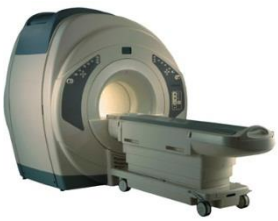
COCIR

Sustainable Competence in Advancing Healthcare

SELF-REGULATORY INITIATIVE FOR MEDICAL IMAGING



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(Version 2: June 2011)

FOREWORD

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 define the methodology driving the SRI. Commitments, results achieved by Industry in fulfilling the set targets and the progress in applying the methodology to new product groups are not presented in this document but can be found in the Annual SRI Status Report and related documentation published on the COCIR website.

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1. COCIR

Founded as a non-profit trade association in 1959, COCIR[1] represents the Radiological, Electromedical and Healthcare IT industry in Europe. 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.

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 Environmental Policy Affairs Focus Group. Its main tasks are:

- to collect environmental information,
- share best practices and
- to drive innovative solutions to reduce adverse environmental impacts
- to advocate COCIR Members interest with Institutions and Regulators

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[1] *For more information: www.cocir.org.*
[2] ***COCIR Company Members:*** *AGFA HealthCare, Alcon, Alert, Belgacom, Bosch, Canon Europe , Care Innovations, Carestream Health, CSC, Elekta, EOS imaging, FujiFilm, GE Healthcare , Hitachi Medical Systems Europe , Hologic, IBA Ion Beam Applications , IBM, Konica Minolta, Microsoft, Oracle, Orange, Philips Healthcare, Qualcomm, Saludnova, Samsung Medison, Shimadzu , Siemens Healthcare, 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. GENERAL METHODOLOGY APPLICABLE TO ALL MODALITIES IN THE SCOPE OF THE SRI

2.1. BACKGROUND

To develop and test a sustaining methodology and approach for this Self-Regulatory Initiative, COCIR first initiated a pilot in 2009, based on ultrasound modality. The SRI 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 Appendix I.

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 SRI Steering Committee to review its methodology and approach to design a generic process that allows participating 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.

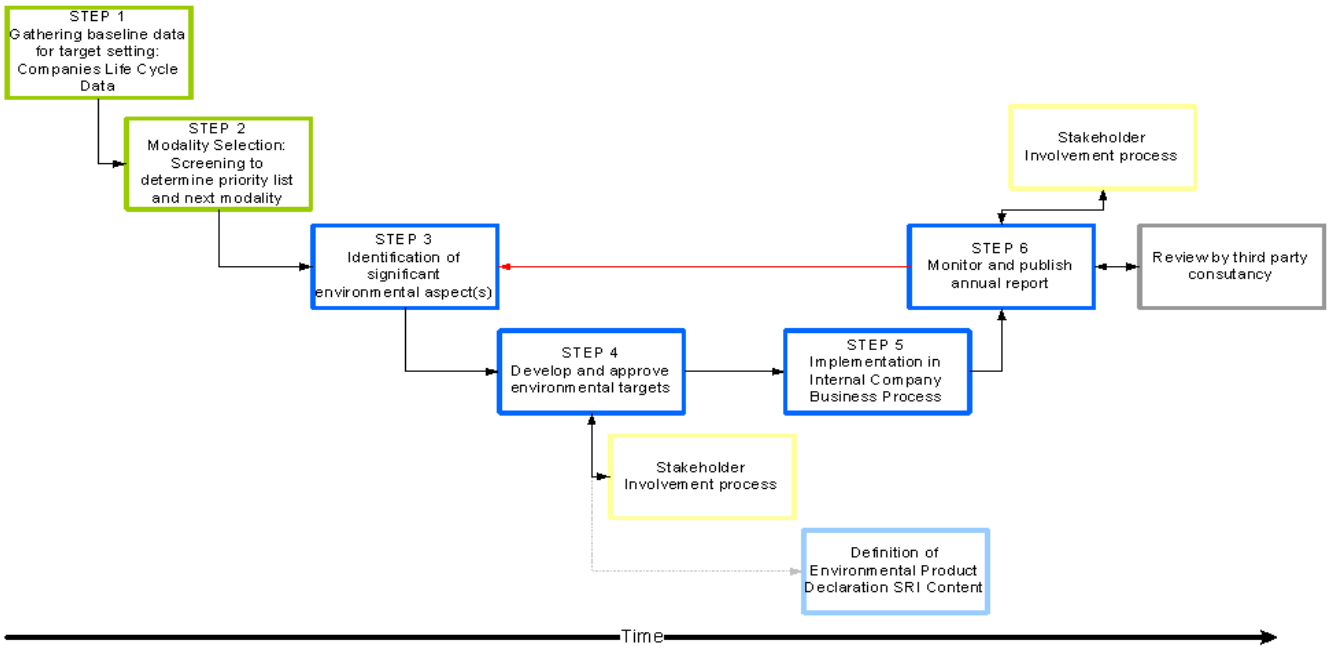
2.2. THE METHODOLOGY (OVERVIEW)

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 step iterative process:



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)

The iterative process allows each modality to be assessed against all environmental aspects, ensuring that for each improvement cycle, the most significant is chosen for a reduction target.

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. After a modality has been selected, 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		☐	☐	☐	☐	☐	☐	☐	☐	

2.3. THE 6 STEPS METHODOLOGY IN DETAIL

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

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.

Step 2: Prioritization and selection of next modality

The second step analyses the baseline data in order to prioritize the modalities for evaluation by ranking the environmental load and other data from each modality.

Two analyses are 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 (see Table 3 in Appendix II).

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.

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

The fourth step defines and derives the Ecodesign target.

1st Phase: Experts of participating companies come together under the supervision of the SC Secretariat to define the functional unit, system boundaries, use scenarios and to develop a measurement methodology able to provide solid and comparable results.

2nd Phase: Companies measure the impact values of the preselected environmental aspect for all the models placed on the market in the reference year and report the values and the sold units to the SC Secretariat

3rd Phase: the SC Secretariat uses the collected values to calculate the target scenarios according to the methodology defined in Appendix 3:

- Baseline
- Business as usual (BAU)
- Best not yet available technology (BnyAT)
- Beyond Business as usual (Beyond BAU)

An external consultancy is hired, if appropriate, to define the modality improvement potential which is required for the BnyAT scenario.

The industry target is set as the target value of the Beyond BAU scenario. The SRI SC decides on a feasible industry reduction target taking into consideration the significance of the impact, the reduction potential, the costs involved for Companies (cost-benefit analysis) and adverse consequences on performances, clinical value and innovation. Before it is

integrated into the companies design targets, the industry target is proposed to the European Commission for discussion.

Step 5: Implementation into company processes

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 SRI SC Secretariat to monitor and report the annual industry progress.

Step 6: Monitoring and reporting

The purpose of the sixth step is to monitor and report on the achievement of the industry target calculated as the average of the annually reported impact values in comparison to the Baseline.

The status of each modality and the progresses that the companies are making are annually reported in the SRI Status Report.

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

3. COMPLIANCE WITH ANNEX VIII REQUIREMENTS OF ECODESIGN DIRECTIVE 2009/125/EC

The Ecodesign Directive sets in Annex VIII requirements for Voluntary Agreements to be recognized as alternatives to regulation. The COCIR SRI has been designed and developed to comply with those requirements.

3.1. 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, the company is charged an entry fee to reflect the reasonable costs for the company to participate in the Initiative. Any change in the list of participating companies will be reflected in the annual SRI Status Report.

Some of the participating companies 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. Therefore, the scope of the SRI reaches well beyond the European boundaries, as the participating companies implement the SRI targets into their internal procedures.

3.2. 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 step methodology incorporates the 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.

A clear defined calculation on how to deliver a Beyond BAU has been introduced in Step 4 of the SRI Methodology v3. The Beyond BAU is calculated and set based on the 3 target scenarios (BAU, BAT, BNAT), to continuously reduce the assessed most significant environmental aspect.

3.3. 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 the Initiative cover at least 80% of units sold in the EU for each of the following modalities in the medical imaging equipment sector.

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

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

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.

3.4. 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 of a pre-selected modality. The target is expressed in physical and measurable terms (specific methodologies could be developed to deal with different environmental aspects).

The baseline is clearly defined (e.g. 2005 for Ultrasound and 2011 for MRI), transparently calculated and reported into the SRI Status Report.

The time span is set equal to the innovation cycle of the specific modality, defined as the time needed to develop a new technology and to bring it on the market (from 3 to 7 years). No interim targets are defined but annual achievements are reported in the SRI Status Report to allow participating companies and stakeholders to monitor closely the achievements. The annual Status Report is validated by an external independent third party.

3.5. 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 Self-Regulatory Initiative documentation and the annual Status Report on the COCIR website (www.cocir.org) in the public section.

With the SRI Status Report the SC informs all stakeholders comprehensively about the Ecodesign activities, successes, and challenges. It is also intended as a basis for dialogue between industry and stakeholders. The SC cordially invites all stakeholders to share their thoughts and encourages comments e.g. via e-mail to corridori@cocir.org.

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

3.6. 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 3, which also outlines the procedure that the SRI Members follow to gather confidential data from companies for each modality, aspect and modality definitions.

Before the data is reported to the stakeholders, an audit by a third party consultancy verifies the accuracy of the SC Secretariat calculations, internal processes and procedures to ensure correctness of reported data.

3.7. ECODESIGN DIRECTIVE ANNEX VIII CLAUSE 7: COST-EFFECTIVENESS OF ADMINISTERING THE SRI

> *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 reasonable burden for participating Companies compared to other policy instruments.

3.8. 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 SRI SC ensures that the environmental design targets set under the Initiative are environmentally sound with regard to other environmental aspects of medical equipment.

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 people's 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, medical device industry has to implement this new state-of-the art technology.

3.9. 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 are expected to have no effect on the COCIR Ecodesign Self-Regulatory Initiative. The SRI SC hopes that the GPP criteria will reflect the findings and methodologies included in this Self-Regulatory Initiative. The SRI SC is not aware of any other factors or incentives that could be negatively affect the Self-Regulatory Initiative.

APPENDIX

APPENDIX I

1. SRI PILOT FOR MODALITY ULTRASOUND

1.1. 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 SRI 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.

1.2. COMMITMENT TO PILOT ULTRASOUND

In the Consultation Forum presentation of 18 November 2009, COCIR had 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.

1.3. PILOT ULTRASOUND AND THE SRIV2

The pilot project on ultrasound equipment has not been reviewed according to new versions of the SRI methodology. The SRI SC decided to apply the 2012 methodology to MRI equipment and to maintain the pilot project under the old SRIv1 methodology as in 2010 participating companies already managed to achieve results in the reduction of the average annual energy consumption per unit.

The new SRIv3 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.

APPENDIX II

1. COCIR SRI GENERIC METHODOLOGY

In this Appendix, the methodology's 6 steps are outlined in more detail such as the procedural overview, the key tasks and deliverables, as well sample templates for each step.

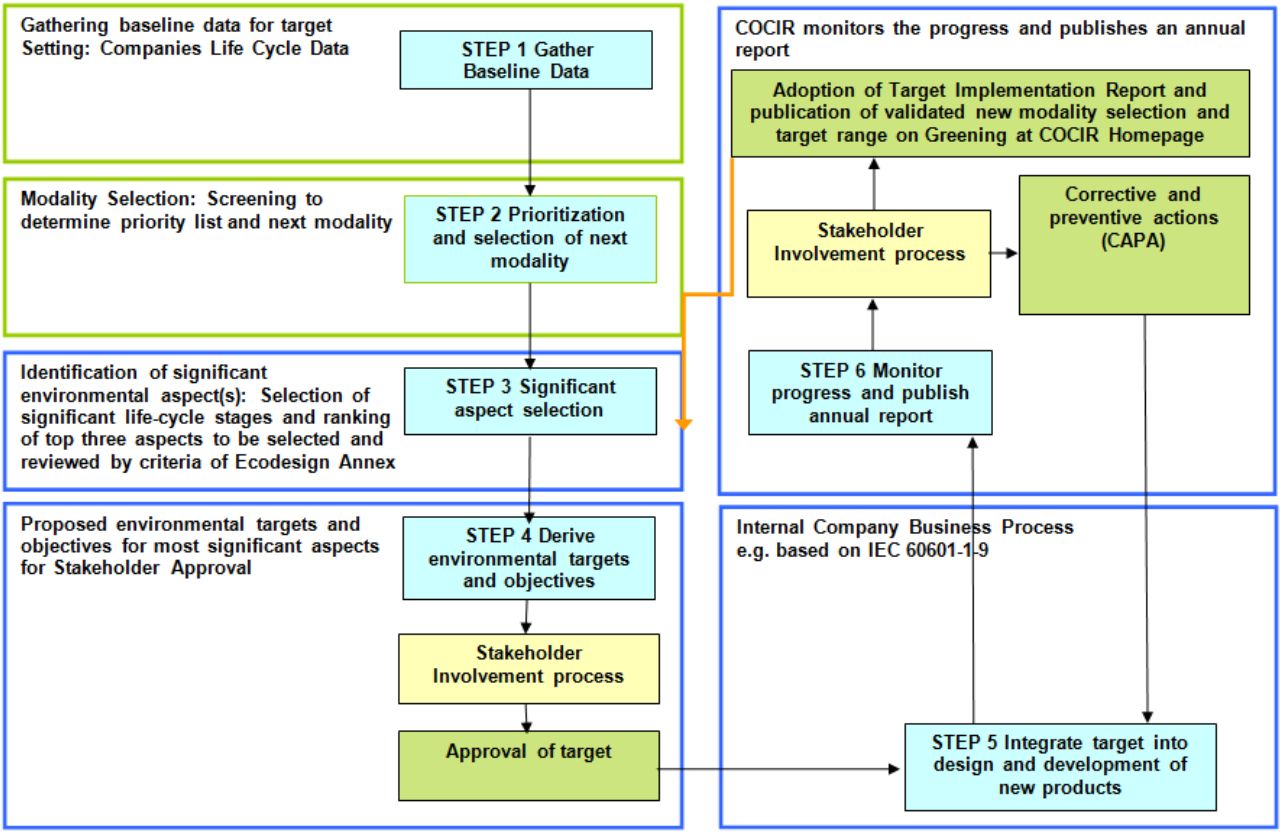
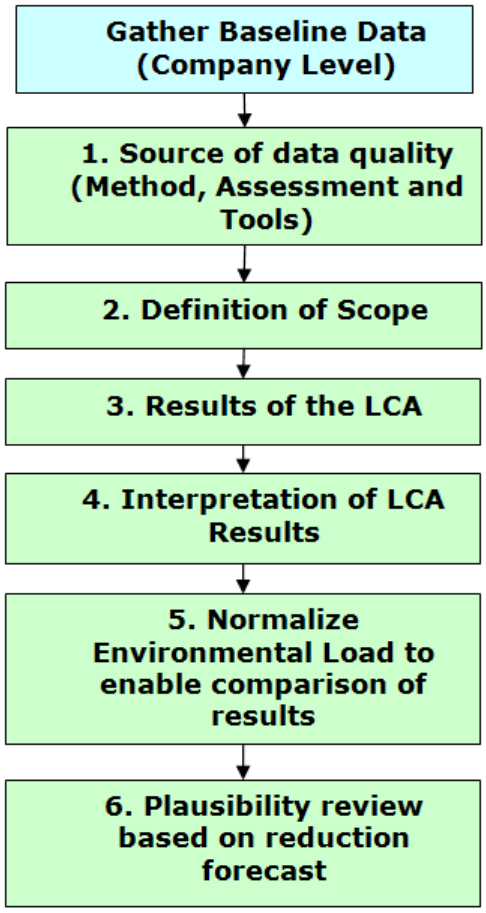


Figure 1: the green boxes signify tasks that need to be done once. The blue boxes cover the four steps that represent a closed loop: to be repeated for continuous improvement and transparency

STEP 1: GATHER BASELINE DATA

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[4] number of companies (able to represent the market), covering the main models[5] 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[6] 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.)
- Percentages 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 percentage
- Reduction forecast of total normalized environmental load in percentage of a modality

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

Table 2: STEP 1 Gather Baseline Data – Exemplary Template for data collection

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

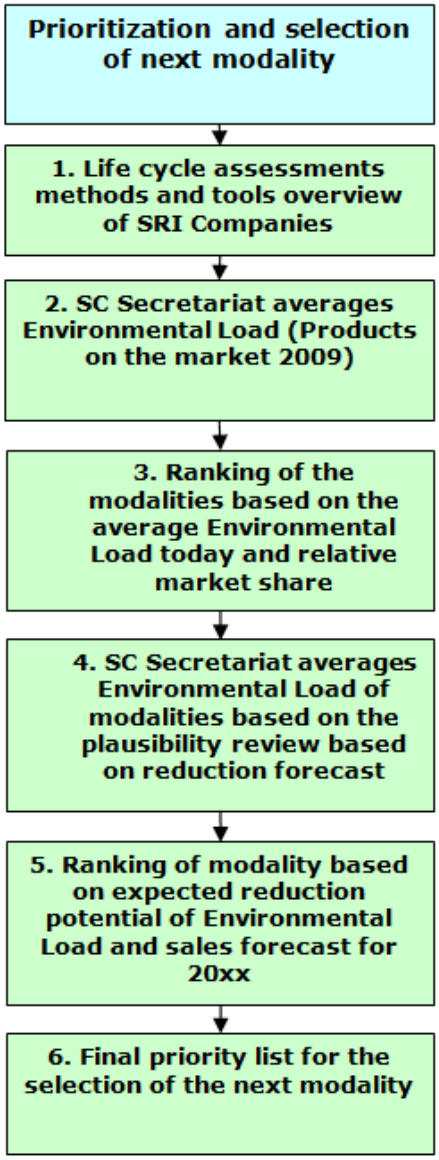
Normalized Environmental load for products on the market 20xx

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

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[7] 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 percentage from STEP 1
- COCIR market data (SHARE)

Deliverables from Step 2

- Plausibility review of LCA data base from STEP 1
- Consolidated Environmental Loads in percentage
- Priority list of modalities (public available)

[7] *SHARE is COCIR internal market statistics data base*

Table 3: 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				

...

STEP 3: IDENTIFICATION OF SIGNIFICANT ENVIRONMENTAL ASPECT(S)

Description

In STEP 3 data on the top 3 environmental aspects[8] 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[9] 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
- 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

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

Table 4: STEP 3 - Identification of significant environmental aspect(s) –Exemplary 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	

STEP 4: DERIVE ENVIRONMENTAL TARGETS AND OBJECTIVES

Phase 1: Definitions

The first phase of STEP 4 is the definition of the functional unit(s), product description, mode definitions, system boundaries and typical use scenario(s) to set a common ground on the identification of the impact values of the selected aspect to define an ecodesign target.

Phase 2: Measurement methodology

The second phase of STEP 4 is the definition of a measurement methodology by an ad hoc group of experts from participating companies, in case no standards are already available. The methodology has to be designed to provide solid, repeatable and comparable data. Moreover the methodology should be able to take into account all different technological options for the reduction of the energy consumption.

Phase 3: Improvement potential

A methodology has been defined in 2012 by an external consultant hired by the SRI SC to identify and quantify the maximum improvement potential for the reduction of the energy consumption of the selected modality.
With the use of templates and direct interviews, the energy consumption is allocated to the different modules of the modality. Experts provide an estimation of the maximum improvement that can be achieved for each module taking into account technologies that are not yet available (under research or expected to be available at the end of the innovation cycle).
The application of the maximum improvement potential to the company BAU provides the company specific BnyAT scenario.

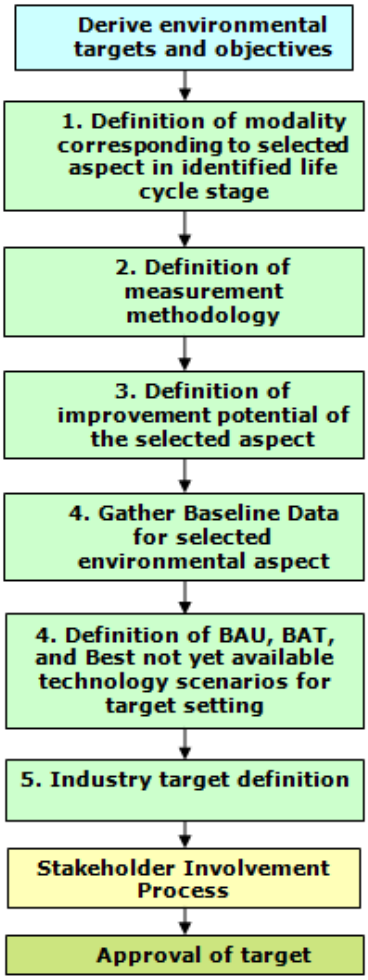


Table 5: Template for data collection for the determination of improvement potential of computer tomography equipment

COMPANY NAME			
CT: ALLOCATION OF THE ENERGY CONSUMPTION PER MODULE PER MODE			
Applicable to the following CT models:	Model1, Model2, ect		
Allocations of energy use (%)	**Off**	**Idle**	**Scan**
Tube and generator chain			
Detector			
Power distribution unit and other power supplies			
Computation, Controls			
Cooling			
Patient table			
Gantry Motor			
	0,00%	0,00%	0,00%

CT: ALLOCATION OF THE ENERGY CONSUMPTION PER MODULE PER MODE			
Applicable to the following CT models:	Model1, Model2, ect		
Possible reduction(%)	**Off**	**Idle**	**Scan**
Tube and generator chain			
Detector			
Power distribution unit and other power supplies			
Computation, Controls			
Cooling			
Patient table			
Gantry Motor			

Phase 4: Collection of baseline data

Using the measurement methodology, Companies measure their equipment placed on the market in the year under consideration and chosen as baseline, and provide the data to the SC Secretariat together with sales data.

Phase 6: Definition of Scenarios

The SRI defines 4 scenarios which are used to calculate the final target. For some scenario more than one methodology has been defined to take into account specific situations.

Baseline scenario: This scenario represents the market fleet average in the year chosen as baseline. The fleet average is calculated as the weighted average of the performances of all models placed on the market against sold units.

Business as usual (BAU) scenario in 20xx: This scenario represents the market fleet average in year 20xx under the assumption that no SRI is in place. The SRI SC defined two methodologies to estimate this scenario which takes into account the expected evolution of the technology, market strategies and existing ecodesign programs.

Best not yet available technology (BnyAT) scenario in 20xx: This scenario represents the market fleet average in 20xx assuming that:

1. All possible improvements have been achieved and
2. All the best available technologies have been used and applied at the same time.

To define this scenario, the data on improvement potentials is used.

Beyond business as usual (**Beyond BAU) scenario:** This scenario represents the market fleet average in 20xx assuming that all reasonable improvements have been implemented. 2 methodologies have been defined by the SRI SC to ensure the scenario is ambitious (better than the BAU scenario) but not unrealistic.

Calculation of the BAU scenario

According to the expected evolution of the environmental aspect, 2 methodologies can be used to estimate this scenario.

Methodology 1: This methodology works fine for modalities for which a steady decrease in the environmental aspect (e.g. energy consumption) is expected as it sets an ambitious starting point for the definition of the target. It is not suited for modalities for which an increase in the energy consumption is expected following the improvement of clinical performances.
This methodology was developed in 2010 and presented in the SRIv2.

The scenario market fleet average is calculated assuming that in 20xx all companies will match the performance of the front runner today. Therefore companies' scenarios are equal to the performance of the front runner[10] and so the fleet average.

Methodology 2: This methodology is more flexible, accurate and provides a better estimation of the scenario. It works fine for all modalities also in case the environmental aspect is expected to increase. This methodology was developed in 2012 in the process of developing the ecodesign target for MRI and presented in 2013 in the SRI v3.

Each Company is required to provide an estimation of its own fleet average in 20xx according to expected market positioning, research patterns and long term strategies. The

[10] *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 as baseline scenario*

weighted average against sales forecast in 20xx provides a good estimation of the market BAU scenario.

Calculation of the BnyAT scenario

Companies' scenarios are derived applying the improvement potentials resulting from the study of the external consultant. The best-not-yet-available technology scenario 20xx is defined as the weighted average against sales forecast in 20xx.

Calculation of the Beyond BAU scenario

This scenario is extremely important as the industry ecodesign target is defined as the value of the Beyond BAU scenario in 20xx. This scenario can be derived by applying two methodologies:

Methodology 1: This methodology was developed in 2009/2010 and presented in the SRI v2. The scenario is calculated as the weighted average of companies' scenarios which are determined as follows (see table 6):

- All companies other than the front runner: Each company is assigned a value equal to the respective baseline value multiplied for the average of the reduction potentials declared by all companies
- Front runner: the front runner is assigned a value equal to its baseline value multiplied for the reduction value he declared as it is reasonable to expect that for the front runner further improvements are more difficult to achieve.

This methodology works well for modalities where the front runner declares the lowest improvement potential. In case this is not true (as shown by the MRI project) this methodology would end in setting a target even more ambitious than the maximum possible improvement potential which is nonsense. Therefore the SRI SC developed an alternative methodology.

Methodology2: This methodology was developed in 2012 and applied to the MRI project. It introduces correction factors to the values declared by Companies as maximum improvement potentials. It is able to take into account the situation where the front runner declares the highest improvement potential.
Each Company scenario is calculated as follows:

- All companies other than the front runner: The Company Beyond BAU scenario is calculated applying the maximum improvement potential to the BAU scenario scaled by a correction factor of 0,75.
- Front runner: The Company Beyond BAU scenario is calculated applying the maximum improvement potential to the BAU scenario scaled by a correction factor of 0,5.

The Beyond BAU scenario fleet average is calculated as the weighted average against sales of the Companies' scenarios.
Correction factors are decided by the SRI SC. They express a reasonable percentage that can be achieved by Companies in the innovation cycle of the maximum improvement possible. The factor is lower for the front runner to take into account the higher marginal cost for improvement.
Additional information on this methodology and its application are reported in the SRI Status Report 2011.

Phase 5: Target definition

The Beyond BAU scenario fleet average is the Industry Ecodesign Target. Companies's specific Beyond BAU fleet averages are the Company targets.

Those results are adopted as target by the SRI SC after evaluation of possible impacts on business and innovation.

Phase 6: Definition of the Innovation cycle

The innovation cycle is defined as the time needed to bring a new technology on the market, from the research and testing phase to the regulatory approval. This period is different for each modality and is used as reference for the target achievement.

Phase 7: Stakeholder involvement process

A report presenting the application of the methodology the new modality, the results and the Industry Target is submitted to the European Commission and presented during the Annual Forum organized in the first quarter of the year. The Annual Forum is open to the participation of Consultation Forum Members and Stakeholders.
Comments and suggestions are evaluated by the SRI SC and used for the definition of the final target which is reported on the annual SRI Status Report.

Figure 2: Stakeholder Involvement Process (validation of target)

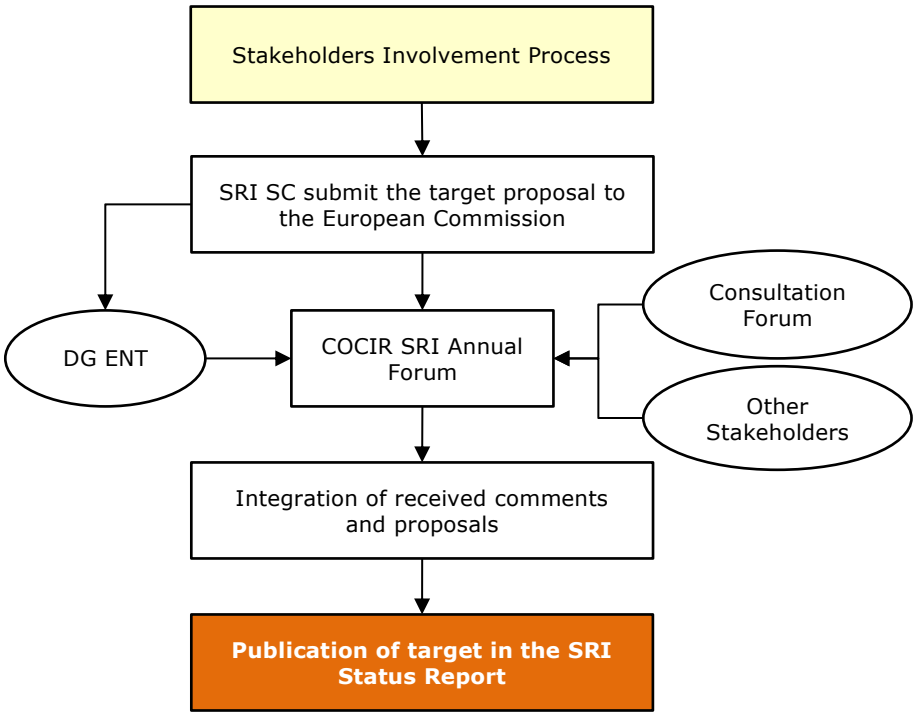


Table 6: STEP 4 Derive environmental targets and objectives – Exemplary spread sheet for the calculation of the scenarios and ecodesign target according to the SRIv2.

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.

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%

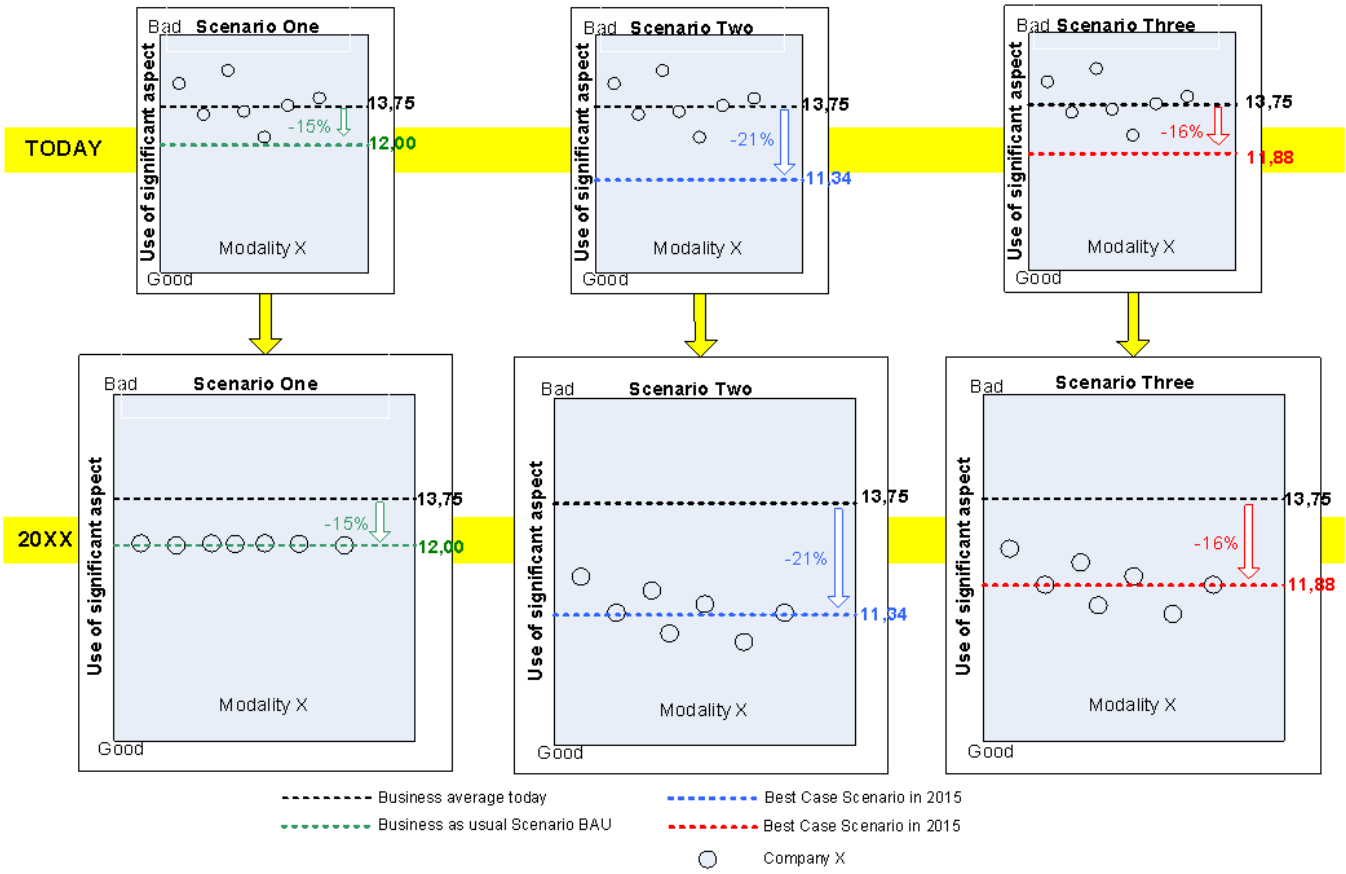
* Absolute average values are reported. They are relevant for the individual company target setting. Especially the average absolute value of Scenario One BAU is important for the individual company to identify itself as the possible top-performer if its aspect value to be equal to the average absolute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

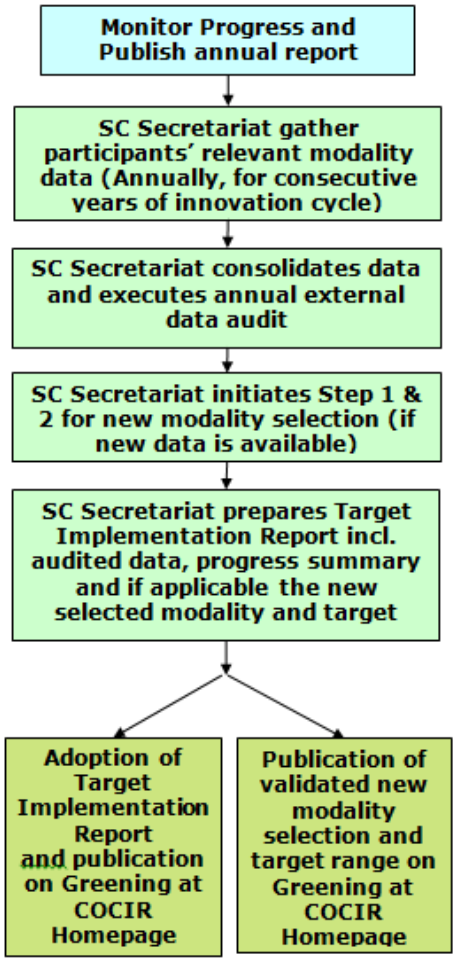
Reduction potential between:	**-12,7%**	**and**	**-17,50 %**
Proposed Target: reduction		**-15,9%**	
Relates to patient throughput improvement		**xxx**	

Figure 3: Definitions of scenarios and determination of ecodesign target (methodology 1)



STEP 6: MONITOR PROGRESS AND PUBLISH ANNUAL REPORT

In STEP 6, the SC Secretariat annually consolidates the participants' data of the implementation of the modality target. Furthermore, SC Secretariat drafts the annual SRI Status Report.
The SRI 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. This report and its content and figures is audited by an external auditor in accordance with the International Standard on Assurance Engagements (ISAE) 3000.
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
Annual reporting cycle data from participating company on target achievement

Deliverables from Step 6
Annual SRI Status Report

SALES FORECAST AND DYNAMIC TARGETS

The determination of many scenarios (BAU, BnyAT and Beyond BAU) is based on sales forecasts in 20xx. As the weighted average method is used the sales of each single model have to be forecast. Therefore the target itself depends very much on the accuracy of sales forecast which, by definition, is more or less a guess.

This level of un-determination has to be taken into consideration when the final achievements will be considered. Therefore, at the end of the innovation cycle:

1. The target will be recalculated according to the real sales in 20xx
2. A simulation is performed using the sales forecasts set during calculation of the target

Those elements would be useful to evaluate the achievements.

APPENDIX III

1. GUIDANCE RISK ASSESSMENT OF SUSTAINABLE DEVELOPMENT

A risk assessment procedure is in place to respond to Clause 8[11] 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.

1.1. 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

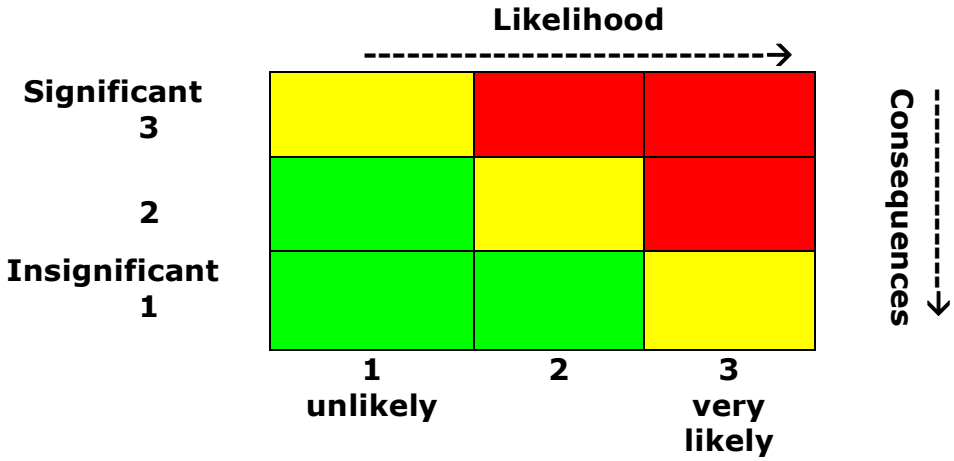
[11] **Sustainability - Criteria 8 of Annex VIII of the Directive ErP 2009/125/EC*

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.

1.2. 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.

1.3. 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.

APPENDIX IV

1. GUIDELINES ON EPD

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 Imaging 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[12]

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

[12] *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