



COCIR



Sustainable Competence  
in Advancing Healthcare



# International Conference on Radiation Protection in Medicine: Setting the Scene for the Next Decade

*Bonn, 03-07 December 2012*

**Manufacturers' role in medical radiation protection:  
The trade association's perspective**

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*COCIR Secretary General*



# Summary

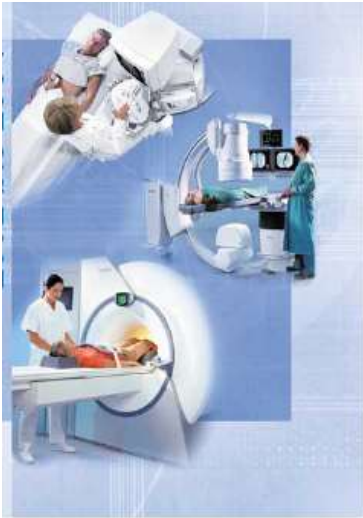
1. An innovative sector
2. COCIR CT manufacturers voluntary self-commitment and impact on CT dose optimization
3. COCIR Recommendations to IAEA



# 1. An innovative sector



# What is COCIR?



COCIR represents the Industry Voice in Medical Imaging, Electromedical and Healthcare IT



Our Industry leads in innovative healthcare technologies and provides solutions for the complete care cycle

Visit our website: [www.cocir.org](http://www.cocir.org)





# COCIR Member Companies





# COCIR National Trade Associations



Belgium



Hungary



Italy



UK



Spain



Netherlands



Finland



Netherlands



France



Germany



Sweden



Turkey



Germany



## **2. COCIR CT manufacturers' voluntary self-commitment and impact on CT dose optimization**



## **COCIR CT manufacturers are committed to ...**

1. ... Improve accurate image quality assessment required for optimizing patient exposures
2. ...Develop continuously the dose reduction technologies and standardisation
3. ...Improve patient centric dose management through IHE-REM profile, dose check, etc.
4. ... Develop extensive product training on existing and new dose reduction techniques





...through a COCIR CT manufacturers' voluntary self-commitment

- **Commitment 1: Characterization of CT Systems Standardized Benchmarking**

**Aim:** To provide transparency and easily understood values that attempt to characterize system performance through standardized test methods and conditions.

**Currently:** Reviewing advanced models for inclusion into product testing to measure image quality & associated dose more objectively than today.

- **Commitment 2: Implementation of Dose Reduction Measures in CT**

**Aim:** To foster the development and propagation of dose reduction/dose management measures across CT products.

**Currently:** Proposing measures for inclusion in international standards (e.g. IEC 60601-2-44). Examples: Dose Check, DICOM SR, IHE-REM...



...through a COCIR CT manufacturers' voluntary self-commitment

- **Commitment 3: Dose Management & Reporting**

**Aim:** To support IHE-REM profile and enhance dose management and reporting capabilities.

**Currently:** Manufacturers have implemented or are implementing Dose Check, DICOM SR, & Access Controls on systems. Additionally, the global physics community is evaluating new dose metrics that may prove usefulness for CT imaging.

- **Commitment 4: Provision of Specific Training Curricula**

**Aim:** To support appropriate, safe and effective use of imaging equipment by the clinical user.

**Currently:** Specific training curricula on existing and new dose reduction techniques, how to use these features in daily practice, and how to enable users to continue to reduce patient dose.



# 4. COCIR recommendations to IAEA



# COCIR recommendations to IAEA

1. Dose reduction in clinical setting is a multi-faceted issue that requires all stakeholders involvement: *IAEA could provide its expertise in these activities*
2. Effective education and dissemination of up-to-date information on dose reduction best practices/training to end users worldwide is crucial: *IAEA could coordinate with key regional partners (i.e. EMAN in Europe) a worldwide platform for education and publishing of materials*
3. Need to improve the mechanism to ensure end users are educated on dose reduction measures and associated clinical practices: *IAEA could develop state-of-the-art standards for a better harmonization of certification requirements for end users*



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

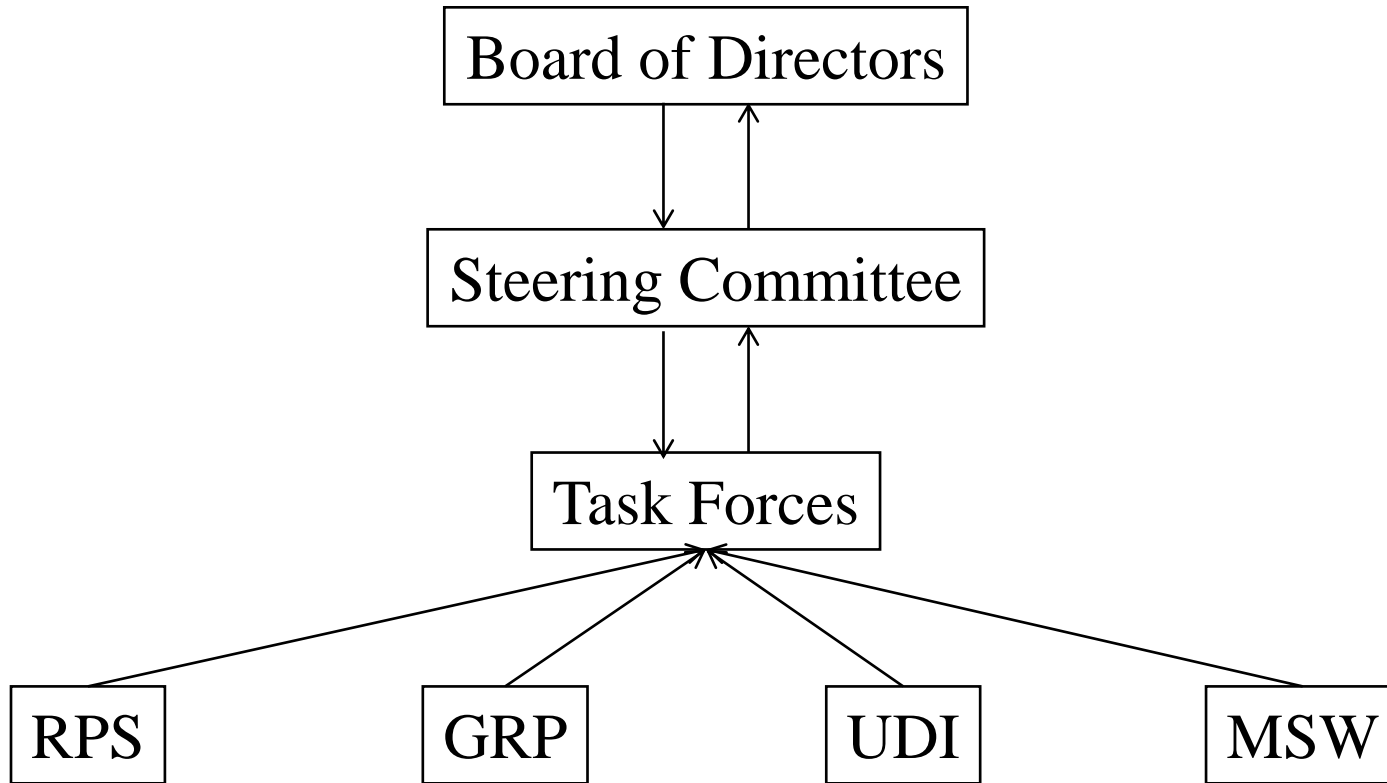
**The Global Industry Voice**

*Existing for more than 10 years*

*Incorporated in 2012*



# CURRENT ORGANIZATIONAL STRUCTURE





# GROWING OPERATIONS

- Incorporation, By-laws
- Funding Members:
- New members:
  - THAIMED (Thailand)
  - IMEDA (Russia)
  - CAMDI (China)
  - ABIMED (Brazil)
- Website [www.globalditta.org](http://www.globalditta.org)





# BUILDING RELATIONSHIPS WITH MULTINATIONAL INSTITUTIONS



## World Health Organization

- Met with WHO 3x in Geneva this year
- Working to establish status as an official partner



## The World Bank Group

- Led a global industry coalition in a consultation as part of the Bank's 2-year procurement review
- White paper posted on World Bank website
- Follow-up meeting next week to discuss implementation of industry recommendations





# BUILDING RELATIONSHIPS WITH INTERNATIONAL REGULATORS



## Asian Harmonization Working Party (AHWP)

- Sponsored the AHWP Annual Conference in Taipei
- Hosted a workshop on medical software at the AHWP Annual Conference
- Pursuing AHWP liaison member status



**IMDRF**

## International Medical Device Regulators Forum (IMDRF)

- Represented in IMDRF Regulated Product Submissions (RPS) WG
- Lead the capital equipment group of the IMDRF UDI WG
- Prepared template for future IMDRF work item on medical software
- Invited to attend Sydney IMDRF Management Committee meeting
- Presented at Open Stakeholders Forums in Singapore and Sydney





**Thank you**



# Back-up slides



## Commitment 1: Characterization of CT Systems Standardized Benchmarking

- Task based image quality assessment being considered for global consistency. Manufacturers involved in discussions with US FDA for pre-market submissions.
  - Human observer studies
  - Model observer studies



# Commitment 2: Implementation of Dose Reduction Measures in CT

- **Part 1: Available Technologies to Date**

<http://www.cocir.org/content.php?level1=20&level2=88&mode=1>

- **Part 2: IEC process and Periodic Industry Assessment**

**IEC 60601-2-44 adopting:**

*Examples*

Preview image – beam over range indicators	Done (Edition 3)
Dose Check - require as global standard	Next edition
Access Controls	In progress
Patient dose metrics – new work item & standard	In progress



# Commitment 3: Dose Management & Reporting

## Dose Management

- **Phase 1: Dose Check**  
Complete – phasing into CT systems



- **Phase 2: Security**  
Access Controls for CT

Standard in approval – NEMA then IEC

- Scanning & protocol privileges
- Patient ID, height, weight & gender
- Emergency Access
- Log File
- System Lock



# Commitment 3: Dose Management & Reporting

## Dose Reporting

- **Phase 1: CTDI<sub>vol</sub>, DLP, & DICOM SR (complete)**

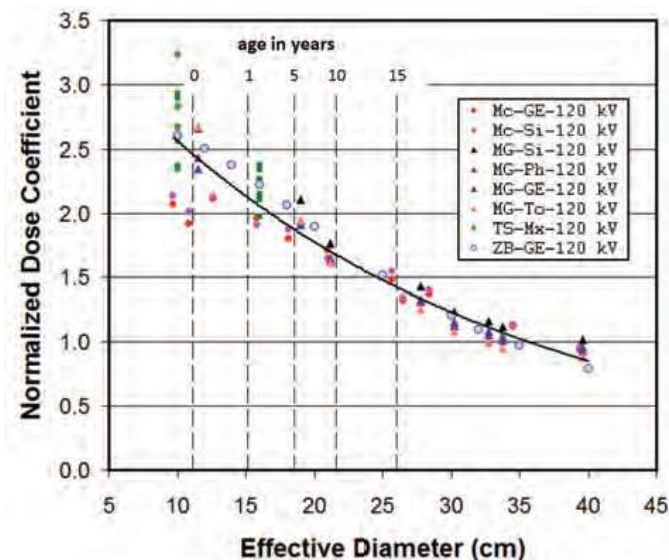
CT systems display accepted dose metrics prior to scan initiation and record these metrics in a post exam DICOM Structured Report – enabling IHE REM, quality assurance, and dose index registries

- **Phase 2 & 3 – Patient centric/Organ dose metrics**

1. Size Adjusted Dose defined for Axial Scans in AAPM **report #204**. New AAPM Task Force to standardize method to calculate for helical scans, including dose modulation (required to move forward) – IEC inclusion being planned

- Complete calculations definition
- Standardize method
- Implementation

2. Organ Dose – Global physicist community and FDA considering different models





## Commitment 4: Provision of Specific Training Curricula

### 1. Manufacturers' domain specific training curricula

- Together with new developments in new CT products and radiation dose reduction techniques, scan protocols and CT user training is very important
- Manufacturers invest in the education of their customers (on site and via course programs)

### 2. Clinician developed

- Societies -such as ESR (ESOR)- and new projects -such as EMAN- develop public and member education programs on radiation dose education and awareness building
- Manufacturers contribute as a stakeholder to these programs