BE comments on a draft self-regulation measure on medical imaging equipment
partly based on the national stakeholder meeting of 4th of November 2009

General comments:

Belgium welcomes the initiative of the industry to propose a Voluntary Agreement (VA) on medical imaging equipment.
However Belgium believes that the initiative presented by the industry during the CF is generally not ambitious enough and too vague. Besides a general target of 6 % to reduce the average energy consumption for the ultrasound sector by 2012, the self-regulation measure does not contain any concrete commitment to improve the environmental performance of products placed on the market between 2010 and 2012.
Furthermore, it is not clearly described in the text that 6 % is a minimum target, and that it is possible that more efforts can be made (as explained during the CF).

Although the self regulatory initiative is done on a voluntary basis, Belgium believes a clear procedure and general approach should be established for all VA's. Before a VA can be discussed in a CF, it should contain at least all necessary aspects (clear scope, concrete commitments, clear market coverage,…). Certain aspects, like reporting, monitoring, revision and sanctions, should be dealt with in a consistent way and should be implemented in the same way for all VA's.
Taking into account the discussions in the CF, the proposal of the VA should be refined. When it can not be changed in a reasonable period of time (the same period should be laid down for all VA's) or when the VA doesn't fulfill the criteria of Directive 2005/32/EC, mandatory Ecodesign requirements have to be available so additional time is not lost. Therefore together with the proposal for a VA, a possible Ecodesign Regulation should be discussed in the CF.

Specific comments:

Scope
The product scope and the definition of ultrasound equipment (see Appendix 5) are not clear enough. Which items should be at least integrated and what is the link with other EuP lots (e.g. lot 3)? For example, which energy savings will already be achieved by the regulations for computers and displays?

Added Value
Although the environmental impact of material procurement accounts for 12%, only energy consumption during the use phase is addressed to begin with (see LCA in Appendix 6). Also the case studies in Appendix 7 highlight improvement based on other parameters than energy consumption (e.g. product volume and weight, packaging weight, content of PVC). Furthermore medical equipment is not included in the RoHS scope before 2013, so the text is misleading on this point. Design, which takes into account resource efficiency and easy dismantling and recovery, is not properly addressed in WEEE.

In conclusion, other environmental parameters besides energy reduction in the use phase should be addressed in the VA.

Representativeness/openness to participation
What is the market coverage of the other targeted companies in the ultrasound sector (see Table 1)? Have they already been contacted so they can be involved in the self-regulatory initiative? Is the annual charge of 3000 € not an obstacle for non members of COCIR to participate in the Steering Committee (see Appendix 2 item 4.2)?

Quantified and staged objectives
Besides one general target of 6% for the whole ultrasound sector, the VA doesn't include any commitment for the signatories.
The text describes a methodology to collect and report data. It contains a lot of plans and initiatives but no real commitments. These concrete commitments should be worked out in steps 4 and 5 of the general methodology. Compliance rates and commitments for each signatory and/or product placed on the market should be worked out.

If the International Standard IEC 60601-1-9 contains clear and useful improvements for design, than the implementation of the Standard should be mandatory for all signatories. Possible concrete commitments are described in Appendix 7 and based on the Environmental Product Declaration in Appendix 9 real commitments for product information are possible. For example a reference to a general list with dangerous substances is not appropriate, but the concentration of the dangerous substances present would be useful as product information.

Furthermore limits for the energy consumption in the scanning, standby and off mode modes and for the battery powered units should be established. The availability of a standby mode should be mandatory.

Also, the maximum energy consumption of ultrasound equipment with the basic function should be defined, and, when technically justified and necessary, higher energy consumption could be allowed for extra functions/features.

Measurement methods to verify the energy consumption should be available.

In general, technical and scientific background information to judge the appropriateness of the VA is missing. For the moment, it is not possible to know if the target of 6% has an added value in comparison to the BAU. The functional unit and benchmarks should be defined.

Involvement of civil society
Following step 4 of the methodology, the objective is set by consensus at the EuP Steering Committee. This Steering Committee should be set up in the same way for all VAs and a real effort to involve civil society should be made.

When the VA is reviewed and new objectives are set, the Consultation Forum should be consulted before. Furthermore all stakeholders of the Consultation Forum should be actively involved in the monitoring and evaluation of the VA. Belgium believes that, following the provisions in the Directive (see art. 18 and Annex VIII of the ErP Directive, point 5), the role of the CF regarding the VAs is not clear.

In conclusion, a harmonized approach for all VAs should be worked out by the Commission.

Reporting and monitoring
Monitoring and reporting (step 6 of the general methodology) is not consistent with Annex VIII of the Ecodesign Directive.

The data reported by participants should be linked to real commitments (limits and compliance rates). The data should be reported to the Commission, the CF, the Regulatory Committee and the Independent Inspector. These data should be published for each signatory with respect of confidentiality.

The fact that some aspects (financial management systems and compliance with medical devices Directive) are already externally audited, is not a reason for not verifying commitments of the VA. Energy savings and other environmental improvements are probably not dealt with in these audits.

A verification procedure, executed by an Independent Inspector, should be set up in a consistent way for all VA's.
If sanctions can not be established for the companies that do not fulfill their commitments, at least the list of the companies that respect the VA should be published.

Following the provisions of the Directive, the role of the CF and the Regulatory Committee regarding the evaluation of the VAs is not clear.

Sustainability
When targets are reviewed (in the case when more powerful imaging technology is developed and placed on the market, see page 47), all stakeholders of the Consultation Forum should be consulted before the VA is adapted.
It is also important that the VA has no negative financial impact for the consumers.

Other
Page 25, item 4.4.3: What is exactly meant by "existing EcoDesign programmes"?

Conclusion
In the current form and without taking into account these comments, Belgium can not accept the VA. Also we wonder before which date a new proposal has to be presented to the CF taking into account the remarks of the meeting of 17/11/09.