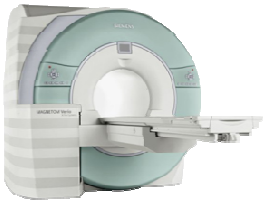
COCIR

Sustainable Competence
in Advancing Healthcare

SELF-REGULATORY INITIATIVE FOR MEDICAL IMAGING EQUIPMENT



VERSION 2.0
December 2011
(Version 1: October 2009)

The provisions of the Self-Regulatory Initiative for Medical Imaging Devices, contained in the present paper and in all the related documentation, have been developed to ensure they have no effect in reducing the performance of the products concerned so as to compromise the clinical condition and safety of patients, safety and health of users or, where applicable, other persons. Such provisions, therefore, must not have any negative impact on health protection.

The Ecodesign Steering Committee

Executive Summary

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 methodology developed by companies in the Medical Electrical Sector in the context of the Self-regulatory Initiative for Medical Imaging Equipment (SRI) under the Ecodesign Directive framework.

Part 1, section 1 to 3 briefly presents the scope of this Self-Regulatory Initiative, namely products covered, participating companies and the procedures and requirements to extend the scope and to allow new companies to join the Initiative. More details can be found in Appendix 3.

Section 4 briefly explains the six-step methodology that has been developed for this initiative. Such methodology allows participating companies to identify environmental impacts of products during their life cycle, to select and prioritize products groups and to set targets for the reduction of the environmental aspects. The methodology is presented in details in Appendix 5.

Section 5 provides an assessment of the compliance of the SRI for Medical Imaging Equipment with all the regulatory requirements in Annex VIII of Directive 2009/125/EC.

Appendix 4 presents the Ultrasound Pilot Project. Participating companies initiated a first non-standardised review of the products in scope to establish the product of initial focus for a pilot, to develop the industry baseline for energy trending, and to establish targets and timing. The appendix provides a description of the product group specifics, example of Life Cycle Assessments, and the excel tool that has been used to gather the relevant baseline data.
The methodology contained in this document will be applied to Ultrasound products in 2014 after MRI, CT, X-ray and Nuclear Medicine that have been identified as presenting higher environmental impacts (step 1 and 2 of the methodology, see annual SRI Status Report). In the meantime the old methodology (SRI v1) for Ultrasound products will be applied by Participating Companies to achieve the set target in reducing energy consumption.

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 are to be published yearly in the SRI Status Report available at COCIR website, www.cocir.org, in the "Greening at COCIR" section.

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

Table of Content

PART 1

PART 2

PART 3

1. Introduction

Founded as a non-profit trade association in 1959, COCIR[1] represents the Radiological, Electromedical and Healthcare IT industry in Europe. As such, COCIR members[2] play a driving role in developing the future of healthcare both in Europe and worldwide. 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. We encourage the use of advanced technology to support healthcare delivery worldwide. COCIR's key objectives include to promote free worldwide trade of medical equipment and to maintain the competitiveness of the European health sector.

A vast majority of products manufactured by COCIR members are medical equipment and as such are regulated through the Medical Device Directive[3] (a New Approach Directive). All products sold in Europe must be CE marked to prove compliance to this Directive. This directive requires that manufacturers comply with Essential Requirements and have a Quality Management System in place to ensure products are designed, produced and put on the market through an established and robust way. It covers also post-market surveillance principles.

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. For further detailed information on COCIR's core competencies and COCIR initiatives in the field of the environment refer to the Appendix.

[1] *For more information: www.cocir.org.*

[2] ***COCIR Company Members:*** *Agfa-Healthcare, Aloka, Bosch, Canon Europe, GE Healthcare, Hitachi Medical Systems Europe, IBA Ion Beam Applications, IBM, Intel, iSoft, Carestream Health, Fujifilm, Elekta, Medison, Konica, Microsoft, Philips Healthcare, Siemens Healthcare, Shimadzu, Toshiba Medical Systems Europe, T-systems*
COCIR National Associations Members: *AGORIA (Belgium), Assobiomedica (Italy), SNITEM (France), ZVEI (Germany), SPECTARIS (Germany) HHT (Netherlands), FENIN (Spain), Swedish MedTech (Sweden), AXREM (UK), FiHTA (Finland), TipGorDer (Turkey), AMDM (Hungary)*

[3] *See Council Directive 93/42/EEC of 14 June 1993, OJ No L 169/1 of 1993-07-12.*

2. COCIR's ambition continued through 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 participate in the Ecodesign Directive through this Self-Regulatory Initiative (SRI) for medical equipment.

COCIR supports the approach 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 Ecodesign 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 proposal for a Voluntary Agreement including the scope, approach, methodology and timeline of the Self-Regulatory Initiative.

Furthermore, it is highlighted how the Self-Regulatory Initiative proposal complies with all regulatory requirements in Annex VIII of Directive 2009/125/EC.

[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.*

3. Scope of Self-Regulatory Initiative

3.1. Product Scope

COCIR and all companies participating in this SRI are committed to produce environmentally sensitive products and to implement ongoing improvements through a self-regulating 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 the largest segments of medical electrical products sold in the European Market.
2. Have a majority COCIR membership representation by market share. Further information on market value, market coverage, and companies can be found in the Appendix 2.3.
3. Be a business-to-business operation.
4. Have SHARE[5] market data available.
5. Have Life Cycle Assessment data available.

3.2. 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).*

3.3. Review of the scope

This Self-Regulatory Initiative is an open-focus project. The Ecodesign SC will add modalities to the current scope when shown to meet the criteria of section 3.1.

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.

3.4. Participating companies

This Self-Regulatory Initiative is endorsed by 11 companies (refer to Appendix 3). 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).

3.5. 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. COCIR has developed a generic procedure for new companies to join the SRI (refer to Appendix 3) for further details).

3.6. The Ecodesign Steering Committee Secretariat

The Ecodesign SC Secretariat (*hereafter SC Secretariat*) is retained by COCIR to manage the SRI. The responsibilities of the SC Secretariat are to:

- collect and retain company-confidential information.
- aggregate company-confidential information to generic industry data.
- execute risk assessments and plausibility checks to ensure correctness of units, values, boundaries, etc.
- report generic industry data to SRI Participants and to the public.
- ensure transparency by publishing SRI policies, procedures, minutes.
- oversee member company interactions, including SC meetings and working group sessions (e.g., modality experts).
- solicit participation to meet inclusiveness requirements.

More information on SC Secretariat can be found in Appendix 3.

---

[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.*

4. General Methodology applicable to all modalities in the scope of the SRI

4.1. Background

To develop and test a sustaining methodology and approach for this Self-Regulatory Initiative, COCIR first initiated a pilot. In 2009, based on the ultrasound pilot, the Ecodesign SC developed a first approach to calculate an industry baseline for energy consumption, to establish targets and timing for this pilot modality. All details concerning this pilot can be found in the Appendix 4.

The experience gained from this pilot, as well as a critical review against the Methodology for Eco-design of Energy-using Products (MEEuP) and the valuable comments received at the Consultation Forum in November 2009 enabled the Ecodesign Steering Committee to review its methodology and approach.

The European Commission reviews and approves self-regulatory approaches (known as Voluntary Agreement) based on the list of minimum requirements of Annex VIII of the Ecodesign Directive 2009/125/EC. The listed topics are the following: openness for participation, added value, representativeness, quantified and staged objectives, involvement of the civil society, monitoring and reporting, as well as cost efficiency of the initiative. Thus, the Ecodesign SC has taken these criteria, together with the lessons learnt from the ultrasound pilot to design a generic process that allows member companies to upkeep their independent internal procedures while agreeing on binding improvement targets.

The result of the thorough analysis and review is a generic 6 steps procedure, which is applicable to all modalities in scope of the SRI (reference section 3.1).

4.2. The methodology (Overview)

The SRI methodology is the process participating companies shall follow to set ecodesign targets for their products and ensure that they are achieved.

The purpose of the SRI methodology is to:

- provide a transparent and continuous process to control the application of ecodesign targets while protecting company confidential information.
- set a priority sequence for the equipment evaluation.
- identify top environmental aspects.
- set environmental targets.
- systematically engage stakeholders.
- monitor and report progress.

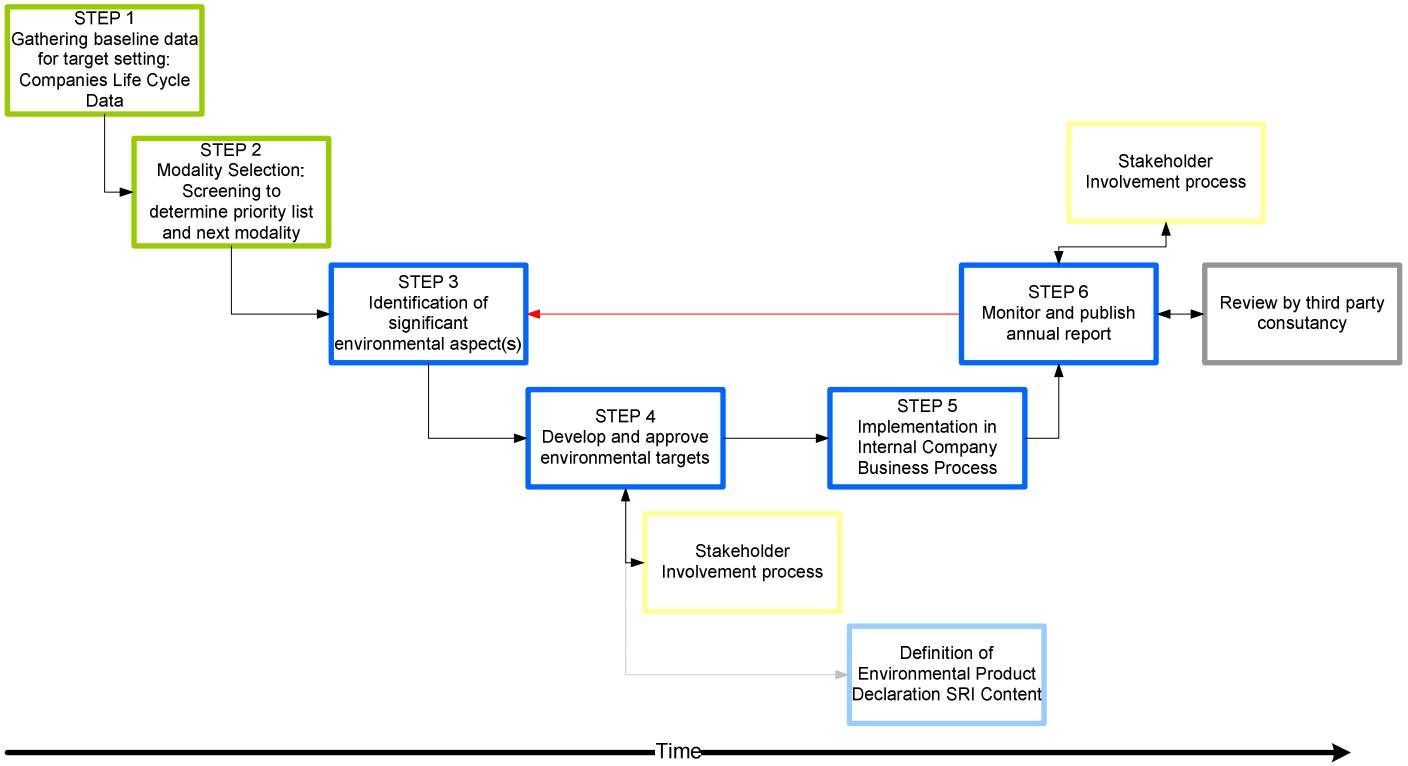
The SRI methodology is based on six key steps (refer to Figure 1). The six steps process accommodates diversity of life cycle assessment methods. Before the data is aggregated at the industry level plausibility checks are accomplished to ensure that a common result is achieved.

The iterative process allows the member companies to offer their confidential internal life cycle assessment data for each modality, life cycle stage and aspect selection processes. This provides a comprehensive analysis which any one single approach could not achieve.

Every year at least one new modality is selected (referring to results from Steps 1 & 2) until all modalities in scope have been chosen and a target is set.

The summary of the baseline data (from Step 1) and the priority list (from Step 2) in the green boxes are enclosed in the annual progress report to ensure a holistic overview of the addressed modalities.. The further process displayed in the blue boxes (Steps 3 to 6) will be applied to each modality in the scope of the initiative.

Figure 1: COCIR's generic methodology developed in 6 Steps to secure continuous improvement of the product-related Ecodesign aspects of their medical imaging equipment



Overview SRI 6 STEPS Methodology (the green boxes signify task that need to be done once . The **blue** boxes cover the four steps that represent a closed loop: to be repeated for continuous improvement and transparency)

After a modality has been selected (via the priority list resulting from Step 1 and 2), it will remain in the continuous improvement circle (Steps 3 to 6). This means that once a modality has been selected and the industry has achieved the target to minimize 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). 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: Example of the time approach to the 6 steps methodology

	2010	2011	2012	2013	2014	2015	2016	2017	2018	20xx
Priority Modality One	Select modality	Achieve target	Achieve target	Achieve target	Achieve target	New target	Achieve target	Achieve target	Achieve target	Achieve target
1. Gather Baseline Data	☐	*Target achievement depends on modality specific innovation cycle (between 3 and 10 years)*					*Target achievement depends on modality specific innovation cycle (between 3 and 10 years)*			
2. Prioritization and selection of next modality	☐									
3. Significant aspect selection	☐					☐				
4. Derive environmental targets and objectives	☐					☐				
5. Integrate target into design and development of new products	☐	☐	☐	☐	☐	☐	☐	☐	☐	
6. Monitor progress and publish annual report	☐	☐	☐	☐	☐	☐	☐	☐	☐	
Priority Modality Two		Select modality	Achieve target	Achieve target	Achieve target	Achieve target	New target	Achieve target	Achieve target	Achieve target
1. Gather Baseline Data			*Target achievement depends on modality specific innovation cycle (between 3 and 10 years)*					*Target achievement depends on modality specific innovation cycle (between 3 and 10 years)*		
2. Prioritization and selection of next modality										
3. Significant aspect selection		☐					☐			
4. Derive environmental targets and objectives		☐					☐			
5. Integrate target into design and development of new products		☐	☐	☐	☐	☐	☐	☐	☐	
6. Monitor progress and publish annual report		☐	☐	☐	☐	☐	☐	☐	☐	

4.3. The 6 steps methodology in detail

In the following the methodology's 6 steps is outlined in more detail. The procedural overview, the key tasks and deliverables, as well the templates for each step are included in Appendix 5**.**

4.3.1. Step 1: Gather baseline data

The purpose of the first step is to establish a baseline for prioritization and improvement. The method of the first step is to collect Member Company Life Cycle Assessment (LCA) data on products in scope of the SRI.

For any future change of the SRI scope, for example including the second group (therapy equipment), the Ecodesign SC includes new modalities based on the internal change management procedures.

The provided information in Step 1 contains typical LCA data per modality and company, including the defined use scenarios, functional units, impact categories and intended use, the percentage of life cycle contribution, the individual environmental load per modality related to the corresponding LCA method, as well as a plausibility check based on expert expectations on the future capacity for innovation of the modality.

All information is collected from COCIR via a standardised template (see Appendix 5).

4.3.2. Step 2: Prioritization and selection of next modality

The purpose of the second step is to analyse the baseline data in order to prioritize the modalities for evaluation. The method of the second step is to rank the environmental load and other data from each modality.

To be able to compare the data and offer a transparent process, the SC Secretariat summarizes the gathered company data in a table similar to following overview (Example see Table 2, or detailed template in Appendix 5).

Table 2: Example of summary of company specific LCA data

Summary of Life Cycle Assessment methods and tools of SRI Companies	
	Company A
Life Cycle impact assessment method	Eco Indicator 99
Software tool	Simapro/EcoScan
Unit of Environmental load	Points
Life Cycle Phases included:	
- Production ("cradle to gate")	x
- Transport (from suppliers, to customers)	x
- Use of product*	x
- End of Life	x
other methodological aspects included:	
- Resource use	x
- Embedded toxicity	
- Emissions to land, air and water	x
- Land use	x
- Others	damage to resources, humans and environment included
* including maintenance and spare parts	

Two analyses are to be performed:

- the averaged environmental load of each modality is scaled by the European sales volume per year in units. This provides the first ranking.
- the second ranking is calculated based on expert forecasts and expected European sales figures per year in units at the end of the innovation cycle (may be different for each modality).

The final priority list for the modality selection results from the average of the two previous rankings (Example see Table 3 or detailed template Appendix 5.1). If changes to the data are necessary (e.g. new modalities will be included, corrections to data need to be done) or additional data is available the ranking will be renewed.

The following Table 3 includes an example of the final summary table: MRI would be the modality with the highest ranking and thus the first modality selected to continue with all further Steps.

The Ecodesign SC agreed to take one modality each year according to the ranking of the priority list into the next iterative steps. Once a modality has been selected for the aspect selection it remains in this continuous improvement cycle.

Table 3: Example of COCIR's final priority list for modality selection

Modality	Interim Ranking	Ranking 20xx	Final Ranking	Comments/ Remarks
MRI	1	1	1	
X-Ray	3	3	3	
CT	2	2	2	
etc.				

The standardised template used for the consolidation of the delivered company data is included in Appendix 5.1.

4.3.3. Step 3: Identification of significant environmental aspect(s) for the selected modality

The purpose of the third step is to analyse and prioritize the three most significant environmental aspects contributing to the total environmental impact of the selected modality. The method of the third step is to rank the data on the top three environmental aspects, including the percentage of their contribution to the total life cycle.

In Step 3 the Ecodesign SC Secretariat asks participating companies to provide the top three significant aspects of the LCA life cycle stage identified as most significant for the selected modality. Companies internally rank these aspects. These individual company rankings are then consolidated by COCIR to identify the industry's top three environmental aspects.

In this step, companies are also asked to provide a risk assessment of the top ranked aspects to minimize the risk of choosing an aspect that may have no or only little reduction potential. Companies have to provide a rationale if they declare that an aspect may not or only marginally be reduced. This might particularly be the case when product innovation is significantly hampered or by a lack of substitutability of specific materials.

Companies could also provide a risk assessment of the top ranked aspects regarding the possible impact on sustainable development (see Appendix 5.2)

On the basis of the provided data and risk assessment on the reduction potential, the most significant aspect is selected for the next step: the definition of a reduction target.

The standardised template used for the collection of the environmental aspect data and the consolidation of the delivered company data is included in Appendix 5.1.

4.3.4. Step 4: Derive environmental targets and objectives for the selected modality

The purpose of the fourth step is to set Ecodesign target(s) on the selected aspect.

The member companies' modality experts come together under the supervision of the COCIR Secretariat to develop:

1. A common definition of the modality and system boundaries
2. Criteria to allocate different models in categories (if needed)
3. A typical use scenario based on real hospital practice (when possible)
4. The functional unit
5. Ranges for parameters and configurations to ensure comparability of the measurements.
6. A methodology to measure the selected environmental aspect (i.e. energy efficiency, energy consumption, etc).

Methodology for measuring environmental aspects
As there are no standards available today for measuring environmental performances for medical imaging equipment, such as energy efficiency, the definition of a methodology which provides solid, comparable and repeatable results is the core of the methodology for setting targets.
Such a methodology can be required to be defined for each modality and for each selected environmental aspect.
Once developed the methodology will be published in the Status Report and will be available to the Regulators and Stakeholders through the website dedicated to the Self-Regulatory Initiative.

Based on the common definitions and the methodology the SC Secretariat asks the companies to measure the performance of each model of the selected modality placed on the market in the years under consideration.

Companies measure their models and report the values and sales according to an ad hoc developed template that will be published in the Status Report.

Estimating the potential for improvement
To define the potential for improvement of the selected aspect the SC Secretariat asks Companies to report an expert judgment in percent on the best possible improvement at the end of the innovation cycle taking also into account technologies under research that are not yet available on the market (best not yet available technologies).

Such information will be collected according to a methodology that will be developed by the Ecodesign SC, with the support of an external independent Consultant, when required. The Consultant collects the data (potential for improvement per module, technological solutions, technologies under research, etc) to ensure complete confidentiality of the provided information and prepares a report that will be published with the Status Report.

The Consultant also collects evidences on the typical innovation cycle of the specific modality. The innovation cycle is defined as the time to develop new or enhanced products and place them on the market. It could vary from 3 years to 7, depending on the complexity of the innovation being brought to market. The following activities take place within the innovation cycle:
- Research and development
- Verification and Validation
- Regulatory Approvals

Setting the target(s)
In the second phase of this step, the SC Secretariat uses the collected values and data to calculate 4 scenarios:
- **Baseline today:** defines the average[11] performance of all the models present on the market in the year chosen as reference year.
- **Business as usual (BAU)**: defines the average performance all the models present on the market at the end of the innovation cycle under the assumption that no SRI is in place, and that all Companies will improve their products to match the performance of the front runner today due to existing ecodesign programs..
- **Best not yet available technology (BnYAT):** defines the average performance of the market (all models) at the end of the innovation cycle assuming that all Companies could achieve the maximum possible reduction of the environmental aspect under consideration, considering technologies not yet available today.

[11] The average value, for each scenario, is calculated as the weighted average of the performance of all models against the number of units sold for each model.

- **Beyond Business as usual:** defines a scenario that is in between the BAU and BnYAT ones. The average of the market at the end of the innovation cycle is used as the industry target.

More detailed information on the scenarios is provided in Appendix 5.

The Ecodesign SC can decide to set as industry target a value that is different from the market average in Beyond as usual scenario, if justified.

The results of this step are two types of targets:

- **Industry target:** that's the target that all the participating companies have to achieve as the average of the market and is equal (unless a different decision is justified) to the value provided in the Beyond as usual scenario. This target is the target against which the success of the initiative has to be assessed.

- **Individual company targets:** Those are improvement targets that each company can derive from the reported scenarios. A company absolute target is equal to the average value provided by the BnYAT scenario. The relative reduction target can be derived comparing this value to the value provided by the company in the baseline scenario (known only to the company). The front runner is assigned a lower target value as the marginal cost of improvement for a front runner is higher than for all the other companies. A company can understand to be the front runner by comparing the provided maximum reduction potential with the BAU scenario average.

For detailed examples on the calculation of the targets refer to Appendix 5.1.

The industry target is published in the Status Report and all participating companies are assessed yearly against it.

Company targets are confidential and known only to the relative company. Such targets are used as an internal tool to assess the yearly success of the initiative, to develop corrective actions and ensure fair competition.

Before it is integrated into company processes, the industry target is proposed to the Consultation Forum for discussion, supported by evidence and reports (see Stakeholder Involvement Process as part of Step 4 in Appendix 5.1).

The standardised template used for the definition of a common modality, gathering the expert judgements and the calculation of the target scenarios is included in Appendix 5. In case more detailed templates are defined, they will be published in the Status Report.

Environmental product declaration

Participating companies will also provide an Environmental Product Declaration (EPD) for the modality for which a target has been set. This EPD, developed on the basis of a study run by the Hamburg authorities and hospitals with the participation of COCIR Members, includes a set of minimum information offered in Appendix 5.4. Publishing this EPD will remain up to each company's own discretion. The Ecodesign SC will examine every year the possibility to make the use of EPD mandatory on the base of the experience gained by companies.

4.3.5. Step 5: Implementation into company processes

The purpose of the fifth step is the integration of the Ecodesign target(s) into the internal company processes. The translation of the target(s) into the company internal product design process remains up to the individual member.

Each year, every company delivers progress data based upon the common definitions of Step 4 enabling the Ecodesign SC Secretariat to monitor and report the annual industry progress.

4.3.6. Step 6: Monitoring and reporting

The purpose of the sixth step is to monitor and report on the achievement of the industry target. The method of the sixth step is to calculate the average of the annually reported values and to compare it to the Baseline and the forecasts.

The status of each modality and the progress that the companies are making is annually reported to the Stakeholders with the SRI Status Report. This separate document is provided at the end of the first quarter of each year.

Before the SRI Status Report is released, a third party consultancy validates the data and all calculations performed by the SC Secretariat.

5. Compliance with Annex VIII requirements of Ecodesign Directive 2009/125/EC

5.1. Ecodesign Directive Annex VIII Clause 1: Openness to participation

> *Self-Regulatory Initiatives shall be open to the participation of third country operators, both in the preparatory and in the implementation phases.*

The membership of COCIR is open to any company in the Radiological and Imaging, Electromedical and Healthcare IT sector. Companies who do not wish to become members of COCIR can still participate in the Self-Regulatory Initiative. In this case, COCIR charges the company a fee to reflect the reasonable costs for the company to participate in the Initiative. A detailed procedure for the inclusion of new companies is outlined in the Appendix 2.2. Any change in participating companies will be reflected in the annual SRI Status Report.

Some of the companies listed in Appendix 3 are third country operators with headquarters located outside the EU. All of these companies are actively involved in the preparatory and implementation phases of this Self-Regulatory Initiative.

To ensure active participation of such third country operators, representatives from these companies attend the Ecodesign SC meetings held at COCIR offices in Brussels or equivalent meeting facilities in central locations. With these meetings the engagement and their active contribution towards the development of the methodology and approach of the third country operators is ensured. Therefore, the scope of the SRI reaches well beyond the European boundaries, as the member companies implement the SRI targets into their internal procedures.

5.2. Ecodesign Directive Annex VIII Clause 2: Added Value

> *Self-regulatory initiatives shall deliver added value (more than 'business as usual') in terms of the improved overall environmental performance of the Ecodesign covered.*

The SRI generic 6 steps methodology incorporates a best possible holistic review of all environmental impact categories since it allows including different state of the art Life Cycle Assessment Methodologies and therefore the respective diversified focus on environmental aspects. Examples are the incorporation of results from the EcoIndicator99, the Cumulated Energy Demand and Toshiba's Factor T.

Furthermore, three sections have been added to include risk assessments to ensure future positive development of patient diagnosis and imaging equipment. The review of readily available LCA data from the companies to select the most significant aspects of a modality and the summary of the included impact categories in Step 2 and 3 of the SRI Methodology ensure that the most significant environmental aspect is addressed with the reduction target.

A clear defined calculation on how to deliver a target for added value (more than 'business as usual') has been introduced in Step 4 of the SRI Methodology: The targets are calculated and set based on target scenarios (BAU, BAT, BNAT), combined with a top runner scenario to continuously reduce the respective assessed most significant environmental aspect.

5.3. Ecodesign Directive Annex VIII Clause 3: Representativeness

> *Industry and their associations taking part in a self-regulatory action shall represent a large majority of the relevant economic sector, with as few exceptions as possible. Care shall be taken to ensure respect for competition rules.*

The participating companies in this Initiative cover at least 80% of units sold in the EU for each of the following modalities in the medical imaging equipment sector (refer to Appendix 2.3 for details):

- Computed Tomography (CT),
- Magnetic Resonance Imaging (MRI),
- Nuclear Medicine,
- Ultrasound,
- X-Ray.

This meets the requirement for the Initiative to represent "a large majority of the relevant economic sector".

The scope of the Initiative is not limited to the modalities described in Section 3 and the membership of COCIR is open to any company in the Radiological and Imaging, Electromedical and Healthcare IT Industry. Companies who do not wish to become members of COCIR can still participate in this Self-Regulatory Initiative.

Industry forums 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 who become members of the COCIR Self-Regulatory Initiative are required to comply with the AntiTrust Guidelines contained in Appendix 3. The AntiTrust Guidelines specifically prohibit anti-competitive behaviour.

5.4. Ecodesign Directive Annex VIII Clause 4: Quantified and staged objectives

> *The objectives defined by the stakeholders shall be set in clear and unambiguous terms, starting from a well-defined baseline. If the self-regulatory initiative covers a long time-span, interim targets shall be included. It must be possible to monitor compliance with objectives and (interim) targets in an affordable and credible way using clear and reliable indicators. Research information and scientific and technological background data shall facilitate the development of these indicators.*

The assessment and calculation of the Ecodesign target is based on the impact of the selected aspect (see Step 3 and 4 of the SRI Methodology) of a pre-selected modality. The impact values are collected according to commonly defined use scenario(s) and functional unit(s). The calculation of the target scenarios by the SC Secretariat offers transparent targets aimed to help stakeholders and the industry itself to understand the ranges and impacts of the different development options.

The Ecodesign targets are based on industry-wide harmonized definitions and calculations. The SC Secretariat presents them to the Ecodesign Steering Committee to agree on a feasible reduction target. Before the targets are implemented by the member companies, the proposed target is sent to the Stakeholder Consultation Forum for validation (see Stakeholder Involvement Process in **Appendix**). Each member company will implement an individually derived target into its company processes and integrate it into the individual business targets (see second phase of Step 4 of the SRI Methodology).

The business as usual scenario presented in Step 4 of the SRI Methodology predicts the average impact of the aspect for new products at the end of the respective innovation cycle under current Ecodesign efforts.

Additionally, the SRI Methodology includes a provision to report the annual interim achievements towards the industry target for each selected modality in a separate SRI Status Report. This report contains fully validated data by a third party consultancy.

5.5. Ecodesign Directive Annex VIII Clause 5: Involvement of Civil Society

> *With a view to ensuring transparency, self-regulatory initiatives shall be publicized, including through the use of the Internet and other electronic means of disseminating information.*
>
> *The same shall apply to interim and final monitoring reports. Stakeholders including Member States, industry, environmental NGOs and consumers' associations shall be invited to comment on a self-regulatory initiative.*

The SC Secretariat publishes the industries Self-Regulatory Initiative document on its website (www.cocir.org) under the section "Greening at COCIR".

The SC Secretariat also publishes an annual performance report on its website. With this report COCIR informs all stakeholders comprehensively about the Ecodesign activities, successes, and challenges. It is intended to initiate a dialogue between the industry and stakeholders.

COCIR cordially invites all stakeholders to share their thoughts and encourages comments e.g. via e-mail to secretariat@cocir.org.

The Ecodesign SC welcomes the participation of Consultation Forum members including a wide representation from Member States, industry, environmental NGOs and consumer associations.

5.6. Ecodesign Directive Annex VIII Clause 6: Monitoring and Reporting

> *Self-regulatory initiatives shall contain a well-designed monitoring system, with clearly identified responsibilities for industry and independent inspectors. The Commission services, in partnership with the parties to the self-regulatory initiative shall be invited to monitor the achievement of the objectives.*
>
> *The plan for monitoring and reporting shall be detailed, transparent and objective. It shall remain for the Commission services, assisted by the Committee referred to in Article 19(1), to consider whether the objectives of the voluntary agreement or other self-regulatory measures have been met.*

The monitoring and reporting plan for the Self-Regulatory Initiative is presented in detail in Appendix 5.1, which also outlines the procedure that the SRI members follow to gather confidential data from companies for each modality, aspect and modality definitions.

These confidential data provided by participants are audited before reported to the SC Secretariat. Thus these data do not require additional auditing for this Self-Regulatory Initiative.

The SC Secretariat's role is to consolidate the confidential data from each company into a single master spread sheet for analysis. It also conveys a plausibility check.

Before the data is reported to the stakeholders, an audit by a third party consultancy verifies the accuracy of the SC Secretariat calculations.

The Ecodesign SC uses only the consolidated data to assess the achievement level of the annual interim targets and therefore if the group is on track to achieve the final target. The data serves as base for the SRI Status Report.

The Ecodesign SC examined the feasibility of a joint "Environmental Product Declaration" (EPD) format, allowing participating companies to individually communicate their product information. The common agreement is included in Appendix 5.4.

5.7. Ecodesign Directive Annex VIII Clause 7: Cost-effectiveness of administering the Self-Regulatory Initiative

> *The cost of administering self-regulatory initiatives, in particular as regards monitoring, shall not lead to a disproportionate administrative burden, as compared to their objectives and to other available policy instruments.*

This requirement is directed to the European Commission and Members States to ensure that the costs and administrative burden that medical imaging equipment manufacturers and other stakeholders including authorities incur through the Self-Regulatory Initiative is not disproportionate compared to other policy instruments. The Ecodesign SC designed the Self-Regulatory Initiative for medical imaging equipment to deliver results under a continuous improvement perspective, without involving administrative burden for participating Companies compared to other policy instruments.

5.8. Ecodesign Directive Annex VIII Clause 8: Sustainability

> *Self-regulatory initiatives shall respond to the policy objectives of this Directive including the integrated approach and shall be consistent with the economic and social dimensions of sustainable development. The protection of consumers' interests (health, quality of life and economic interests) shall be integrated.*

The Ecodesign SC ensures that the environmental design targets set under the Initiative are environmentally sound with regard to other environmental aspects of medical equipment. This is ensured with the review of the process against the criteria in Annex I of the Directive 2009/125/EC in Step 3 of the SRI Methodology (for details refer to Appendix 5.1).

Regarding other elements of sustainability, it is important to note that new medical equipment are designed to give better and earlier diagnosis, more effective and successful treatments and completely new treatments. In other words, the primary function of a medical device is to protect consumers' health and quality of life.

Under this Self-Regulatory Initiative, the healthcare industry aims to overcome the increased energy consumption in imaging modules, e.g. by making energy savings in other aspects of ultrasound equipment design. However, if new, even more powerful imaging technology is developed in the next innovation cycles, the Medical Equipment Directives obliges the medical device industry to implement this new state-of-the art technology.

As part of this Self-Regulatory Initiative, the participants continue to monitor the development of new imaging technology and determine its compatibility with the requirement of delivering improved consumers' health and quality of life.

5.9. Ecodesign Directive Annex VIII Clause 9: Incentive compatibility

Self-regulatory initiatives are unlikely to deliver the expected results if other factors and incentives – market pressure, taxes, and legislation at national level – send contradictory signals to participants in the commitment. Policy consistency is essential in this regard and shall be taken into consideration when assessing the effectiveness of the initiative.

The European Commission has issued a Communication on 16 July 2008–COM (2008) 400- entitled: Public procurement for a better environment. A building block of the 'Action Plan on Sustainable Consumption and Production and Sustainable Industrial Policy (SCP/SIP)' aiming at improving the energy and environmental performances of products.

The Communication, also commonly known as Green Public Procurement (GPP), is an initiative addressing all key industries including "equipment used in the health sector" and serves as policy instrument for member states guiding their procurement decisions addressing current energy and health concerns. Although the Communication does not in particular cover energy consumption it states "the core GPP criteria would be set at the level of the energy efficiency requirements".

For the time being, the GPP and developed Training Toolkit with 3 modules are expected to have no effect on the COCIR Ecodesign Self-Regulatory Initiative. The Ecodesign SC hopes that the GPP criteria will reflect the findings included in this Self-Regulatory Initiative. The Ecodesign SC is not aware of any other factors or incentives that could affect the Self-Regulatory Initiative.

Part 2

Appendix

APPENDIX 1

1. COCIR Overview

1.1. Background information on COCIR

Founded as a non-profit trade association in 1959, COCIR represents the Radiological, Electromedical and Healthcare IT industry in Europe. As such, COCIR members[1] play a driving role in developing the future of healthcare both in Europe and worldwide. COCIR is committed to supporting its members and communicating 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. We encourage the use of advanced technology to support healthcare delivery worldwide. COCIR's key objectives include promoting free worldwide trade of medical equipment and maintaining the competitiveness of the European health sector.

For more information: www.cocir.org.

A vast majority of products manufactured by COCIR members are medical equipment and as such are regulated through the Medical equipment Directive[2] (a New Approach Directive). All products sold in Europe must be CE marked to prove compliance to this Directive. This directive requires products to comply with Essential Requirements and that a Quality Management System is in place to ensure products are designed, produced and put on the market through an established and robust way. It covers also post-market surveillance principles.

1.2. COCIR Core Competencies

Those competencies are as follows:

- **Market Statistics** (Medical Imaging and Healthcare IT Intelligence Centre): COCIR established more than 10 years ago a platform to gather market statistics data very useful to better understand the global coverage and providing COCIR members with data per product groups and per country. Focus is on Diagnostic Imaging and Healthcare IT. As of today data are collected from COCIR company members on a quarterly basis (sales and orders) for more than 50 countries. Those data are accessible to COCIR companies including their figures into the process. The application used is robust and includes confidentiality rules. A study was performed in 2009 on Age Profile more specifically for CT, MRI and Nuclear Medicine

- **eHealth:** COCIR is actively involved in all discussions linked to eHealth. Refer to COCIR Position Paper providing 10 Recommendations (http://www.cocir.org/uploads/documents/-24-cocir_pp_ehealth_rel_short.pdf).

---

[1] ***COCIR Company Members:*** *Agfa-Healthcare, Aloka, Bosch, Canon Europe, GE Healthcare, Hitachi Medical Systems Europe, IBA Ion Beam Applications, IBM, Intel, iSoft, Carestream Health, Fujifilm, Elekta, Medison, Konica, Microsoft, Philips Healthcare, Siemens Healthcare, Shimadzu, Toshiba Medical Systems Europe, T-systems*
COCIR National Associations Members: *AGORIA (Belgium), Assobiomedica (Italy), SNITEM (France), ZVEI (Germany), SPECTARIS (Germany) HHT (Netherlands), FENIN (Spain), Swedish MedTech (Sweden), AXREM (UK), FiHTA (Finland), TipGorDer (Turkey), AMDM (Hungary)*

[2] *See Council Directive 93/42/EEC of 14 June 1993, OJ No L 169/1 of 1993-07-12.*

- **Contribution to sustainable healthcare** with Institutions and other stakeholders (Europe). Refer to COCIR White Paper on sustainable Healthcare systems (http://www.cocir.org/uploads/documents/-24-cocir_pp_ehealth_rel_short.pdf).

- **Regulatory Activities and Standardisation** (EU and Global). COCIR is involved in various activities linked to regulatory framework affecting Medical Electrical in Europe and globally. With regards to standardisation refer to COCIR Position Paper (http://www.cocir.org/uploads/documents/-38--608-cocir_vision_and_recommendations_on_standardisation_5_june_2009.pdf).

- **Environment** (EU and Global). In 2000 COCIR created the Focus Group Environmental Affairs. Main tasks: Collecting environmental information, sharing best practices and driving innovative solutions to reduce adverse environmental impacts. COCIR has long track records showing its leadership in this domain for Medical Equipment.

1.3. COCIR Initiatives in the field of environment

COCIR has taken several initiatives in the environmental domain introducing Ecodesign Initiatives in different ways:

- **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)[3], 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[4]. A version 2, endorsed by MITA (US Trade

[3] *See COM(2008) 397, Brussels, 16.7.2008.*

[4] *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.*

Association) and JIRA (Japanese Trade Association), was published in September **2009.** In addition, COCIR published its 1st Industry Standard (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.

1.4. History of COCIR's SRI

COCIR, furthering the past intensively, explored opportunities and took a number of initiatives (refer to previous section) 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**[5] aims and objectives and commits to proactively participate in the Ecodesign Directive through this Self-Regulatory Initiative (SRI) for medical equipment.

COCIR supports the approach 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.

COCIR, on behalf of its member companies, presented its initial proposals for this Self-Regulatory Initiative to the Consultation Forum meeting on **28 May 2008**. The Consultation Forum welcomed this approach because it could achieve the same overall objective as an implementation measure but would avoid potential negative business impact. In particular, the Consultation Forum emphasised that "*regulation would risk hampering innovation in the medical equipment sector, where technology evolves rapidly"*[6]*.*

Based on this positive feedback, COCIR decided in **September 2008** to establish an independent Ecodesign Steering Committee *(hereafter: Ecodesign SC)* in order to further develop this Initiative and take proactive actions.

Strategic Directions and Action Plan was the basis to get formal engagement from participating companies to engage in this process. The governance of this Committee is provided in Appendix 3*.*

This present document provides the industry's detailed proposal for a Voluntary Agreement including the scope, approach, methodology and timeline of this Self-Regulatory Initiative. Section 5 of part 1 highlights how COCIR's proposal complies with all regulatory requirements in Annex VIII of Directive 2009/125/EC.

[5] *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.*

[6] *Minutes from Consultation Forum of 28 May 2008, CF-2008-15-EC.*

APPENDIX 2

2. Scope of COCIR's Self-Regulatory Initiative

2.1. Change of Modalities in Scope

This Self-Regulatory Initiative is an open-focus project. The Ecodesign SC will add modalities to the current scope when shown to meet the following criteria to determine specific modalities for self-regulation. To be included in the SRI, modalities must:

1. Represent a large segments of medical imaging products sold in the European Market.
2. Have a majority SRI participant representation by market share. Further information on market value, market coverage, and companies can be found in the Appendix 2.
3. Be a business-to-business operation.
4. Have SHARE market data available.
5. Have Life Cycle Assessment data available.

When a new modality is added to the SRI scope, the Ecodesign SC will revise the priority list (refer to STEP 2, Appendix 5.1) 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 added the task to assess therapy modalities, even if they are not imaging equipment, for their environmental impact, to cover modalities from all member companies. Examples for therapy modalities are Linear Accelerators and Particle Therapy.

2.2. Participation of Companies

To be included in the initiative a new company must also offer the following:

- CEO Commitment, signed MoU and AntiTrust Statement (see appendix 3)
- Sign SHARE Non-Disclosure Statement, in both cases if and if not also member of COCIR (to ensure quality market data is available for STEP 2 of the SRI Methodology)
- Be able to follow COCIR Market Statistics definitions of product categories. If a modality cannot fit into existing COCIR categories, a new product category may be defined if members represent >80% of the market segment.

If all data for the application is complete, the ErP Steering Committee will confirm the membership during its regular meetings in Brussels.

2.3. Market relevance

Medical equipment plays an important role in contributing to enhance the quality of life of citizens during the whole care cycle (prevention, diagnostic, therapy and care).

Table 4 provides an overview on market value, market coverage, and companies to be invited to join the Self-Regulatory Initiative for the Imaging Modalities currently 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).

Table 4: Medical Imaging - EU market[7] share for modalities currently within the scope of this Initiative

Modality		2009 Market Value[8]	2010 Market Value[9]	Estimated EU Market Coverage[10]	Other targeted companies[11]
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

[7] *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*
[8] *COCIR Imaging Market Statistics source*
[9] *COCIR Imaging Market Statistics source*
[10] *COCIR estimationbased on SHARE data*
[11] *COCIR plans to contact those companies over time*

APPENDIX 3

3. COCIR Governance

3.1. Ecodesign Steering Committee Governance

C O C I R I N T E R N A L P R O C E D U R E

ISSUE DATE: 08/04/2009	PG 28 OF 11	COCIR: Ecodesign 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: 28/006/2011 – amended as requested by PWC for the review of the SRI Status Report 2011
DISTRIBUTION TO: ErP 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 Ecodesign Steering Committee which focuses on a proactive approach for an integrated product policy and a continuous improvement of COCIR products.

2. SCOPE

This procedure applies to all companies who have committed to participate in the 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. Creation of the Steering Committee

The COCIR Environmental Policy Focus Group created a Steering Committee for this Self-Regulatory Initiative. This Committee meets regularly to:

1. Define and improve the methodology for all modalities.
2. Evaluate the results of 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 Ecodesign 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. 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 Ecodesign 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 and 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 Ecodesign 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. Ecodesign 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 other interested stakeholders upon their requests.

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 from the Ecodesign SC Secretariat upon specific request.

6. Roles and responsibilities

6.1. 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 Ecodesign 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 Ecodesign 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 Ecodesign 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.

6.2. 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 Ecodesign Steering Committee. They shall contribute to the continuous improvement of the SRI by offering their expertise in face-to-face meetings/TCONs whenever applicable.

6.3. 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 Ecodesign 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 Ecodesign methodology.
9. To execute all plausibility checks to ensure correctness of calculation as prescribed in the Ecodesign methodology.
10. To report generic industry data to the Ecodesign 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.

7. Monitoring and reporting activities

7.1. Data collection (quantitative and qualitative)

Collected company-confidential information cannot be shared with the Ecodesign Steering Committee unless the Ecodesign 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.

7.2. Annual SRI Status Report

The annual SRI Status Report is responsibility of the SC Secretariat.

The Ecodesign 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.

8. 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 Ecodesign 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 Ecodesign 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 Ecodesign 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 Ecodesign Steering Committee Secretariat,
- Reviewing draft consolidated report,
- Validating the final 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 applicable for 2009, 2010 and 2011 and will be revised by January 2012.

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 Ecodesign Self-Regulatory Steering Committee to represent our company.

_____
Name

_____
Position

_____
Signature

_____
Date

Acknowledgement from Ecodesign Steering Committee Secretariat

For COCIR

_____
Nicole Denjoy
Secretary General

_____
Date Signed

APPENDIX 4

4. SRI Pilot for modality ultrasound

4.1. History

When COCIR and the participating companies started to develop the Self-Regulatory Initiative, the methodology and approach was a new terrain for all. Participating companies initiated a first non-standardised review of the products in scope to establish the product of initial focus for a pilot, to develop the industry baseline for energy trending, and to establish targets and timing. The Ecodesign Steering Committee, which had been established for the organisation of the Self-Regulatory Initiative, was determined to start with the ultrasound product in 2009.

In 2009, all contributing manufacturers worked on an initial screening of all the modalities in scope and concluded to select ultrasound as the pilot. The final choice of ultrasound was based on the following reasons:

- Ultrasound equipment is manufactured by most of the COCIR participating companies in the SRI (Aloka, GEHC, Hitachi, Medison, Philips, Siemens and Toshiba). This was an important point, assuming that the highest degree of precision in communication and harmonization would be required to come to satisfying targets. Thus, the inclusion of the highest number of manufacturers steepened the learning curve.

- COCIR ultrasound manufacturers companies represent 80% of all ultrasound units sold in the EU, the remaining vendors are known.

- COCIR members have a good understanding of environmental aspects and opportunities to reduce environmental impacts for ultrasound equipment. Most of the manufacturers are engaged in Life Cycle Analysis projects and focus on the Ecodesign of their products (examples in Appendix 4.4). This established expertise was to be included in the development of a customized methodology for the medical equipment industry.

- Ultrasound equipment is much less complex, including fewer components compared to other modalities in the medical imaging sector. Taking ultrasound as example was easier and faster to learn and to develop a methodology, to establish company internal processes to assess environmental aspects, create targets, and to change technologies. Also, as these new processes will have big impacts to all core business processes in particular product life cycle management within each company, supply chain and customer relationship management, a thorough and

This Appendix Section includes all details on the ultrasound equipment pilot. It includes a description of the modality specifics, example of Life Cycle Assessments, and the Excel tool that has been used to gather the relevant baseline data. Furthermore, it includes additional information the target setting procedure of this pilot. The current progress in achieving the target is part of the annual SRI Status Report.

4.2. Commitment to pilot ultrasound

In the Consultation Forum presentation of 18 November 2009, COCIR has set and presented a target for the pilot to additionally reduce the average energy consumption of new ultrasound products placed on the market until 2012 (refer to the annual SRI Status Report). This was the first reduction target that the SRI members have committed to and it will remain unchanged until achieved in 2012.

4.3. Pilot ultrasound and the SRIv2

The pilot project on ultrasound equipment has not been reviewed according to the new SRIv2 methodology. The Ecodesign SC decided to apply the new methodology to MRI equipment and to maintain the pilot project under the old SRIv1 methodology as in 2010 participating companies managed to achieve results in the reduction of the average annual energy consumption per unit.

The new SRIv2 methodology will be applied to Ultrasound as last modality. A new target will be set according to the new procedure (for details on the timelines and priority of the modality ultrasound refer to the annual SRI Status Report) and ultrasound equipment will enter the continuous improvement cycle. Thus, the commitment of the participants of the SRI remains unchanged: to ambitiously set targets to reduce adverse environmental impacts of ultrasound products.

Additional information on SRIv1 methodology and the Ultrasound Project are available in the 'SRIv1 – Self-Regulatory Initiative for medical Imaging Equipment".

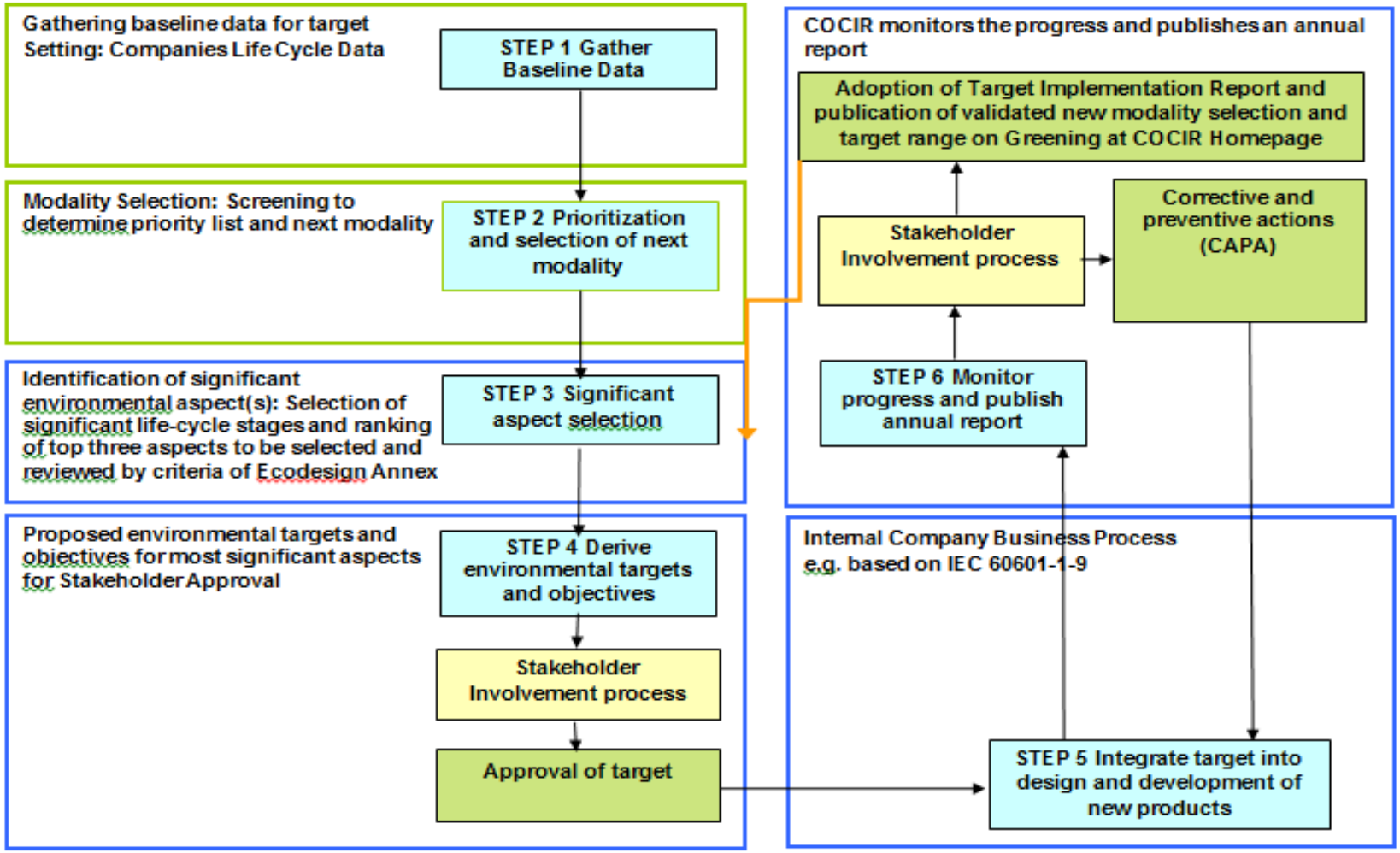
Achievements in the pilot projects will be published yearly on the SRI Status Report, the reporting tool chosen by the Steering Committee.

Both the documents are available at the COCIR website, www.cocir.org in the "Greening at COCIR Section".

APPENDIX 5

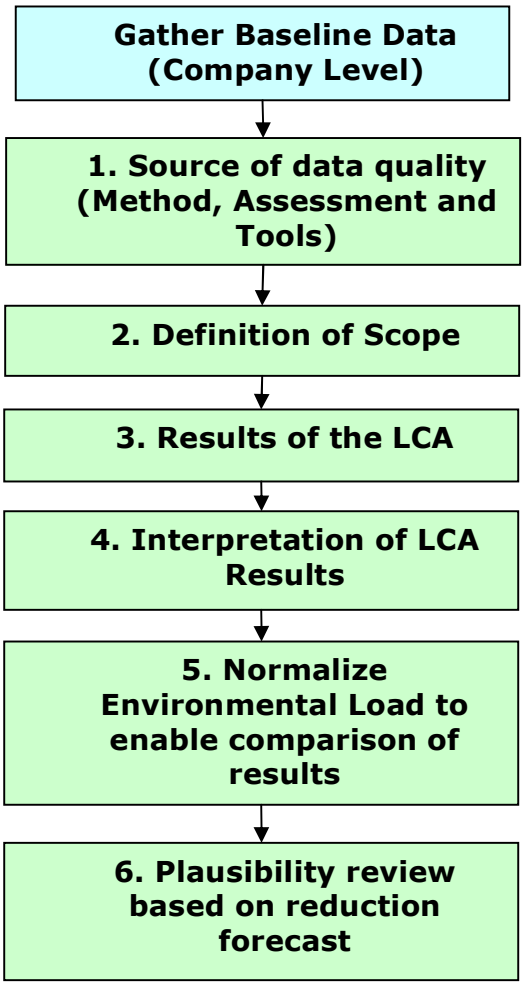
5. COCIR SRI Generic Methodology

Figure 8: Overview SRI 6 STEPS Approach (the green boxes signify task that need to be done once. The blue boxes cover the four steps that represent a closed loop: to be repeated for continuous improvement and transparency)



5.1. Detailed Process Explanation for SRI Generic Methodology Steps

5.1.1. STEP 1 Gather Baseline Data (for details please see following extracts from our Excel tool describing an exemplary case)



Description
In STEP 1 basic modality data are gathered from all participating companies. Currently available life cycle data (or other relevant data) is collected from a sufficient[12] number of companies (able to represent the market), covering the main models[13] of all modalities in the scope of the SRI. To ensure the verifiability of the data, the companies list an interpretation of the results according to ISO 14044. The concluded normalized[14] environmental load, displayed as percentage, and an expert based risk assessment for the next generation product on the total reduction potential per modality serves as baseline data for STEP 2.
Input data into Step 1
- Typical LCA data per modality and company (use scenario, functional unit, impact categories, intended use, etc.) - % Life Cycle contributions - Individual environmental load per modality (related to individual LCA method) - Individual company input on interpretation of LCA results - Plausibility check based on company internal expert judgements
Deliverables from Step 1
- Normalized company specific environmental load in % - Reduction forecast of total normalized environmental load in % of a modality

[12] *"Sufficient" corresponds to companies at least representing 50% of the total market.*
[13] *"main products" corresponds to common configurations of a modality*
[14] *Definition of normalized: modalities are normalized against the use periods e.g. 10 years in order to compare.*

STEP 1 Gather Baseline Data – Template for data collection (modalities have been reduced for better Visualization)

Exemplary Template STEP 1: Gather Baseline Data	Confidential: For ErP Internal process only (see SOP)

Currently only exemplary data is shown.

Company:	XYZ	

1. Source of data quality*:	
Life cycle impact assessment method	e.g. Cumulated Energy Demand (CED)
Software tool	e.g. Excel
Unit of Environmental load	e.g. MWh
Other methodological aspects	
Resource use	
Embedded toxicity	
Emissions to land, air and water	
Land use	
others	C02 estimation, recycling possibilities

*Methodological choices, allocation rules, category indicators, etc.

2. Definition of Scope:

Modality	MR	CT	...
Definition of System	*please insert*	*please insert*	
Company model(s)	*MR xyz (Please specify model name and Tesla)*	*CT xyz (Please specify model name and slides)*	
Intended use	diagnosis	diagnosis	
Typical use scenario including operation modes	- 240 days per year - System Off (58% per day) - Ready for measurement (17% per day) - Typical measurement (25% per day) (typical measurement is the average of maximum and standby power) 10 years	- 168h/week total: - System off (70% = 118h); - System on (14% = 24,27h); - System rot(14% = 24.27h); - Scan Mean (1% =1,46h) - 70 Patients with 1.5 exams per patient; 10 sec per scan 10 years	
Individual Functional Unit*	10 yrs modality use (typical scenario)	10 yrs modality use (typical scenario)	
Year(s) for which assessments are valid	>2005	>2005	

*Definition according to ISO 14001

3. Results of the LCA* :

Modality	MR	CT	...
Production ("cradle to gate")	20%	20%	
Transport (from suppliers, to customers)	5%	5%	
Use of product **	70%	70%	
End of Life	5%	5%	

*Life Cycle Contribution in % (only if life cycle is considered in LCA study of company xyz)
**including maintenance and spare parts

4. Interpretation of LCA Results*

Modality	MR	CT	...
The purpose of the LCA	comparison of existing product with successor to identify most significant improvement options		
Conclusion of the LCA results	Energy use is 80% of the total impact		
Limitations identified by the data quality	Based on data source from Europe, consumables are out of scope		
Other conclusions			

*Align with criteria of ISO 14044

5. Normalized* Environmental Load to enable comparison of results

Modality	MR	CT	...
Environmental Load* (e.g. MWh)	5000	1000	
Normalized to equal use periods (years) *	5000	1000	
Normalized Environmental load 2009**	100,00%	20,00%	

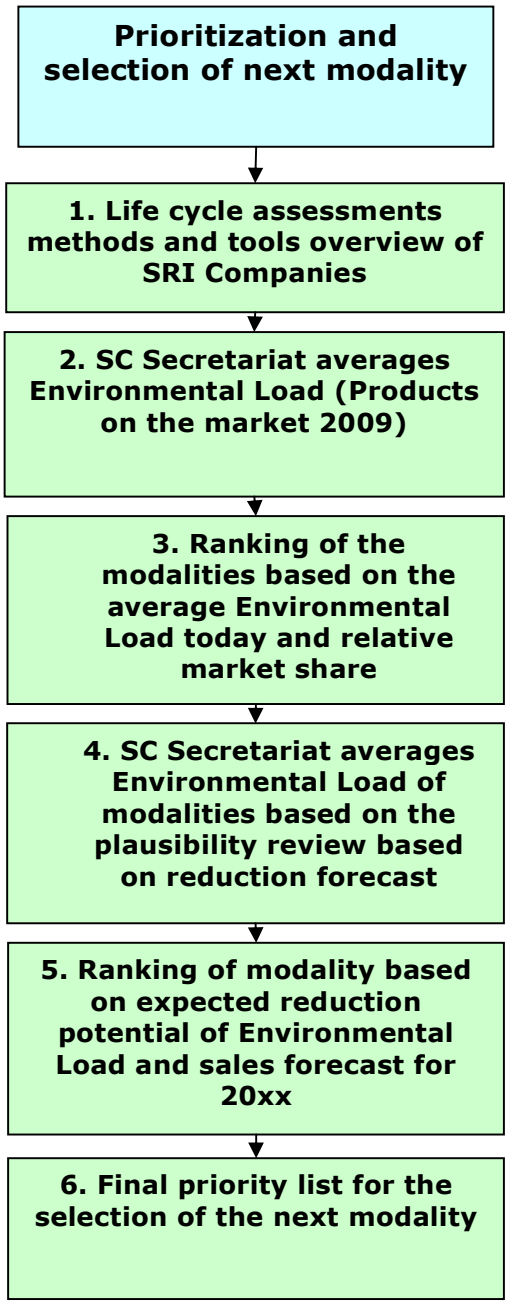
* Modalities are normalized against the use periods e.g. 10 years in order to obtain comparable figures

6. Plausibility review based on reduction forecast

Normalized Environmental load for products on the market 20xx

Modalities	MR	CT	...
Company A (including reduction forecast)	70%		
Expected Products on the Market 20xx	1250		

5.1.2. STEP 2 Prioritization and selection of next modality



Description	In STEP 2, the practiced LCA methods and tools of the individual companies are listed to provide an overview of the integration of the various environmental aspects. The company LCA results from STEP 1 are then consolidated. A plausibility check of the data is performed to demonstrate the accuracy, the information source of the data quality and the scope. Subsequently, the environmental loads (from STEP 1) are weighted with current data on units in the EU market based on SHARE[15] data. A second ranking, based on the expert judgements on factors such as feasible technological developments and the complexity of the product, as well as on sales forecasts of the next generation equipment offers a first insight on reduction potentials. The final priority list, used to select the next modality consists of the averages of the two previously calculated rankings.
Input data into Step 2	- Individual company data on LCA from STEP 1 - Individual averaged Environmental loads in % from STEP 1 - COCIR market data (SHARE)
Deliverables from Step 2	- Plausibility review of LCA data base from STEP 1 - Consolidated Environmental Loads in % - Priority list of modalities (public available)

[15] *SHARE is COCIRs internal market statistics data base*

STEP 2 Prioritization and selection of next modality – Template for data collection (example)

Exemplary Template STEP 2: Prioritization and selection of next modality	Confidential: For ErP Internal process only (see SOP)

Currently only exemplary data is shown.

1. Life cycle assessments methods and tools overview of SRI Companies

Company	Company A	Company B	Company C	Company D	Company X
Life Cycle impact assessment method	Eco Indicator 99	Cumulated Energy Demand (CED)			
Software tool	Simapro/ EcoScan	Excel			
Unit of Environmental load	Pt				
Life Cycle Phases included:					
- Production ("cradle to gate")	x				
- Transport (from suppliers, to customers)	x				
- Use of product*	x				
- End of Life	x				
other methodological aspects included:					
- Resource use	x				
- Embedded toxicity					
- Emissions to land, air and water	x				
- Land use	x				
- Others	damage to resources, humans and environment included				
* including maintenance and spare parts					

2. COCIR average Environmental Load (Products on the market 2009)

	Normalized Environmental load today					
Modality	**MR**	**CT**	**X-Ray Angio**	**NM**	**US**	**…**
Company A	100	0,20				
Company B	100	0,25				
Company C	100	0,15				
Company D	100	0,30				
Company X	100	0,20				
		1,10				
Average normalized environmental load*	100	0,22				
Products on Market in 2009 in EU **	1000	2000				

Normalized Environmental load 2009***

Priority list products on the market

* sum company A-X / number of companies

** from COCIR internal market stats (SHARE)

3. Ranking of the modalities based on the average Environmental Load today and their relative market share

Modality	Average normalized environmental load*	Sales Volume EU total (units in 2009)	% modality related to total units sold in EU	% modality x average environmental load of modality	Ranking
MR	100,00%	**1000**	**2,60%**	**2,60%**	**1**
CT	22,00%	2000	5,19%	1,14%	3
X-Ray Angio	4,80%	10000	25,97%	1,25%	2
Others	….	….	….	…	
	Σ	**38500**	(total no of units)		

4. COCIR average Environmental Load of modalities based on the plausibility review based on reduction forecast

	Normalized Environmental load for products in 20xx					
Modalities	**MR**	**CT**	**X-Ray**	**NM (e.g. PET)**	**US**	**…**
Company A (including reduction forecast)	70%					
Company B (including reduction forecast)	80%					
Company C (including reduction forecast)	75%					
Company D (including reduction forecast)	85%					
Company X (including reduction forecast)	80%					
Average environmental load*	78%					
Expected Products on the Market 20xx **	1000	2000	10000	500	25000	

* sum company A-Z / number of companies

** from market stats 2015

5. Ranking of modality based on expected reduction potential of Environmental Load and sales forecast for 20xx

Modality	Average normalized expected environmental load*	Sales Volume EU total (units in 20xx)	% modality related to total units sold in EU	% modality x average environmental load of modality	Ranking 20xx
MR	78,00%	1000	2,60%	2,03%	1
CT	22,00%	2000	5,19%	1,14%	3
X-Ray Angio	4,80%	10000	25,97%	1,25%	2
Others	….	….	….	….	
		Σ 25600	(total no of units)		

6. Final Priority list for the selection of the next modality

Modality	Interim Ranking	Ranking 20xx	Final Ranking	Comments/ Rational/ Remarks
MR	1	1	1	
CT	3	3	3	
X-Ray Angio				

…

5.1.3. STEP 3 Identification of significant environmental aspect(s)

Description	In STEP 3 data on the top 3 environmental aspects[16] are collected from the individual companies. This data set will further include an internal expert based risk assessment on the declared top ranked aspects. The SC Secretariat takes this data and averages the results from the single reported aspects to get a ranking of the overall top 3 environmental aspects. This allows to identify the most significant aspect. The risk assessments are used to get an insight[17] on the reduction potential of the top aspects. It is also an opportunity for the industry experts to include their expectations on the impacts of a possible reduction of the respective aspect, in order not to hamper medical innovation. If there is no significant risk for the top aspect, it is to be selected for the target setting in STEP 4.
Input data into Step 3	- Individual company ranking of the associated most significant aspects per identified life cycle stage - Individual company risk assessment against the identified aspects (see Annex for recommendation) - Info and status of activities towards Annex 1, Part 1 of Ecodesign Directive
Deliverables from Step 3	- Most significant life cycle stage - Three most significant aspects within industry (only for selected modality) - Risk mitigation needs - Results of Annex 1, Part 1 industry review per modality

[16] *"Top ranked" corresponds to the results from the individual company LCA data results.*
[17] *Sometimes there might be a top ranked aspect that may not have a large reduction potential due to technological, monetary or safety burdens*

STEP 3 Identification of significant environmental aspect(s) – Template for data collection

Exemplary Template STEP 3: Identification of significant environmental aspect(s)	Confidential data

Currently only exemplary data is shown.

1. Individual Identification and Ranking of Top 3 environmental aspects per company

Company A

Three most significant aspects	Value and Unit	Contribution to total environmental impact (in %, whole life cycle)	Internal Ranking*
Energy consumption	12 kWh	86%	1
Aluminum	2800 kg	3%	2
Copper	450 kg	0,20%	3

Company B

Three most significant aspects	Value and Unit	Contribution to total environmental impact (in %, whole life cycle)	Internal Ranking
Energy consumption	15 kWh		1
Copper	500 kg		2
Aluminum	2900 kg		3

Company C

Three most significant aspects	Value and Unit	Contribution to total environmental impact (in %, whole life cycle)	Internal Ranking
Aluminum	3100 kg		1
Energy consumption	13 kWh		2
Copper	550 kg		3

Company D

Three most significant aspects	Value and Unit	Contribution to total environmental impact (in %, whole life cycle)	Internal Ranking
aluminum	3000 kg		1
Energy consumption	15 kWh		2
Copper	600 kg		3

* With the help of the "internal ranking" each company will identify the ranking of its top 3 environmental aspects in order for COCIR to compare aspects.

2. Identification of most significant environmental aspect (consolidated by COCIR based on cumulated internal ranking of companies)

Aspects	Average contribution to total environmental impact	Average (internal ranking)	Final COCIR Ranking
Energy consumption	0,215	1,5	**1**
Aluminum	0,0075	1,75	2
Copper	0,0005	2,75	3

3. Company Expert judgment on possible impacts of reduction of top ranked aspect

Company	Modality	Life Cycle Stage	Aspect	Improvement possible (Yes/No)	Risk mitigation required/ needed (important for target setting)
Company A	MR	Use Phase	Energy consumption	Yes	e.g. reduction of at least 20% possible by zero boil off
Company B	MR	Use Phase	Energy consumption	Yes	
Company C	MR	Use Phase	Energy consumption	Yes	
Company X	MR	Use Phase	Energy consumption	Yes	

4. Announcement of final decision on the selection of the top environmental aspect for STEP 4, target setting

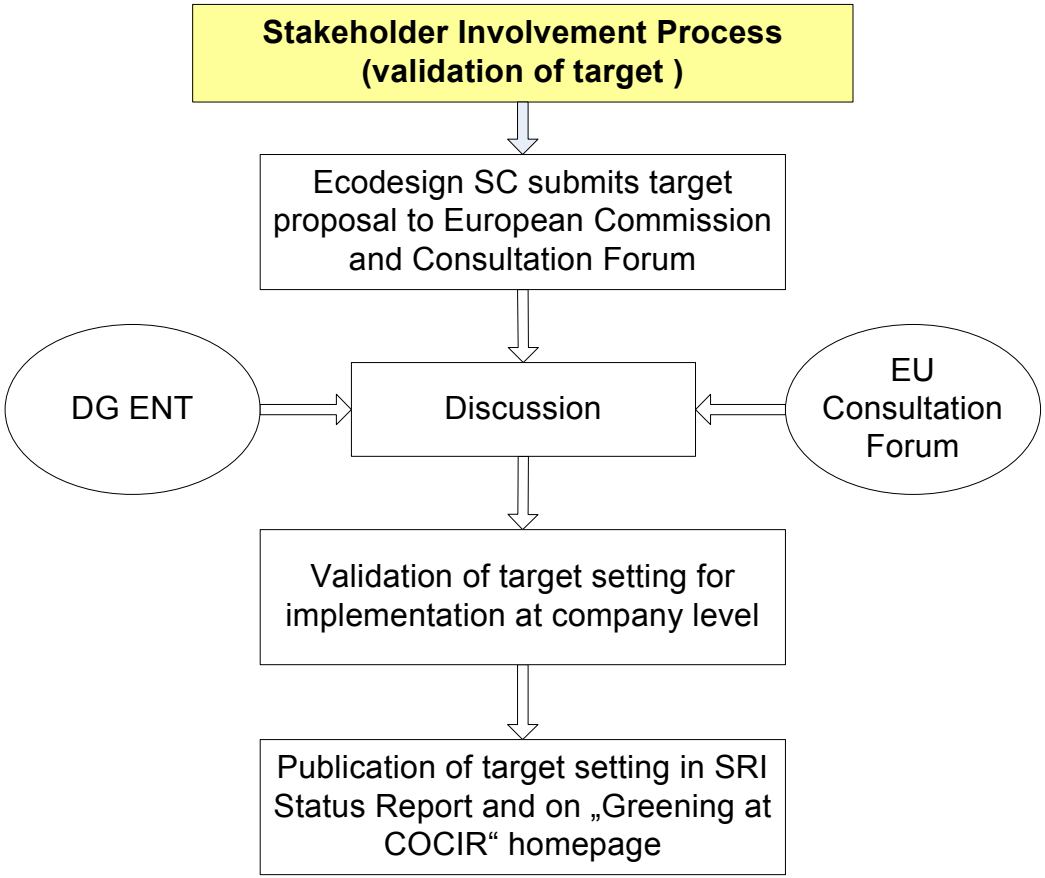
Identified environmental aspect for target setting :	Energy consumption
Risk mitigation needs/ limitations:	all reduction above 20% will have significant impact to planned innovations

Additional Review: ErP Directive 2009/125/EC, Annex 1.3, Part 1	
Environmental criteria	**Assessment**
(a) weight and volume of the product;	
(b) use of materials issued from recycling activities;	
(c) consumption of energy, water and other resources throughout the life cycle;	
(d) use of substances classified as hazardous to health and/or the environment according to Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packing and labeling;;	
(e) quantity and nature of consumables needed for proper use and maintenance;	
(f) ease for reuse and recycling as expressed through: number of materials and components used, use of standard components, time necessary for disassembly, complexity of tools necessary for disassembly, use of component and material coding standards for;	
(g) incorporation of used components;	
(h) avoidance of technical solutions detrimental to reuse and recycling of components and whole appliances	
(i) extension of lifetime as expressed through: minimum guaranteed lifetime, minimum time for availability of spare parts, modularity, upgradeability, reparability	
(j) amounts of waste generated and amounts of hazardous waste generated	
(k) emissions to air (greenhouse gases, acidifying agents, volatile organic compounds, ozone depleting substances, persistent organic pollutants, heavy metals, fine particulate and suspended particulate matter) without prejudice to Directive 97/68/EC of	
(l) emissions to water (heavy metals, substances with an adverse effect on the oxygen balance, persistent organic pollutants)	
(m) emissions to soil (especially leakage and spills of dangerous substances during the use phase of the product, and the potential for leaching upon its disposal as waste)	

5.1.4. STEP 4 Derive environmental targets and objectives

Description	In STEP 4 a common functional unit(s), product description and typical use scenario(s) are defined to set a common ground on the identification of the impact values of the selected aspect. It may be possible that high, medium and low range definitions are developed to reflect the complexity of the products and its respective purposes. As the definitions are set, the companies are asked to deliver the values according to the mutual target scenario. Furthermore, the company experts individually provide feasibility data on the improvement forecast for the respective aspect for the next innovation cycle (successor product). This data serves as the basis to calculate the target setting scenarios (BAU, BAT, Best not yet available technology). By additionally choosing the best performer (front runner), it is possible to define a suitable average business performance. The proposal for an ambitious target that will be presented to the stakeholders is thus based on the previously defined target scenarios for the selected, highest ranked aspect (which has been chosen based on available LCA data in STEP 3).
Input data into Step 4	- Individual company input on common definition of modality (ies), use scenario(s) and functional unit(s) - Individual company data on aspect performance related to common modality, scenario and functional unit - Individual technical expert judgement on feasible improvement options
Deliverables from Step 4	- BAU Scenario - BAT Scenario - Best not yet available Technology Scenario - Ranges for target setting - Reduction target proposal –beyond BAU- for selected environmental aspect from STEP 3

STEP 4 Exemplary Stakeholder Involvement Process (validation of target)



Description	In this sequence of STEP 4 the proposed target is released and sent to the stakeholders for review. Only after the stakeholders have reviewed the previous steps, the targets are implemented into the internal company processes.
Input data into Step 4	- Target proposal: beyond BAU - Results of innovation assessment - Stakeholder feedback and improvement suggestions
Deliverables from Step 4	- Target ready for implementation

Exemplary STEP 4 Derive environmental targets and objectives – Template for data collection (example)

Exemplary Template STEP 4: Derive environmental targets and objectives	***Confidential Data - is not enclosed in Report!***

Currently only exemplary data is shown.

1. Definition of modality corresponding to selected aspect in identified life cycle stage

	high	*medium*	*low*
Definition of modality*			
Typical use scenario*			

* If one product cannot be defined via SHARE an option is to use high, medium and low range scenario and product, resulting from the discussion between company experts. *Note: Modality should be consistent with SHARE*

Example for a target scenario:

2. Gather Baseline Data for selected environmental aspect (based on point 1.)

	Company A	**Company B**	**Company C**	**Company D**
Aspect related to standard use scenario or functional unit e.g. energy use kWh operational mode	12	15	13	15
Average environmental aspect (related to functional unit(s))	13,75			

3. Gather Company Expert judgment on feasible improvement (expert judgement - Best NOT yet available technology (20xx)) for later verification of final target (related to functional unit and use scenario)*

Forecast individual feasible improvement per Company (Expert judgment)	**-10%**	-19%	-20%	-21%
Average feasible improvement for SRI companies (expert judgment - Best NOT yet available technology (20xx))	-17,50%			

* Expert judgment of individual companies for aspect that has been selected in the previous step

Note: The top-performer can identify itself as the leader by recognizing its aspect value (indicated in red in table 2 this page) to be equal to the average absolute value of the Scenario BAU (second scenario average in table 4 next page). This company will be allowed to set itself its declared expert judgment improvement potential percentage, if this it lower than the BAU percentage. This principle will be automatically included from COCIR in the calculation of the overall proposed target.

4. Definition of BAU, BAT, and Best not yet available technology scenarios for target setting range

Scenario	Company A	Company B	Company C	Company D	(absolute) average of aspect (all SRI companies)*	Range for setting targets	Description
Energy use kWh of individual companies - today - (Incl. Frontrunner considered as BAT)	12,0	15,0	13,0	15,0	13,75	baseline today	
Scenario One Energy use (kWh) BAU - 20xx -	12,0	12,0	12,0	12,0	12,00	-12,7%	All SRI companies will aim to achieve **in average** what the front runner has achieved today (goal to mutually achieve -12.7%)
Scenario Two Energy use (kWh) Best NOT yet available technology -20xx-	9,9	12,38	10,73	12,33	11,34	-17,5%	**Each** individual SRI company will strive to achieve what has been predicted on average by the experts **(-17,50%)**
Scenario Three Energy use (kWh) BEYOND BAU - 20xx	10,8	12,38	10,73	12,38	11,57	-15,9%	**Each** individual company will strive to achieve what is possible on avg. today **(-17,50%, except Front Runner -10%)**, adding up to a total improvement -15,9%

* Absolute average values are reported. They are relevant for the individual company target setting. Especially the average absolute value of Scenario One BAU is important for the individual company to identify itself as the possible top-performer if its aspect value to be equal to the average absolute value.
Note: An additional incentive for the designer can be abstracted from the table since the company can see the average value of absolute performance and thus determine its actual standing. So there will be no extra need to report confidential information to individual members.

5. Target Range and final proposed target

Reduction potential between:	**-12,7%**	**and**	**-17,50%**
Proposed Target: reduction		**-15,9%**	
Relates to patient throughput improvement		**xxx**	

How scenarios are derived and target values calculated

For the reason of providing easy to understand examples in this section, the average of each scenario is calculated as a simple average, assuming that companies place on the market the same number of units. When setting real targets, the average will be calculated as a weighted average against the units sold.

Baseline scenario today (table 2): The 4 reported values (12, 15, 13, 15) for the four companies are calculated considering the average performance, measured according to the specific methodology, of all the models of the selected modality placed on the market by each company. Then the scenario average is calculated. Individual values are confidential and not disclosed to participating companies.

Reduction potential (table 3): the possible reduction potential values to be achieved in the innovation cycle are declared by individual companies on the basis of expert judgement, taking into account technologies under research and development and on the basis of a study that will be performed by a third party consultant, mandated by the Ecodesign SC.

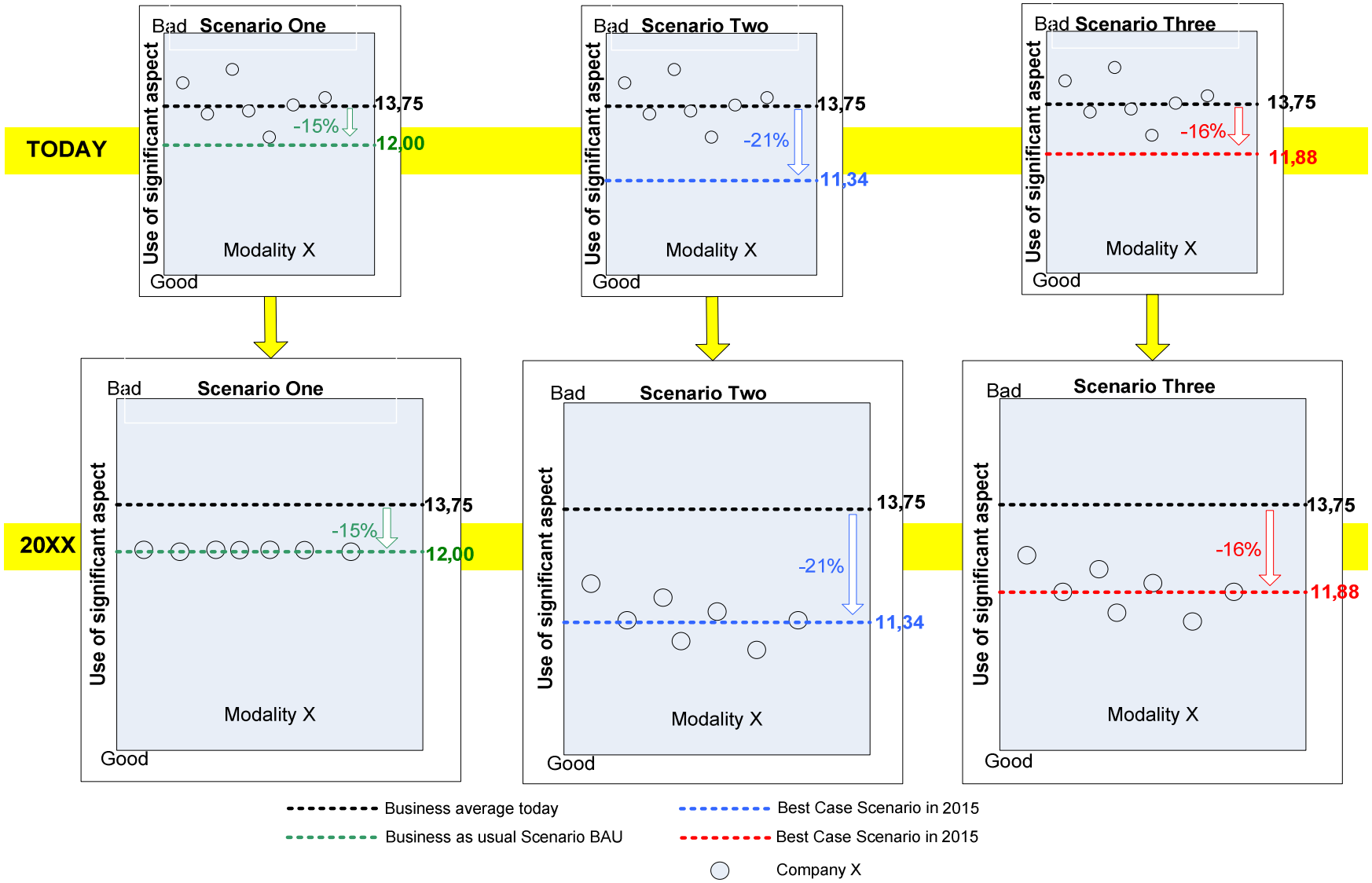
Scenario one: BAU - Business as usual in 20xx (table 4): The values are calculated assuming that in 20xx all companies will match the performance of the front runner today. Therefore all values are equal to the performance of the front runner. The front runner (and no one else) could understand he is the front runner as the average of the scenario is equal to the value he declared for the baseline scenario.

Scenario two: (BnyAT) Best not yet available technology in 20xx (table 4): The values are calculated applying to each company performance in the baseline scenario the average declared reduction potential (table 3). It represents the scenario in 20xx assuming that all the companies manage to achieve the average of maximum estimated reductions. Such scenario has very little chances to be achieved.

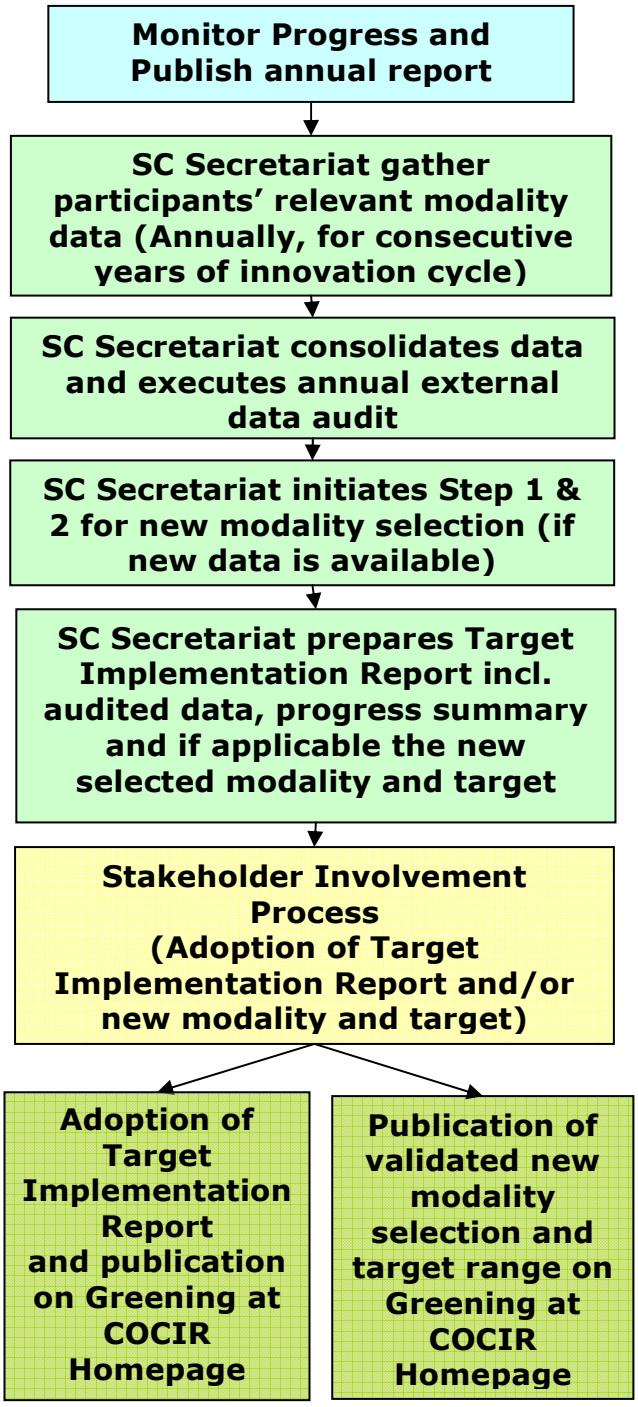
Scenario three: (Beyond BAU) Beyond business as usual (table 4): The values in table 4 are equal to the values in Scenario 2, except for the front runner (1^{st} column). The value for the front runner is calculated by applying to his baseline performance (table 2) the reduction value he declared. This has been decided as reducing the environmental aspect is harder for the front runner that needs to see his efforts recognized by the methodology.
The front runner determines that he is the front runner, by comparing his baseline value with scenario 1. If the two values are equal, that means he is the front runner and he can apply , as company target, the reduction value he declared, instead of the average of the reduction values.

The average value in the Beyond BAU scenario is chosen by the Ecodesign SC as Industry target against which the success of the voluntary agreement has to be assessed. The individual company values in the Beyond BAU scenario are the individual company targets that will be used to ensure the successful achievement of the initiative.

Exemplary visualization *of target scenarios STEP* 4



5.1.5. STEP 6 Monitor Progress and Publish annual report



Description	In STEP 6, SC Secretariat annually consolidates the participants' data of the implementation of the modality target. This data is externally audited. Furthermore, SC Secretariat drafts the annual target implementation report. The status report describes the status of the target implementation and at the end of each target period, the result of the target achievement. The duration of the target cycle depends on the innovation cycle of each modality. As long as not all modalities have been selected, the report also includes the remaining modalities in the priority list for the selection of the next modality. This is included until all modalities are in the SRI scope. Additionally, participating companies may publish product related "Environmental Product Declarations", so called EPD.
Input into Step 6	- End of annual reporting cycle data from participating company on target achievement
Deliverables from Step 6	- Target Implementation Report (Status Report in Annex of this SRI documentation)

Exemplary STEP 6 Monitoring and Reporting Template

Exemplary Template of Status Report for Generic Methodology of BAT, BAU and Best not yet available technology scenarios and Beyond BAU for target setting range and annual progress report	**Confidential Data - is not enclosed in Report!**

Currently only exemplary data is shown.

	Company A	Company B	Company C	Company D	(absolute) average of aspect (all SRI companies)*	Range for target setting	Description
Energy use (kWh) of individual companies today (including **BAT**)	12,00	15,00	13,00	15,00	13,75	-	Baseline today
Scenario One Energy use (kWh) BAU (20xx)	12,00	12,00	12,00	12,00	12,00	-12,7%	All SRI companies will aim to achieve in average what the front runner has achieved today
Scenario Two Energy use (kWh) Best NOT yet available technology (20xx)	9,90	12,38	10,73	12,38	11,34	-17,5%	Each company will strive to achieve what is predicted on average by the experts
Scenario Three Energy use (kWh) BEYOND BAU (20xx)	10,80	13,09	11,35	13,09	12,08	-13,6%	Each company will strive to achieve what is predicted on average but the front runner (only what the respective company predicted)

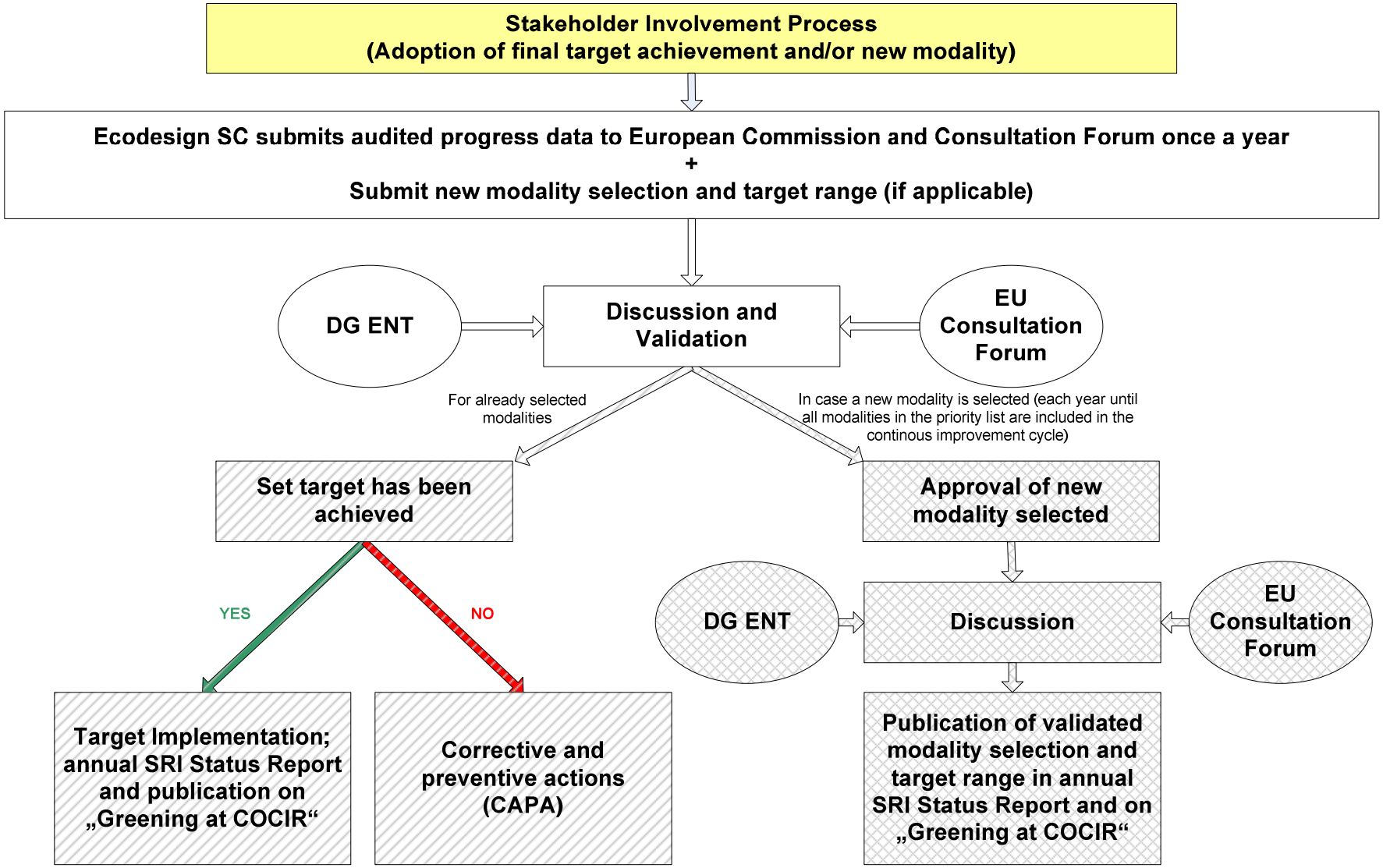
* Absolute average values are reported. They are relevant for the individual company target setting. Especially the average absolute value of Scenario One BAU is important for the individual company to identify itself as the possible top-performer if its aspect value to be equal to the average absolute value.

Note: An additional incentive for the designer can be abstracted from the table since the company can see the average value of absolute performance and thus determine its actual standing. So there will be no extra need for reporting confidential information to individual members.

	Company A	Company B	Company C	Company D	(absolute) Average of Aspect (all SRI companies)	Improvement achieved	Description
Energy use (kWh) of individual companies today (including **BAT**)	12,00	15,00	13,00	15,00	13,75	-	Baseline
Annual progress achieved Year One	12,00	13,00	10,00	15,00	12,50	9%	Each company reports the actual values in year one. The absolute average (12,50) is then compared to the baseline (13,75).
Annual progress achieved Year Two	12,00	13,00	10,00	12,00	11,75	15%	Each company reports the actual values in the respective year. The absolute average (11,75) is then compared to the baseline (13,75).
Annual progress achieved Year Three	11,00	13,00	10,00	12,00	11,50	16%	Each company reports the actual values in the respective year. The absolute average (11,50) is then compared to the baseline (13,75).

Reduction potential between:					**-15% and 21%**
Proposed Target					**- 16%**
Target achieved in Year One					**-9%**
Target achieved in Year Two					**- 15 %**
Target achieved in Year Three					**- 16 %**

STEP 6 Stakeholder Involvement Process (Adoption of final target achievement and/or new modality)



5.2. Guidance Template for Step 3 – Guidance Risk Assessment of sustainable development

A risk assessment procedure is in place to respond to Clause 8[18] of Annex VIII of the Ecodesign Directive 2009/125/EC, securing an integrated approach that protects equally the interests of consumers, healthcare, quality of life and economic interests.

This Risk Assessment assesses the impacts on future developments, which may be expected from the restriction of the respective top-ranked aspects, throughout all member companies, company sites, facilities, operations, and products. Therefore, this method provides a common approach across all member companies to evaluate and dedicate a measure of risks and significance for respective aspects, impacts, and obligations for innovations to ensure a truly sustainable development as defined in the Directive 2009/125/EC.

Objective: Establishing, implementing, and maintaining procedures to fulfil requirements regarding the:

- Evaluation, assessment, and dedicating a measure of risk to aspects, impacts and obligations;
- Identification and dedication of significance.

5.2.1. Risk Assessment process

1) Determine if sustainable development is expected to be impacted by the reduction of the aspect? (Choose one answer)

- **Yes**
- **No**

If **No**, the aspect may be chosen for the further COCIR SRI process and the following questions may be disregarded.

If **Yes**, assess the level of **consequence**. Answer the following questions:

- What happens if the aspect is reduced drastically? What are the main impacts?
  - **3-** Realization of planned innovations not possible, e.g. expansion of diameter of Magnetic Resonance tube
  - **2-** Realization of planned innovations hindered, e.g. innovation is only possible if aspect is substituted by significantly more expensive substance
  - **1-** Realization of planned innovations is possible if aspect is substituted by equally available and equally costly substance

To assess the level of **likelihood** of the consequence(s), answer the following questions:

- What is the likelihood of the occurrence of the consequence? (Please use one of the options below to determine the likelihood!)
  - **3**-The consequence will occur in 100% of the cases
  - **2-**The consequence is likely to occur
  - **1-**There is no consequence or only minor impacts on innovations

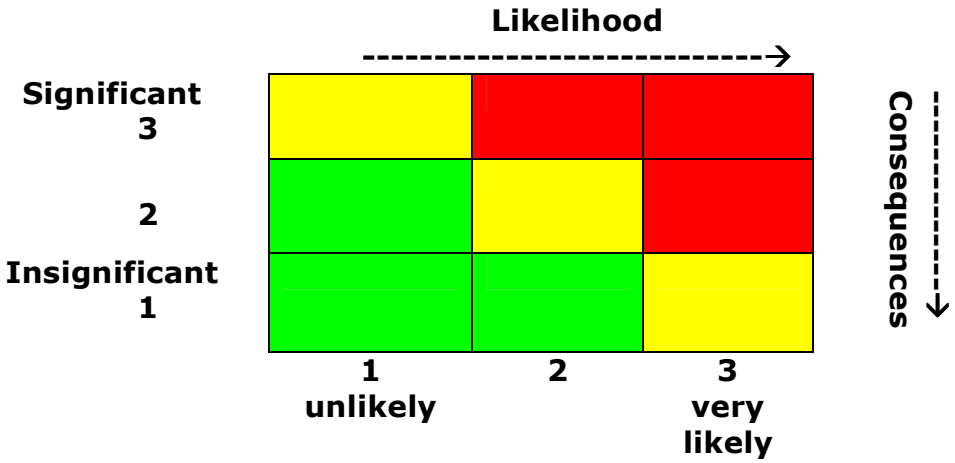
[18] **Sustainability - Criteria 8 of Annex VIII of the Directive ErPEcodesign 2009/125/EC*

Self-regulatory initiatives must respond to the policy objectives of this Directive, including the integrated approach, and must be consistent with the economic and social dimensions of sustainable development. The protection of the interests of consumers, health, quality of life and economic interests, must be integrated.

For most adequate answers on the consequences and likelihood according to the risk matrix below the questionnaire is based on the local expert judgments.

The combination of the questions delivers coordinators for the matrix, and delivers thus the risk levels of the innovation for consumers, health, quality of live and economic interests.

5.2.2. Risk Assessment Matrix



The following risk levels are defined:

- Green zone → LOW risk, risk observation is needed.
- Yellow zone → MEDIUM risk, risk control is needed.
- Red zone → HIGH risk, risk reduction actions are necessary.

5.2.3. Risk Assessment Conclusion

(1) If the majority of the companies come to independent judgment that the reduction of the selected aspect will have severe consequences (red zone), another aspect will be chosen and also tested for its impacts.
(2) If the majority of the companies come to independent judgment that the reduction of the selected aspect will have considerable consequences (yellow zone), another aspect may be chosen and tested for its impacts
(3) If the majority of the companies come to independent judgment that the reduction of the selected aspect will have negligible consequences (green zone), this aspect will be selected for target setting.

5.3. 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.

5.3.1. 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 requires to the company 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 will monitor 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 CF
If the industry target is missed, the SC Secretariat will communicate to the EC and CF about the situation and the corrective action of the industry group. Evidence, if appropriate, will be submitted to the EC and CF 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 CF.)

5.3.2. Enforcement mechanism

Company targets are used internal tool from Companies to decide how to direct their improvements and to help the Ecodesign 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, to be investigated, is the creation of the "Ecodesign SRI Label" Companies able to reach their company targets will be allowed to display this Ecodesign SRI label. Other possibilities are actually under discussion. The definition of the mechanism, its detailed rules and functioning scheme is part of the 2012 working plan.

5.4. Common Approach on Environmental Product Declaration – Guidance Document

The following template has been designed and agreed upon as an explicit answer to stakeholder demands. The design enables the individual member companies to systematically use the Environmental Product Declaration to communicate the most significant aspect(s) that the SRI sets for each targeted modality.

The common format includes three main sections. The first, indicated in orange, represents mandatory content to the common format. This mandatory information includes the type of modality and the industry target set for this modality. It also contains the targeted aspect for the specific product and information on compliance with related standards (based on the requirements of Annex 1.3 of the ErP Directive).
The second and third sections are recommendation of the SRI SC to its members. The light blue section covers all strong recommendations. The dark blue section offers optional contents to be included in a commonly formatted EPD.

Proposal for MINIMUM EPD REQUIREMENT including SRI targets and aspects **Proper definition of "Product" and use phase need to be established**		
SRI CONTENT - mandatory		
SRI	**"Product xxx is part of the SRI Ecodesign Initiative for Medical Equipment to reduce the total energy consumption of units sold by xx % until Year xxxx."**	
		Unit
v	Energy use according to specific scenarios and operating conditions	kWh[19]
Strongly recommended:		

Energy related	**Unit**
CO_2 footprint in use phase according to specific scenarios and operating conditions	kg

Environmentally relevant content/weight information		**Unit**
Product		
	Weight of product	kg
	Type and number of batteries	list
	Relevant materials content - e.g. list RoHS, REACH SVHC, BoMcheck…	list

[19] *This unit depends on the targeted environmental aspect. In this case it is "energy use " and thus "kWh". It might also be a material, e.g. "copper" and thus "kg".*

Packaging		
	Weight	kg
	composition	list
	recyclable material content	%

Additional Ecologically relevant information	Unit
End of life aspects	
refurbishing program available for the system	yes/no
re-use of components program available for the system components	yes/no
cleaning disinfection needed yes/no, if yes which chemicals	yes/no
Information for user and recyclers (includes WEEE recycling passport info)	describe

Optional

Energy related	**Unit**
Patient throughput for standard operation or energy per analysis	pat/day
Waste during normal use (hazardous /non-hazardous/predefined categories?)	kg
Emissions during normal use (hazardous /non-hazardous?)	kg

Additional Ecologically relevant information	Unit
heat dissipation output - operating, stand-by, cooling,	kWh
start up time	min

Additional relevant information	Unit
Power and material saving options (e.g. to previous product)	describe
Additional End of Life aspects	
material recycling possibilities, Cradle to Cradle	describe
ease of dismantling	describe
Life cycle impact - company specific -	
% impact per LCA phase (e.g.10% materials, 80% use; specify LCIA method)	%/ describe
Noise, radiation, vibration, EMC	dB(A)

Other Health and Safety related information	Unit
voluntary actions (product and/ or company specific)	describe
CSR related	describe
Environmental education	describe

Part 3

Glossary of Terms

A

Audit - systematic, independent and documented process for obtaining evidence and objectively evaluation to determine the extent to which the audit criteria are fulfilled

Audit criteria - set of policies, procedures or requirements

Audit evidence - records, statements of fact or other information, which are relevant to the audit criteria and verifiable

Audit findings - results of the evaluation of the collected audit evidence against audit criteria

B

Business as usual scenario (BAU): scenario under the basic assumption that , given the situation today, at the end of the innovation cycle, all the competitors will match the best performing player on the market.

Best available technology (BAT) – 'BAT' is a technology already available on the market, or at least whose feasibility has already been demonstrated in minimizing environmental impacts and is expected to be introduced within 1 to 3 years. It helps in defining medium-term ecodesign targets.

Best not yet available technology (BnyAT) – 'BnyAT' refers to technology, which has the potential to lead to further (environmental) performance improvements, but is still under research and development and can be considered as a future option / trend. It helps in identifying long-term ecodesign options.

Best not yet available technology scenario (BnyAT): scenario based on the assumption that companies could reach, at the end of the innovation cycle, a reduction of the environmental aspect equal to the average of the maximum reduction potential values they declared.

Beyond as usual scenario (Beyond BAU): scenario based on the assumption that in the innovation cycle companies will improve their products according to the average reduction of the BnyAT scenario, except the best performing company (front runner today) that will improve the performance according to its own prediction, as improvements for the front runner are more difficult to obtain. The average value obtained from this scenario is chosen as the target for the next innovation cycle.

C

Completeness check - process of verifying whether information from the phases of a life cycle assessment is sufficient for reaching conclusions in accordance with the goal and scope definition

Consistency check - process of verifying that the assumptions, methods and data are consistently applied throughout the study and are in accordance with the goal and scope definition performed before conclusions are reached

Continuous improvement - recurring process of enhancing the environmental management system in order to achieve improvements in overall environmental performance consistent with the organization's environmental policy

Corrective action - action to eliminate the cause of a detected nonconformity

Criteria - a principle or standard by which something may be judged or decided

Critical review - process intended to ensure consistency between a life cycle assessment and the principles and requirements of the International Standards on life cycle assessment

D

Data quality - characteristics of data that relate to their ability to satisfy stated requirements

Data source - origin of data

E

Environmental aspect - an element or function of a product that can interact with the environment during its life cycle;

Environmental impact - any change to the environment wholly or partially resulting from a product during its life cycle

Environmental load – relative burden on the environment caused by the corresponding modality.

F

Functional unit - quantified performance of a product system for use as a reference unit

G

H

I

Indicators - quantitative, qualitative or descriptive measures that when periodically evaluated and monitored show the direction of change

Industry targets – agreed goals resulting from the Self-Regulatory Initiative methodology that equally apply to all participating manufacturers of the targeted modality.

Innovation Cycle - The innovation cycle is defined as the time to develop new or enhanced products and place them on the market. It could vary from 3 years to 7, depending on the complexity of the innovation being brought to market. The following activities take place within the innovation cycle:

- Research and development
- Verification and Validation
- Regulatory Approvals

Interim targets – goals belonging to or connected with an intervening period of time.

Impact values – parameters agreed by the producers that define an environmental aspects.

J

K

L

Life cycle - consecutive and interlinked stages of a product system, from raw material acquisition or generation from natural resources to final disposal

Life Cycle Assessment (LCA) - compilation and evaluation of the inputs, outputs and the potential environmental impacts of a product system throughout its life cycle

Life cycle interpretation - phase of life cycle assessment in which the findings of either the inventory analysis or the impact assessment, or both, are evaluated in relation to the defined goal and scope in order to reach conclusions and recommendations

LCA phases – a Life Cycle Assessment consists of four main phases (goal and scope, inventory analysis, impact assessment and interpretation)

M

Modality - any of the various types of equipment or probes used to acquire images of the body, such as radiography, ultrasound and magnetic resonance imaging

Modality system - a group or combination of interrelated, interdependent, or interacting modalities

Monitoring - continuous or periodic assessment

N

O

P

Plausibility check – process to verify if data or information is seemingly or apparently valid, likely, or acceptable

Preventive action - action to eliminate the cause of a potential nonconformity

Procedure - specified way to carry out an activity or a process

Process - set of interrelated or interacting activities that transforms inputs into outputs

Q

R

Risk assessment - qualitative and quantitative evaluation of the risk posed to human health, the environment and/or the industry by the actual or potential absence and/or reduction of specific aspects.

Representativeness - qualitative assessment of the degree to which the data reflect the true population of interest

S

Scope - includes a description of physical locations, organizational units, activities and processes, modalities, as well as the time period covered.

Sensitivity analysis - systematic procedures for estimating the effects of the choices made regarding methods and data on the outcome of a study

Sensitivity check - process of verifying that the information obtained from a sensitivity analysis is relevant for reaching the conclusions and for giving recommendations

Sustainable development - meeting the needs of the present without compromising the ability of future generations to meet their own needs

T

Transparency - open, comprehensive and understandable presentation of information

U

Use scenario - A Use Scenario is a defined, goal-oriented set of applications of object defined as functional unit

V

W

X

Y

Z