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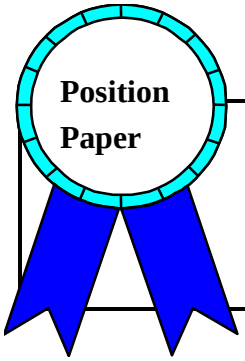

Eco-Management and Audit Scheme (EMAS)

September 1994

This position paper has been prepared by an inter-federation working group and represents the consensus of the members of all major trade associations of the European Medical Device Industry (MDI) (COCIR, EDMA, EUCOMED, IAPM) on the Council Regulation on Community Eco Management and Audit Schemes (CEMAS).

The MDI welcomes the commission's initiative on CEMAS as one way to manage environmental issues effectively. It opens the opportunity for participating sites within the EU to demonstrate their commitment to the environment. Customers and the general public can be reassured that the environmental impact of products has been considered and minimised during design and production. CEMAS sets standards for the adequate management of environmental liability issues which may be important to investors.

Industry is presently adapting their quality systems for products according to requirements of the Medical Device Directives (MDD). Standardisation of quality systems has led to the recognition that principles applied for products can be applied for unwanted products as waste or emissions as well. After finishing this step it would be logical to extend quality management principles to eco-management so as to benefit from improved efficiency and to reinforce continuous environmental improvement performance.

Time scale for implementation of CEMAS should take account of the size, environmental impact and risk of the MDI sites. The trade associations will be a conduit for spreading experience with CEMAS to all members with emphasis on helping small and medium size sites.

CONCLUSION

The voluntary nature of the regulation is welcomed as it allows each MDI site to implement EMAS at a place which takes into account the following facts:

a) Mandatory compliance with existing environmental regulations on local and national level

b) Status of implementation of quality management systems, e.g., ISO 9000/29000 series, and product specific regulations, e.g., MDD, USA GMP

c) The economic situation of the site due to the constraints on health care budgets within Member States

As far as the implementation process is concerned a step-by-step approach is proposed to upgrade or implement the CEMAS elements in the suggested order:

1. Develop a company environmental policy
2. Maintain and update a legislation register
3. Undergo a base line environmental review
4. Maintain and update a register of environmental effects
5. Establish accountabilities and responsibilities within the organisations
6. Instigate performance improvement programs
7. Develop an environmental statement program
8. Start the official registration process to CEMAS

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NOTE TO THE MDI TRADE ASSOCIATIONS

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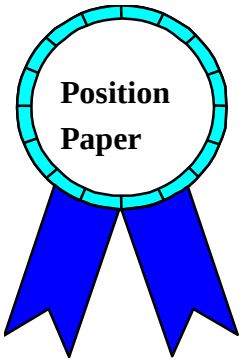

Upon the Commission's review of CEMAS scheduled till 13 July 1998 it should be made clear that:

a) The scheme needs to be kept voluntary for sites in the MDI for reasons given in the position paper

b) The possibility should be maintained of independent self audits as opposed to external audits. External audits could compromise the auditees protection of know how and would for smaller sites be a disproportional increase in costs

c) Legal compliance is reached with compliance to EC/EU regulatory requirements that compliance with more stringent local requirements can already be regarded as step towards continuous improvements for the environment.

MEDICAL DEVICE INDUSTRY

COCIR
COORDINATION COMMITTEE OF THE RADIOLOGICAL AND ELECTROMEDICAL INDUSTRY

EDMA
EUROPEAN DIAGNOSTIC MANUFACTURER ASSOCIATION

EUCOMED
EUROPEAN CONFEDERATION OF MEDICAL SUPPLIERS ASSOCIATIONS

IAPM
INTERNATIONAL ASSOCIATION OF MEDICAL PROSTHESIS MANUFACTURERS