COCIR
SELF-REGULATORY INITIATIVE
FOR MEDICAL IMAGING EQUIPMENT
2009-2013

COCIR
SUSTAINABLE COMPETENCE IN ADVANCING HEALTHCARE

European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry

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1. INTRODUCTION

COCIR Member Companies believe in being proactive about ecodesign in the medical device industry and fully supports the Ecodesign Directive aims and objectives.

The objective of this document is to present to stakeholders and interested parties the commitment of companies in the Medical Electrical Sector to develop a Self-regulatory Initiative for Medical Imaging Equipment (SRI) in the context of the Ecodesign Directive.

The methodology driving the SRI, results achieved by Industry in fulfilling the set targets in reducing environmental aspects and the progress in applying the methodology to new product groups (one new group every year) are not presented in this document but can be found in the following documentation published on the COCIR website:

- SRI Methodology v3
- Annual SRI Status Report and related documentation.

Through the SRI COCIR Companies commit to proactively participate in active Ecodesign while continuing to take advantage of new technologies for improved medical care

2. REVIEW BY INDEPENDENT PARTY

The Steering Committee mandated an external independent party, PricewaterhouseCoopers AG WPG (PwC) to perform a limited assurance engagement on the preparation process of selected data of the Status Report for the year 2010/2012, in accordance with the International Standard on Assurance Engagements (ISAE) 3000 'Assurance Engagements other than Audits or Reviews of Historical Information', enacted by the IAASB.

Within the scope of PwC work the following procedures, amongst others, have been performed:

- Inquiries of personnel at the SRI Steering Committee Secretariat (COCIR) responsible for the preparation of the SRI Status Report regarding the process to prepare the Report and the underlying internal control system;
- Inspection and sample testing of the systems and process documentation for collection, analysis and aggregation of the selected data;
- Recalculation of the aggregation and KPIs calculation for selected data;
- Analytical procedures on selected data;
- Inspection of documents regarding the description of the SRI six step methodology (SRI V2) and its application to MRI as detailed in 'Magnetic resonance Equipment (MRI) - Study on the potential for environmental improvement by the aspect of energy efficiency' and 'Magnetic Resonance – Measurement of energy consumption'.

Data and figures marked with the ✓ logo have been in the scope of the PwC review.

3. COCIR

Founded as a non-profit trade association in 1959, COCIR[1] represents the Radiological, Electromedical and Healthcare IT industry in Europe. COCIR is committed to support its members and communicate with its partners in Europe and beyond on issues which affect the medical technology sector and the health of EU citizens. COCIR also works with various organisations promoting harmonised international standards and regulatory control that respects the quality and effectiveness of medical equipment and healthcare IT systems without compromising the safety of patients and users.
COCIR's key objectives include to promote free worldwide trade of medical equipment and to maintain the competitiveness of the European health sector.

3.1. COCIR INITIATIVES IN THE FIELD OF ENVIRONMENT

One of COCIR's key competencies is in the field of the **Environment** (EU and Global). In 2000 COCIR created the Focus Group Environmental Affairs. Its main tasks are:

- to collect environmental information,
- share best practices and
- to drive innovative solutions to reduce adverse environmental impacts.

Supported by COCIR's long track record in leadership in this domain for Medical Equipment, a variety of initiatives were started in the field of the environment.

2000, from the beginning COCIR is developing solutions to integrate the approach of "Integrated Product Policy". In the front is the idea "Thinking in life cycles". COCIR supported solutions for "Gathering information from supply chain regarding substances", "Take back used Products", "Refurbished Systems" and very first version of "Environmental Product Declarations".

2002 - 2007, in the field of **International Standardisation**: COCIR member companies contributed to the development of an internationally-recognized standard integrating Ecodesign into the product design and development process for all electromedical equipment. International Electro-technical Commission (IEC) published the International Standard IEC 60601-1-9: Environmentally Conscious Design of Medical Electrical Equipment in July 2007. The standard provides a systematic approach for product designers to address all life cycle aspects when they design new medical equipment.

In **2006**, in the field of **Integrated Product Policy**, as advocated by the EU's Action Plan on Sustainable Consumption and Production and Sustainable Industrial Policy (SCP/SIP)[2], COCIR member companies participated in an Integrated Product Policy project with the Hamburg authorities and hospitals. Operators and manufacturers of medical equipment jointly developed a standardised list of criteria for ecological product information to allow hospitals to make a balanced ecological and economical purchasing decision.

Keeping up with the latest inventions in medical technology often involves replacing equipment in medical practice before it reaches the end of its useful life. COCIR published in **2007** a version 1 of **Good Refurbishment Process** (GRP) describing in 5 steps how manufacturers effectively refurbish equipment to ensure quality, safety and effectiveness of medical imaging equipment. Evidence-based data are showing this process contributing to a Recycling Economy[3]. A version 2, endorsed by MITA (US Trade Association) and JIRA (Japanese Trade Association), was published in September **2009.** In addition, COCIR published its 1st Industry Standard

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[1] *For more information: www.cocir.org.*
[2] *See COM(2008) 397, Brussels, 16.7.2008.*
[3] It has been verified that the typical reduction of energy input due to refurbishment of used medical equipment compared with the manufacturing of a new piece of equipment is 100% for a new device to only 27% for the refurbished device. An estimated 1, 6 billion Euros are spent on refurbished equipment globally, 50% of this is sold in the U.S. and the EU alone. Source: COCIR internal data.

(http://www.cocir.org/uploads/documents/-560-cocir_industry_standard1806.pdf).

COCIR published in **2008** a **guide** on REACH requirements for component suppliers and equipment manufacturers
http://www.cocir.org/uploads/documents/32-697-guide_to_reach_requirements_for_component_suppliers_and_equipment_manufacturers.pdf.

In **2008**, COCIR launched a **web-based database for substances declarations under REACH, RoHS, Batteries and Packaging directives called BOMcheck**. This centralized open-access database provides a cost-effective approach for manufacturers to work with their suppliers to reduce hazardous substances in products. The system improves the quality and availability of substance information across the supply chain and this enables manufacturers to reduce the environmental aspects of new product designs. This initiative is benefiting not only COCIR members but also to all electronic industries. This initiative is hosted by COCIR but includes a vast list of industries in the electronic domain. A Steering Committee has been established and is continuing to monitor progress of this tool. For more information: www.bomcheck.net.

3.2. COCIR'S AMBITION CONTINUED THROUGH THE ECODESIGN INITIATIVE

COCIR explored opportunities and took a number of initiatives to improve the environmental performance of medical equipment. In the same spirit our industry continues its effort to maximize efficiency of the equipment and services while contributing to a greener environment. Our vision as a responsible, sustainable and highly innovative industry sector is to cover environmental aspects early in the process from research and development through production, comprising also post-production throughout the total life cycle of our products.

COCIR member companies fully support the **Ecodesign Directive**[4] aims and objectives and commit to proactively engage in ecodesign through this Self-Regulatory Initiative (SRI) for medical equipment.

COCIR supports the approach of the Ecodesign Directive as outlined through the following Recitals 16 and 17:

(16) Priority should be given to alternative courses of action such as self-regulation by industry where such action is likely to deliver the policy objectives faster or in a less costly manner than mandatory requirements,

(17) Self-regulation, including voluntary agreements offered as unilateral commitments by industry, can provide for quick progress due to rapid and cost-effective implementation, and allows for flexible and appropriate adaptation to technological options and market sensitivities.

In September, 2008 COCIR established the SRI Steering Committee *(hereafter: Ecodesign SC)* in order to further develop COCIR's Self-Regulatory Initiative and take proactive actions.

This present document provides the industry's detailed committments for a Voluntary Agreement including the scope, approach and timeline of the Self-Regulatory Initiative.

[4] Directive 2009/125/EC of 21 October 2009 establishing a framework for the setting of Ecodesign requirements for energy-related products, replacing Directive 2005/32/EC of July 2005 known as EuP Directive.

4. PARTICIPATING COMPANIES

This Self-Regulatory Initiative is endorsed by 11 companies. The Ecodesign SC was constituted by representatives of those 11 companies in September 2008 in order to establish a consensus on the SRI methodology and the management of this project.
COCIR company members participating in this Self-Regulatory Initiative represent at least 80% of the sales of each of the diagnostic imaging modalities in Europe.
For the purpose of this documentation, all current and future companies participating, i.e. committed to the proposal presented in this initiative, are defined as member companies or participants. A Memorandum of Understanding (MoU) including AntiTrust Guidelines for industry self-regulation has been developed so that any company can join the initiative (refer to Appendix 3).

Table X: participating companies

Participating companies 2009/2012	
Agfa HealthCare	IBA Ion Beam Applications
Aloka	Philips Healthcare
Elekta	Samsung Medison Europe
Fujifilm	Siemens Healthcare
GE Healthcare	Toshiba Medical Systems Europe
Hitachi Medical Systems Europe	

4.1. PROCESS FOR OTHER COMPANIES TO JOIN

Participation in this Self-Regulatory Initiative is open to all COCIR member and non-member companies placing medical equipment on the European market. Companies willing to join the COCIR SRI can contact the Ecodesign SC Secretariat: corridori@cocir.org

5. SCOPE OF THE SELF-REGULATORY INITIATIVE

5.1. PRODUCT SCOPE

COCIR and all companies participating in the SRI are committed to produce environmentally friendly products and to implement improvements through a well-defined and transparent methodology.

The scope for the Self-Regulatory Initiative for Medical Electrical Equipment is defined as environmental aspects related to the medical electrical imaging equipment placed on the EU market.

Within this scope, several inclusion criteria are applied to determine specific product groups (hereafter "modalities") for self-regulation. To be included in the SRI, modalities must:

1. Represent large segments of medical electrical products sold in the European Market.
2. Account for at least 80% of market coverage of participating companies.
3. Be a business-to-business operation.
4. Have SHARE[5] market data available.
5. Have Life Cycle Assessment data available.

5.2. INITIAL MODALITIES COVERED

The Ecodesign SC has determined the following modalities meet the criteria in section 3.1 for inclusion in scope of the SRI:

Diagnostic Imaging Modalities:

- Computed Tomography (CT)[6],
- Magnetic Resonance Imaging (MRI)[7],
- Nuclear Medicine[8],
- Ultrasound[9],
- X-Ray[10].

[5] *COCIR Web-based Market Statistics Analysis and Reporting Program*

[6] *Computed tomography, or CT, is a medical imaging method employing tomography created by computer processing. Digital geometry processing is used to generate a three-dimensional image of the inside of an object from a large series of two-dimensional X-ray images (slices) taken around a single axis of rotation.*

[7] *Magnetic Resonance Imaging, or MRI, is primarily a medical imaging technique most commonly used in radiology to visualize the internal structure and function of the body. MRI provides much greater contrast between the different soft tissues of the body than computed tomography (CT) does, making it especially useful in neurological (brain), musculoskeletal, cardiovascular, and oncological (cancer) imaging.*

[8] *Nuclear medicine is a branch or specialty of medicine and medical imaging that uses radioactive isotopes (radionuclides) and relies on the process of radioactive decay in the diagnosis and treatment of disease. In nuclear medicine procedures, radionuclides are combined with other chemical compounds or pharmaceuticals to form radiopharmaceuticals. These radiopharmaceuticals, once administered to the patient, can localize to specific organs or cellular receptors. This unique ability of radiopharmaceticals allow nuclear medicine to diagnose or treat a disease based on the cellular function and physiology rather than relying on the anatomy.*

[9] *Ultrasound is an imaging technique used to visualize subcutaneous body structures including tendons, muscles, joints, vessels and internal organs for possible pathology or lesions. Ultrasound, also known as obstetric sonography, is commonly used during pregnancy and is widely recognized by the public. There is a plethora of diagnostic and therapeutic applications practiced in medicine (incl. in cardiology, anesthesiology, urology, gastro-enterology, vascular, etc).*

[10] *X-Ray, is obtaining diagnostic information by using imaging techniques based on X-radiation directed through the patients body to produce images (radiographs) on photographic film or a fluoroscope. X-ray photon energy would typically be in the energy range of 30-150 keV. Radiography is used to produce images of disease in all parts of the body. In case of Computerized Radiography (CR) photographic film is replaced by a charged plate, from which charge is knocked off by exposure to X-rays. The resultant image is read by a laser beam, then stored digitally or printed out. Digital radiography (DR) in which X-ray images are acquired in digital format, allowing the storage of images on hard disk and their subsequent retrieval and interpretation using TV monitors.*

5.3. REVIEW OF THE SCOPE

This Self-Regulatory Initiative is an open-focus project. When a new modality is added to the SRI scope, the Ecodesign SC will revise the priority list to ensure efforts are aimed at the most meaningful results. All other steps will follow the generic sequence of the SRI methodology.
The Ecodesign SC assesses therapy modalities for their environmental impact on the European market, to cover modalities from all member companies. Examples for therapy modalities are Linear Accelerators and Particle Therapy.

6. MARKET RELEVANCE

Considering the particular market of medical imaging devices, where only a few multinational companies are competing, the SRI Steering Committee decided that 80% or market share has to be covered by participating companies for a modality to be included in the scope.
Market value and market coverage are activities monitored over the past 10 years through the COCIR Imaging Market Statistics Focus Group. Also refer to Age Profile Edition 2009 (http://www.cocir.org/uploads/documents/-609-new_members_ws_-_del._3_-_cocir_age_profile_17_june_2009.pdf).

Medical Imaging - EU market[11] share for modalities currently within the scope of this Initiative

Modality		2009 Market Value[12]	2010 Market Value[13]	Estimated EU Market Coverage[14]	Other targeted companies[15]
Computer Tomography (CT)		581 M€	566 M€	98 %	Some international ones
Magnetic Resonance Imaging (MRI)		708 M€	777 M€	96%	Esaote, Fonar, Aurora, Medrad, Neusoft[11]
Nuclear Medicine (SPECT, PET)		244 M€	240 M€	98%	Mediso[11]
Ultrasound		801 M€	814 M€	82 %	Esaote, Sonosite, Mindray, Ultrasonix, Zonare
X-ray	**Cardio (45%)**	377 M€	380 M€	92 %	None[11]
	Others (55%)	503 M€	569 M€	65 %	Approx. 50 companies

[11] Countries included: Estonia, Latvia, Lithuania, Bosnia, Bulgaria, Croatia, Czech Republic, Hungary, Poland, Romania, Serbia, Slovakia, Slovenia, Ukraine, Portugal, Spain, Denmark, Finland, Norway, Sweden, Ireland, UK, Austria, Belgium, France, Germany, Greece, Italy, Netherlands, Switzerland
[12] COCIR Imaging Market Statistics source
[13] COCIR Imaging Market Statistics source
[14] COCIR estimationbased on SHARE data
[15] COCIR plans to contact those companies over time

7. COMMITMENT

7.1.MODALITIES IN SCOPE

Every year at least one new modality is selected and the methodology applied to derive ecodesign targets.

After a modality has been selected it will remain in the continuous improvement circle. This means that once a modality has been selected and the industry has achieved the target to minimize/reduce the aspect with the highest environmental impact and potential for improvement, another assessment of the most significant aspects will be done. Following the methodology, the industry will choose the aspect with the highest impact and derive a new target.

The duration to achieve the adopted target depends on the modality and its specific innovation cycles (between 3 and 10 years, to be defined with the ecodesign target). For a visualisation refer to Table 1.

The current standing for the included imaging modalities within this methodology are reported annually in the SRI Status Report.

Table 1: Indicative example of time plan for the 6 steps methodology

Modality	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
MRI	T.D.	Implementing target					T.A.	T.D.	Implementing target			
CT		T.D.	Implementing target					T.A.	T.D.	Implementing target		
Modality 3			T.D.	Implementing target				T.A.	T.D.	Implementing target		
Modality 4				T.D.	Implementing target				T.A.	T.D.	Implementing target	
Modality 5					T.D.	Implementing target			T.A.	T.D.	Implementing target	
Modality 6						T.D.	Implementing target					

T.D. Target development

T.A. Target achieved

8. ECODESIGN TARGETS FOR ULTRASOUND

The industry Ecodesign SC has set in 2009 a target to reduce by 2012 the average annual energy consumption per unit of new ultrasound products placed on the market by 25% compared to the 2005 baseline.

The target was set on the basis of an expert judgment on realistic feasibility to improve the already existing ecodesign programs.

To reach the 25% target, according to table 3, participating companies should reduce the average annual energy consumption per unit by ✓14,5% from 2009 to 2012.
The average annual energy consumption per unit will be reduced despite new products will have increased functionality and will deliver even more healthcare benefits to patients.

The target to reduce average annual energy consumption of new ultrasound products placed on the market by ✓14,5% between 2009 and 2012 translates to a reduction in average annual energy consumption from ✓808 kWh per unit per year in 2009 down to ✓691 kWh per unit per year in 2012.

Based on predicted EU27 annual sales in 2012 by COCIR companies of 22.316[16] units, this is equivalent to a total energy saving of 2.610.972 kWh for 2012 compared to 2009. This is equivalent to 885 ton[17] of CO_2.

Year	Total annual sales	Total annual sales as a % of 2005 annual sales	Total annual energy consumption of all new products sold	Total annual energy consumption of all new products as a % of 2005 annual energy consumption	Actual average annual energy consumption of all new products sold in kWh (per unit and year)	Actual average annual energy consumption of all new products compared to 2005	Targeted average annual energy consumption of all new products sold	Targeted annual energy consumption of all new products compared to 2005
	Units[18]		kWh[19]		kWh/unit year		kWh/unit year	
2005	17099	100%	15.757.081	100,00%	922	100,00%	-	
2006	20260	118%	17.536.665	111,29%	866	93,9%	-	
2007	21526	126%	17.193.454	109,12%	799	86,7%	-	
2008	22316	130%	16.606.971	105,39%	744	80,8%	-	
2009	17273	101%	13.975.406	88,69%	808	87,8%		
----------Entry into force of SRI for Ultrasound equipment----------								
2010							769	83,5%
2011							730	79,2%
2012							691	75,0%

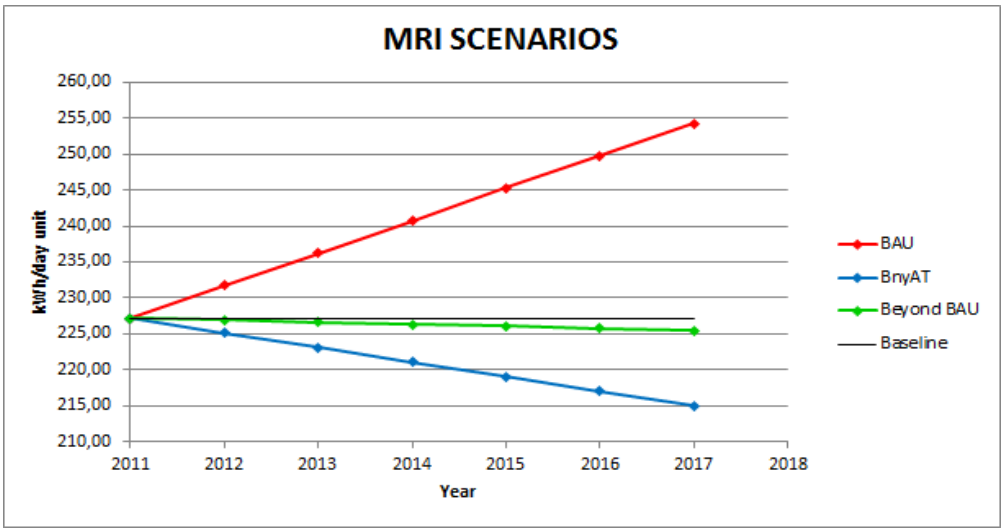
[16] *Estimated sales in 2012 to be equal to pre-crisis sales volume in 2008*
[17] *Conversion factor gCO2/kWh = 339. Average value for Europe 27 in 2009. Source: CO2 Emissions from Fuel Combustion (2011 Edition), IEA, Paris.The conversion factor has been updated to 2009 value compared to the Status Report 2010 where the 2008 value has been used.*
[18] *Units sold each calendar year provided by Companies*
[19] *Energy consumption for each model placed on the market in the calendar year provided by Companies*

9. ECODESIGN TARGET FOR MRI

Companies producing MRI equipment participating in the SRI commit not to increase the average energy consumption in off and ready-to-scan mode in 2017 compared to the 2011 baseline. Without the COCIR SRI, the energy consumption would have increased around 12% by 2017.

Table 2: calculated values for year 2010-2011 and forecast until 2017 under the assumption of a linear trend

	Sold units[20]	Total daily energy consumption (kWh)[21]	Average daily energy consumption per unit (kWh/d)	Beyond BAU	BAU
2011	✓385	✓86.887	✓227,4		
2012				226,96	231,81
2013				226,72	236,43
2014				226,49	241,05
2015				226,26	245,68
2016				226,02	250,30
2017				225,79	254,92



The reduction compared with the BAU baseline implies that the SRI will save in 2017 around 7548[22] kWh per unit sold according to the Beyond as usual scenario, equivalent to more than 2,55 tons of CO_2[23] per year per unit saved.

[20] *Sold units data provided by Companies for each model placed on the market in the calendar year 2011*

[21] *Measured energy consumption data provided by Companies for each model placed on the market in the calendar year 2011. Normalized values against sales will be added from 2012 on.*

[22] *Assuming 5 days per week, 52 weeks per year*

[23] *Conversion factor gCO2/kWh = 339. Average value for Europe 27 in 2009. Source: CO2 Emissions from Fuel Combustion (2011 Edition), IEA, Paris.*

APPENDIX I

SRI STEERING COMMITTEE GOVERNANCE

COCIR INTERNAL PROCEDURE

ISSUE DATE: 08/04/2009		COCIR: SRI Steering Committee Governance

SECTION	HISTORY
ENVIRONMENT	Rev 1: 27/05/2010 Rev 2: 02/03/2011 – amended to reflect the new SRIv2 documentation Rev 3: 28/06/2011 – amended as requested by PWC for the review of the SRI Status Report 2011
DISTRIBUTION TO: SRI Steering Committee	

Document Number	Document owner	Approved by
COCIR ENVI 09 01	SC Secretariat	ErP SC

1. PURPOSE

This document provides all details on the Governance of the SRI Steering Committee which focuses on a proactive approach for an integrated product policy and a continuous improvement of medical imaging devices.

2. SCOPE

This procedure applies to all companies who have committed to participate in the COCIR Ecodesign Self-Regulatory Initiative.
In general, companies eligible to participate can be:

- COCIR company members present in the field of medical electrical equipment,
- Companies placing medical electrical equipment on the European market.

Note: Refurbished products are out of the scope of this initiative.

3. OBJECTIVE

This procedure creates a clear and transparent process for all relevant stakeholders interested in this initiative. It includes roles and responsibilities of participating members.

4. PROCEDURE

4.1. Tasks of the SRI Steering Committee

This Committee meets regularly to:

1. Define and improve the methodology for all modalities.
2. Evaluate the results for each modality.
3. Define common industry targets based on the methodology.
4. Review performance against the targets.
5. Hire any additional experts when needed.
6. Agree any additional costs where needed.
7. Draft and review the SRI Status Report, to notify the European Commission and all interested stakeholders periodically.

4.2. Constitution

The first SRI Steering Committee (Kick-off) was held on 8 April 2009 in Brussels. The following companies have endorsed the strategy and action plan until today:

1. Agfa
2. Hitachi (Aloka)
3. Elekta
4. Fujifilm
5. GE
6. Hitachi
7. IBA
8. Philips
9. Siemens
10. Samsung (Medison)
11. Toshiba.

4.3. Chair and deputy chairs

The chair and deputy chairs are elected:

- by their company to represent them in this committee. They shall have a profile and competencies directly linked to the Ecodesign Directive and other environmental activities within their companies,
- by the SRI Steering Committee members.

Volunteering chairs and deputy chairs were proposed and vote took place at the kick-off meeting. Those candidates were elected unanimously.

Chairman: Freimut Schroeder, Siemens
Deputy Chairman 1: Hans van der Wel, Philips
Deputy Chair 2: Beth Hulse / James Vetro, GEHC

Those elected persons can, in case of unavailability, be represented by a designee.

4.4. Budget/Financing

The budget for this SRI is managed independently outside the scope of COCIR core budget. This budget is under the ultimate responsibility of the SRI Steering Committee.

Any other company willing to engage in this process will have to pay an annual charge corresponding to administrative and overall handling of the processes implied in this Initiative.

5. RULES

5.1. Chair/Deputy chairs

The elected chair and deputy chairs work in tandem. If the chair cannot attend meetings/telephone conference (TCON) one of the deputy chairs can replace him/her.

5.2. SRI Steering Committee Secretariat

SC Secretariat is ensured by the COCIR Office.

5.3. Data gathering

The data gathered from each participating company is compiled by the SC Secretariat to include them into a consolidated format and master file.
Outsourcing of this task is possible with the condition that the mandated organization complies with confidentiality rules described in section 5.1.7 and 7.1.

5.4. Participation in Meetings/TCONs

Meetings dates and contents to be covered are discussed and agreed upon between the chair and the SC Secretariat. All SRI companies are strongly recommended to participate in all meetings/TCONs either through their designated representative or an alternative designee.
Members of the Consultation Forum (such as regulatory authorities, EC or NGOs) can participate provided they inform the secretariat in advance. They will be accepted as observers.

5.5. Organization of Meetings/TCONs and accessibility

Ecodesign SC Secretariat will notify the participating companies via mail about meetings. Records are kept, where appropriate, as this constitutes part of the data that can be audited at any time. Such records will be posted under COCIR members-only web-site. A specific passcode will be provided to any participating companies, as well as members of the EU Stakeholder Consultation Forum and EU Commission upon request, and other interested stakeholders if deemed appropriate.

5.6. Vote

All reasonable efforts shall be taken to ensure that the decisions of the Steering Committee are taken on the basis of a consensus.
However, where consensus on an issue cannot be achieved in the course of a meeting of the Steering Committee, a call for an indicative vote may be made by the Steering Committee Chair or by 2/3 of the participants.

5.7. Confidentiality rules

It is crucial to respect confidentiality whenever company data are discussed, either through TCONs or face-to-face meetings or submitted via mail. This means that no specific company name or data shall be mentioned whenever progress is measured on data collection. It shall be ensured that no confidential company information can be identified by data provided.

5.8. Access to non-confidential documentation and procedures

Any interested member of the EU Stakeholder Consultation Forum is allowed to access non-confidential data and other documentation linked to this activity. This data is available on the COCIR website or can be requested to the Ecodesign SC Secretariat.

5.9. ROLES AND RESPONSIBILITIES

5.10. Participating companies

For companies to be eligible to participate in this initiative they must:

- Sign an official commitment to the Self-Regulatory Initiative and send it to the SC Secretariat (see Appendix 1),
- Appoint representative(s) to the SRI Steering Committee with authority to represent and ability to make decisions for the company on all aspects of the Ecodesign Self-Regulatory Initiative.

Participating companies are responsible for:

- Providing data when requested by the SRI Steering Committee Secretariat.
- Reviewing draft consolidated report(s) of each step of the Ecodesign methodology.
- Validating the final annual SRI Status Report prior to third party audit and publication,
- If no feedback is received by a certain date, it is understood there are no objections. The matter will then be considered as agreed and the process will continue,
- Implementing the set target(s), derived according to the Ecodesign methodology adopted by the SRI Steering Committee and ensuring to meet the target(s).
- Contributing to the continuous improvement of the SRI by offering their expertise in face-to-face meetings/TCONs whenever applicable.

New companies joining the initiative cannot contribute in ongoing target achievement process for specific modalities. This will ensure comparability between reported figures in past years.

5.11. Chair & deputy chairs

The chair and deputy chairs must allocate sufficient time to prepare the meetings and TCONs with the support of the SC Secretariat.
The chair and deputy chairs are eligible to represent the Ecodesign SC in specific external meetings/conferences, provided this is discussed and agreed in advance within the SRI Steering Committee. They shall contribute to the continuous improvement of the SRI by offering their expertise in face-to-face meetings/TCONs whenever applicable.

5.12. Ecodesign SC Secretariat

The Ecodesign SC Secretariat is responsible:

1. To organize meetings/TCONs.
2. To encourage participation and commitment of all companies
3. To ensure the delivery of information/data by the companies as required.
4. To arrange necessary appointments with the European Commission/ EU Consultation Forum upon request.
5. To ensure that contracts, when needed, are validated by the SRI Steering Committee.
6. To keep all documentation in separate files and consolidated format for auditing purposes.
7. To collect and retain company-confidential information.
8. To perform all aggregation tasks of company-confidential information into generic industry data as prescribed in the SRI methodology.
9. To execute all plausibility checks to ensure correctness of calculation as prescribed in the SRI methodology.
10. To report generic industry data to the SRI SC and to the public in form of the SRI Status Report.
11. To ensure transparency by publishing SRI policies, procedures, minutes.
12. To oversee member company interactions, including SC meetings and subgroup sessions (e.g. modality experts).
13. To solicit participation to meet inclusiveness requirements.

6. MONITORING AND REPORTING ACTIVITIES

6.1. Data collection (quantitative and qualitative)

Collected company-confidential information cannot be shared with the SRI Steering Committee unless the SC Secretariat has compiled data into generic industry data from
- at least three participating companies and
- at least the three companies with the highest market share.

6.2. Annual SRI Status Report

The annual SRI Status Report is responsibility of the SC Secretariat.
The SRI Steering Committee has the responsibility to review the draft report and to validate and approve the final report prior to the external audit and making it publicly available.
The Report shall be approved during a periodic meeting by participating members or by written statement following a request from the SC Secretariat.
In order to produce a report including necessary data to show evidence that targets are effectively met, those data are collected and consolidated via the Ecodesign SC Secretariat.

7. CONTACTS

SC Secretariat
Email: corridori@cocir.org
Tel: 027068966

SPECIMEN

Memorandum of Understanding

Between

European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR)

And

[Company name] based in ……..

[Brussels]

[Date to be completed]

MEMORANDUM OF UNDERSTANDING (MOU)

This Memorandum of Understanding (MoU) is entered into and made effective on this [date] by and between:

I. Parties

1. European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR), a non-profit trade association founded in 1959 with seat in Brussels representing the medical technology industry in Europe (referred to in this MoU as "COCIR").
2. [Company name] based in ..... distributing medical imaging equipment in Europe.

II. Purpose

Whereas

- COCIR represents the Radiological, Electromedical and Healthcare IT Industry voice of its corporate members and its National Trade Associations in Europe and outside when necessary. COCIR acts as a communication channel between its members, the institutions and other regulatory bodies mainly in Europe and outside when necessary;
- COCIR is hosting the SRI Steering Committee that was put in place on 08 April 2008 to coordinate activities of Ecodesign Self-Regulatory Initiative currently covering the industry sector of medical imaging;
- [company name] is distributing medical electrical equipment in Europe comprise in one of the following modalities: Computed Tomography, Magnetic Resonance Imaging, Ultrasound, X-Ray or Nuclear Medicine;
- [company name] is committed to complying with the responsibilities described hereafter.

COCIR and ..... [company name] execute this MoU for the following purposes:

1. To allow [company name] to engage in this initiative
2. To increase market coverage for the specific product group(s)

III. COCIR & [company name] Key roles

III.I.COCIR

COCIR over years has developed through its industry members core competencies on capital investment products in the field of imaging, electromedical and healthcare IT.
COCIR Office will ensure that appropriate support is given to this initiative either through the SC Secretariat.
The SC secretariat will be responsible for:

- Organizing meetings/TCONs,
- Making sure participating company is committed and delivering information/data as required,
- Making necessary appointments with EC upon request,
- Making sure that contracts when needed are validated by the SRI Steering Committee,
- Keep all documentation in separate files for auditing purposes.

More details can be found in Appendix 3 of SRI Version 2

III.II. [company name]

To be eligible to participate in this initiative the company agrees to:

- Sign this official commitment to the Self-Regulatory Initiative and send it to the COCIR Office,
- Appoint representative(s) to the COCIR SRI Steering Committee with authority to

represent and make decisions for the company on all aspects of the Ecodesign Self-Regulatory Initiative. This nominated person will represent the company in the Steering Committee,

- Comply with the AntiTrust guidelines (detailed in Annex to MoU).

Participating companies are responsible for:

- Providing data when requested by the SRI Steering Committee Secretariat,
- Reviewing draft consolidated annual status report,
- Validating the final status report prior to publication.
- If feedback is not received by a certain date, it is understood there are no objection from the [company name], process will continue and not be stopped unnecessarily.

Participating company or trade association agrees to pay an annual charge corresponding to administrative and overall handling of this process implied in this Initiative. This amount is revised yearly by the SRI Steering Committee.

ANNEX TO MOU

Antitrust Guidelines

Industry forums which are designed to share information can give rise to AntiTrust risk, in particular in relation to allegations of collusion by participants in the same market). Accordingly, all companies and trade associations who become members of the Initiative (collectively "Participating Companies") are required to comply with the following guidelines in connection with participation in the Initiative. Prior to any and all meetings associated with the Initiative, or subgroups thereof, the Members in that meeting shall be reminded of these guidelines and their obligation of compliance herewith.

1. The Ecodesign Self-Regulatory Initiative and its committees or activities shall not be used for the purpose of bringing about or attempting to bring about any understanding or agreement, written or oral, formal or informal, express or implied, between and among competitors with regard to their prices, terms or conditions of sale, distribution, volume of production, territories, customers, or credit terms.

2. In connection with participation in the Initiative, there shall be no discussion, communication, agreement or disclosure among Members that are actual or potential competitors, regarding commercially sensitive information, and in particular their prices, discounts or terms or conditions of sale or licensing of products or services, pricing methods, profits, profit margins or cost data, production plans, market shares, sales territories or markets, allocation of territories or customers, or any limitation on the timing, cost or volume of their research, production or sales.

3. Each Member of the Initiative is obligated and expected to exercise its independent business judgment in determining its commercial strategy, including pricing its services or products, dealing with its customers and suppliers, and choosing the markets in which it will compete.

4. Members of the Initiative, in connection with their participation in the Initiative, shall not enter into any agreement or understanding among themselves to refrain, or to encourage others to refrain, from purchasing any raw materials, product, equipment, services or other supplies from any supplier or vendor or from dealing with any supplier or vendor.

5. Members of the Initiative, in connection with their participation in COCIR Ecodesign Self-Regulatory Initiative, shall not attempt to prevent any person from gaining access to any market or customer for goods and services, or attempt to prevent any person from obtaining a supply of goods or services or otherwise purchasing goods or services freely in the market.

COMMITMENT
to
COCIR Ecodesign Self-Regulatory Initiative

(to be signed by Company Officer engaging its company or association in this Initiative)

[Company Name] commits to participate in and support the Ecodesign Self-Regulatory Initiative.

We designate _____ to be the representative(s) appointed to the SRI Self-Regulatory Steering Committee to represent our company.

_____
Name

_____
Position

_____
Signature

_____
Date

Acknowledgement from SRI Steering Committee Secretariat

For COCIR

_____
Nicole Denjoy
Secretary General

_____
Date Signed

APPENDIX II

NON-COMPLIANCE WITH ERP SRI TARGET(S)

Wording in Ecodesign Directive:
Where there is sufficient evidence that a product might be non-compliant, the Member State shall take the necessary measures which, depending on the gravity of the non-compliance, can go as far as the prohibition of the placing on the market of the product until compliance is established.

PROCESS FOR ERP SELF-REGULATORY INITIATIVE FOR MEDICAL ELECTRICAL EQUIPMENT:
Each company ensures commitment to SRI set company and industry targets.

Company target at risk for a specific modality.
If during annual interim review the SC Secretariat finds that a company target is at risk, the SC Secretariat informs he Company and requires a corrective action plan (kept confidential) and communicates to the Ecodesign SC (the company name will remain anonymous). The SC Secretariat evaluates the action plan and monitors the annual progress of the company. The SC secretariat annually determines if the company target non-compliance will impact the industry target.

Company non-compliance
If the company is not able to reach its target at the end of the innovation cycle, the SC Secretariat communicates to the Steering Committee chairs that will add an agenda point to the following meeting.

Industry target at risk
In case the industry target is at risk the SC Secretariat informs the Ecodesign SC that will develop an industry corrective action.

Reporting to the EC
If the industry target is missed, the SC Secretariat will communicate to the EC about the situation and the corrective action of the industry group. Evidence, if appropriate, will be submitted to the EC about the reasons for non-complying with the set target (the name of the company/companies missing the target will not be disclosed to the EC).

Enforcement Mechanism
Company targets are used as an internal tool by the SRI Steering Committee to decide how to direct their improvements and to help the SRI SC to reach the final industry target. Nonetheless, the Ecodesign SC is studying a mechanism to "enforce" the SRI to ensure maximum efforts by all the participating companies in achieving their respective company targets and a level playing field.
One possible solution, under investigation, is the creation of the "Ecodesign SRI Label". Companies able to reach their individual targets will be allowed to display this Ecodesign SRI label. Other possibilities are actually under discussion.