

**Position Paper on the RoHS Directive
by Category 8-Related Industry Associations in Japan
for Consideration by European Commission**

[1] Background

The medical device industry, which includes sensor, has a very wide range of medical applications. Medical devices have been contributing to the health of the people by supporting medical diagnosis and the provision of treatment.

Considering the importance of the medical device industry, the following four Category 8-related industry associations in Japan attends Environmental Issue Committee of JFMDA (THE JAPAN FEDERATION OF MEDICAL DEVICES ASSOCIATIONS) and have been discussing the RoHS Directive from the viewpoint of Category 8-related medical device industries and generated this position paper that is presented to the European Commission on behalf of Japanese Category 8-related industry associations.

The industry associations are listed below along with their key products at JFMDA

JAIMA: Japan Analytical Instruments Manufacturers Association

<http://www.jaima.or.jp/english/index-e.phd>

In-vitro Diagnostics Clinical instruments

JIRA: Japan Industries Association of Radiological Systems

<http://www.jira-net.or.jp/e/index.htm>

X-ray systems, (including the therapeutic systems, mobile X-ray systems, Dental X-ray systems)

CT systems, CR systems

Nuclear medicine system (including PET and SPECT)

MRI systems

Related items & accessories (devices, appliances, parts)

Image Processor System

Diagnostic ultrasound systems.

Therapeutic systems

JMOIA: Japan Medical-Optical Equipment Industrial Association

Medical endoscope

Ophthalmic equipment

Spectacle equipment

Colposcope

Operating microscope

JMED: Japan Medical Devices Manufacturers Association

<http://www.jmed.jp/>

Syringe pump

Infusion pump

Blood pressure monitor

Electric thermometer

Roller pump

[2] Example Applications of the medical devices

Firstly, by developing the medical device technology, the medical device industries contribute to improvements in the quality of medical care, including quality of life (QOL) in the medical field.

Secondly, the medical device industries contribute to the furthering of medical innovation in the Health Service.

Thirdly, by developing medical device/systems using information technology (IT), the medical device industries contribute to the development as well as to the introduction of new medical technology to the customers.

The use of X-rays in medicine has a 100-year history and has been used for screening (mass screening etc.) in the maintenance of people's health. CT systems (which are frequently seen on TV these days) are also manufactured. CT systems are able to quickly acquire sectional images of a person's body while the patient is passing through the tunnel gantry. To acquire diagnostic CT images, patients have previously had to hold their breath for a period, however thanks to rapidly-advancing CT technology, images can now be acquired even more quickly, substantially reducing the duration of breath-holding. Our industry also handles MRI systems, which utilize a magnetic field. In the same manner as CT systems, MRI systems acquire images while the patient is in the gantry. Although MRI has always been somewhat noisy, it is effective in obtaining various types of patient information that cannot be obtained by CT systems, and improvements in noise reduction are constantly made. Clinical test instruments and systems are used for in-vitro clinical testing, which mainly handle blood, urine, and the like, or for in-vivo clinical testing. Other analytical instruments are used in the field of biotechnology. The medical device industries are always striving to make diagnosis more comfortable for the patient, and system operation easier for physicians.

Thus, there is an extremely wide range of applications of measurement technologies. Considered individually, however, each application is not necessarily highly volume because of the necessity (for example), of making a very specific, precise, highly reliable measurement. And as mentioned above, the measuring principle or design of applications may depend upon the fundamental physical characteristics of the relevant substances, some of which are now banned by RoHS.

These are very important characteristics of Category 8 applications that must take into consideration as we work to meet the requirement of Directive 2002/95/EC. Reliability is a key point especially for control applications, Accuracy is another key point that is indispensable for precision measurement application. Use of alternatives to RoHS-banned substances may require design change. Reasonable time for evaluation and qualification is necessary if we are to provide customers with the same performance that they receive from

existing products.

In view of these facts and considering the reasonably planned life cycle of Category 8 applications currently on the market, a transition period of at least 10 years from now on is required.

[3] Characteristics of the medical device industries

Based on the above, key points related to the medical device industries are:

- Contribution to the health benefiting by advanced and innovative technologies
- Production of "mother tools" for various industries
- Long product life (10-20years)
- Products managed as industrial waste at the end of he life cycle
- Some custom-designed key components that enable specific precise measurements.
- Low volume but wide range of applications
- Very limited supply chain for custom designed components
- Low environmental impact due to low volume and waste management
- In need of reasonable time period to evaluate reliability, accuracy and traceability after design changes

[4] Fundamental policy of Category 8-related industry associations in Japan

Category 8-related industry associations in Japan agree

- to meet the requirements of Directive 2002/95/EC proactively.
- to create an achievable transition program that includes parts suppliers.
- to propose reasonable exemptions for applications that depend on the fundamental physical properties of RoHS-banned substances.

[5] Proposed exemptions

Although we fully understand the intention of this directive, we have listed the substances that are often used in medical devices (diagnostic, therapeutic, radiological, shielding and protective equipment, clinical test instruments) that should be exempted from the restriction. We ask you this time to exempt these listed substances when used as materials in medical equipment and to continue exemption of use of substances mentioned in Annex "Applications of lead, mercury, cadmium, and hexavalent chrome, which are exempted from the requirements of Article 4(1)" to the RoHS Directive Article 4(2) issued in February 2003. Further, if the benefits of substances that are used as raw materials for medical equipment (e.g. sensors) are greater than the risks that they pose to the environment or health and safety, we do not believe that the supply of such substances should be restricted, or that research and development of equipment using such substances should be hindered. We think that environmental safety should be ensured through safety control measures for the manufacture, use, disposal and recycling of such equipment

Category 8 related industry associations in Japan propose following exemptions for Directive 2002/95/EC. The attachment shows the types of equipment, the substances that should be exempted from the restriction, the current status of the use of each substance, the reasons for exemption, and other relevant descriptions. We hope that our suggestion will be adopted. Thank you very much.

(Enclosed you will find)

81_FMDA RoHS Position Paper of Category 8_Final_20060316.pdf

82_RoHS-JFMDA-Generic exemption_Final_20060316.pdf

83_RoHS-JFMDA-Generic exemption_Others_Final.pdf

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