COCIR CT MANUFACTURERS' VOLUNTARY COMMITMENT REGARDING CT DOSE OPTIMIZATION

2016 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

Note: Completed commitments have been removed from this annual report as agreed during the 2015 annual meeting between HERCA and COCIR.

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 2016 Annual Report defines the 2015 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.

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.

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 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 2015

As part of this ongoing commitment, CT manufacturers have requested IEC SC62B MT-30[2] consider 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:
    a. http://www.aapm.org/pubs/reports/RPT_204.pdf
    b. https://www.aapm.org/pubs/reports/RPT_220.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[3] 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 a revised IEC 61223 "Acceptance and Constancy standard." It was determined at the September 2015 MT-30 meeting that this standard will be released as IEC 61223-3-5 and will combine methods for acceptance and constancy as well as an automatic exposure control (attenuation based mA modulation) functional test method. The committee intends to bypass the committee draft (CD) stage and move directly to a committee draft for vote (CDV) after the March 2016 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 (PT62985) with the aim to release a new standard as IEC 62985 Ed 1.0. PT62985 has continued to develop the standard during the March and September 2015 MT-30 meetings and held a focused meeting in February 2016. The project team continues to address technical challenges as they work towards a March 2016 committee draft (CD).

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. Additionally, the CT-IQ Task Force is drafting this assessment method and submits the outline in Appendix for consideration and feedback from HERCA.

[2] *Maintenance Team 30*
[3] *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, and not the dose to the patient.

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

Developments 2015
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 February 2015.
- IEC 62985 Ed. 1.0 "Methods for calculating Size Specific Dose Estimate (SSDE) on Computed Tomography" project team (PT62985) formed with the goal to release a 1st committee draft by March of 2016 and a forecasted publication date of August of 2018. A focused meeting was held in February 2016 to resolve remaining technical questions and complete committee draft for review at the March MT-30 meeting.

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.

Part 2:
Q3 2011: Participate in Clinician developed training activities.
Status: Ongoing

Developments 2015

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[4] principle in daily operational practice.
As a contribution to this multi-stakeholder process, COCIR and the CT manufacturers are engaged in awareness programs and meetings organized by other stakeholders, for example, the ESR - EuroSafe Imaging Campaign (COCIR is a permanent member of the steering committee) and ICRP/WHO/IAEA conferences among others.

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 multi-stakeholders' 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.

[4] As Low As Reasonably Achievable.

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A DIVISION OF NEMA®

1300 North 17th Street ▪ Suite 900
Arlington, Virginia 22209
Tel: 703.841.3200
Fax: 703.841.3392
www.medicalimaging.org

Draft Dose Reduction Claim Process Outline

Background: The MITA CT Image Quality (IQ) Task Force designed a reference phantom for objective quantification of head and body Low Contrast Detectability (LCD). This methodology offers the potential to quantitatively assess LCD for clinical protocols in the body and in the head in relation to dose. During development, it was found that many approaches are valid and that different approaches may be appropriate depending on the situation.

I. Introduction
   a. IR exhibits non-linear behavior
   b. Traditional metrics such as MTF and NPS are not reflective of system-wide performance
   c. Task-based approach used for dose reduction claims

II. Low Contrast Detectability task
   a. Noise-limited detectability task
   b. Does not encompass all aspects of image quality

III. Observer studies
   a. Many observer are valid
      i. Human
      ii. Model
         1. Prewhitening MO
         2. Non-Prewhitening
   b. Many experimental setups are valid
      i. Alternative forced choice tests
      ii. Can test both location known and location unknown
      iii. Search
   c. Misc
      i. Scan start angle not important
      ii. Contiguous slices okay to use (correlations negligible impact)
      iii. Impact of z-smoothing significant
      iv. Images of end of test object should be dropped
      v. Bias in signal absent ROI must be avoided/controlled for

vi. More than 1 reduced dose level should be examined to avoid hitting "sweet spots"

IV. Phantom
   a. Amenable to human and model observer studies
      i. All lesions size/HU combinations can be studied with single dose
      ii. Enough room to create usable ROI (moving rod within ROI to create location unknown studies
      iii. Radially symmetric pin position to generate same noise correlations
      iv. Uniform background chosen because repeatable
      v. Test objects have some inherent tolerance (some phantoms high/some phantoms low); must be mindful
      vi. Different contrast helpful in head and body
      vii. Energy independent (not good for examining impact of kVp)