COCIR CT Manufacturers' Voluntary Commitment Regarding CT Dose

2014 Annual Report

Preamble

This 2nd Annual Report defines the COCIR CT manufacturers' voluntary commitment to HERCA as a result of the meeting held in Bern on 14 June 2010. Updates have been made as appropriate following the progress and evolution of the commitments.

The CT manufacturers agree to work under the umbrella of their European Trade Association, COCIR, to ensure a joint approach. 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 provision of specific training curricula. The manufacturers agree to complete the voluntary commitments outlined within and provide yearly updates with regard to their status and deliverables. Additionally, if significant delays or advancements in the timelines are expected these are agreed to be communicated in a timely manner.

General 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, Commitment 1 is to be reformulated as follows:

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 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. The CT manufacturers are convinced that this methodology offers the potential to quantitatively assess the 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, will be closely involved in this process, be regularly informed about the status of the process and be invited to participate in the analysis of the results. For transparency purposes, CT manufacturers will make available details on test conditions for dose related claims. COCIR and HERCA will install 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.

The previous formulation of Commitment 1 can be found in Annex 1

Estimated Timelines

Part 1:

- **Phase 1 (Q1 2011)**

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). Starting on this date CT manufacturers agree to phase in reporting of these values on new and select CT platforms.

- **Phase 2 (Q3 2011)**

Status: Completed (using Annex 1 formulation) with revision in Q1 2012 (letter sent to HERCA on 03 February 2012)

Representative image quality and dose measurements at standardized scan conditions (representing four clinical scans) and using standardized measurement techniques. Starting on this date CT manufacturers agree to phase in reporting of these values on new and select CT platforms. CT manufacturers completed a pilot round of testing these methods and reported results on a single CT platform for each manufacturer. As discussed above, CT manufacturers will continue to develop more advanced methods of image quality assessment (as outlined in Part 2 below) *vs* continuing to report results from the test method defined above.

Part 2:

Status: Reformulated, ongoing

The scientific community has been working on an analytical model that would provide a normalised figure of merit that represents CT dose efficiency. However, at present there is no consensus on a single figure of merit for image quality/dose assessment.

Actions from 2013: Ongoing activity in coordination with MITA CT Image Quality Task Force, including reference phantom design for head and body image quality, in order to establish an objective quantification of LCD measurements versus exposure level, which was not possible with previous methods.

Commitment 2: Implementation of dose reduction measures in CT

Background

The CT manufacturers commit to continued innovation in dose reduction and optimized dose management. 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 member manufacturers. CT manufacturers commit to 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 will identify Safety Measures Against Excessive X-Ray radiation 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 harmonized standards. 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:

- **Q4 2010**

Status: completed in Q1 2011 (Letter sent to HERCA on 04 March 2011 and update sent in July 2013)

CT manufacturers are working through MITA to provide an updated overview of available technologies. An updated list was provided to HERCA in July 2013.

Part 2:

- **Periodic industry assessment**

Status: On-going.

CT manufacturers will continue 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 will occur semi-annually for input to the IEC committee meetings starting with the Fall of 2011 meeting. This feedback is on-going.

During the Sept. 2013 MT-30 meeting, a successor standard to IEC 61223-3-5 and 61223-2-6 (Acceptance and Constancy Testing) incorporating automatic exposure control functional test methodologies and additional image quality metrics, such as noise power spectrum, was discussed. Physicists and manufacturers are to complete additional evaluations and testing to refine the methodologies, finish writing the standard, and demonstrate feasibility.

Additionally, MT-30 is considering an SSDE standard based on the AAPM Task Group (TG) 204 report. Technical questions remain with the determination of a patient size metric (based on progress of AAPM TG220) and will need to be resolved before the final standard can be released. However, a new work item is to be introduced in Q1'2014, and the expected time for MT-30 to begin formalizing the draft of the standard is Q3'2014.

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

Commitment 3: Dose management and reporting

Background
CT manufacturers continually aim to improve the user interface for dose prescription. CT manufacturers have displayed CTDIvol 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 two 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 DRLs 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 will improve CT Dose reporting by working towards a more patient relevant estimate of dose. We are working with scientific community to define this.

Estimated timelines
CT Dose Management
• Phase 1 - Q3 2010: standard defined, Q1 2011: start of deployment of 1st capabilities: Dose Check Feature
Status: completed (Q1 2011)
The MITA Dose Check standard was published in 2010 and all COCIR CT manufacturers now provide the Dose Check feature capability.
Dose Check provides a tool for institutions to set dose notification levels and provide feedback to the operator when limits are exceeded as listed in NEMA XR 25-2010.

• Phase 2 - Q4 2011: standard to be defined, Q3 2013: start of deployment of 1st capabilities: Security – conceptual.
Status: completed (Q1 2014)
The MITA Access Controls standard was published in October 2012 as NEMA XR-26-2012, and deployment on forward production systems has begun as of Q1 2014.
This will provide enhanced ability for the user to control access and audit for setting items like dose notification levels and the saving of protocols.

CT Dose Reporting
• Phase 1 - Q1 2011: start of deployment on newly released CT models: Dose reporting
Status: completed in Q1 2011
All COCIR CT manufacturers display $CTDI_{vol}$ and DLP and offer DICOM Radiation Dose Structured Reporting.
– Display of $CTDI_{vol}$ and DLP, the most universal and accepted method at this time.

– Delivery of DICOM SR (Structured Reporting) for dose feature, which will enable imaging institutions to start with the implementation of automated exposure dose reporting based on the IHE REM (Radiation Exposure Monitoring) profile which allows third party programs to tabulate dose statistics for a scanner or collection of scanners at a site.

• Phase 2 - Q4 2011: Improved patient centric dose indication.
Status: in progress (as noted in Commitment 2)
– AAPM TG204 Report was published in 2011. Following this, AAPM TG220, which includes manufacturers' representatives, is working to resolve outstanding issues from the TG204 report, including size estimation technique. The output of this task group will be a sound and robust method to calculate the Size Specific Dose Estimate (SSDE).
– CT Manufacturers intend to propose a new work item for IEC MT-30 to develop an international standard for SSDE. The proposal for this work item will be submitted in Q1 2014. Expected time for MT-30 to begin work: Q3 2014.
– As noted above, although significant progress has been made and there are solutions on the market that will currently calculate SSDE, timelines for implementation on CT systems will depend on accepted scientific consensus and standardization.

• Phase 3 - Q4 2012 : Patient Dose estimation.
Status: monitoring scientific community publications
– CT manufacturers will continue to participate in the efforts by the scientific community to investigate ways to more accurately estimate patient dose. Currently, there is no accepted nor easily achievable method to calculate actual absorbed radiation dose to an individual patient's organs.
– CT manufacturers appreciate HERCA participation in the IEC to develop a standard method.
– Timelines depend on accepted scientific consensus. Experience in obtaining scientific consensus on and standardizing SSDE shows that the original timeline for a patient dose estimate such as "organ dose" or similar was significantly too short. Scientific work continues in this area, e.g., in AAPM TG246, and manufacturers will continue to participate.

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, on how to deploy these product features in daily practice, and to enable users to continue to reduce patient dose.

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

- **Q3 2011**

Part 1:

Status: Completed (Invitation letter sent to HERCA on 03 December 2012)

CT manufacturers informed current situation to HERCA by providing an overview of training categories with real examples. Complete. CT Manufacturers have informed HERCA about their continuous investment in training programs that clearly show commitment to end-user education. Existing and new dose reduction features and scan protocols for specific CT equipment continue to develop, and CT manufacturers have integrated upgrades on this topic into their standard education programs.
The manufacturers' process of updating curricula and the creation of new curricula is in sync with the release of a new product model, or a new software version on an existing product model.

Part 2:

Status: Ongoing

In addition we propose a dialogue with HERCA in conjunction with our periodic updates on potential revision of training curricula based on user needs in order to improve effectiveness. CT manufactures have shown commitment to contribute as one of the stakeholders to initiatives such as EMAN and the EuroSafe Imaging campaign – see Annex 2 for COCIR's contribution to EuroSafe's poster session at ECR2014 – and confirm continued commitment to similar initiatives.

Conclusion

As the 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 items above will help in this process.

For a contemporary and unhesitant implementation the COCIR CT manufacturers propose the roadmap and timing as outlined in the voluntary commitment to be completed in the stated phases. COCIR CT manufacturers propose to update HERCA yearly on the progress and challenges associated with the voluntary commitment.

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.

Nicole Denjoy
COCIR Secretary General

Annex 1: Original Formulation of Commitment 1 Prior to December 2013

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 a CT system is very difficult and may result in a limited and insufficient characterization of system performance. Multiple international expert task groups from the physics community trying to define one single parameter to characterize a CT system have not succeeded so far. Therefore, we believe that the development of a standardized benchmarking will need to be based on several Image Quality and Dose Parameters.

Aim

CT manufacturers aim to provide transparency and easily understood values that attempt to characterize system performance through standardized test methods and conditions.

Concept

Dose efficiency requires dose measurement and image quality assessment to be done simultaneously. Initially the concept for this commitment was to define as close to standard test methods/parameters as possible and perform measurements of dose and critical image quality parameters for 4 representative clinical protocols that cover approximately 70% of clinical scans (standard head, high resolution head, standard body, high resolution body). These results were then intended to be available for use in future analytical expressions to produce four figures of merit, one for each representative protocol. The COCIR CT Manufacturers reported the test conditions and methods as well as pilot results for one system type per manufacturer to HERCA in March 2012. Significant experience was gained during this process and concerns regarding reproducibility as well as usefulness to the clinical end user were raised. Additionally, the science of image quality and dose assessment continued to evolve during this time, potentially creating more appropriate concepts for future dose and image quality comparison. Specifically, CT manufacturers' scientists are pursuing advanced test methods and phantoms to more accurately describe CT system performance for low contrast detectability, these methods would apply not only for filtered back projection but also iterative reconstruction algorithms. Given this work, manufacturers proposed in March 2012 that future work in the realm of characterization of CT systems and standardized benchmarking should be based on these advanced methods currently being developed with the US FDA.

Annex 2: COCIR Contribution to EuroSafe Campaign Poster Session at ECR2014

ESR EUROSAFE IMAGING

How our company contributes to radiation protection
COCIR - European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry

COCIR supports the EuroSafe Imaging campaign: working together for patient safety

Be part of the European Society of Radiology's radiation protection initiative, become a Friend of EuroSafe Imaging. www.eurosafeimaging.org

COCIR welcomes the launch of the EuroSafe Imaging campaign to promote awareness and build collaboration around the importance of radiological imaging, while taking measures to protect patients from unnecessary exposure to radiation. COCIR is committed to promoting the campaign, raising awareness and training amongst radiologists, and helping accelerate the use of technologies in Europe that can help meet the campaign's objectives.

COCIR's four Es: Endorse, Explain, Enhance, Educate

COCIR welcomes the European Society of Radiology's EuroSafe Imaging campaign to promote awareness and build collaboration around the optimised use of radiological imaging, as industry and healthcare professionals share a long history of pioneering technologies to reduce and optimise exposure to radiation.

Innovative technologies are crucial elements in improving clinical outcome. Amongst other technologies, x-ray, CT, radiation therapy, interventional procedures are used at all stages of patient care: screening, early diagnosis, treatment planning, monitoring and therapeutic procedures.

The industry continuously develops technologies to minimise radiation dose to patients and healthcare professionals. For example:

- Moving conventional radiology to digital radiology
- Introducing major technology breakthroughs to achieve low-dose CT
- Measuring and monitoring dose through management software

COCIR encourages healthcare providers to prioritise dose reduction and dose optimisation when replacing ageing equipment or planning new investment.

COCIR also supports the European Society of Radiology in the promotion of training and education for healthcare professionals.

COCIR welcomes the newly published European Union legislation that promotes dose reduction to improve patient safety and support the EuroSafe campaign.

We appreciate initiatives to improve safety and encourage the European Union to promote the faster introduction of dose optimisation – both through guidance to Member States and the use of its own funding mechanisms.

COCIR's commitment to radiation dose optimisation and reduction

COCIR technologies – supporting clinicians, benefiting patients

Ionising radiation has been used for over a century in medical imaging with untold benefits to patients. Though rising radiation doses from increasing medical procedures is of concern, it is important to recognise the benefit of a quality imaging examination that addresses pertinent clinical issues affecting patient care. Examinations should only be conducted when necessary and at the lowest radiation dose consistent with acquisition of the desired clinical information and in adherence to the principle of ALARA - as low as reasonably achievable – widely used in radiological protection.

COCIR's members work with clinicians to design new and improved technologies. Dose alert and reduction features have been available on CT systems and recent advances have been made to help clinicians better optimise radiation dose to patients: "Low-dose" CT provides the same clinical image quality using reduced radiation doses comparable to conventional x-ray, and new software has been introduced to measure, track and estimate patient dose.

Some hospitals in Europe now use these technologies, benefiting patients, clinicians and increasing efficiency, but others are still to replace ageing equipment or introduce "low-dose" systems for sensitive populations such as children or patients requiring multiple examinations. With the principle of ALARA reinforced in new EU legislation[1], COCIR expects these technologies to become more prevalent in Europe and urges the EU to use funding mechanisms, such as structural funds, to assist eligible countries to adopt them.

COCIR – partnering for radiation protection in Europe

COCIR's CT manufacturers have worked with the Heads of Europe's Radiation Protection Control Authorities (HERCA) and issued a voluntary commitment on dose awareness and reduction in May, 2011. Work is ongoing in collaboration with other stakeholders (HERCA, scientific community, ESR, EMAN, EFRS, etc) on standardisation of dose reduction claims and dose estimation through phantom development and dose metrics such as size-specific dose estimate (SSDE).

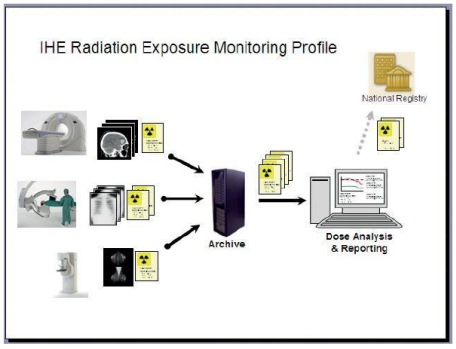
COCIR's Radiation Task Force monitors regulations affecting medical devices using ionising radiation and assesses the impact of regulatory changes related to radiation dose. The Task Force is seeking harmonisation of those requirements across Europe, and has engaged in regular dialogue with the European Commission Directorate General for Energy (ENER) on the recasting of the EURATOM Directives and the EU guidelines on Radiation Protection (RP 162).

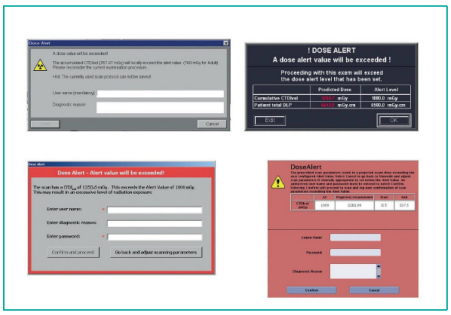
1 Council Directive 2013/59/EURATOM laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, 5 December 2013

Dose reduction technologies in CT systems

The following innovative features in CT systems allow for reduced dose in examinations, and enabl hospitals to monitor and prevent excesses in the total dose given to a patient over a given perio of time:

1. Iterative reconstruction technology - improves image quality and allows considerable dose savings
2. Dose modulation options – optimise dose for different patient sizes and can reduce dose to sensitive organs
3. Predefined protocols for adults and children
   - Provision of specific training curricula
   - Promotion of dose awareness
   - Leveraging system dose reduction features
4. Dose management and reporting
   - Radiation exposure monitoring (IHE-REM profile) (see Fig. 1)
   - Dose alert feature (see Fig. 2)
   - Access control to dose reference level settings, etc.





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