ROLE OF EQUIPMENT MANUFACTURERS FOR PREVENTING EQUIPMENT FAULTS AND OTHER ERRORS, AND PROVIDING SPECIFIC TRAINING

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SUMMARY

• What is DITTA
• Role of manufacturers in radiation safety
• Value of innovative technologies
• Obsolescence of equipment
• Role of manufacturers in training and education
• Communication platform with regulators
• DITTA recommendations
DITTA is a non-profit trade association, created in 2000 and incorporated in 2012. It represents more than 600 companies around the globe.

DITTA covers the following industry sectors:
1. Diagnostic imaging,
2. Radiation therapy,
3. Healthcare IT,
4. Electromedical
5. Radiopharmaceuticals

Our Industry leads in state-of-art advanced technology and provides integrated solutions covering the complete care cycle.
DITTA membership is currently comprised of COCIR (Europe), JIRA (Japan), ITAC (Canada), MEDEC (Canada), MITA (United States), THAIMED (Thailand), IMEDA (Russia), CAMDI (China), ABIMED (Brazil) and KMDICA (Korea).

DITTA includes more than 600 companies worldwide.

DITTA enables participating associations and their member companies to work more effectively with international policymakers, organizations, professional associations and stakeholders.

Since 2015, DITTA has the status of NGO in official relations with World Health Organisation.

In May 2016 DITTA signed a partnership agreement with the World Bank to support the Bank procurement in medical technologies.
• Prevention of accidents is a shared responsibility involving regulators, users and industry. Industry plays an important role.

• Industry continues to work with clinicians to design and develop technologies to constantly improve patient safety.

• Industry has advanced in technologies to optimize dose to patients, minimize risks while improving image quality and safety features to avoid accidental or unintended exposures.

Continuous Improvement via ISO 14971 Risk Management & QMS processes
DITTA supports the **Bonn call for action**. Manufacturers key engagement towards radiation safety:

1. **Improved safety** of medical devices by enhancing the radiation protection features in the design of both physical equipment and software and to make these available as default features rather than optional extra features;

2. Support the development of technical solutions for **reduction of radiation exposure** of patients, while maintaining clinical outcome, as well as of health workers;

3. Enhance the provision of **training tools and support for users** that is specific to the particular medical devices, taking into account radiation protection and safety aspects;

4. Address the **special needs of health care settings** with limited infrastructure, such as sustainability and performance of equipment, whether new or refurbished;

5. **Strengthen cooperation** and communication with appropriate stakeholders, such as health professionals and professional societies;

6. **Efficient communication with health and radiation regulatory authorities** and their representative organizations.
Dose management features developed by manufacturers

- Predefined Protocols for Adults and Children
- Dedicated Infant Imaging Mode
- Dose alerts and notifications (Dose Check)
- Automatic tube current modulation (AEC)
- Advanced tube and collimator design
- Dose Modulation Options
- Beam Shaping and modulation
- Dose efficient x-ray detection
- Image Reconstruction and Post-processing
- Dose reporting (DICOM Radiation Dose Structured Reporting)
Dose optimization is a key element of radiation protection. DITTA identified ‘significant’ triggers in the technological, medical and regulatory areas. For instance, CT dose modulation and CT iterative reconstruction algorithm technologies, which dramatically reduce the required X-Ray dose.
EXAMPLE : DOSE REDUCTION IN MAMMOGRAPHY

Improvements in dose-reduction technologies in breast imaging can now continually optimize dose while improving diagnostic image quality.
Despite this, the uptake of new technologies is slow (COCIR 2016 report on density and ageing profile).

- One quarter of theComputed Tomography installed base falls below accepted standards for radiation dose optimization.
- More than 3000 scanners in Europe are not suitable for upgrade (dose modulation and iterative reconstruction engines).

The European Society of Radiology (ESR) has recognised the clinical importance of planning for timely replacement of equipment. In 2014, ESR published a position paper stating that; “Equipment less than five years old is state-of-the-art technology. Properly maintained equipment between six and ten years old is suitable for practice, but radiology departments should develop a strategy to replace them. Machines over ten years old must be replaced.”
MANUFACTURERS’ ROLE IN TRAINING AND EDUCATION

• The role of education and training is also an extremely important tool to ensure safety.

• Manufacturer’s training is designed to support customer facilities in an effort to improve operating knowledge and increase the skill level of personnel. These programs consist of a variety of delivery mechanisms such as:
  ✓ **Hands-on and didactic training** to reinforce skills needed to operate equipment
  ✓ **Operator Manuals** to demonstrate information on dose optimization tools and dose reduction strategies
  ✓ **Information on dose** related displays, indices, and where dose information is located
  ✓ **Onsite training**, classroom instruction, remote instructor-led training and observation, online tutorial self-help, telephone support, publications, seminars, peer to peer physician training, and industry association educational material.
MANUFACTURERS’ ROLE IN TRAINING AND EDUCATION

• In Europe, DITTA is partnering with ESR and ESTRO and in discussion with EFOMP* and EFRS by:
  – Supporting and participating in training initiatives and projects (EFOMP ESMPE School on CT in 2018, on radiotherapy in 2019)
  – Supporting the creation of training tools by professional societies (e.g. EUTEMPE-RX and EUTEMPE-RO)
  – EuroSafe

• In US, DITTA is cooperating with ACR, ASTRO, AAPM and ASRT on:
  – ImageGently
  – ImageWisely
  – AAPM Working Group: Alliance for quality CT

*EFOMP: European Society of Medical Physicists
EU EXAMPLE ON SUCCESSFUL PLATFORM WITH REGULATORS

• In Europe COCIR dedicates resources to activities on training (and dose optimization) in cooperation with authorities (HERCA, IAEA)
  ✓ Voluntary Commitment with HERCA on CT Dose Optimization which includes commitments on training:
    ➢ The offering of vendor specific equipment training curricula to the CT user, and the offering of continuing professional education optional training.
    ➢ Keeping the vendor’s equipment training curricula updated with the recent developments that lead to dose reduction and dose transparency.
  ✓ Participation in IAEA training courses, i.e.: "Training course on radiation safety in brachytherapy", 14 to 18 November 2016.

• Post market reporting requirements for accidental or unintended exposure
  ✓ EURATOM (EU)
  ✓ 21CFR Subchapter J

• Vigilance reporting of incidents and field safety corrective actions
  ✓ EU Medical Device Directive
  ✓ US 21CFR 803 medical device reporting, 806 reporting of corrections and removals
1. **Ensure continuous training and education of users**
   - It is the healthcare providers’ responsibility, to assess and maintain their equipment, their own staffs’ competency and to liaise with the relevant manufacturers for their training requirements as well as to enable their staff to participate in training and education.

2. **Adopt the latest technologies**
   - DITTA encourages healthcare providers to adopt the latest technologies, which provide the opportunity to improve quality, efficacy, patient safety and productivity. Currently, most purchase decisions are price-driven and fail to consider any ‘incremental value’ the technology or method provides.

3. **Replace obsolescent equipment that cannot be upgraded**
   - DITTA calls upon national and regional governments and policy-makers to support replacing technologically obsolescent equipment that cannot be upgraded to ensure comprehensive, coherent and sustained investment.

4. **Support smart and transparent procurement**
   - Support smart and transparent procurement processes are in place and include maintenance/servicing as well as training of users, to ensure fair competition.

Industry remains committed in improving radiation safety in healthcare by continuing to innovate and partner with regulators and clinicians.
THANK YOU!

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