DITTA GLOBAL DIAGNOSTIC IMAGING, HEALTHCARE IT & RADIATION THERAPY TRADE ASSOCIATION

2nd Regional IRPA WHO IOMP Workshop on RADIOLOGICAL PROTECTION CULTURE in MEDICINE (RPCM)

World Health Organization (WHO) Headquarters in Geneva, 30 Nov- 2 December 2015

-

Manufacturers' point of view for developing a RPCM in European Countries

Michel Baelen, PhD
COCIR Radiation Protection Focus Group Chair and DITTA WHO Working Group Member

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Key Topics

- Disclosure
- Updates about DITTA
- Industry supports reduction in unnecessary exposure
- Technology Innovation
- Key players in radiation dose reduction initiatives
- Radiation safety standards and guidelines
- Industry opinion
- Questions and Discussions

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DISCLOSURE

Michel Baelen, PhD

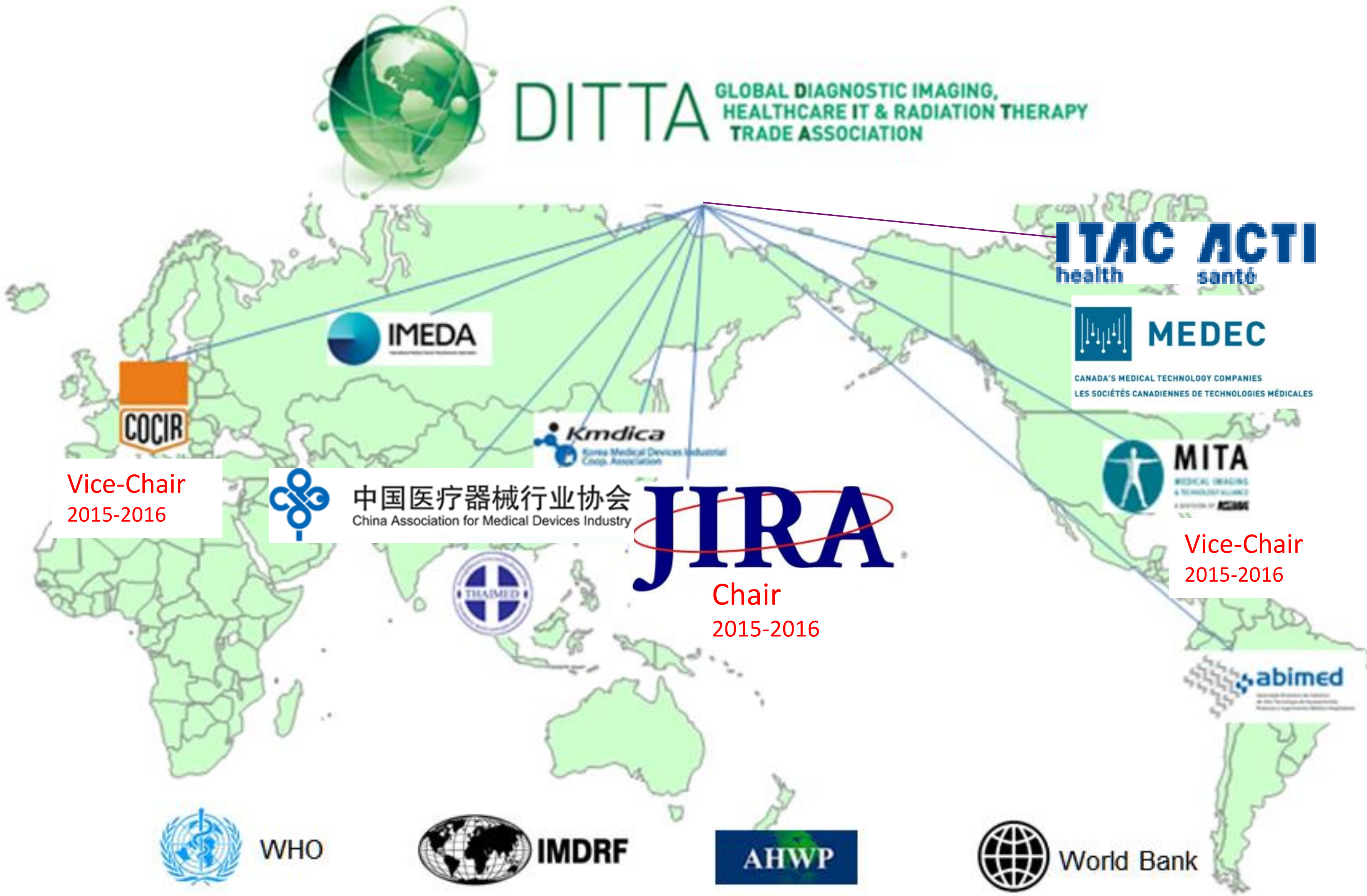
- employed by Ion Beam Applications s.a. (IBA) as the Health Policy Compliance Director

and

- is chair of the COCIR Focus Group on Radiation Protection and an active member of the DITTA WHO Working Group

DITTA represents the global diagnostic imaging, healthcare IT, radiation therapy industries.

All following information can be publicly disclosed!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中国医疗器械行业协会
China Association for Medical Devices Industry
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Chair
2015-2016
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UPDATES ABOUT DITTA

DITTA GLOBAL DIAGNOSTIC IMAGING, HEALTHCARE IT & RADIATION THERAPY TRADE ASSOCIATION

- Granted NGO status in official relations with WHO
- Established formal liaison with AHWP*
- Expanded its Working Groups:

  - Mirroring the International Medical Device Regulators' Forum (IMDRF)
    - Regulated Products Submissions (RPS)
    - Unique Device Identification (UDI)
    - Medical Device Single Audit Proposal (MDSAP)
    - Software as a Medical Device (SaMD)
  - Environmental WG; working towards the UN/Basel Convention
  - World Bank WG; for World Bank Procurement Policies
  - Refurbishment WG; Standards for refurbishment/refurbished products
  - 2 new groups : 1 on standards + 1 on WHO activities

** Asian Harmonization Working Party*

INDUSTRY SUPPORTS REDUCTION IN UNNECESSARY EXPOSURE (1 OF 6)

1. Patients treated with Radiotherapy have tumors that might be life threatening while patients getting Radiation imaging are not necessary ill. Therefore the ALARA principle apply in a differentiated manner between radiotherapy and radiology.
    a) Consider the Cost/benefit approach to balance damage response of cell for radiation dose to normal tissues compared to cancer tissues or to enhance information quality for diagnostic

    b) New treatment techniques continuously improve conformance of dose distribution to the target volume while decreasing the dose level to surrounding healthy tissues. That results in a better separation between the Tumor Control Probability and the Normal Tissue Complication Probability
    - Treatment of cancer based on ALARA risk reduction principle, reducing dose given outside the tumour to Organs at Risk and healthy tissues, which automatically will reduce the risk on side effects (if dose reduced level is below threshold value) The ultimate aim of all innovation:
    - Real-time monitoring of the patient and the treatment delivery will make sure that the dose is properly concentrated in the target and minimize harm to organs-at-risk
    - Improving effectivity through Radio sensitization methods

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INDUSTRY SUPPORTS REDUCTION IN UNNECESSARY EXPOSURE (2 OF 6)

2. Integration of imaging with treatment delivery have become standard for the accurate positioning of the patients in treatment position and radiation delivery :
   - Imaging in treatment position: 2D imaging, Stereoscopic imaging or cone-beam tomography (CBCT) *, ultrasonic devices, embedded Magnetic Resonance Imaging (MRI)…
   - Examples of techniques enhancing reduction in unnecessary exposure: (still research in-progress products)
     - ✓ Range control innovation in Proton Therapy* in Pencil beam Scanning (PBS) **,
     - ✓ Dynamic Collimation System for improved beam penumbra control in PBS
     - ✓ …
3. DICOM international data format standards for storage of diagnostic imaging and radiation therapy information in Electronic Medical Records (EMR)

** These are the two cases referred to in this presentation as Technology Innovation for RPCM in Radiation oncology*

*** Pencil beam scanning (PBS) is a proton therapy delivery technique delivering radiation dose in a spot-by-spot fashion one energy layer at a time*

INDUSTRY SUPPORTS REDUCTION IN UNNECESSARY EXPOSURE (3 OF 6)

Diagnostic Imaging:

- Digital imaging with image processing to significantly reduce unusable x-ray images
- More sensitive and high resolution detectors are improving image quality while reducing dose to the patient
- Software tools for image analysis - pattern recognition – to assist Radiologists in the review of the images.

- **Collaboration with HERCA for CT dose optimisation**
  - The development and implementation of a standardized benchmarking of CT systems by characterizing the dose efficiency related to image quality
  - The implementation of dose reduction measures in CT
  - The implementation of dose management and reporting tools
  - The provision of specific training curricula

INDUSTRY SUPPORTS REDUCTION IN UNNECESSARY EXPOSURE (4 OF 6)

Radiation Therapy (1)

- High precision dose delivery - IGRT, IMRT, VMAT, IMPT and Robotic techniques - allow for very conformal delivery of the treatment dose to the target volume .
- New forms of treatment – single fraction or hypo-fractionated Radiosurgery
- Hard-Wedges and individual absorbers are replaced (less scattering, less neutron dose) by dynamic techniques
- Superior treatment plans are achieved with IMRT and VMAT using low energy (below activation threshold) photon beams (reduction in neutron dose.
- Inverse 3D treatment planning with advanced dose calculation algorithms (Monte Carlo, AAA*) allows for multi-parameter optimization of treatment plans
- Knowledge-Based planning provides interdepartmental benchmarking and comparison with expert users
- Motion management - gating or active tracking of moving targets
- Imaging based reduction of patient set-up errors
- On-line dosimetry and treatment verification using MV Imaging

** Anisotropic Analytical Algortihm*

INDUSTRY SUPPORTS REDUCTION IN UNNECESSARY EXPOSURE (5 OF 6)

Radiation Therapy (2)

- Intensive training programs for the clinical team (MD, RTT, medical physicist)
- Manufacturer`s education programs and workflow related hands-on to enhance Access to Care

Challenges and Chances:

- Sophisticated equipment and new treatment techniques (delivery of high doses in a short time – radiosurgery) requires adequately trained staff - “we need more educated drivers”
- Research in imaging using “non-ionizing radiation techniques” – e.g. optical imaging, Ultrasound, MRI
- Radiation Biology research to clinically exploit all capabilities that are technically possible.
- Develop and support QA strategies to make treatments safer

INDUSTRY SUPPORTS REDUCTION IN UNNECESSARY EXPOSURE (6 OF 6)

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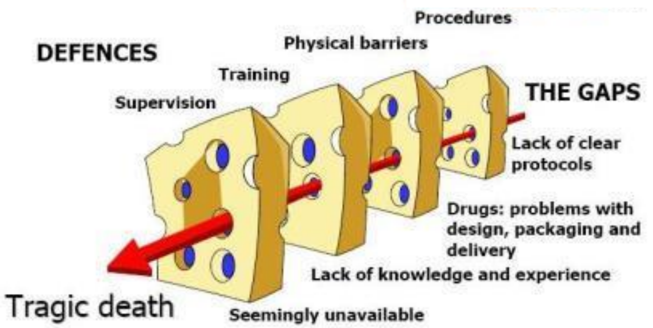
4. Medical Devices Vigilance Reporting of adverse incidents and Field Safety Corrective Action (FSCA) associated with internal trends analysis triggering design risk analysis are build on the CAPA processes. The Medical Device manufacturers have these processes in place as part of their ISO 13485 Quality Management Systems

Medical Device Manufacturers are already addressing the WHO concern summarized as follows:
"When will health care pass the orange-wire test?" *

- Engineers wouldn't simply patch up the orange wire
- they would investigate the whole fleet to make sure there wasn't a problem.

Sir Liam Donaldson
Chairman, World Alliance for Patient Safety, WHO

The Swiss Cheese model *



*: «Orange Wire» in the Lancet by Sir Liam Donaldson: http://mrsaactionuk.net/ips2011.html

COCIR JIRA MEDEC MITA THAIMED IMEDA 中国医疗器械行业协会 China Association for Medical Devices Industry abimed Kmdica Korea Medical Devices Industrial Coop. Association ITAC health

TECHNOLOGY INNOVATION

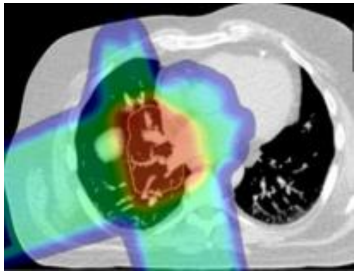
RANGE CONTROL IN PENCIL BEAM SCANNING

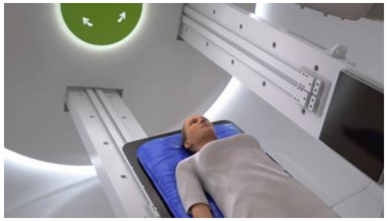
Why is Gamma Prompt (GP) range control Innovation needed?

ORIGINS OF RANGE INACCURACY DETECTED BY GP

1. CT scanner
2. Planning (contouring + simulation)
3. Irradiation
   - 20-30 fractions ⇨ anatomical changes
   - Patient setup (positioning errors)
   - Machine accuracy

     (beam energy, spot position)

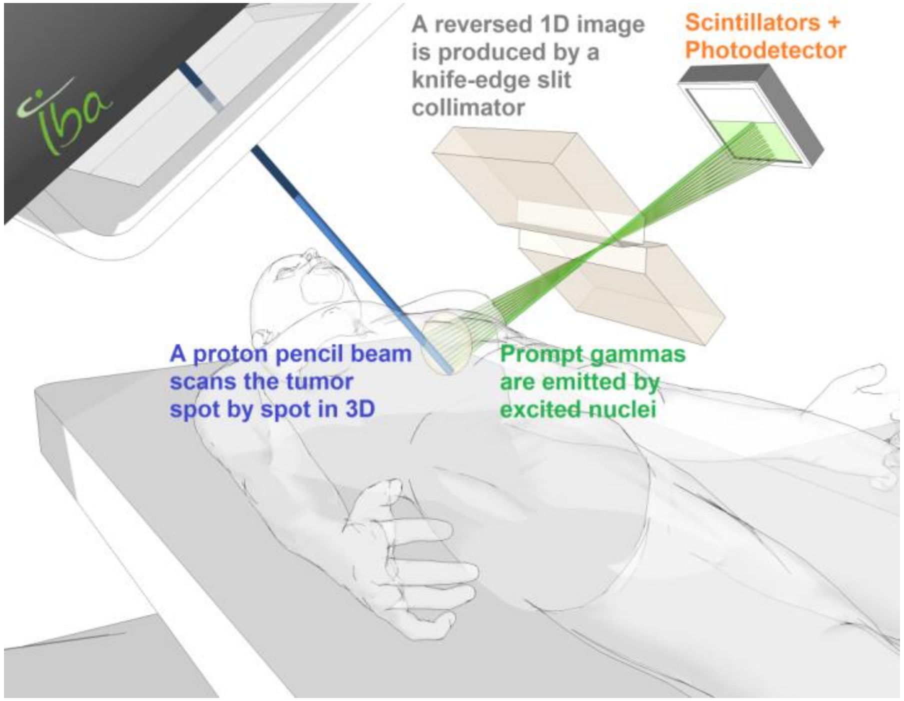




TECHNOLOGY INNOVATION

RANGE CONTROL IN PENCIL BEAM SCANNING

How does it work?



Intended application:

Measurement of the depth at which the beam stops in the patient in PBS mode

Target performance:

Instantaneous verification with an accuracy better than half the distal margin for a selection of critical spots

Points of attention:

Simplicity, cost effectiveness

TECHNOLOGY INNOVATION

RANGE CONTROL IN PENCIL BEAM SCANNING

Research outcomes in clinical conditions

Partners:

European NoVel Imaging Systems for ION therapy (Entervision) and Intervision founded by European Union, XGLab –Milano (Italy), IBA (Belgium), Catholic University of Louvain -UCL (Belgium), Université Libre de Bruxelles - ULB (Belgium), Fond National de Recherche Scientifique - FNRS (Belgium), Institut de Physique Nucleaire de Lyon and INSA (France), Politecnico Milano (Italy), Center for Innovation in Radiation Oncology- OncoRay (Germany), Perelman school of medicine from the University of Pennsylvania (USA)

Research

2006

APPLIED PHYSICS LETTERS 89, 183517 (2006)

Prompt gamma measurements for locating the dose falloff region in the proton therapy

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The location of the distal falloff in the proton therapy is an important but often uncertain parameter as different tissue elements are traversed by the beam. A multilayered collimator system has been constructed as a practical means to locate the dose ends by measuring prompt gammas. The collimator is designed to moderate and capture fast neutrons and to prevent unwanted gammas from reaching the scintillation detector. The system has been studied using Monte Carlo technique and has been tested in the beam energy range of 100–200 MeV. Measurements clearly indicated correlations between the gamma distributions and the distal falloff regions. © 2006 *American Institute of Physics*. [DOI: 10.1063/1.2378561]

Proton beam therapy is a high-quality radiation therapy modality in terms of precise dose deposit to the tumor volume prescribed in a cancer patient.[1-3] Hadron beams in general have an advantage in the dose distribution over conventional radiation modalities such as 6–20 MeV photons due to the presence of a Bragg peak. The photons inherently deposit higher integrated doses in the normal tissue of a patients body compared to the protons.[4] The higher dose at the Bragg peak is the result of the increase in the stopping power or energy deposit per unit length inversely proportional to the square of the ion velocity as expressed by the Bethe-Bloch formula.[5] These characteristics of the proton beam therapy result in reducing unnecessary dose to the normal tissues. However, this advantage takes some risks in that the critical tissue located near the end of the proton range can be subject to receiving under- or overdoses if the range is not accurately known. In the planning of radiation treatments the most usual method of defining the ranges is based on the information of electron density distributions attained from the CT images. Hence, it is difficult to fully consider complicated atomic compositions of different tissue elements, which makes the proton range uncertain even to the extent of 1–2 cm.[6] To fully utilize the beneficial physical properties of a proton beam, it is often required to irradiate the tumor region in a precision better than 1–2 mm.

Unlike the photons of conventional radiation therapy, the therapeutic proton or heavier ion beams stop inside the treatment volume, and thus it is not feasible to directly detect the end of the dose deposit. To monitor the range it is needed to detect gammas emitted from nuclear reactions, and there are two kinds of gammas that can be used: (1) coincident gammas from the production of positron emission isotopes and (2) prompt gammas from excitations of the target nuclei by the proton bombardment. The former method provides the same resolution and image quality of positron emission tomography (PET), and has been tested for the carbon beam therapy.[7,8] However, the proton beam has a different mechanism in producing the PET isotopes; i.e., activity of positron emitters is induced in the target nuclei, while fragments of the projectile nuclei are the main sources of activities in the heavy ion therapy. Consequently for the proton therapy, the dose distribution determined by the energy deposit mismatches with the distribution of the isotopes by nuclear reaction. Also, it has been observed that the time lag between treatment and PET scanning can affect determination of the range presumably due to the isotopes of different half-lives.[9] However, a direct comparison between the convolution image by more sophisticated Monte Carlo simulation and the PET signal may reveal the range more accurately.[10] The prompt gammas, on the other hand, are generated by various interaction mechanisms of a proton beam with a target being characterized by the decay time much less than 1 s. In the case of water phantom the prompt gammas come from the interaction with oxygen.

The use of prompt gammas has been suggested to correlate with the distal falloff,[11,12] which was based on Monte Carlo simulation results using GEANT (Ref. 13) or MCNPX,[14] but no attempt of experimental study has been made before. The principle is simple that the range can be determined by counting the gammas emitted from the 90° of the beam direction as depicted in Fig. 1. We chose the design of the collimator to suppress fast neutrons and to select gammas passing only the collimation hole. The high-energy spallation neutrons are the major background deterring the signal gammas. These are highly forward oriented, but still strong enough to compete with the signal collected at 90° if not adequately shielded. The prompt gamma scanner (PGS) consists of three layers of shielding against neutrons generated from the phantom. The paraffin layer moderates the high-energy neutrons, the B_4C powder capturing the neutrons by the $B(n,\gamma)$ reaction, and finally the lead layer blocking the

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CLINICAL

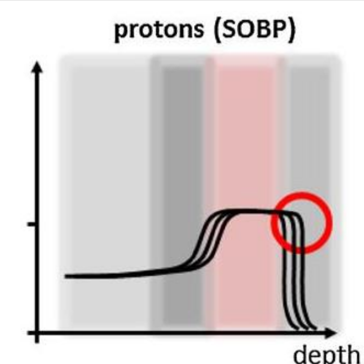
DOTmed.com - World's first proton therapy Prompt Gamma Camera goes clinical - **October 20, 2015**

….

Prompt Gamma Camera deployed and several successive fractions of treatment received by a cancer patient

Prof. Dr. med. Michael Baumann:

"…**It allow us to take further advantage of the unique characteristics of the proton treatment modality**"



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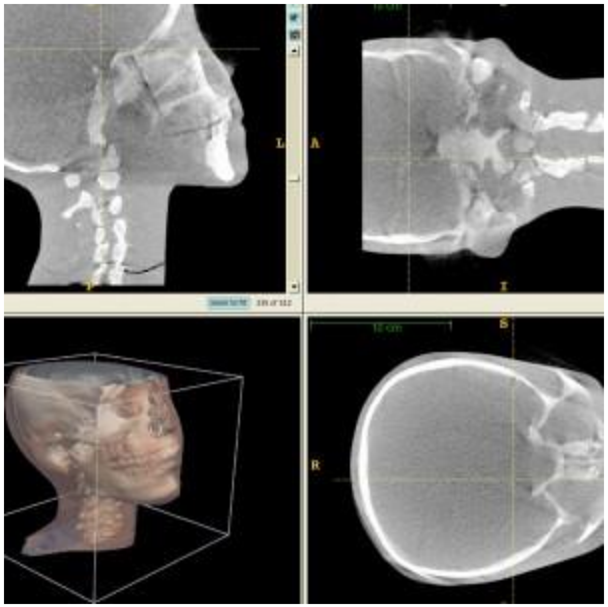
TECHNOLOGY INNOVATION WHEN IMAGING (CONE BEAM CT) AND THERAPY JOIN FORCES



Corrected CBCT image from scatter-induced shading artifact reduce important proton range errors

- Cone Beam computed tomography (Cone Beam CT) uses 3-D volumetric imaging with improved contrast
- Anatomical changes including patient weight loss, tumor shrinkage, cavity filling, etc…

Since this is already longtime available in X-Ray RT, the first treatment is now completed with Proton Therapy Specific Cone Beam CT (December 29, 2014)

http://www.itnonline.com/content/iba-announces-first-completed-treatment-proton-therapy-specific-cone-beam-ct

Proton dose calculation on scatter-corrected CBCT image: Feasibility study for adaptive proton therapy

Yang-Kyun Park, Gregory C. Sharp, Justin Phillips, and Brian A. Winey

Citation: Medical Physics **42**, 4449 (2015); doi: 10.1118/1.4923179

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KEY PLAYERS IN RADIATION DOSE REDUCTION INITIATIVES

- **Key Professional Societies in Europe**
  - EFOMP (European Federation of Organisations for Medical Physics)
  - ESR (European Society of Radiology)
  - ESTRO (European Society for Radiotherapy and Oncology): Radiation Oncologists, Medical Physicists, Radiobiologists and RTTs (Radiation Therapists)
- **Active Industry Associations**
  - MITA (Medical Imaging & Technology Alliance)
  - COCIR – European Trade Association
  - JIRA – Japanese Trade Association
- **Governmental Agencies and supporting bodies**
  - European Commission (EU DG Energy and Growth)
  - HERCA (Heads of European Radiological protection Competent Authorities)
  - IAEA (International Atomic Energy Agency)
  - IEC (International Electro Technical Commission)

RADIATION SAFETY STANDARDS AND GUIDELINES

1. Guidelines based on Multiple Cooperation with EFOMP, ESR and ESTRO
   - Eutempe RX - Education and training of Medical Physicists for them to become Medical Physics Expert (MPE) in Radiology (EQF level 8)
   - Education and training of Medical Physicists for them to become Medical Physics Expert (MPE) in Radiotherapy (EQF level 8) in similar lines as the EUTEMEP-RX
2. References used for presumption of coformity to the essential requirements of the Euratom Basic Safety Standard and the EC/93/42, DITTA members are involved in Standardization and scientific committees
   - All Collateral standards from the IEC 60601-1 and IEC 60601-2
   - IEC 62304, IEC 62304:2006+AMD1:2015 CSV : Medical device software - Software life cycle processes
   - IEC 60731:2011: Medical electrical equipment - Dosimeters with ionization chambers as used in radiotherapy
   - AAPM Reports No 46 and 62
   - European Commission Radiation Protection report RP91 and RP162
   - IAEA Technical reports 374, 115, 430, 1540, 1583 …
3. Guideline from Euramet technical committee for ionizing radiation
   - E.g., JRP HLT09 MetrExtRT : Metrology for radiotherapy using complex radiation fields

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INDUSTRY OPINION

1. IAEA Safety Standards for protecting people and the environment - Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards: General Safety Requirements Part 3
   - As of Today, International Criteria for Acceptability of Medical Radiological and Radiotherapy Equipment still unpublished
2. Radiation protection standards are currently maintained by the International Scientists Committees and Users Experts
   - Acceptance criteria are subject to adjustments from each MPE involved in each different country/Region/Hospital. **How can we improve the situation for better internationalization and harmonization of best practices in Radiation Protection?**

In radiation protection, manufacturers need an international and harmonized regulatory framework. For complex medical devices being sometimes fixed installations, a stable regulatory environment evolving through adequate transition periods should be compatible with the length of the development cycles (5 to 11 years)

QUESTIONS AND DISCUSSION

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THANK YOU

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