COCIR CT MANUFACTURERS' VOLUNTARY COMMITMENT REGARDING CT DOSE OPTIMIZATION

2015 Annual Report

Preamble

In 2010 discussions took place between COCIR and the Heads of European Radiation Competent Authorities (HERCA) on CT industry commitment in reducing radiation dose for CT equipment. A dedicated COCIR Task Force was created and a COCIR CT manufacturers' voluntary commitment was signed in May 2011.

The aim of this commitment is to further the initiatives of improving dose reporting, promoting transparency in dose efficacy, continuing reduction of medical exposures, and providing specific training curricula. The manufacturers agree to complete the voluntary commitments outlined within and provide yearly updates on:

1. Characterization of CT Systems Standardized Benchmarking
2. Implementation of dose reduction measures in CT
3. Dose management and reporting
4. Provision of specific training curricula

The CT manufacturers agree to work under the umbrella of their European Trade Association, COCIR, to ensure a joint approach. If significant delays or advancements in the timelines are expected these are agreed to be communicated in a timely manner.

This 2015 Annual Report defines the 2014 progresses and achievements of the COCIR CT manufacturers.

Statement from CT manufacturers

As the developers of sophisticated scanners, CT manufacturers acknowledge their unique role in the process to help optimize patient CT dose in the health care setting. This can be accomplished through 4 major items:

Commitment 1
Characterization of CT systems standardized benchmarking

As agreed with HERCA in December 2013 and further reviewed in April 2014 at the annual face-to-face meeting, Commitment 1 has been reformulated.

Background

Scan conditions and parameter settings currently used for the specification of image quality and dose differ from vendor to vendor. Therefore, a direct comparison of CT systems can be challenging. Unfortunately, the definition of one single parameter to characterize dose efficiency of a modern CT system with Iterative Reconstruction Methods, is not currently feasible. COCIR CT manufacturers and HERCA agree that for the current moment no single figure of merit can accurately reflect CT dose efficiency.

Scientific groups are currently working on new pathways for characterization of CT performance.

Aim CT manufacturers aim to provide transparency and easily understood values for the end users that attempt to characterize system performance for the clinical tasks through standardized test methods and conditions.

Concept The COCIR CT manufacturers are and will continue to actively participate in the MITA[1] CT Image Quality (IQ) Task Force that is investigating a new phantom and bench testing methodology for assessing Low Contrast Detectability (LCD) and the associated dose level. This methodology offers the potential to quantitatively assess LCD for clinical protocols in the body and in the head in relation to dose. HERCA, through its Panel of Advisers (PoA) in CT technology, has been involved in this process, regularly informed about the status of the process and invited to participate in the analysis of the results. For transparency purposes, CT manufacturers will continue to make available details on test conditions for dose related claims. COCIR and HERCA installed a platform of communication on a yearly basis to address the tasks of clinical detectability and work closely together to improve the understanding of CT dose efficiency.

Estimated Timelines

Part 1:

- **Phase 1**

Status: Completed in Q1 2011

Provide standardized dose values for different shaped or flat filter settings (per IEC 60601-2-44 Edition 3.0 Standardized base testing).

- **Phase 2**

Status: Completed (using Annex 1 formulation in 2014 report) in Q1 2012

CT manufacturers completed a pilot round of testing of these methods and reported results on a single CT platform for each manufacturer.

- **Developments 2014**

As agreed in 2014, CT manufacturers will continue to develop more appropriate methods of image quality assessment (as outlined in Part 2 below) and will not report results from the test method defined above.

Part 2:

Status: Reformulated in 2014, as follows:

The COCIR CT manufacturers have, through the coordination of the MITA CT Image Quality (IQ) Task Force, designed a reference phantom for objective quantification of head and body LCD measurements versus exposure level. As discussed previously this objective quantification was not present in CT system performance data nor was it possible with previous methods. CT manufacturers commit and are in coordination with the HERCA PoA to document this assessment method, including the phantom, test method and resulting image quality and dose performance claims in an appropriate trade journal or publication.

[1] *US Medical Imaging and Technology Alliance* http://www.medicalimaging.org/

Commitment 2
Implementation of dose reduction measures in CT

Background
As manufacturers of CT equipment, dose reduction has always been a high priority, as can be seen by the long history of dose reduction features developed by the members. The CT manufacturers commit to:

1. continued innovation in dose reduction and optimized dose management
2. a standardized process by which they drive dose reduction features into what can be considered the "state-of-the-art – standard general practice" and thus included in the base configuration for CT scanners.

Aim
The aim of this commitment is to foster the development and propagation of dose reduction measures across CT products, with the acknowledgement that certain measures may not be feasible or relevant for implementation on certain product configurations and therefore not appropriate for inclusion in a list of capabilities required on base product configurations. This commitment will standardize a process for periodically incorporating appropriate dose reduction capabilities into a standard/list that defines the minimum required (therefore not available as saleable options) on new base CT system configurations available for sale.

Concept
CT manufacturers commit to identify standard dose reduction measures using the IEC process (IEC 60601-2-44). By using this process the periodicity for proposing new dose reduction capabilities will be semi-annual. Based on these proposals, the capabilities will be evaluated for identification in the CT particular standard. Following this identification a timeline is developed to add these as base capabilities on forward production systems. This timeline is then driven and required by adoption of the standard at national level. CT manufacturers will additionally evaluate the inclusion of dose reduction capabilities in similarly configured installed base products as part of this process. CT manufacturers commit to providing an updated overview of currently available technologies on a periodic basis.

Estimated timelines

Part 1:
List of dose management features
Status: completed in Q1 2011 (Letter sent to HERCA on 04 March 2011 and update sent in July 2013)
"CT Manufacturer List of Dose Management Features"[2] provided to HERCA.

Part 2:
Periodic industry assessment
Status: On-going.
CT manufacturers have continued to work with Industry Associations (COCIR, MITA) to assess current "state-of-the-art - standard general practice" dose management capabilities, and will move to have these capabilities listed in the IEC "Particular requirements for the basic safety and essential performance of X-ray equipment for

[2] *http://cocir.org/fileadmin/5_Initiatives/COCIR_CT_MANUFACTURER_List_of_Dose_ManagementFeatures_05_July_2013.pdf*

computed tomography" (60601-2-44), making these capabilities part of future base CT product configurations. This assessment occurred semi-annually for input to the IEC committee meetings starting with the fall of 2011 meeting.

Developments 2014

As part of this ongoing commitment, CT manufacturers submitted their periodic recommendations on Sept. 2014 to IEC SC62B MT-30[3] requesting consideration of the following topics for inclusion in upcoming IEC standards applicable to CT equipment (note that some of these recommendations have carried over from previous years recommendations):

1. Incorporating Size Specific Dose Estimate (SSDE), consistent with the American Association of Physicists in Medicine (AAPM) TG 204 report (http://www.aapm.org/pubs/reports/RPT_204.pdf).
2. Including new image quality and dose metrics based on iterative technology. For example, observers studies (model or human) as being discussed between CT manufacturers and the US Food and Drug Administration (FDA) in the MITA CT IQ Task Force.
3. Harmonizing regional requirements in the revision of the Acceptance (IEC 61223-3-5) and Constancy (IEC 61223-2-6) testing standards for CT devices to improve global adoption. For example an automatic exposure control (attenuation based mA modulation) functional test method would be useful.
4. Consider incorporating NEMA[4] XR 26-2012: Access Controls for Computed Tomography: Identification, Interlocks, and Logs, into the next edition of IEC 60601-2-44.
5. Include an alert when an adult protocol is selected for a pediatric patient. Pediatric alert could be incorporated in the next edition of IEC 60601-2-44.

MT-30 intends to release a draft for comments of the new IEC 61223 "Acceptance and Constancy standard" after their March 2015 meeting. Additionally, MT-30 is developing an SSDE standard based on the AAPM Task Group (TG) 220 report. MT-30 has formed a new project team with the aim to release a new standard as IEC 62985 Ed 1.0. They will begin working on this standard in March 2015.

MT-30 is monitoring progress of scientific endeavours, e.g., AAPM TG246, for progress related to organ dose metrics appropriate for dose reporting.

The MITA CT-IQ Task force, along with other representatives from several vendors, participated in a FDA webinar on June 10, 2014. The FDA presented a model observer program for evaluating task-based image quality, which they developed, and released to the public domain. This promises to provide more uniform claims of Low Contrast detectability and dose reduction claims across all vendors. COCIR shared the content of the webinar with HERCA on 15 October 2014.

[3] *Maintenance Team 30*
[4] *US Association of Electrical Equipment and Medical Imaging Manufacturers http://www.nema.org/*

Commitment 3
Dose management and reporting

Background
CT manufacturers continually aim to improve the user interface for dose prescription. CT manufacturers have displayed $CTDI_{vol}$ and DLP on CT scanners which are well defined dose metrics. This provides a way to characterize the output of CT scanners.

Aim
CT manufacturers aim to support the IHE REM profile and enhance users' dose management and reporting capabilities. This is best accomplished through conformance to accepted communication standards such as DICOM SR as well as the newly developed dose checking standard (NEMA XR 25-2010). Effective implementation and responsibility of follow through on this concept lies with the user community and is in the realm of the practice of medicine. The COCIR CT manufacturers have made significant progress towards this commitment over the last three years. The ability for users to practice CT dose management is being enhanced through dose reporting capabilities, automated dose notifications, and access controls, with many of the CT manufacturers' commitments complete or nearly complete. With respect to improving CT dose metrics, significant effort is still needed to reach a scientific consensus, however great progress has been made.

Concept
There are 2 ways to do this:

- CT manufacturers have agreed to provide the ability for institutions to set notification values or Diagnostic Reference Levels for each protocol and give user feed-back when dose index is exceeded. It will be deployed on new releases of CT products and most similarly compatible installed base systems. This complies with the MITA Dose check standard (NEMA XR 25-2010).
- CT manufacturers remain committed to improving CT Dose reporting by working towards a more patient relevant estimate of dose with the cooperation of the scientific community.

Estimated timelines

CT Dose Management

• Phase 1
Q3 2010: standard NEMA XR 25-2010 defined
Q1 2011: start of deployment of 1st capabilities: Dose Check Feature
Status: completed (Q1 2011)
Definition of a standard on "dose checking" and deployment of the ability to set notification and alert values or DRLs for each protocol and give user feed-back when dose index is exceeded.

• Phase 2
Q4 2011: standard NEMA XR-26-2012 published
Q3 2013: deployment of 1st capabilities: Security features.
Status: completed (Q1 2014)
MITA Access Controls standard was published in October 2012 as NEMA XR-26-2012, and deployment on forward production systems has begun.

CT Dose Reporting

• **Phase 1**
Q1 2011: start of deployment on newly released CT models: Dose reporting
Status: completed (Q1 2011)
Implement display $CTDI_{vol}$ and DLP and offer DICOM Radiation Dose Structured Reporting.

• **Phase 2**
Q4 2011: Improved patient centric dose indication.
Status: in progress (as noted in Commitment 2).

Developments 2014
AAPM TG204 Report was published in 2011. Following this, AAPM TG220, which includes manufacturers' representatives, worked to resolve outstanding issues from the TG204 report including size estimation technique. The final TG220 report was released in September, 2014. This report provides a "robust and scientifically sound metric for automatically estimating patient size in CT that would account for patient attenuation and allow routine determination of SSDE for all patients, with little or no user intervention".
- Starting in September 2012, COCIR has promoted the adoption of SSDE as an IEC new work item. With the publication of the AAPM TG220 report, a key obstacle for standardizing SSDE was resolved.
- In June 2014 this new working item was submitted by the CT Manufacturers through MITA and accepted by IEC TC 62 MT-30 as of January 2015.

• **Phase 3**
Q4 2012 : Patient Dose estimation.
Status: Monitoring scientific community publications
As agreed during the April 2014 face-to-face meeting with HERCA regulators, current and developing (SSDE) dose indices are appropriate for dose optimization and patient management. COCIR CT manufacturers and HERCA agreed to monitor the scientific community progress and will re-assess appropriateness of new metrics based on scientific consensus and users' needs.

Commitment 4
Provision of specific training curricula

Background
CT manufacturers share with HERCA the concern for keeping the CT user well trained on dose optimization and dose awareness in daily practice. This is of particular importance with the growing number of dose reduction features in CT products.

Aim
CT manufacturers' aim is to ensure the appropriate, safe and effective use of imaging equipment by the clinical user. This includes the provision of specific training curricula on existing and new dose reduction techniques provided by manufacturers, on how to deploy these product features in daily practice, and to enable users to continue to reduce patient dose. This does not include the clinical users' obligations after industry training has been performed and doesn't cover clinical protocols.

Concept
CT manufacturers are committed to make a significant contribution to this aim via:

1. The offering of vendor specific equipment training curricula to the CT user, and through user programs that help CT operators optimizing the patient dose settings on their scanners, and the offering of continuing professional education optional training.

2. Keeping the vendor's equipment training curricula updated with the recent developments that lead to dose reduction and dose transparency. Examples include new product features about dose reporting via DICOM SR, IHE REM, and the Dose Check feature.

3. Being a committed stakeholder, the CT manufacturers will contribute to HERCA related initiatives, such as EMAN, that focus on a cooperative concerted action by all stakeholders for developing a better practice in the management of ionizing radiation dose in CT environments. CT manufacturers welcome invitations to these initiatives.

Training and awareness on dose reduction is a broad process that involves more stakeholders to work together on practical approaches that can step up and maintain an active dose reduction policy in daily practice.

Whilst the CT manufacturers accept their responsibility for maintaining the proper competence levels of their trainers, it is the facilities' responsibility to assess and maintain their equipment user's competency and make arrangements with the relevant manufacturers for their training requirements.

Estimated timelines

Part 1:
Status: Completed Q3 2011
CT manufacturers offer education and training programs to ensure that the CT user is well trained on dose optimization, and facilitates dose awareness during the daily practice with specific CT equipment. A list of training programs has been provided to HERCA. Integration of upgrades on dose reduction features and scan protocols are added to their standard education programs during development.

Part 2:
Status: Ongoing

Developments 2014
The role of CT manufacturers and other stakeholders in education and training has been well described in the HERCA Position Paper: "The process of CT dose optimization through education and training and role of CT Manufacturers" published in October 2014.
As a next step, CT manufacturers and HERCA acknowledge the need for raising the awareness via involvement of other stakeholders. The target is a concerted action that contributes to the adoption of CT dose optimization and the ALARA[5] principle in daily operational practice.

[5] As Low As Reasonably Achievable.

As a contribution to this multi-stakeholder process, COCIR and the CT manufacturers have been active over the last year in a number of awareness programs and meetings organized by other stakeholders, including:

- CT manufacturers have promoted the COCIR-HERCA collaboration and dose optimization activities to other stakeholders via presentations and round tables discussions at a variety of external Meetings and Conferences.
- Most notable at the International Conference on Radiation Protection in Medicine 2014, Varna, Bulgaria (http://rpm2014.org). The audience showed great interest by asking several questions after the presentation.
- CT manufacturers continue collaboration with ESR in their active support to the EuroSafe Imaging Campaign (www.eurosafeimaging.org) for example by participating in the Steering Committee meeting bi-annually.

Conclusion

As developers of sophisticated scanners, CT manufacturers acknowledge their unique role in the process of optimizing patient dose in the health care setting. We believe the 4 elements of the voluntary commitment will help in this process.

COCIR CT manufacturers have appreciated coordination with HERCA on yearly progress and challenges associated with this commitment and commend HERCA for having organized multistakeholders' meeting starting in 2014 as complementary roles of other stakeholders are of high importance

Additional updates will be made if there are significant changes or challenges which result in a significant advancement or delay in the roadmap.

COCIR is representing the following CT manufacturers, which cover the majority of the installed base of CT systems in Europe: General Electric Healthcare, Philips Healthcare, Siemens Healthcare, and Toshiba Medical Systems. These CT manufacturers voluntarily commit to work toward the road map outlined above and ensure timely, effective and consistent implementation of the plan through COCIR's coordination. Therefore, COCIR, as the CT manufacturers' representative, will coordinate and direct these activities appropriately with HERCA in Europe.

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