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Quality Assurance in Intraoperative Radiotherapy

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I have no conflict of interest

Introduction

Importance of Quality Assurance (QA)

Quality Assurance (QA) is all about ensuring that a product or service meets certain standards of quality, reliability and performance.

It's a process/oriented approach that focuses on preventing defects by improving processes.

It's a way to ensure that every step, in production or delivery, leads to a high-quality final outcome.

Quality Assurance in Radiotherapy is the set of all procedures that guarantee the consistency of the medical prescription and the safety of fulfilling this prescription, i.e. the correct, precise and accurate delivery of the dose, and therefore:

- maximum curative dose to the tumor (target) ✅
- minimum dose to the surrounding critical organs ✅
- adequate monitoring of the patient aimed at determining the final outcome of the treatment ✅
- minimum exposure of the personnel ✅

Introduction

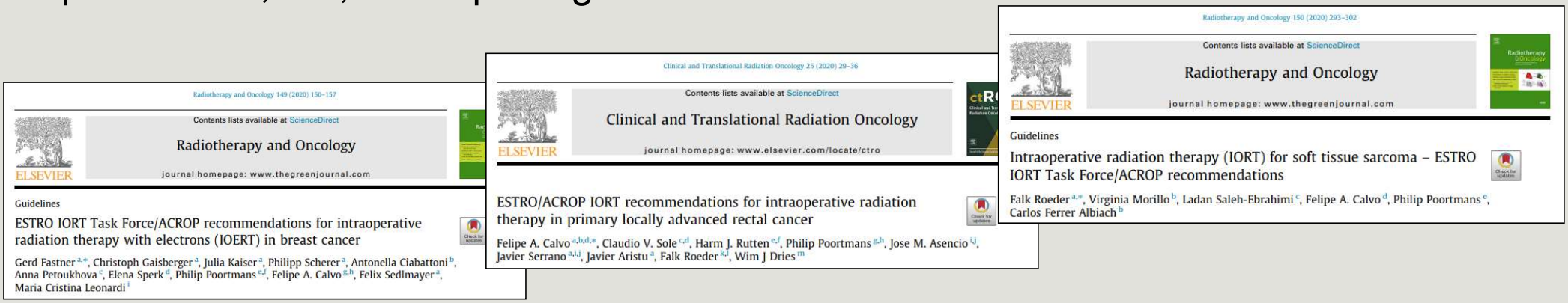
Importance of Quality Assurance (QA)

Recommendations for QA standards in RT have been published by several national and international organizations: NCRP, IAEA, AAPM, ASTRO, ESTRO, ACR, AIRO, AIFM,…

Introduction

Importance of Quality Assurance (QA)

ESTRO Guidelines: The European Society for Therapeutic Radiology and Oncology also offers guidelines, specifically for IORT.
These guidelines are developed by the ESTRO/ACROP (Advisory Committee for Radiation Oncology Practice) and cover clinical and technical aspects of IORT.
They provide recommendations on patient selection, diagnostic and therapeutic procedures, QA, and reporting.



Radiotherapy and Oncology 149 (2020) 150–157

Contents lists available at ScienceDirect

Radiotherapy and Oncology

journal homepage: www.thegreenjournal.com

Guidelines

ESTRO IORT Task Force/ACROP recommendations for intraoperative radiation therapy with electrons (IOERT) in breast cancer

Gerd Fastner [a,*], Christoph Gaisberger [a], Julia Kaiser [a], Philipp Scherer [a], Antonella Ciabattoni [b], Anna Petoukhova [c], Elena Sperk [d], Philip Poortmans [e,f], Felipe A. Calvo [g,h], Felix Sedlmayer [a], Maria Cristina Leonardi [i]

Clinical and Translational Radiation Oncology 25 (2020) 29–36

Contents lists available at ScienceDirect

Clinical and Translational Radiation Oncology

journal homepage: www.elsevier.com/locate/ctro

ESTRO/ACROP IORT recommendations for intraoperative radiation therapy in primary locally advanced rectal cancer

Felipe A. Calvo [a,b,d,*], Claudio V. Sole [c,d], Harm J. Rutten [e,f], Philip Poortmans [g,h], Jose M. Asencio [i,j], Javier Serrano [a,j,j], Javier Aristu [a], Falk Roeder [k,l], Wim J Dries [m]

Radiotherapy and Oncology 150 (2020) 293–302

Contents lists available at ScienceDirect

Radiotherapy and Oncology

journal homepage: www.thegreenjournal.com

Guidelines

Intraoperative radiation therapy (IORT) for soft tissue sarcoma – ESTRO IORT Task Force/ACROP recommendations

Falk Roeder [a,*], Virginia Morillo [b], Ladan Saleh-Ebrahimi [c], Felipe A. Calvo [d], Philip Poortmans [e], Carlos Ferrer Albiach [b]

Introduction

Importance of Quality Assurance (QA)

Quality Assurance (QA) in radiotherapy is crucial to ensure the safety and effectiveness. It involves structured procedures and actions aimed at maintaining high standards in treatments.

Here are some key aspects:

1. **Quality Control (QC)**: Regular checks to ensure that equipment and procedures meet established standards.
   It includes calibration of machines, routine maintenance and verification of treatment plans
2. **Treatment Delivery**: Ensuring that the prescribed dose of radiation is accurately delivered to the target, while minimizing exposure to surrounding healthy tissues
3. **Patient Monitoring**: Continuous monitoring to assess the effectiveness of the treatment and make necessary adjustments (IGRT, SGRT)
4. **Personnel Training**: Ongoing education and training for medical physicists, radiologists and other staff, to keep them updated with the latest QA procedures and technologies
5. **Accident Prevention**: Implementing measures to prevent accidents and minimize risks of exposure

Introduction

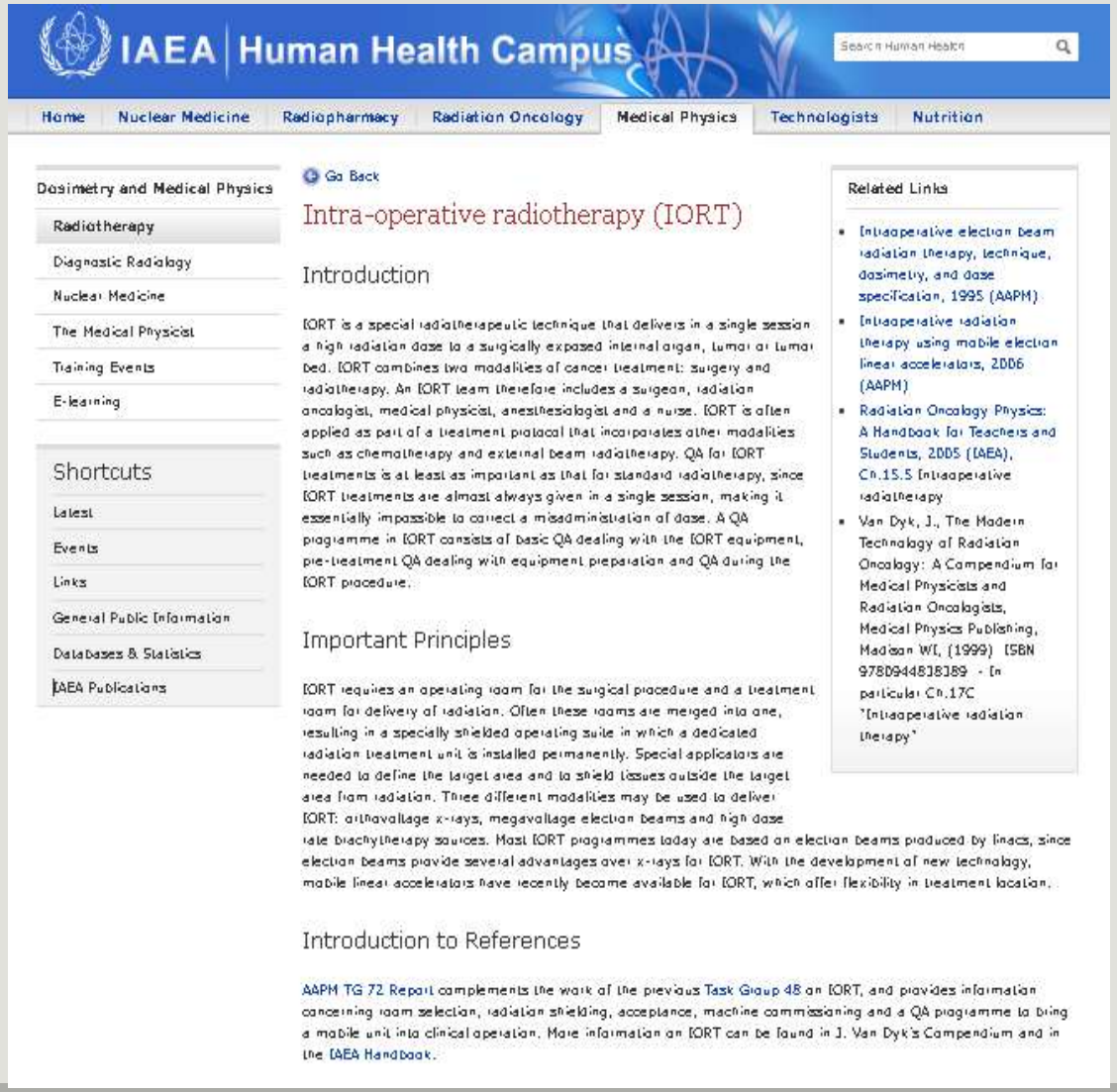
Importance of Quality Assurance (QA) in IORT

Quality Assurance (QA) in Intraoperative Radiotherapy (IORT) is essential to ensure the safety and effectiveness of this specialized treatment.
Here are some key components:

1.Basic QA: This involves regular checks and maintenance of the equipment to ensure it is functioning correctl y

2.Pre-treatment QA:
Includes preparing the equipment and verifying that everything is set up correctly before the procedure

3.During-treatment QA:
Continuous monitoring during the IORT procedure to ensure that the correct dose is being delivered accurately



Importance of Quality Assurance (QA) in IORT

Basic QA in IORT

- **Equipment Checks and Maintenance**
  - Regular calibration
  - Routine inspections
  - Manteinance Procedures

Regular Calibration

•**Purpose**: Ensures that the equipment delivers the correct dose of radiation

•**Process**: Calibration should be conducted using certified dosimetry equipment and should follow established protocols, typically at specific intervals (daily, weekly, monthly)

Routine Inspections

•**Daily Checks**:
- Verify the proper functioning of key components
- Check the alignment of the radiation beam with the surgical site

•**Weekly Checks**:
- Inspections of mechanical and electrical components
- Verify the radiation output

•**Monthly/Quarterly Checks**:
- Comprehensive inspection of the entire IORT system
- Testing of software and hardware integration to ensure seamless operation

Maintenance Procedures

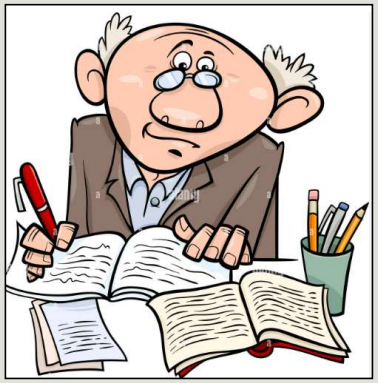
•**Preventive Maintenance**:
- •Scheduled maintenance activities to prevent equipment breakdowns
- •Includes cleaning, lubrication and replacement of worn-out parts

•**Corrective Maintenance**:
- •Immediate action to repair or replace faulty components

Documentation

•Maintain detailed logs of all the activities

•Record any incidents or issues encountered and actions taken to resolve them



- **Pre-treatment QA**
  - Verification of setup
  - Dosimetry checks

Verification of Setup

•**Purpose**: Ensures that all equipment and parameters are set correctly before treatment begins

•**Process**:

- **Patient Positioning**: Verify the patient is correctly positioned
  Imaging techniques to confirm the target area???
- **Equipment Alignment**: Check that the IORT device is accurately aligned with the surgical field
- **Parameter Settings**: Confirm that all treatment parameters (dose, energy, level) are set according to the previsional plan (???)
- **Simulation(???)**: Conduct a dry run without radiation to ensure that the systems are functioning correctly

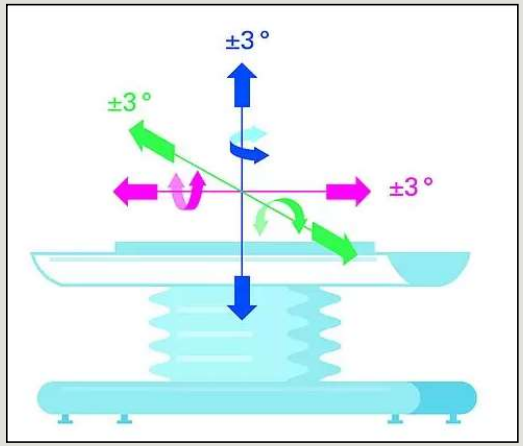
Dosimetry Checks:

•**Purpose**: Verify the accuracy of the dose delivery

•**Process**:

- **Dosimeter Placement**: At specified locations within the surgical
- **Dose Calculation**: Compare the measured dose with the planned dose and adjust settings if discrepancies are found
- **Verification Tools**: Utilize advanced tools like phantom studies to verify dose distributi on and accuracy

- **During-treatment QA**
  - Continuous monitoring
  - Real-time adjustments



Continuous Monitoring

•**Purpose**: Ensure that the treatment is proceeding as planned and that any deviations are promptly identified and addressed

•**Process**:

- **Radiation Dosimetry**: Continuously measure radiation doses in real time, using in vivo dosimeters
- **Imaging and Alignment**: Use imaging technologies and visual control to monitor the position of the device and the target area
- **System Performance**: Regularly check the status of the IORT equipment to dete ct any malfunctions or anomalies

Real-time Adjustments

•**Purpose**: To ensure optimal dose delivery and patient safety

•**Process**:

- **Dose Modifications**: Adjust the radiation dose, based on real-time dosimetry feedback
- **Equipment Alignment**: Realign the IORT device if any shifts or movemen ts are detected during the procedure
- **Patient Positioning**: Modify patient positioning if needed to ensure the target area remains precisely in line with the radiation beam

The *Istituto Superiore di Sanità* is the main technical and scientific reference structure of the Italian National Health Service

- **Local Regulations**
  - Specific regulations in Italy

In Italy, the **Istituto Superiore di Sanità (ISS)**, which is the National Institute of Health, has established guidelines for QA in I ORT.

Developed in collaboration with various medical professionals, including radiation oncologists, medical physicists, surgeons and anesthetists

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The document has been shared by all the Italian Radiotherapy Centers, Medical Physics Services and Scientific Associations most involved in the IORT practice:

Italian Association of Radiotherapy and Clinical Oncology (AIRO)
Italian Association of Medical Physics (AIFM)
Italian Society of Surgery (SIC)
Italian Society of Oncological Surgery (SICO)
Italian Association of Breast Surgery (ANISC)
Italian Association of Medical Oncology (AIOM)
Italian Society of Anesthesia, Analgesia, Intensive Care and Intensive Care (SIAARTI)
Italian Society of Medical Radiology (SIRM)
National Federation of Technical Health Orders of Medical Radiology and of Technical Health Professions, Rehabilitation and Prevention (FNO TSRM-PSTRP)
Italian Association of Radio-Oncology and Health Physics Technicians (AITRO)
Italian Association of Nurses of Oncological Radiotherapy (AIIRO)
National Federation of Nursing Colleges (FNOPI)

Topics of the Update

- *Clinical Indications and Rationale*: breast, prostate, pancreas, gastric and rectum locally advanced, soft tissue sarcoma, gynaecological tumors, vertebral metastasis;
- *Dosimetric aspects*: reference and non-reference conditions, acceptance and commissioning, quality control, in-vivo dosimetry, Monte Carlo simulation code;
- *Radiation protection issues*
- *FMEA risk analysis*
- *Health Technology Assessment (HTA)*
- *Practical and organisational aspects*
- *Geometrical and dosimetrical critical issues in IOERT*

B1: INDICATIONS FOR TREATMENT WITH ELECTRONS AND PHOTONS

Clinical, histological, biomolecular and radiological criteria for the main diseases

BREAST
- single dose. Refer to national and international guidelines (AIRO, ASTRO, ESTRO);
- boosts have broader indications because they include external beam radiation therapy.

PROSTATE
- exclusive treatment without prostatectomy or combined with pelvic lymphadenectomy and/or pelvic RT with external beams;
- "exclusive" adjuvant treatment after radical prostatectomy with pelvic lymphadenectomy;
- treatment of relapses with or without external beam pelvic RT.

PANCREAS
- anticipated boost in resectable carcinoma with external beam RT with or without chemotherapy;
- additional boost after preoperative radio-chemotherapy in borderline carcinoma;
- single dose with a symptomatic-palliative objective in unresectable carcinoma.

RECTUM
- additional boost in advanced carcinoma/relapses after preoperative radio-chemotherapy;
- additional boost in advanced carcinoma in the presence of R1-R2;
- re-treatment after previous RT with external beams in multimodal re-treatment programs with or without chemotherapy.

B Appendix

Main indications for quality assurance in electron and photon IORT treatments

B1: INDICATIONS FOR TREATMENT WITH ELECTRONS AND PHOTONS

Clinical, histological, biomolecular and radiological criteria for the main disease

SARCOMAS of SOFT TISSUES

Boosts

additional *boost* in programs with pre- or postoperative RT with or without chemotherapy both for the limbs and for the retroperitoneum.

STOMACH

Boosts

additional *boost* in programs with pre- (less common) or postoperative RT with or without chemotherapy

GYNAECOLOGY

additional *boost* in locally advanced/relapsing cervical cancer after pre-operative radio-chemotherapy;
re-treatment (adjuvant or exclusive) after previous external beam RT in multi-modal retreatment programs with or without chemotherapy.

BONE METASTASES

KYPHO IORT (only photons).

SPECIAL SITUATIONS

IORT in pregnancy (in the case of treatment with electrons)

Feasible in selected cases in the second trimester of pregnancy, estimating beforehand the dose to the foetus and and performing an in vivo dose assessment.

IORT in patients with CIED

Feasible in selected cases estimating beforehand the dose to the device, planning a treatment set-up such as to maintain the minimum safe distance between the field edge and the device, and then making an in vivo dose assessment, if any.

Geometric and Dosimetric Issues of the Update

Physical-dosimetric aspects of IORT, such as treatment optimisation and radiation protection of operators, have been deepened.
Concerning the IOeRT, major revisions refer to:

- *reference dosimetry, with specific recommendations for an appropriate use of ionization chambers in high-dose-per-pulse electron beams*
- *dosimetry under non-reference conditions, with indications for detectors characterisation, and output factors and correction factors determination*
- *strategies to define an appropriate (and stable) geometric treatment set-up*
- *implementation of an effective in-vivo dosimetry programme*
- *identification of geometric and dosimetric critical issues and implementation of strategies to mitigate them*
- *implementation of a periodic quality control programme on measurement equipment and instrumentation to maintain the quality standards in the performance*

Why has IORT been so downsized in Italy in recent years?

1.Resource Allocation: IORT requires specialized equipment and trained personnel,which can be resource-intensive

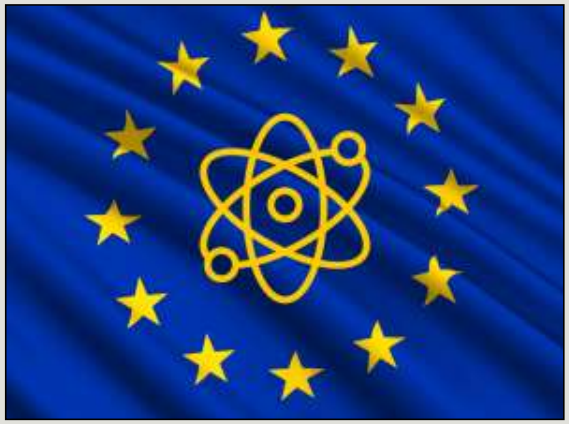
2.Technological Advancements: Newer technologies and treatment methods may offer similar or better outcomes with fewer complications (SBRT, radiosurgery,…)

3.Clinical Evidence: The effectiveness of IORT compared to other treatments may not be consistently supported by clinical evidence, leading to its reduced use (breast,…)

4.Regulatory and Financial Constraints: Changes in healthcare regulations and funding can impact the availability and use of IORT. **Financial constraints** may limit the ability of hospitals to invest in the necessary infrastructure.

Furthermore…

Legislative Decree 101 of 31/07/20 transposes in Italy the Directive 2013 // 597 Euratom on the controls on ionizing radiation. Which is the impact?



Legislative Decree 101 (Law 101), has played a role in the reduction of interest in IOeRT.

This decree, implemented on July 31, 2020, establishes stringent safety standards for the use of ionizing radiation. While these regulations are crucial for ensuring patient and worker safety, they have also increased the complexity and cost of implementing IOeRT.

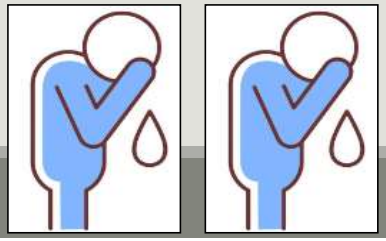
The regulatory requirements and the need for rigorous safety measures have made it more challenging for hospitals to maintain and expand IOeRT services.

This has contributed to the downsizing of IORT in Italy in recent years.

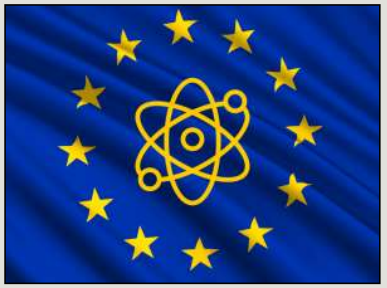
ART 163: Medical-radiological equipment

Linear accelerators with nominal energy greater than 1 MeV used in RT and acquired after the entry into force of this decree must be equipped with systems for recording and verifying treatment parameters; equipment already in operation must be equipped with such systems within 2 years from the date of entry into force of this decree.

Legislative Decree No. 203 of 11/25/22 “Supplementary and Corrective Provision of Legislative Decree No. 101 of 7/31/20”



The need for Record and Verify systems has negatively impacted the use of mobile linear accelerators for IOeRT



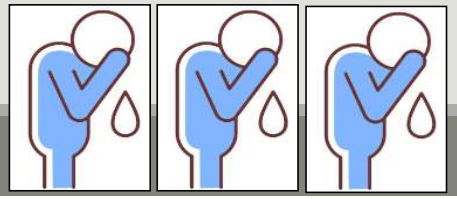
While R&V systems are essential for ensuring accurate and safe radiation delivery, they can add complexity and cost to the setup and operation of mobile linear accelerators.
Here are some key points:

1.Integration Challenges: Integrating R&V systems with mobile linear accelerators can be technically complex

2.Cost Considerations: The additional cost of implementing R&V systems can be a barrier for some hospitals

3.Training and Maintenance: Proper training for staff and regular maintenance of R&V systems are necessary to ensure their effective use, which can be resource-intensive

4.Benefits of R&V: reducing human error and improving treatment accuracy



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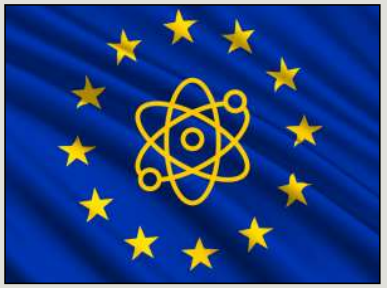

The parameters that uniquely identify the treatment are exclusively three: energy, number of monitor units, applicator.

These parameters are determined only *a posteriori,* after surgical preparation of the target

Therefore, for the IOeRT technique, the needs of the R&V system are reduced to:

- before the treatment: verify the correctness of the applicator mechanically mounted on the device
- during the treatment: perform in vivo dosimetry, if technically possible
- during and after the treatment: correctly record both the data of the treatment set and those of the treatment performed

- **Future Perspectives**
  - Innovations and improvements in QA processes

1.Advanced Imaging Technologies: The integration of intraoperative ultrasound and CT, can enhance the precision of target localization

2.Mobile Linear Accelerators: Mobile linear accelerators offers greater flexib ility in treatment location

3.Automated QA Systems: Implementing automated QA can streamline the QA process and reduce human error

4.Artificial Intelligence (AI): AI and machine learning algorithms can be used to analyze large datasets, predict potential issues, and optimize treatment p lans

5.Enhanced Training Programs: Continuous education and training programs for medical professionals involved in IORT

6.Standardization of Protocols: Developing and implementing standardized QA protocols across different institutions can ensure uniformity

7.Specific QA: Tailoring QA processes to individual patient needs and anatom ical variations

Diving deeper into QA for IORT

1.Patient-Specific Challenges: How does QA adapt to ensure optimal outcomes for each individual ?

2.Ethical Considerations: What are the ethical implications of new technologies and innovations in QA? How do we balance technological advancement with patient safety and care?

3.Interdisciplinary Collaboration: Different specialists working together in QA What roles do surgeons, radiation oncologists, and medical physicists play? How can this collaboration be optimized?

4.Shared Platforms: Implementing shared digital platforms where team members can access patient data, and QA logs

5.Defined Protocols: Having clear, well-documented protocols

Quality Assurance in Radiotherapy is the set of all procedures that guarantee the consistency of the medical prescription and the safety of fulfilling this prescription, i.e. the correct, precise and accurate delivery of the dose, and therefore

- maximum curative dose to the tumor (target) ✅
- minimum dose to the surrounding critical organs ✅
- adequate monitoring of the patient aimed at determining the final outcome of the treatment ✅
- minimum exposure of the personnel ✅
- R&V ❌

Despite these challenges, IORT remains a valuable treatment option for certain patients and ongoing research

THANK YOU!!