tomography number accuracy: deviation was >10% in water HU up to 30 cm, but now it is revised to being protocol-based. Computed tomography light suspension level differentiates between XX and YY. Spatial resolution was shifted to "high contrast spatial resolution" and uses a modular transfer function. Material density quantification accuracy has been added for information only, not current level yet.

Considering dual-energy X-ray absorptiometry, the entrance surface is updated to not include backscatter. X-ray generator levels unchanged. Moved to framework proposed by AAPM and American College of Radiology to consider equipment drift, so the new suspension level uses historical quality control data.

Q&A:

- P. Toroi: Comment on tube voltage/kV meter. The level comes from the AAPM. Non-invasive measurements involve knowing the spectrum, which we don't know necessarily know.

  - Answer: If the meters are used properly, the meters come with system-specific correction factors, and hence it is possible to calculate the kV accurately (<3%). It is up to the MPE to understand their equipment's uncertainty and determine what their measurement means.
  - A note will be added about the proper use of the tools for this measurement.

- K. Bacher: I concur with P. Toroi: the measurement and calibration of these devices are not perfect nor simple. The criteria for measuring kV in computed tomography/mammography/radiology are prone to higher uncertainties and the report should provide instructions on how to use them correctly.
  - Answer: Agreed, but these are important measurements, especially in pediatric.

- P. Toroi: There is an IEC standard on multimeters.
- Czech Republic representative: Continuing the kV discussion: why do we need to measure the kV? Does it bring any additional information? A kV problem will appear in the other tests, and considering the difficulty of kV measuring, then better to keep only the other tests.
  - Answer: Yes, all these parameters are interconnected, but then we only need a very short list of parameters that include many reasons. And an MPE should be able to do the test correctly, and this is the role of the MPE.

- M. Bambrilla: Dosimeters in mammography also need and have different calibration factors, and adding this requirement in RP 162 promoted the right development of these conversion factors for multi-meters. And it is not true that necessarily a deviation in kV can be spotted in a different measurement.
- COCIR representative: Computed tomography manufacturers see problems in making this a hard requirement. Non-invasive meters make this measurement assuming spectrum shape, and the meters may not have the right spectra if the spectrum models are not available. We challenge that this measurement is required; kV does affect dose, but we measure computed tomography dose index and other dose metrics and therefore can be addressed this way.
- A. England, EFRS: Asked whether 3D positioning cameras in computed tomography systems were considered.
  - Answer: CARE did not consider this and received no comment on this but have added a suspension level on laser positioners.

2.8 "Stakeholder perspectives" – Various

M. Kortesniemi, ESR, presented on the importance of acceptability criteria and updating RP 162 to account for new criteria and technology to diagnostic and interventional radiology, which are included in the presentation.

A. England, EFRS, presented on the EFRS perspectives on the draft report, which are included in the presentation.

P. Toroi, IEC, rather than giving a presentation, mentioned comments from the IEC.

- When they are part of the system, kerma–area product meter accuracy should be changed to ±35% to be consistent with IEC standard. Also, these meters are highly energy-dependent, so ±35% is too strict.
- Mammography: Uniformity test should be done without polymethyl methacrylate since this introduces another variable.

- Mammography: Repeated tube voltage accuracy for mammography: Not needed to be repeated for different filters, only for one, since tube voltage does not change with different filters.
- Mammography: Image receptor response function for mammography: Checking response function according to the IAEA should be enough.

A. Lajunen, HERCA, presented on the HERCA perspectives on the draft report.

V. Gershan, IAEA, presented on IAEA-related publications and then provided comments on a number of sections and proposed levels, which are included in the presentation.

2.9 "Member State experiences/good practice examples" – P. Gilligan (Ireland/EFOMP)

The presentation initially focused on the critical task of establishing and implementing acceptability criteria for medical imaging equipment across European member states. An objective of his talk was to examine the implications of the mandate requiring states to adopt specific criteria to determine when corrective actions, including taking equipment out of service, are necessary. He framed the discussion around whether these 'suspension levels' reflect equipment quality and how they impact patient safety.

The speaker emphasized the role of the EFOMP in promoting RP 162, which has become a foundational standard for quality management systems throughout the EU. He noted that RP162 is now directly integrated into the core curriculum for training MPEs in diagnostic and interventional radiology. However, he highlighted a significant challenge: a shortage of MPEs in Europe, a situation that becomes increasingly acute in Eastern Europe. This shortage complicates the delivery of mandatory acceptability and safety criteria.

Furthermore, the speaker advocated for viewing these technical standards through an ethical lens. He argued that the document must promote "doing good and avoiding harm" while ensuring justice and fairness in the distribution of the advantages and disadvantages of bringing in new criteria. The ultimate goal is to serve the dignity of patients by delivering safe equipment that performs according to clinical needs through tests that are proportionate and justified.

A significant portion of the talk was dedicated to the 'Irish experiment,' drawing on the speaker's career and the work of his colleagues. Historically, Ireland relied heavily on the UK's approach, which combined testing methodologies with tolerances. Currently, Irish regulatory authorities, such as the Health Information and Quality Authority, focused on patient protection, and the Environmental Protection Agency, focused on staff and public protection, refer directly to RP 162 and other international standards.

The speaker shared a cautionary tale regarding the legislative implementation of criteria. In 1998, Irish parliamentarians attempted to write specific criteria directly into law but mistakenly listed units as mGy instead of µGy, creating an error that remained in legal force for years. This example served to argue that it is safer to have dynamic references to carefully considered professional standards rather than static, potentially erroneous, legislative text.

In his personal experience, the speaker noted that equipment suspensions are rare due to modern reliability, but they are often clear-cut when they do occur, particularly in the dental sector. He cited extreme examples of mechanical drift in dental X-ray units, where machines were so unstable that staff had to hold them in place or patients had to lie on stools while the unit 'swung by' during exposure. He also addressed the pressure on field-based physicists who must test a wide variety of equipment from different vendors under tight clinical schedules while maintaining high reproducibility and minimum uncertainty.

2.10 "Open discussion"

The discussion opened with a comment regarding the removal of incident air kerma and dosimetry aspects in dental imaging criteria. R. Pauwels responded that these values were removed primarily because of the difficulty in finding updated, referenced values. It is better to omit a value than to 'come up with a new value out of thin air' without a solid scientific reference, though having a sensible dosimetry value would ideally improve patient safety.

A participant from Portugal raised concerns about the time required to perform these tests, especially in small facilities with only one X-ray machine. Taking a room out of action for several hours for testing has a direct negative impact on patient availability. The participant also questioned the rigidity of criteria, noting that some failures, such as minor uniformity issues, might not actually impact clinical image quality. He argued for a distinction between critical and non-critical levels so that equipment is not unnecessarily authorized for removal from service when clinical images remain unaffected.

Further technical points were raised by audience members regarding specific imaging modalities. M. Carrara noted that kV measurements in computed tomography remain a 'methodologically unsolved issue' and suggested that the report should include an introductory paragraph framing these complexities for educational purposes. He also pointed out the absence of image quality levels in breast radiology, noting that it is difficult to provide standardized levels because of the wide variety of different phantoms used across the field.

The integration of artificial intelligence was another topic of interest. While speakers agreed it might be too early to set specific performance levels, M. Carrara suggested that the report's introductory sections should mention its entry into the field and explain why it is currently excluded from the criteria. Moreover, he pointed out the omission of IAEA TRS 457, a code of practice for X-ray imaging dosimetry, and recommended its inclusion to guide medical physicists in their measurements. Finally, there was a request for the document to clearly define a transition period between previous and the new standards to assist regulatory bodies in updating legislation.

2.11 "Summary and conclusions" – M. Brambilla

In the final summary, M. Brambilla addressed several recurring misconceptions. He emphasized that the consortium is not "ideologically against" image quality criteria; rather, they lack the specific, non-uniform references needed to include them in a straightforward way. He invited the community to provide referenced suggestions for inclusion.

M Brambilla clarified the definition of suspension levels. He explained that suspension levels are not intended for periodic quality control. While this is a periodic task established by an MPE to monitor performance, suspension levels are meant to be assessed when an MPE suspects something is going wrong or when equipment is nearing its end-of-life. He stressed that MPEs do not need to check all criteria periodically, only those suspected of failing.

Regarding the impact on clinical service, it was clarified that suspension does not mean the only option is to stop using the machine. The document allows for a risk assessment as an alternative approach. For instance, if a detector has a uniformity issue that does not impact the clinical image, an MPE can perform a risk assessment to keep the machine in service for a limited time while waiting for a service technician to arrive, rather than immediately halting patient care.

Finally, acknowledging the desire for a comprehensive methodology guide for every test, M. Brambilla explained that the current project's scope, funding and time were limited.

Instead of rewriting existing methodologies found in IAEA, EFOMP or other documents, the project aims to provide a living document with links to these external, freely available resources. He concluded by thanking the participants for their lively discussion and noted that all objections would be considered during the next round of consultation.

Overall conclusions and suggested follow-up actions

Aside from the changes described above, which will be implemented in the final draft, further feedback is welcomed, but suggestions for changes should be specific and accompanied by a reference.

4.3 Session 3: Acceptability Criteria in Nuclear Medicine

Aims of the session

The nuclear medicine session addressed how the revision of the RP 162 criteria for acceptability of medical radiological equipment document should reflect current technology, clinical practice, and regulatory needs, including hybrid imaging, quantitative single-photon-emission computed tomography (SPECT) and PET, new therapeutic radionuclides, radionuclide calibrator traceability, and the role of the MPE.

Summary of presentations

During these sessions addressing radionuclide calibrators, well counters and probes as well as gamma cameras and SPECT, PET, stakeholder views, the Belgian Member State experience and the open discussion, participants broadly supported the revision, while stressing that the document should clearly distinguish between acceptance testing, routine quality-assurance action levels, and true suspension levels/acceptability criteria. A recurrent message was that suspension decisions should not be based solely on numerical thresholds, but also on a risk assessment considering both the technical and clinical impact.

3.12 “Radionuclide calibrators, well counters and probes” – L. Imbert

The proposed revision for radionuclide calibrators focused on criteria that are clinically meaningful and traceable over the equipment life cycle. For radionuclide calibrators, the main criteria discussed included background, daily constancy, and geometry dependence. Geometry dependence was considered particularly relevant at acceptance testing, but since it should not change substantially during the life cycle of the device, it was considered less relevant as an acceptability criterion.

A specific technical point was raised concerning the background criterion for radionuclide calibrators, where the limit should be expressed in terms of activity rather than count rate. In addition, the recently published IEC report on radionuclide calibrators should be mentioned in the introduction to the radionuclide calibrator section of the CARE document and explicitly reflected in the tables defining criteria and suspension levels.

For well counters and probes, the proposed quality criteria included energy peaking, energy resolution, background count rate, and reproducibility or precision. The discussion underlined the need for traceable calibration sources, especially as nuclear medicine increasingly uses new diagnostic and therapeutic radionuclides. Participants also requested more guidance on how to measure each parameter, including information on the measurement set-up, analysis method, and uncertainty considerations. It was also noted that a generic suspension threshold of more than 10% may be difficult to apply across all radionuclides and calibrator geometries, and that radionuclide-specific guidance may therefore be required. In general, more guidance on specific suspension levels for beta- and alpha-emitting radionuclides was considered desirable, particularly for new therapeutic applications.

3.13 "Gamma cameras and SPECT" – L. Imbert

The gamma-camera and SPECT discussion focused on ensuring that the revised acceptability criteria reflect current equipment and clinical use. Key technology developments that were mentioned included cadmium-zinc-telluride detectors, hybrid SPECT–CT, advanced reconstruction methods, and the expanding role of ^{177}Lu SPECT in supporting therapeutic applications. More specifically, the clinical importance of quantitative SPECT was emphasized, particularly because SPECT activity estimates are increasingly used as a basis for absorbed dose assessment and treatment verification.

The proposed additions include whole-body uniformity and whole-body scan speed, in addition to system planar resolution and sensitivity. For reconstructed SPECT images, recovery coefficients were discussed as potential criteria, but with the important qualification that these should be linked to reconstruction protocols used in clinical practice.

For hybrid SPECT–CT systems, the computed tomography component should be explicitly cross-referenced to the computed tomography chapter. A possible distinction was discussed between diagnostic computed tomography and low-dose or auxiliary computed tomography, with the latter primarily used for attenuation correction or anatomical localization. However, because no clear and generally accepted definition of the different computed tomography modes is currently available, the consensus was that it would be challenging to distinguish between computed tomography types at this stage. Therefore, all computed tomography scans should currently be considered under the computed tomography chapter, with indication-specific optimization left to the local MPE.

Additional comments addressed the need for the revised document to more clearly define the relationship between nuclear medicine suspension levels and indication-specific image-quality requirements, like the way diagnostic reference levels are clinically defined depending on the device and clinical application. In this regard, more detailed guidance was requested on the clinical relevance of quantitative accuracy thresholds.

3.14 "Gamma cameras and SPECT" – M. Koole

The proposed PET update highlighted the need to incorporate major technological innovations that have emerged since the publication of RP 162. As such, the revised introduction will include time-of-flight PET, digital SiPM detector systems, and long axial field-of-view PET. It also considers that PET-only systems are currently no longer available on the market, such that only hybrid PET–CT systems were considered.

The presentation proposed moving away from physical parameters used at acceptance testing as suspension criteria. Instead, recovery coefficients were proposed as a more clinically relevant metric than spatial resolution, especially in the context of resolution modelling and iterative reconstruction. This approach aims to align acceptability criteria more closely with image quality in clinically reconstructed images.

During the discussion, it was emphasized that the reconstruction parameters used in clinical practice should be considered when defining or applying criteria such as recovery coefficient values. Stakeholders also suggested that PET sensitivity and spatial resolution should at least remain part of acceptance testing and performance documentation of PET–CT systems.

3.15 "Stakeholder views" – Various

Speaking on behalf of EANM, K. Bacher expressed support for the proposed update of RP 162. He welcomed the incorporation of recent developments in nuclear medicine, including the use of radionuclide calibrators for new therapeutic isotopes and the increasing importance of SPECT activity quantification for dosimetry and treatment planning. EANM supported harmonized suspension levels and the proposed update of suspension criteria.

At the same time, EANM identified several limitations requiring further work, including the need for specific suspension levels for beta- and alpha-emitting radionuclides, where a general suspension level of >10% could prove challenging to apply across all radionuclides. In addition, more extensive guidance on how parameters should be measured would be welcomed, as would more detail on the evaluation of activity quantification and attenuation correction. EANM also raised the question of whether all diagnostic computed tomography requirements should be applicable to hybrid SPECT–CT and PET–CT systems. Finally, software upgrades and artificial intelligence were not considered within the scope of the current revision, but this exclusion should be made clear in the introduction.

Luis Brualla Gonzalez, EFOMP, placed the revision in the context of the BSSD and the responsibilities of competent authorities. The central role of the MPE was emphasized, with the MPE supporting equipment performance management, risk assessment, and clinical decision-making. Acceptability criteria should therefore support, rather than replace, the professional judgement of the MPE.

EFOMP welcomed the justification for revising RP 162 but requested further clarification in several areas. These included the limited accessibility of IEC standards, the concern that some Category B suspension levels may correspond more closely to quality-assurance action levels than to true suspension criteria, and the need for concise descriptions of each test and its analysis. EFOMP also stressed that, where thresholds are not available, the local MPE should define and document applicable quantitative criteria.

EFOMP further recommended retaining or explicitly addressing PET sensitivity and spatial resolution among the parameters to be considered, adding cross-references to the computed tomography chapter for this component of SPECT–CT and PET–CT systems, and strengthening radionuclide calibrator guidance, including traceability. In addition, relevant artefacts should be described more explicitly, and operational availability or uptime should be considered in relation to patient access. Finally, EFOMP requested that the role of risk assessment and the role of the MPE be clarified throughout the revised document.

A. Lajunen, HERCA, reported that only a limited number of comments had been received from its stakeholder group during the consultation. These were mainly minor comments, which were being incorporated into the revision. HERCA nevertheless welcomed the value of bringing all acceptability criteria together in one document and drew particular attention to the importance of the radionuclide calibrator section.

Marco Carrara, IAEA, presented activities of the Dosimetry and Medical Radiation Physics Section, with a strong focus on metrology and traceability. Ongoing work aims to strengthen traceability capabilities in laboratories, particularly for nuclear medicine. A joint initiative with BIPM CCRI(II) was mentioned as relevant to improving measurement capability and infrastructure. The notes also refer to an update of IAEA guidance on metrology in nuclear medicine and to future work on quality assurance for SPECT systems. The forthcoming 2026 IEC report on radionuclide calibrators was identified as an important reference for the CARE revision.

No specific comments were made by C. Brusasco, COCIR.

3.16 “Member State experience” – K. Bacher, Belgium

The Belgian example highlighted the need for a regulatory framework that is both robust and adaptable. Embedding too much technical detail directly in core legislation can be problematic, because changes to royal decrees are slow and require parliamentary approval. Belgium therefore uses technical rules under the authority of the Federal Agency for Nuclear Control, which can be updated more rapidly after consultation with relevant professional bodies such as the Belgian Society of Nuclear Medicine. This approach allows acceptability criteria to be updated within months rather than years.

The Belgian presentation also emphasized the protected role of the MPE, who is certified by application field, with the possibility of double certification. An internal department of medical physics, with a head who can communicate directly with hospital management, was presented to support the independence of the MPE, provided that sufficient resources are available.

The role of the MPE was described as important in the final decision-making regarding the suspension of medical devices using ionizing radiation. In the Belgian setting, corrective measures within a defined period, such as three months, may be required, while a risk assessment by the MPE may justify how suspension levels are interpreted or, in specific circumstances, overruled. Acceptance testing guidance for medical imaging systems was also discussed, including the need to allocate sufficient time for testing, since this is not specified in legislation, and the use of suspension levels as acceptance criteria. The need to account for combined uncertainty in parameter evaluation was also mentioned, as was the possibility of considering image-quality parameters as both device-specific and indication-specific, by analogy with diagnostic reference levels. Other discussion points included criteria for software, structured dose reporting, requirements for low-dose computed tomography and a code of practice for traceability in nuclear medicine.

3.17 "Open discussion"

The open discussion consolidated several recurring themes. Participants supported the harmonization of acceptability criteria across Europe but also recognized that national implementation must allow sufficient flexibility for local regulatory structures, equipment configurations, and clinical use cases. This is particularly important in nuclear medicine, where new developments in the use of novel radionuclides, hybrid imaging, and quantitative reconstruction make overly rigid criteria vulnerable to rapid obsolescence.

A central point was the need to distinguish between suspension levels, acceptance criteria, and quality-assurance action levels. A suspension criterion should indicate when intervention is required, potentially including removal from service, whereas an action level may trigger investigation, corrective action, or enhanced monitoring. The revised document should therefore avoid presenting all thresholds as equivalent.

The role of the MPE emerged as a unifying principle. The revised criteria should give MPEs a clear framework for documented judgement, including risk assessment, local quantitative criteria where universal thresholds are not available, and clinical context when equipment performance deviates from nominal values.

Overall conclusions and suggested follow-up actions

There was broad support for updating RP 162 to better reflect current nuclear medicine technology and practice, particularly hybrid imaging, quantitative SPECT, long axial field-of-view PET, and the increasing use of new diagnostic and therapeutic radionuclides. Participants agreed that the revised document should provide harmonized acceptability criteria while allowing sufficient flexibility for national implementation, local equipment configurations, and clinical use cases.

A recurrent conclusion was that the revised document should more clearly distinguish between suspension levels, quality-assurance action levels, and acceptance-test criteria. Suspension levels should indicate when intervention may be required, potentially including removal from service, whereas quality assurance action levels may trigger investigation, corrective action, or enhanced monitoring.

For radionuclide calibrators, well counters, and probes, the revision should place strong emphasis on traceability, appropriate units, source characteristics, and practical measurement guidance. The forthcoming IEC report on radionuclide calibrators should be reflected not only in the introductory text, but also in the criteria tables. In particular, the

background criterion for radionuclide calibrators should be reviewed to determine whether limits should be expressed in terms of activity rather than count rate. The document should also provide concise descriptions of the relevant tests, analysis methods, and uncertainty considerations, including information on source type, radionuclide, geometry, and traceability chain.

The feasibility of a generic suspension threshold of more than 10% should be reconsidered, as such a threshold may be difficult to apply consistently across all radionuclides, measurement geometries, and clinical situations. Additional guidance, or at least a roadmap, is needed for beta- and alpha-emitting radionuclides, where specific suspension levels are currently limited or lacking.

For SPECT and PET systems, acceptability criteria should be linked more closely to clinically relevant image-quality metrics and clinically used reconstruction protocols, rather than relying only on physical performance parameters. For SPECT, whole-body uniformity and whole-body scan-speed criteria should be added or clarified. For PET, the revised document should clarify whether recovery coefficients, spatial resolution, and sensitivity should be retained, replaced, or combined, and how reconstructed-image metrics should be related to clinical reconstruction protocols.

Hybrid SPECT–CT and PET–CT systems require careful cross-referencing to the computed tomography chapter. Until a clear and generally accepted distinction is available between diagnostic and low-dose computed tomography and when used primarily for attenuation correction or localization, all computed tomography components should be considered under the computed tomography chapter, with indication-specific optimization left to the local MPE.

Finally, the role of the MPE should be strengthened throughout the revised document. The MPE should be explicitly positioned as the professional responsible for documented local criteria where universal thresholds are not available, risk assessment, uncertainty evaluation, and advice on suspension, corrective action or continued clinical use.

4.4 Session 4: Acceptability Criteria in Radiotherapy

Aims of the session

The aim of this session was to present and discuss the current draft of the document for linear accelerators, computed tomography simulators, kilovoltage units, particle therapy, brachytherapy, treatment planning systems (TPSs) and dosimetry equipment used in radiotherapy.

Summary of presentations

4.18 “LINACS, CT simulators, megavoltage imaging” – O. Blanck

In the report update for linacs the multi-leaf collimator part was expanded. Many items in the tables regarding linacs were updated, e.g., dose monitoring and uniformity of radiation fields. Megavoltage imaging, CBCT and stereotactic radiotherapy were supposed to be so important that they were addressed in individual sections.

Radiotherapy simulators and ^{60}Co units are no longer in the field, so these devices were not considered any more in the report update. However, Gamma Knife using ^{60}Co sources is taken into account in the stereotactic radiosurgery section.

Sections for computed tomography simulators in radiotherapy as well as radiotherapeutic kilovoltage units remain mostly unchanged. Not covered are MR-linacs and PET-linacs. For these no appropriate references could be found.

For megavoltage imaging in particular the dosimetry with these detectors is added to the report. In the stereotactic radiosurgery section new items are small field dosimetry, surface guidance, and end-to-end testing. Also the Cyberknife was added; here references from the Canadian Organization of Medical Physicists were used.

In the computed tomography simulator section 4D computed tomography was added to consider motion management and computed tomography numbers, while positioning lasers were updated.

It is under discussion if radiation fields have today in the era of image guidance less importance as in previous years.

Q&A:

- Q: M. Carrara (IAEA): Are O-ring linacs in the update? A: No. No references found.
- Q: C. Hurkmans (ESTRO): Are FFF-profiles considered? A: Yes, they are in – perhaps not formulated perfectly. C. Hurkmans will provide an additional reference.
- Q: C. Drexler (COCIR): Comments to O-ring linac: Halcyon is in IEC standard. They have many parallels to C-arm linacs. Manufacturer specifications, e.g., for Cyberknife, can also be used. A: vendors give acceptance levels but no suspension levels. Not all vendor data can be implemented in the document. This would be too much.
- Q: L. Brualla Gonzalez (EFOMP): Dosimetric leaf gap? A: Removed from the report, as they are system specific.
- Q: L. Brualla Gonzalez (EFOMP): Is surface guidance covered? A: Yes, add-on equipment is referenced. It is the stereotactic section.
- Q: L. Brualla Gonzalez (EFOMP): What about motion management systems for linacs? A: They are in via the end-to-end test.
- Q: E. Gershkevitsh (ESTRO): About displacement vectors in stereotactic treatment, are all axis of rotation included, including couch? A: The problem is the specific definition of the end-to-end tests. It is published and well defined by AAPM and German Society for Medical Physics. Tests should be close to clinical practice, e.g. couch rotation.
- Q: E. Gershkevitsh (ESTRO): Which coordinate system in stereotactic radiosurgery should be used when my kV system gives a displacement vector? A: It is specified in some publications, e.g., AAPM reports. Should be close to clinical practice. It is covered in end-to-end test.

4.19 "Particle therapy" – S. Lorentini

Particle therapy is a completely new section. Suspension levels are derived from IEC references, mainly IEC 60601 – Part 2-64, as well as AAPM reports. The new section covers all delivery techniques currently available in particle therapy, i.e., passive scattering, uniform scanning, pencil beam scanning.

One sub-section is on beam delivery. Here suspension levels for energy and gantry are listed. The dose monitoring system is the topic of the next table. Parameters like reproducibility and linearity of monitor unit delivery are considered. Like for linacs depth dose and lateral dose profiles have also defined suspension levels. Suspension levels for indications of radiation fields are X-ray vs. laser isocentre, coincidence of treatment and imaging coordinate system, etc. Patient support is taken into account in an extra table. Parameters include overshoot in linear and rotational movements, speed for these movements, accuracy of patient support in all axes and in rotation movement as well as displacements after emergency interruptions.

It was highlighted that the presented levels are suspension levels and these are not equivalent to acceptance and commissioning levels which are typically tighter.

Q&A:

- Q: L. Brualla Gonzalez (EFOMP): Why do dose monitor units have no supension level but an interlock? A: This comes from an IEC standard.
- Q: L. Brualla Gonzalez (EFOMP): Perhaps gantry isocentricity fits better than in the CBCT section. A: Not all facilities have CBCT, but this will be clarified.
- Q: L. Brualla Gonzalez (EFOMP): In output constancy are two suspension levels, maybe use only the most resticted one? A: This depends on the beam delivering technique, e.g., pencil beam scanning has a combination of many energy layers.

4.20 "Brachytherapy" – F.A. Siebert

The talk started with a brief introduction of the topic, followed by the presentation of the criteria and the results of the literature review performed during the very first phase of the project to identify the documents containing the suspension levels. Then the updates proposed respect to the previous version of the RP 162 document were shown, in particular for what concerns the discard of outdated devices like iridium wires, the inclusion of new devices, like ultrasound systems, stepping devices and TPSs, covered by section 5.7.2 of the new document, and the proposed suspension levels for low-dose-rate sources. The fact that both electron- and beta-emitting sources were not considered for the update of the RP 162 document was mentioned. An overview of the proposed suspension levels for brachytherapy to be included in the updated version of RP 162 document, in particular Table 32, was presented, both for what concerns the source calibration and the application tools, an ultrasound system and stepping device. In the end an example of a clinical scenario has been reported to explain how to manage the meeting of a suspension level in the daily clinical practice. In particular the example concerned the exceeding of the suspension level for the mean reference air-kerma rate of seeds respect to the value reported by the source certificate. It was highlighted as an assessment performed by the MPE in agreement with the reference clinician is recommended.

During the discussion time, several questions were raised. They are listed below, together with the speaker's answer.

- Q: M. Carrara (IAEA). Suspension level for HDR source: why 3% and not 5%? A: The value will be checked.
- Q: J. van de Kamer. What about suspension levels for applicators malfunctioning? A: We tried to find good references dealing with suspension levels for applicators, but they are not available.
- Q: C. Drexler (COCIR). What about applicators and transfer guide tube? As they can affect the source position overall. A: They are considered in the draft as shown in the presentation, differently from the previous version of RP 162 document wherein only the applicator length was covered, now also the guide tubes are considered. In addition, a comment on the high-dose-rate source suspension level was provided. 3% was only for the activity of the source, while 5% is for the overall chain including the primary calibration, the instrumentation and so on. This was asked to be specified in the table.
- Q: P. Toroi (IEC). Comment on the fact that the uncertainties should be applied to the measurements performed by the medical physicist in site instead of using the value provided in the certificate. A: We refer to GEC-ESTRO recommendation wherein is written that you can use your own measurements or the one provided by the manufacturer certification.

- Q: L. Brualla (EFOMP). For individual sources for low dose rates the reported value of 5% could be too strict when thinking to temporary ophthalmic applications with ^{125}I. A: In principle it could be, but every source is measured, sterilized and implanted. The suspension level should not be too tight because it could be dangerous; there's a risk to stop the procedure quite often.

4.21 "TPSs and Dosimetry" – E. Gershkevitsh

The talk started with an introductory part stating that the TPS section of the RP 162 document has been substantially updated to reflect modern radiotherapy delivery techniques, like IMRT/VMAT and stereotactic applications, as well as different modalities such as photons, electrons, light ions and brachytherapy. It was pointed out that the majority of tests for photon and electron beams are based on the AAPM MPPG5b (2022) document. While for what concerns the dosimetry section, after deep initial discussion, it has been decided to update only the reference dosimetry equipment part, based on IEC 60731 (2016) standard. Then a table describing the proposed modifications to the current version of the RP 162 document for TPSs was presented. In particular what is not included, (e.g., contouring tools, margin expansion algorithms, NTCP/TCP and other biological indices, adaptive radiotherapy, and record & verify systems), what is new (test parameters for IMRT/VMAT, electrons, light ions, brachytherapy and end-to-end audits), what has been updated (for photon beams complex geometries the suspension level was increased from 3% to 5%), what remains unchanged (i.e., basic photon beams parameters). It has been pointed out that TPS performance strongly depends on the input data and beam modelling and not just on the system or algorithms themselves. In addition, for specific technique performance the end results reported in Table 33 also depends on linacs, TPS models, hardware and software devices used for patient-specific quality assurance (PSQA), and selected parameters. Examples of the most discussed suspension levels for TPS testing criteria were provided both for IMRT/VMAT and SRS/SBRT photon beams. As for TPSs, also for dosimetry a table describing the proposed modifications to the current version of the RP 162 document was presented. In particular it was pointed out as nothing has changed for the accessories like thermometer, barometer and ruler. The level for recombination loss was updated from 0.5% to 1%, while concerning what is new a clear division was done between reference and field class instruments, detector and measurements assembly and from cylindrical and planes parallel ionization chambers. Furthermore, a list of what was not included, e.g., scanning systems except electrometers and positioning accuracy, detectors for relative and in-vivo dosimetry and PSQA devices, was presented. A final note was reported at the end of the presentation to state that a scanning phantom electrometer is formally categorized as a field-class instrument.

During the discussion time, several questions were raised. They are listed below, together with the speaker's answer.

- Q: P. Toroi (IEC). A new IEC standard dealing with solid state detector will be published soon. Please mention it in the introduction of dosimetry section. A: Solid state detectors are not considered in the updated version of the document.
- Q: J. van de Kamer. Question about gamma passing rate: necessary a guideline on how to use this indicator and how to interpret it as suspension levels. As gamma analysis is used for PSQA at single patient level, how can be considered as suspension level. This should be clarified in the document. A: The table presented for TPS is valid only when a user updates the version of the software or something changes in the delivery machine, it should not be meant for periodic quality assurance. Probably we could remove the term patient-specific quality assurance.

- Q: C. Hurkmans (ESTRO). Few lines of presentation/discussion on the chosen metrics (gamma factor) should be included in the introductory part of the section. A: This point is well taken, as one can see no specific devices for PSQA were included in the table because there are so many different parameters to take into account. It can be re-iterated that there is an uncertainty budget to take into account.
- Q1: L. Brualla (EFOMP). Suspension level for CT number to linear stopping power: should stay in the TPS section or in the one of CT simulators? A1: it refers to proton therapy. In any case there is discussion in literature saying that the attention should be moved from the deviation in terms of CT numbers to the deviation in terms of dose prediction accuracy. We will remove the entry from CT simulator section. Q2: Suspension level for output factors set to 2%. Not clear compared to what. A2: This is a relative output factor defined for fields larger than 5×5 cm^2 and the suspension level applies when comparing the measurements and the calculated value. The filed size should be specified in the document, we will do. Q3: G stands for global gamma? What value the global approach refers to? A3: Yes, it refers to global gamma approach and the maximum measured dose is considered. Q4: Array detectors are not considered in the table, but they are very important. A4: They are not considered because there are no published data. Q5: In the dosimetry table it is not clear the double lines approach between electrometer and ICs, the structure of the table is difficult to interpret. Some values appear repeated or insufficiently explained A5: We can re-arrange it.
- Q: M. Carrara (IAEA): Please use the IAEA TRS-398 nomenclature in the tables of the dosimetry section, instead of the IEC nomenclature. In addition, please review the requested tests especially for electrometers and if there are tests requiring equipment typically not available in a radiotherapy department please remove them. A: It has been taken 1 to 1 from IEC standard, but we can re-arrange and make it clearer. And we can leave only the tests that are easy to be performed by medical physicists at hospital level.

4.22 "Stakeholder perspectives" – Various

C. Hurkmans, ESTRO, clarified the role of the MPE, who is recognized as 'the expert' in the RP162 document. However, this should be highlighted much more clearly in the document at the beginning. He also highlighted the problem with Gamma analysis and the uncertainties arising from the measurement equipment and software. Absolut and strict values could result in suspension requirements which could be patient, plan, equipment, software or situation specific (e.g., very complex treatments may not consistently meet the presented requirement).

Note from O. Blanck for this summary: A new publication was just accepted on clinical practice of PSQA in stereotactic radiotherapy from the German Society for Medical Physics working group for physics and technology in stereotactic radiotherapy, which should be cited in this context. The document was forwarded to E. Gershkevitsh for processing. Further, C. Hurkmans sent specific notes and questions after the talk.

L. Brualla Gonzalez, EFOMP, presented the differences in equipment for radiotherapy, with the main problem that the different equipment is interconnected which may have received a separate section and separate suspension levels. Interconnection inaccuracies or errors may not be captured by the current approach of the RP 162, and a comprehensive risk analysis is required but not reflected in RP 162. Fuhrer, he elaborated on ambiguous wording and limited references for interpretation on more than 30 suspension levels but

did not give any specific details or suggestions to changes necessary. He also raised the question if it was ok to remove the radiotherapy simulators.

Note from O. Blanck for this summary: He raised an important point, however, did not provide details and did not make specific suggestions to overcome the ambiguity. He will be contacted after the meeting and asked for details and suggestions.

C. Drexler, COCIR, did not present and had nothing to add. Another COCIR representative commented instead that some of the suspension levels are below the limits currently used in clinical practice, and they will try to provide some updates in the next 4 weeks.

Comment from E. Gershkevitsh: This is most welcome if COCIR can provide further references and limits.

Comment from M. Brambilla: To repeat, suspension levels are only for systems in clinical use.

Comment from F. Maksan: The purpose of the document to update the suspension levels and the general concept of medical physics and suspension levels and measurement is fully untouched.

A. Lajunen, HERCA, reported no further comments.

M. Carrara, IAEA, repeated his comments from the last session and talk. One point was to add the well-type chamber. Update references with IAEA documents, Human Health Series No. 31 and Technical Specifications of Radiotherapy Equipment for Cancer Treatment, to supplement the ICE references was suggested.

Note from O. Blanck for this summary: We will include the references accordingly.

J. Allen, IEC, noted IEC 60976 and 60977 are referenced by the RP 162 and the RP 162 update; however, the IEC will take out the action and suspension levels of their report updates of 60976 and 60977. He clearly outlined the reasoning why the IEC went down this path to value excellence rather than minimal requirements and also elaborated on daily changes of the machine which may exceed the limits despite still working fine otherwise. He also mentioned that tolerance and action level should have been implemented. On details, he mentioned to be careful to use absolute values in comparison to difference to baseline which might better reflect clinical practice in current practice, e.g., flatness.

Note from O. Blanck for this summary: The changes in the reference documents IEC 60976 and 60977 are known at the time of drafting the RP 162 update. If the updates are published before the publication of the RP 162 update, the references need to be changed or the references to the older IEC documents may still be used accordingly.

4.23 “Member State experiences” – P. Almendral, Spain

He presented on the big change in the national legislation, on guidelines and the use of RP162 in Spain.

4.24 “Open discussion”

The discussion was brief, as many points were already raised in the session. On the online question on tomotherapy specific suspension levels, O. Blanck remarked, again, to provide a reference with specific suspension levels for all suggestion for addition to the RP 162 update.

Overall conclusions and suggested follow-up actions

The EFOMP representative will send suggestions for re-organising the radiotherapy tables and possible additions and deletions. These will be considered for the final draft. Most of the remaining feedback was focused on applicators, suspension levels for guide tubes and high-dose-rate sources, gamma metrics for performance evaluation of TPSs and the structure of the dosimetry table. These comments will also be considered, and the dosimetry table will be re-arranged to make reading easier.

4.5 Session 5: Conclusion

4.25 "Open discussion"

The discussion opened with a proposal from J. Damilakis, who asked whether the EC should move away from traditional publications toward 'living documents.' Given that technology evolves much faster than the typical publication cycles, the speaker suggested establishing a permanent advisory committee coordinated by the EC composed of stakeholders such as relevant professional and scientific societies, the IEC and the IAEA. This committee would facilitate real-time data exchange between users and manufacturers to decide when suspension levels need updating. In response, the EC, represented by G. Simeonov, acknowledged that the traditional method of updating key documents is becoming increasingly difficult to maintain. However, he noted that the EC currently lacks the institutional tools for such a permanent advisory structure. He pointed to the "Joint Action" model used by competent authorities as a potential umbrella for future professional collaboration.

A significant portion of the debate centred on the definition and application of suspension levels versus acceptability criteria. One participant argued that suspension level is a more appropriate term because it implies a clear action: if a machine meets this level, it must be suspended from use. A critical question was raised regarding the legal consequences if a patient is injured by a machine found to be outside these levels in hindsight.

The consensus was that suspension levels should never be reached if a quality assurance programme is functioning correctly. The project's philosophy posits a hierarchy of limits: acceptance levels (strictest, for new equipment), remedial levels (intermediate, for maintenance triggers), and suspension levels (absolute safety limit). If a parameter reaches the suspension level, it indicates a failure in the periodic quality control process, as the deviation should have been detected and corrected at the remedial stage.

COCIR representative C. Drexler emphasized that they do not operate in a vacuum; they are governed by the MDR and International Organization for Standardization quality management systems. Modern equipment rarely degrades slowly; instead, components typically fail and are replaced with parts that restore the machine to a 'like-new' state. A major concern for manufacturers is the lack of uniformity across Europe; they described a 'nightmare' scenario where they must comply with 27 different sets of national criteria. P. Toroi mentioned that processes take time, and she does not expect huge differences in suspension levels in the coming years.

The discussion also touched on the global market. A participant expressed concern about protecting the European market from substandard installations arriving from other regions. The EC clarified that the MDR and the CE marking process serve as the legal gateway to ensure all medical devices meet specific safety and risk criteria before entering the market. Furthermore, while the EC aims for convergence, it admitted it has no legal mandate to enforce absolute uniformity in radiation protection.

A recurring point of discussion was the accessibility of IEC standards. Because many suspension levels are derived from IEC documentation, which is not freely available, many

medical physicists find it difficult to verify the exact testing procedures. Dr. Paula Toroi mentions that she also has no free access to ICE publications. To bypass this hurdle, the representative of ESTRO C. Hurkmans suggested that the project could provide training sessions or webinars focused on the procedures for testing rather than just the numeric values. Describing a procedure is generally not considered a copyright violation, unlike transcribing the full standard. This would help harmonize the implementation of the guidelines across member states. M. Brambilla mentions that at in the upcoming European Congress of Medical Physics in Valencia, he will provide details about CARE. However, a dissemination strategy is not included in CARE's aims. The Dutch representative J. van de Kamer mentioned that national member societies of professional and scientific organizations could disseminate CARE outcomes.

4.26 "Summary, conclusion, closing" – M. Brambilla, F. Maksan

In his concluding remarks, M. Brambilla expressed his gratitude for the high level of engagement and detailed suggestions received during the workshop. He emphasized that the update is not merely a list of numbers but a 'philosophy of attitude' regarding equipment safety. He clarified several firm points to prevent future confusion.

- Suspension levels are not acceptance criteria; they are generally weaker and should not be used as the standard for purchasing new equipment.
- There is no fixed periodicity for testing suspension levels because they are safety triggers, not remedial tools for periodic quality control.
- MPEs are encouraged to set more stringent local criteria in consultation with clinical specialists if they wish to achieve higher standards of quality than the minimum safety levels provided in the document.

He concluded by noting that while the project does not have the power to enforce these criteria, it offers a robust, multi-stakeholder-vetted instrument for national regulators to adopt.

F. Maksan, representing the EC, provided the final words of the workshop, echoing the need for a finalized document while offering several words of caution. He noted that while the EC aims to publish quickly, the definition of fast can vary, and the document must still pass through several internal clearances and the Article 31 group of experts. He warned participants that the draft currently circulating has no formal value until it is officially published by the EC; levels and values may still change based on the final rounds of consultation.

Finally, he strongly advised member states not to enshrine specific numeric values directly into their national law. Doing so creates a 'legal gray area' where authorities might be forced to work against outdated values if technology or international standards change before the law can be amended. With these considerations, the workshop was officially closed.