COCIR

SUSTAINABLE COMPETENCE IN ADVANCING **HEALTHCARE**

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

QUESTIONS AND ANSWERS

ON THE SELF-REGULATORY INITIATIVE FOR MEDICAL IMAGING EQUIPMENT





DECEMBER 2011

This "Questions and Answers" document on the Self-Regulatory Initiative for Medical Imaging equipment has been developed by the ErP Steering Committee in order to provide to all interested parties and the public a useful tool to understand the basic concepts of the Initiative and the methodology used in this initiative.

The questions address all specific and technical issues, questions and comments received from all Stakeholders, Consultation Forum members and the European Commission. This document also provides a better and easier explanation on some procedures that are included in the core SRIv2 documentation.

This document will be updated on a regular basis and progressively enriched as soon as new questions will be received.

Updates of such document will be posted on the COCIR public website in the section "Greening at COCIR section".

QUESTIONS AND ANSWERS

COCIR SELF-REGULATORY INITIATIVE FOR MEDICAL IMAGING EQUIPMENT

GENERAL

1. What is the background for COCIR SRI?

COCIR, representing the Radiological, Electromedical and Healthcare IT industry in Europe, was the first trade association to develop its own internationally recognized standard for integrating EcoDesign into the product design and development process (see IEC 60601-1-9: Environmentally Conscious Design of Medical Electrical Equipment). This standard follows the same basic principles as required by the Integrated Product Policy (IPP) approach of the EU.

COCIR industry has track records by which they pro-actively embedded environmental objectives throughout the products life cycles often in the very design of our products.

The Ecodesign Directive provides for criteria, listed in Annex VIII, to assess a unilateral voluntary agreements (or self-regulatory initiatives) by industry. Such agreements could be preferred to implementing measures as they can ensure the achieving of targets in a quicker and/or more efficient way.

During the EC Consultation Forum meeting on **28 May 2008** COCIR presented its first proposal for an industry-led Self-Regulatory Initiative.

Based on this positive feedback, COCIR decided in **September 2008** to establish the Ecodesign Steering Committee in order to further develop this Initiative and develop the methodology.

In **May 2009** the developed methodology (*hereafter SRIv1*) was applied to ultrasound products in a pilot project to gather experience from practical implementation.

In **November 2009** the methodology and the pilot project on ultrasound products was presented to the Consultation Forum. Comments were gathered for further improvements.

In **2010** COCIR and the Steering Committee worked on the SRIv1 to update and improve it taking into account the comments received from the Members of the Consultation forum, the EC and the lessons learned from the Ultrasound pilot project.

2. What is the difference between the SRIv1 and the new SRIv2?

The SRIv2 is the evolution of the SRIv1 methodology. Both based on a six step approach and a continuous improvement loop.

The SRIv2 provides for new instruments for the decision process in steps 1, 2 and 3, based on LCA and sales data gathered from companies. These new tools allow transparency in the process.

In Step 3 the environmental aspect to be targeted is selected through a ranking of the top 3 environmental aspects. This allows for separate risk assessments, a greater transparency on the impact of the top aspects and objective reasoning for the selection of the aspect with the highest impact.

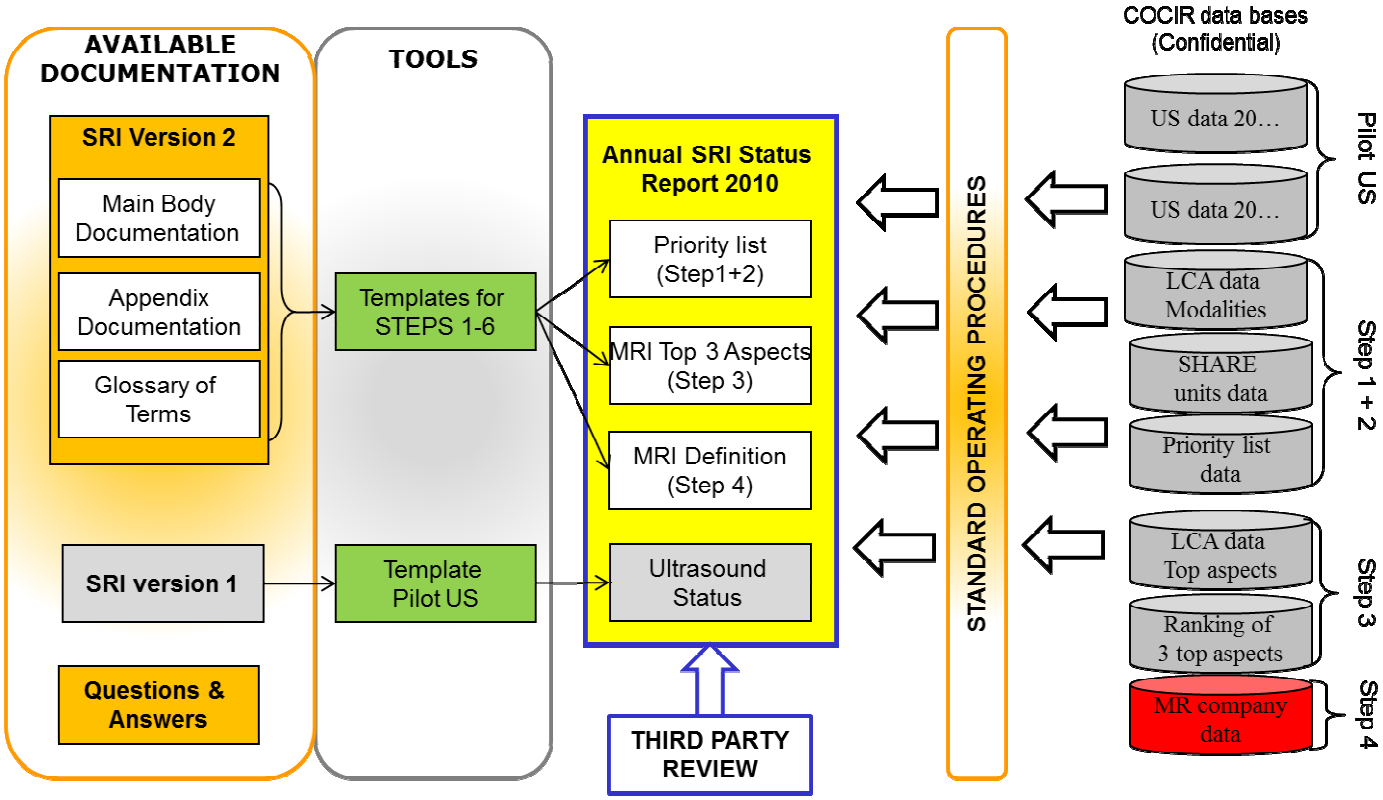
The biggest difference between the two versions of the methodology is Step 4, regarding the ways target are set (see answers 21-22 on target setting). With the new methodology many aspects of the MEEUP have been taken on-board providing a transparent process that could set ambitious targets compared to the business as

usual scenario.

The boundaries of the modality will be fully harmonized since the industry will develop a common definition for each modality before targets are defined. This common definition includes all relevant consideration on the key parameters such as product features, use hours, typical applications, and patient throughput. This data is based on practice experience from each company and aims to allow accounting for a utility unit of the modality.

The SRIv2 also provides for:

a) A format for the Environmental Product Declaration
b) A procedure for enforcing the SRI, dealing with Companies not able to meet the set targets
c) An easy procedure to add new products in the scope or to enlarge the participation to new companies.



3. What is the objective and target of COCIR's SRI?

The objective of the SRI is to establish a common methodology for the healthcare imaging industry in order to establish good ecodesign practice and methods reducing the most significant environmental aspects of imaging equipment life cycle. This approach shall contribute to measure and minimize environmental aspects of imaging products over all life cycles in a reasonable and effective way.

This approach of identifying product specific environmental aspects and targets will allow achieving the same overall objective as an implementing measure in the framework of the Ecodesign directive but will avoid potential negative impact on medical devices by maintaining full design flexibility, enabling to continuously adapt to fast changing technologies and allowing to provide better and earlier diagnostics, more effective and successful patient treatment and completely new treatments methods.

4. Which product groups are covered?

The SRI covers medical imaging equipment (diagnosis). Imaging includes all tests that produce images or pictures of the bodies inside. In the future therapy applications could be added in the scope.

The five modalities that are covered by the SRI are:

- Magnetic resonance equipment (MRI)
- Computer tomography (CT)
- Nuclear medicine (NM)
- X-ray
- Ultrasound (US)

5. Which are the participating companies?

The following companies participate to the Self-regulatory initiative

- Agfa HealthCare
- Aloka Holding Europe
- Elekta
- FujiFilm
- General Electric Healthcare
- Hitachi Medical Systems
- Ion Beam Applications
- Philips Healthcare
- Samsung Medison Europe
- Siemens Healthcare
- Toshiba Medical Systems Corporation

The table summarizes the companies participating in the SRI for Medical Imaging Equipment and the modalities marketed in EU.

	MRI	CT	NM	X-RAY	US
Agfa HealthCare				✓	
Aloka					✓
Elekta				✓	
Fujifilm				✓	
GE Healthcare	✓	✓	✓	✓	✓
Hitachi Medical Systems Europe	✓	✓			✓
IBA Ion Beam Applications			✓		
Samsung Medison Europe					✓
Philips Healthcare	✓	✓	✓	✓	✓
Siemens Healthcare	✓	✓	✓	✓	✓
Toshiba Medical Systems Europe	✓	✓		✓	✓

6. Who can join the SRI and how?

Enlarging the participation to prevent free riders and to increase the representativeness of delivered results is in the interest of COCIR and the Participating Companies.

Any company marketing medical devices in the scope of the SRI in the EU market can join the initiative provided that all the requirements laid down in Appendix 3 of the SRIv2 Methodology are satisfied.

The fee for new companies to join the initiative has been set not to constitute an obstacle to join the initiative, just to partially compensate the administrative costs. This indication could be found in Appendix 3 of the SRIv2 „Steering Committee Governance procedure".

7. What is the market coverage of the participating companies?

The Steering Committee ensures that the SRI covers modalities for which about 80% of market coverage is ensured.

The following table summarizes the market value of the modalities in scope and the market coverage of participating companies.

Modality		2009 Market Value	2010 Market Value	Estimated EU Market Coverage*	Other targeted companies
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
Nuclear Medicine (SPECT, PET)		**244 M€**	**240 M€**	**98%**	Mediso
Ultrasound		**801 M€**	**814 M€**	**82 %**	Esaote, Sonosite, Mindray, Ultrasonix, Zonare
X-ray	**Cardio (45%)**	**377 M€**	**380 M€**	**92 %**	None
	Others (55%)	**204 M€**	**186 M€**	**65 %**	Approx. 50 companies

*Best estimation based on companies knowledge and SHARE data

8. Where all the documentation could be found?

All the documentation related to the SRI for medical Imaging Equipment could be found on the COCIR website, http://www.cocir.it at the "Greening at COCIR" section.

METHODOLOGY

9. How does the methodology works?

The EuP Steering Committee developed the methodology in six steps which will guarantee a transparent process to set tight timetables, targets and distribute responsibilities.
The six steps create a framework under the principle of continuous improvement. Once one cycle is completed the process starts from the beginning. By taking this step-by-step approach it is possible to put special attention on reviewing all phases of each product group during its life cycle including the design and development phases. Additionally, it is possible to report results from each step taken.

10. What are the six steps?

Below each of the six steps is briefly introduced

Step 1 and 2: Screening to determine which modality should be addressed next

In step one and two all the modalities in the scope of the SRI are evaluated and a priority list is defined. Participating companies gather Life Cycle Assessment data, that are then aggregated and analysed by the SC Secretariat, research and development information, post-production phases, sales volume[1], innovation cycle and customer requirements. According to the priority list the Ecodesign Steering Committee decides which modality will be considered next. These two steps are run once at the starting point of the SRI and can be run again when new modalities will be added to the scope.

Step 3: Identify the most significant environmental aspects for the specific modality

All participating companies provide LCA data to identify the most significant life cycle environmental aspects of the modality. The result is assessed against the review of the environmental criteria as listed in Annex 1.3 of the Ecodesign Directive.

Step 4: Set target and objectives for most significant environmental aspects

The SRI Steering Committee will develop common definitions for the modality, such as system boundaries, functional units, categorizations, use scenarios and most important a test procedure to measure the energy consumption.

Such test procedure needs to be developed from scratch, as nothing similar is already in place as it was for other sectors such as white goods, PCs, monitors, or lamps.
The procedure must be defined to allow companies to test all their product models obtaining consistent and comparable data.
The procedure will be publicly available and published on the COCIR website dedicated area.
All the data obtained by using the procedure are then used to set targets according to the methodology STEP 4 (see answer 21 and 22 on how targets are set)

[1] *Sales volume is collected through SHARE, the COCIR web based market statistics database*

Step 5: Integrate target into design and development of new products

After the targets are established, the participants will implement them into the design and development of new products. Given the time needed before actual final products are available on the market the methodology foresees a period to achieve the target equal to the innovation cycle that is modality specific (e.g. 3 years for ultrasound and 5 years for magnetic resonance imaging equipment).

Step 6: Monitoring and reporting

The EuP Steering Committee will provide annual progress reports indicating the achievements compared to the target agreed. The consolidated results will be reviewed by the EuP Steering Committee that will provide the report to the EU Commission, the Consultation Forum and make it available also on the COCIR website dedicated area.

Each participant will ensure that the environmental design targets are met and may decide to communicate to their customers by adding the information to the Environmental Product Declaration. A standardized format has been developed for the EPD on the basis of the results of a German Integrated Product Policy (IPP) project in Hamburg (for details see www.ipp-medizintechnik.hamburg.de/en) for ecological product information allowing hospitals to make a balanced ecological and economical purchasing decision.

Once the targets have been achieved, the steps 3 and 4 will be repeated on the same modality and the outcome with possible new target(s) on the most significant environmental aspects(s) for the next period re-assessed. This will allow for an ecologically and economically successful approach to reach ambitious goals.

11. Which environmental aspects will be targeted?

The SRIv2 methodology allows the Steering committee to target the most relevant environmental aspects. Experience shows that for energy using products, normally the energy consumption during the use phase is the most relevant one.
Step 3 of the methodology ranks all the aspects and the most relevant will be submitted to step 4 for the target setting process. At the end of the innovation cycle step 3 is applied again and a new environmental aspect could result as the most significant and will then be submitted to step 4.
The SRIv2 methodology allows the Self-regulatory Initiative to address all the environmental aspects and not only energy consumption.

12. How the potential for improvement is assessed?

Unlike other simpler equipment, the MEEUP methodology is generally not suited to determine the potential for improvement for most medical imaging equipment.
Technical solutions to improve environmental performances are very product specific and could hardly be adapted to products of different companies. Moreover technical solutions are extremely confidential and patent covered and cannot be disclosed.
The SRIv2 methodology requires company experts to assess the potential for improvement of the top 3 selected environmental aspects and to provide a rationale If the potential is low. The judgement will be based on the best available knowledge and on the results of the measurements that would allow assessing the best available technology.

13.When all the modalities will be covered by the SRI?

Participating Companies committed to apply the SRI methodology to a new modality every year, so that by 2015 all the modalities will have entered the improvement cycle.

For each modality expert groups need to develop common definitions for system boundaries, functional units, categorizations, use scenarios and most important a test procedure to measure the energy consumption. The process is harmonized for all modalities, except the test standard that have to be customized for each modality.

As the whole process, in a preparatory study, according to the MEEUP methodology, could take very long, we believe that committing to target at least one new modality each year is indeed ambitious yet achievable.

Moreover the fleet approach on which the methodology is based allows companies to obtain results even for the year following the setting of the targets. On the contrary, under the MEEUP approach targets could enter into force only after a certain time period (more than 1 year). For more information see answer 14.

14.When will the SRI start to affect the environmental impacts of products?

For the Ultrasound pilot project that has been developed in the beginning of 2009, the concurrent process of eco-efficient improvement has started. New business processes have been established in each member company, new data has been gathered, helping to gain new insights and aiming for concrete improvements.
According to the innovation cycle duration of 3 years for Ultrasound equipment, new products, developed according to the Ecodesign requirements set by the SRI would be available on the market starting from 2012.
As the methodology is based on the fleet approach, before 2012 it is possible to obtain results, acting on the market mix and, if where possible, introducing additional Ecodesign concepts in product development. A classical approach targeting product specific performances would not have obtained results before 2012 with the placing on the market of new product generations. For MRI, the process will start to obtain first results during 2012.

15.When the methodology will be revised or amended?

The methodology and the annual reports are published on the COCIR website. Any stakeholder or public authority is invited to submit comments to improve the efficacy of the initiative.
The Methodology will be updated regularly according to the lessons learnt in the practical implementation without compromising data comparability. Any changes in the methodology will be also published in the annual report.

16.What savings could be obtained through the SRI initiative?

Actually it is possible to answer to this question only for ultrasound products as MRI definition of a test measurement procedure is still on-going.
The target set from 2010 for ultrasounds foresees a reduction of energy consumption during the use phase of 25% compared to 2005 baseline, or to 14,5%% compared to 2009, year in which the initiative has been launched.
According to market data, every year about 20.000 units are placed on the market, with an average energy consumption of 808 kWh per year per unit.
The energy savings for 2012 will be equal to about 2.610.972 kWh compared to 2009 levels.

17.How is stakeholder participation ensured?

The SRIv2 methodology provides for a constant exchange of views with stakeholders. Step 4, regarding target setting defines a procedure to submit targets to the European Commission and to the Consultation Forum for endorsement.

The annual Status Report is the tool that will be used to communicate yearly to EC and CF about the achievements towards the targets and to collect comments and suggestions.

The publicly available section of the COCIR website will offer all the related material and will be also used to gather comments from stakeholders.
Consultation forum members will be granted the access to a specific area of the website where reserved documentation is available.

Members of the Consultation Forum are also invited to attend the meetings of the Ecodesign Steering Committee.

TARGET SETTING

18.What is the "fleet approach" for target setting?

The Self-Regulatory initiative for Medical Imaging Equipment adopts an approach called "fleet approach" that has been widely discussed during the decisional process of the first EuP Directive (2005/32/CE).
Such approach differs from the traditional approach used for Implementing Measures.

The traditional approach defines specific minimum threshold values of specific product performances (e.g. energy efficiency or water consumption). Products with performance lower than the threshold levels are not allowed to be placed on the market. Environmental impacts are reduced as each product on the market has to respect the minimum values.

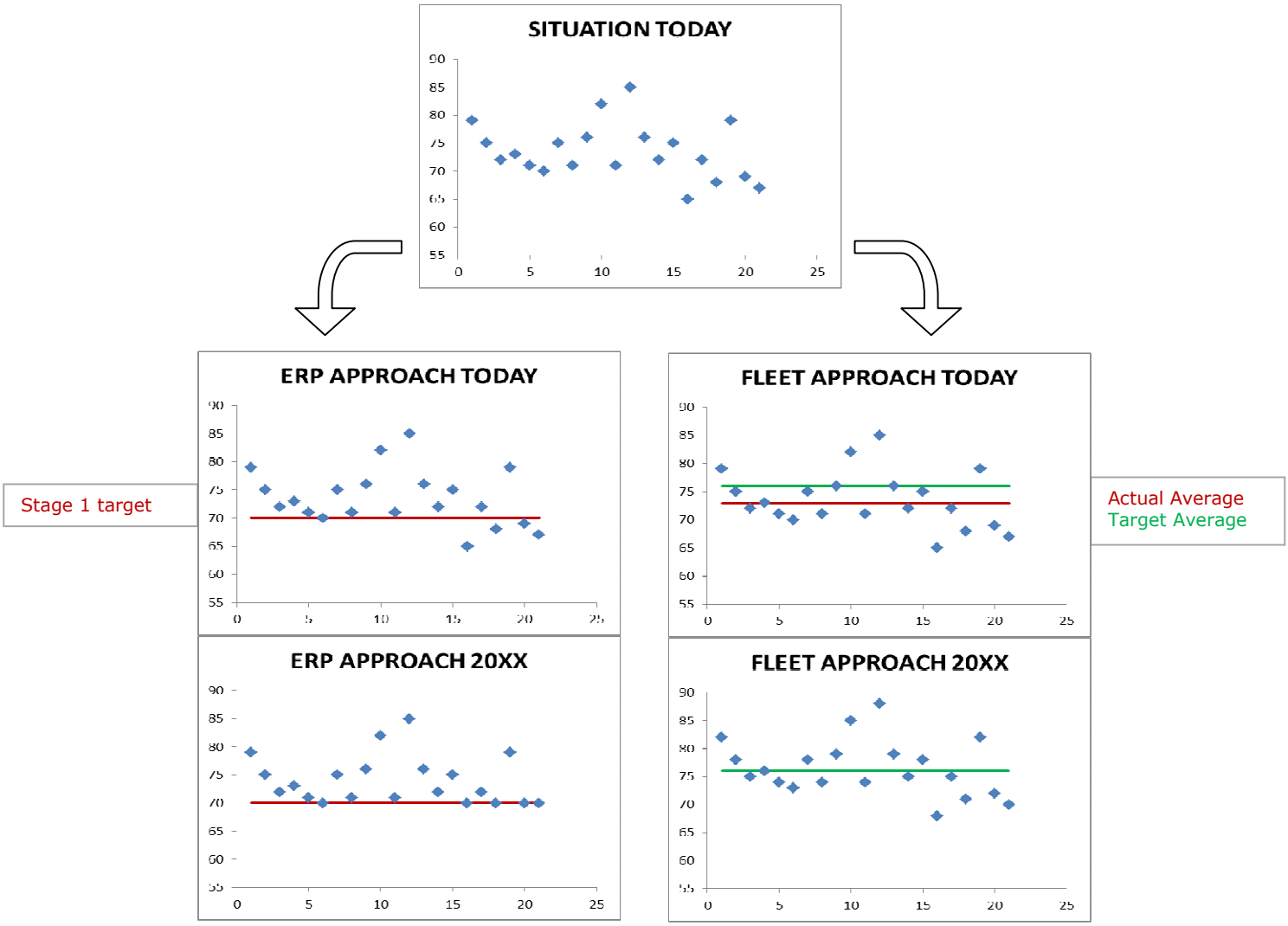
The respect of such levels can be evaluated by testing product according to specific procedures and is enforced by market control activities under the New Legislative Framework.

The fleet approach if very different. Targets do not refer to specific product performances but to the average performance of all the products placed on the market.

A company could produce a wide range of equipment, some of them with higher performance and other with lower one. All the products could be placed on the market, as long as their average is higher than the minimum threshold level.

To calculate the market average value it is necessary to know the single performance of any product placed on the market. This operation is provided in step 4 of the methodology.

The improvement of the environmental performance is ensured by the improvement of the average performance of the market, as shown in the picture below that represent a hypothetical distribution of performances (e.g. energy efficiency) of the models present on the market and how the two approaches act.



19.Why the fleet approach is important for the medical imaging sector?

The fleet approach is very important for the Medical Imaging Sector as it provides for ambitious results as the traditional approach but leaves companies the flexibility in approaching product design.

The Medical sector is a sector with high technological content and high investments in research and development where legal requirements on environmental performances could hamper or block the development of new life-saving and patient treatment technologies.

Furthermore, it has to be considered that the approval of a new product, according to Medical Devices Directives is a complex and time consuming process, meaning that the innovation cycle is generally some years long (e.g. 3 years for ultrasound and 5 years for MRI).

The fleet approach allows company to invest in research and development and to place on the market new generations of products as the reduction of environmental impacts could be pursued at different levels and with different instruments (i.e. the market mix).

Another reason for the decision to implement a "fleet" approach is the market composition. The sector is represented by a few companies (e.g. 5 companies for MRI) covering quite 100% of the EU Market. Moreover such companies are marketing a limited number of models.
All these characteristics allow the fleet approach to work correctly, by collecting all the market and environmental performance data from companies (in a fragmented market such an approach would be hard to apply and to assess).

Another very important element for choosing the fleet approach has been the capability of the methodology to deliver results in a very short time. Under the classic approach, the implementation of Ecodesign requirements on performances, such as energy efficiency can only be implemented in new product generations. As the innovation cycle could be longer than 5 years for certain modalities that would mean that no results could be achieved before such time.
The "fleet" approach allows companies to get results even from the first year by acting on the market mix.

20. What are the "business as usual scenario", the "best not yet available scenario" and the "beyond as usual scenario"?

It has to be noted that participating companies have been involved for years in Ecodesign activities to improve the performance of their products reducing at the same time the environmental impacts as much as possible. The pilot ultrasound shows clearly the reduction in energy consumption due to the Ecodesign commitment of companies.

To determine a target, 3 different scenarios are defined according to different assumptions based on expert judgement.

Business as usual scenario (BAU): the basic assumption is that given the situation today, during the innovation cycle all the competitors will invest in research to match the best performing players on the market. This assumption is very strong, especially in a sector where environmental performances are not the main driver for purchase choices of hospitals, public authorities or healthcare institutions. Nonetheless this assumption will ensure that ambitious targets will be set.

Best not yet available technology scenario (BnyAT): each company provides a reasoned reduction value, based on the "best not yet available technology" (technology not yet available but still in the research and development phase) that could be achieved during the innovation cycle. The scenario is based on the assumption that all the companies could reach a reduction equal to the provided reduction values.

Beyond as usual scenario (Beyond BAU): This scenario is based on the assumption that in the innovation cycle all the players will improve their products according to the average reduction of the BnyAT, except the best performing company 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.

21.How targets are set?

In the table provided by SRIv2, appendix 5, all the company possible performance improvements and the different scenarios are reported.

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 to be equal to the average absolute value of the Scenario One BAU. 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 -14.6%)
Scenario Two Energy use (kWh) Best NOT yet available technology -20xx-	9,9	12,375	10,725	12,375	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.

In the Beyond BAU scenario, values are obtained by assuming that all companies could reduce the aspect by the average of the values provided by companies in the BnyAT (17,5%), except the best performing company that is assumed to reduce the aspect according to its own prevision (marginal improvements are harder to obtain by front runners). The average of the obtained values is the reduction target industry shall achieve in the innovation cycles that will be submitted to the consultation forum.

22.Are targets set at industry or company level?

The SRIv2 methodology provides for both targets, industry and company specific ones.
The target set as the average of the Beyond BAU is the **industry target** that all the companies are committed to ensure. Achievement regarding this target will be reported yearly in the status report.

In the table above, grey cells would not be communicated to companies as such data are to be considered as confidential. Each company is anyway able to derive its own target (average of BnyAT scenario).
The best performer could read he is the best performer as the BAU average is equal to its declared performance. That means that the company target is the value he declared as reduction value for the BnyAT scenario.
All the other companies could read their reduction target as the average of the BnyAT scenario.
Each company will be assessed against the company specific target and any non-compliance will be treated according to the non-compliance procedure set in the SRI Appendix 5.3.

23.Why targets are not staged?

The methodology allows participating companies to set a target on the most significant environmental aspect over a period of time equal to the innovation cycle of the modality (i.e. 5 years for MRI, 3 years for Ultrasound). At the end of each cycle, a new evaluation of the most significant environmental aspect will be performed to ensure continuous improvement.

Due to the fast technological development of the sector, forecasting a target for the next generation of products would be very inaccurate. Moreover the potential for improvement for medical imaging devices is generally not very high due to ecodesign commitment and efforts of the past years, and to the very high technological content of the equipment. This means that most probably, the next cycle will target a different environmental aspect (e.g. for MRI the first aspects to be targeted is energy consumption during the use phase. The next one could probably be the helium consumption).

For the aforementioned reasons the SRIv2 does not set staged targets with further, more ambitious tier in, but provides for a continuous improvement cycle.

24.Are targets mandatory?

In a voluntary agreement industry or company targets cannot be mandatory as for target sets by European legislation.
It is the main interest of participating companies to comply with the target they set.

25.How is the initiative enforced?

The Steering Committee took into serious consideration the mechanism to show compliance with set targets and to handle non-complying producers, as an important tool to avoid market distortions.

Nonetheless the approach to enforcement has to take into account the approach adopted for target setting.

The SRIv2 methodology, as said in answer 22**,** sets an industry target that applies to the average performance of all products placed on the market but also defines a specific company target.

Such company specific targets will be enforced according to the non-compliance procedure (see Appendix 5 of SRIv2) that allows the Steering Committee to take action towards a company that is not able to reach its own target by forbidding it to use the SRI Ecodesign Label (the label will be defined in 2012, after successful endorsement of the Initiative by the European Commission)

26. Will there be a label on products, like for white goods?

A key factor in all the Implementing regulations under the ErP directive is the labelling of products with specific labels providing info on the product environmental performances like the energy label for white goods. The aim of the label is to provide consumers enough information to allow them a reasoned purchase, preferring energy efficient products.

Medical Imaging Devices are large and highly technological machines that are sold to hospitals, or health care institutions. The purchase process is very different from the one for refrigerators. All the technical information about performances is contained in the technical documentation of the product and is discussed and agreed between the sellers and the purchaser in a business-to-business transaction.

In such a process, a label affixed on the product is of little of no use at all.

To provide transparent information on products environmental performances, the Steering Committee developed a format for an Environmental Product Declaration, on the basis of the results of a German Integrated Product Policy (IPP) project in Hamburg.

The EPD will not be mandatory but could be voluntarily used by companies. The reason behind this decision is to have a transitional period to gather experience about its usefulness, how it is understood and used by the market and how it can interact with public procurement.

An SRI Ecodesign label will be developed, after successful endorsement by the European Commission of the Initiative. Such label will be used by companies on products and catalogues. Companies not able to reach their specific company targets will be forbidden the use of the label.

27. Could the label be used to determine if a product complies with the set targets?

The label cannot be used to evaluate conformity with targets. Targets are set at company and industry level, meaning that the average performance of all products marketed by the company have to meet a certain target (fleet approach).

The values declared on the EPD shall not be misunderstood as a tool to verify compliance of products with targets.

REPORTING

28.What is the SRI status report?

The annual Status Report is the annual reporting tool developed by the Steering Committee to inform the European Commission and the stakeholders about the yearly achievements towards the set targets.
For each new modality all the methodology step will be reported so the on-going work could be monitored according to the project plan.
The status report will also contain news and information on new companies joining the initiative or new sections or amendment to the methodology.

The annual Status Report is available on the COCIR website in the dedicated area.

29.How is the correctness of reported data ensured?

The Status Report and the table reporting the achievements towards the targets are reviewed every year by an external independent party, PriceWaterhouseCoopers. The review will give assurance that all the data have been collected and treated correctly and according to the established procedures that have been put in place to reduce as much as possible any kind of errors or irregularities.

ULTRASOUND PILOT PROJECT

30.What is the ultrasound pilot project?

The pilot project on ultrasound equipment has been launched in 2009 to gain practical experience to better define the Self-Regulatory Initiative.
The project applies to all Ultrasound equipment and set a target on the average energy consumption per unit of products placed on the market in the year under consideration.
This value is obtained as the rapport between the total energy consumption of all the products placed on the market and the total number of products placed on the market in the same year.
The Steering Committee committed to reduce the average energy consumption per unit of 14,5% by 2012 that represent a 25% reduction compared to 2005 baseline.

The project was very useful for gathering information and lessons that have been used, together with the comments received from Consultation Forum Members, to update the SRIv1 during 2010 to the new SRIv2 methodology.

The steering Committee decided to maintain the project as it is and to keep it running until 2012 according to the old methodology.

31.Why is the ultrasound pilot based on the old SRIv1 methodology?

With the new methodology SRIv2 ready, the Steering Committee decided to start to apply it to other modalities and to keep running the ultrasound pilot according to the old methodology. In fact the ultrasound project, even if far from perfect, was already producing results for 2010. With the application of the new methodology the project should have been restarted and so the achievements of 2010 would had been lost.

All the results achieved by the project are published on the SRI Status Report 2010, together with the on-going works for other modalities.

After all the other modalities will be targeted, the new methodology will be applied to ultrasound equipment that will enter the continuous improvement cycle.

32. What target has been set for Ultrasound equipment?

The Steering Committee committed to reduce the average energy consumption per unit of 14,5% by 2012 that represent a 25% reduction compared to 2005 baseline.
The target will be achieved by improving the energy performance of ultrasound equipment and by changing the market mix.

33. Where are the achievement published?

Every year the Steering Committee will publish the Annual Status Report. The SRI Status Report 2010 would be soon available at COCIR website.

34. When will the new methodology be applied to ultrasound equipment?

In 2014/2015 the new methodology SRIv2 will be applied to Ultrasound equipment. Step 3 and 4 will be applied, a new target will be set for the following innovation cycle and ultrasound will enter the continuous improvements cycle.

For any additional information on the
Self-regulatory Initiative for Medical Imaging Equipment
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