COCIR
SUSTAINABLE COMPETENCE IN ADVANCING HEALTHCARE
European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry

COCIR Position Paper

on the Proposal for a Directive laying down basic safety standards for protection against the dangers arising from exposure to ionizing radiation[1]

COCIR is the leading voice of the radiological industry in Europe and our members are major manufacturers of computed tomography (CT), nuclear medicine and radiotherapy equipment.

In the context of the revision of the Basic Safety Standards (BSS) Directive, our members reviewed with great attention the content of the Commission's proposal merging the directives 97/43/Euratom and 96/29/Euratom.

COCIR welcomes the Commission's simplification of the regulatory environment and the update to latest scientific data as well as international recommendations of the European regulatory framework for the protection against ionizing radiation. Today, the EU regulates the safety and performance of ionizing radiation emitting medical devices primarily through its Mmedical devices directive (MDD) 93/42/EEC. This is done in view of a risk-benefit justification of medical exposure since our products intend to support medical practitioners. Thus, ionizing radiation is intentionally used to the benefit of patients.
The main principles of BSS (Optimization, Justification and Reduction of Risk) are covered by the essential requirements in the MDD.
There is an important distinction between our sector and industrial use of technologies involving ionizing radiation: Medical equipment manufacturers have implemented dose reduction measures, dose management and reporting systems and provide specific training.

COCIR members have noticed that several new requirements introduced by the recast affect the placing on the market of medical devices. This causes new administrative burden to the manufacturers without obvious benefit for the safety of the patient and the users of the device.

The following 2 points present a particular concern for us:

1. **The procedure of authorization described in Chapter V, Article 21, introduces a pre-market approval** where the manufacturer intending to place on the market a new device will have to wait 6 months until being informed by the competent authorities of the decision allowing him to access the market. This procedure will hamper the innovation and will lengthen the delays for placing new devices on the market. This pre-market approval is also conflicting with the CE marking procedure according to the MDD, where placing on the market is allowed without pre-market approval. Moreover, according to this procedure of authorization, all Member States shall be provided with the information communicated by the manufacturer and will make their own decision. This means that a device may be allowed in some countries and rejected in other ones, which is conflicting with the free circulation of goods.

   COCIR recommends that the communication of information to the competent authority may be acceptable, under the condition that it is required only once in Europe and then recognized by the other countries without repeating the communication. The procedure of authorization should be avoided as it may conflict with the CE marking procedure.

2. **Article 59 gives the possibility to EU Member States to generate their own acceptance testing**. This would create additional burden and cost without bringing additional benefit.

   COCIR recommends that the new BSS directive explicitly requires EU Member States to adopt European Guideline (like RP162) or European standards currently developed by Standardization Organization as acceptance criteria for medical radiological equipment.

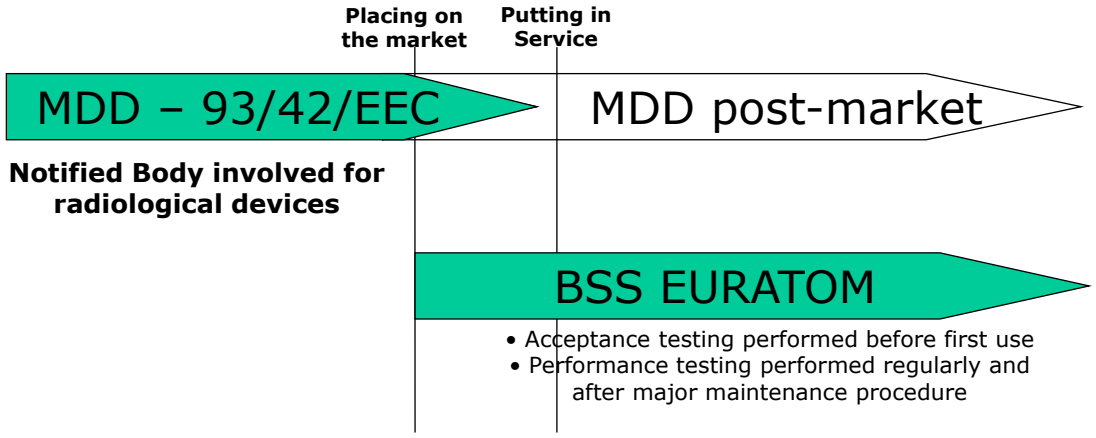
[1] http://ec.europa.eu/energy/nuclear/radiation_protection/doc/com_2011_0593.pdf.

DETAILED BRIEFING

General comments

A general assumption for medical devices is that under the "presumption of conformity" approach -the fulfillment of standards harmonized under the MDD- medical devices can be placed on the market according to this directive. The proposed BSS Euratom directive must not bring any conflicting requirements with the MDD.

1. For medical devices, the directive shall be limited to requirements on the use and maintenance (if at all applicable to medical devices). The BSS Euratom directive should be shown as complementary to the Medical devices directive 93/42/EEC. Therefore cross references should be made to the MDD to keep consistency with the existing text (Article 1(8)). The complementarity between the Medical devices directive and the new BSS Euratom directive should be clarified as follow:



2. To keep the consistency with the MDD, the new BSS Euratom directive should require the EU Member States to apply the same acceptance criteria in the entire EU, based on European harmonized standards.

3. If at all necessary, a specific directive for medical devices should be developed for maintenance and use.

Why COCIR requests these amendments:
1. Conflicts with free trade principles of medical devices within the EU should be avoided.
The domain of manufacturing and placing on the market is globally and comprehensively covered by the MDD. This directive sufficiently addresses the protection of patients, operators and environment.

2. The goal should be to reduce/harmonize the various national requirements on radiation protection and safety for medical devices.

3. For medical devices, ionizing radiation is an intended use.

Article 4 - Definitions

Text from the European Commission:
1. Article 4 (75): Interventional radiology means the use of X-ray imaging techniques, in addition to those involving ultrasound or magnetic resonance imaging or other non-ionizing radiation techniques, to introduce and guide devices in the body for diagnostic or treatment purposes;

2. Article 4 (96).

Alternative text suggested by COCIR: use definition from IEC60601-2-43
1. Article 4 (75): Interventional radiology means an invasive procedure (involving the introduction of a device, such as a needle or a catheter into the PATIENT) using RADIOSCOPY as the principal means of guidance, and intended to effect treatment or diagnosis of the medical condition of the PATIENT

2. Article 4 (96): Committed equivalent dose ($H_T(\square)$) means …

It is given by: $$H_T(\tau) = \int_{t_0}^{t_0+\tau} \dot{H}_T(t)dt$$

for an intake time at t_0 where
$\dot{H}_T(t)$ is the relevant equivalent dose rate (in tissue T) at time t, …

Why COCIR requests these amendments:
1. Article 4 (75): Only high dose applications should be regulated by this BSS Euratom directive. As a definition of high dose, COCIR proposes the limit as defined in standard IEC/EN 60601-2-43 (i.e. a dose area product greater than 100 Gy * cm^2).

2. Article 4 (96): Typographic problem in the integral expression for committed equivalent dose. Ampersand must be replaced with superposed dot (twice) and subscript T for tissue must be added (twice).

Article 12 - Dose limits for apprentices and students

Text from the European Commission:
1. The dose limits for apprentices aged 18 years or over and students aged 18 years or over who, in the course of their studies, are obliged to work with radiation sources shall be the same as the dose limits for occupational exposure laid down in Article 10.
2. The limit on the effective dose for apprentices aged between 16 and 18 years and for students aged between 16 and 18 years who, in the course of their studies, are obliged to work with radiation sources shall be 6 mSv per year.
In addition to limits of effective dose laid down in the first subparagraph, the following limits on equivalent dose shall apply:
(a) the limit on the equivalent dose for the lens of the eye shall be 20 mSv in a year;
(b) the limit on the equivalent dose for the skin shall be 150 mSv in a year, averaged over any area of 1 cm², regardless of the area exposed;
(c) the limit on the equivalent dose for the hands, forearms, feet and ankles shall be 150 mSv in a year.
3. The dose limits for apprentices and students who are not subject to the provisions of paragraphs 1 and 2 shall be the same as the dose limits for members of the public as specified in Article 13.

Alternative text suggested by COCIR:
COCIR recommends deleting this section.

Why COCIR requests these amendments:
There should not be any differentiation in the protection of apprentices and students.

Article 21 - Justification of practices with apparatus or products emitting ionising radiation

Text from the European Commission:
1. Member States shall require any undertaking intending to manufacture or import or export a new type of apparatus or product emitting ionising radiation to provide the competent authorities with relevant information such as that listed in Annex III, Section A, in order to enable the authorities, on the basis of assessment of information set out in Annex III, Section B, to decide whether the intended use of the apparatus or product can be justified.

2. The competent authority shall share the information received according to paragraph 1 with the competent authorities of the other Member States to allow them to take their own decision on the justification of the intended use of the apparatus or product.

3. The undertaking shall be informed on the decisions of the Member States' competent authorities within a period of 6 months.

Alternative text suggested by COCIR:
1. Member States shall require any undertaking intending to manufacture or import or export a new type of apparatus or product emitting ionizing radiation to keep at the disposal of the competent authority of the Member State in which he has its registered place of business, the information such as that listed in Annex III, Section A, in order to enable the authorities to decide whether the intended use of the apparatus or product can be justified.

2. The competent authority shall share the information received according to paragraph 1 with the competent authorities of the other Member States and inform them on the decision on the justification of the intended use of the apparatus or product. This decision shall apply to all Member States.

3. The undertaking shall be informed on the decisions of the Member States' competent authorities within a period of ~~6~~ 2 months.

4. Sections 1 to 3 of Article 21 do not apply to medical devices compliant to Medical devices directive 93/42/EEC as their intended use is already justified according to the Risk/Benefit approach in Annex I of the MDD.

Why COCIR requests these amendments:
COCIR recommends exempting medical devices from Article 21 and Annex III and referring to MDD.

New requirements would affect the placing on the market of new devices and would cause new administrative burden to the manufacturers without obvious benefit for the safety of the patient and the users of the device. There is the risk of multiple authorization procedures with the possibility of different conclusions in different EU Member States. This is also in conflict with regulation for free circulation of goods within the EU. The competent authorities for radiation

protection have the power to refuse the placing of the device on their national market, hence creating inhomogeneous situation in Europe.

Regarding point 3, a time period of 6 months is too long and introduces unnecessary delay in the placing on the market of new medical equipment. A period similar to the one existing for the approval of clinical investigations seems more reasonable.

The mentioned "Justification of practices" is already well organized and controlled by existing medical device regulations (i.e. MDD etc.), and a common European approach is already applied.

The draft BSS Euratom directive might undermine existing and efficient EU regulations by transferring responsibilities back to each of the EU Member States. For example the CE-marking would be challenged.

According to this procedure of authorization, all EU Member States shall be provided with the information communicated by the manufacturer and will make their own decision. This means that a device may be allowed in some countries and rejected in other ones, which is conflicting with the free circulation of goods.

Article 28.5 - Authorisation procedure

Text from the European Commission:
5. Member States shall require the undertaking to promptly notify the occurrence of any significant event resulting or liable to result in the exposure of an individual beyond the operational limits or conditions of operation specified in licensing requirements with regard to occupational or public exposure or as defined by the authorities for medical exposure.

Alternative text suggested by COCIR:
5. Member States shall require the undertaking to promptly notify the occurrence of any significant event resulting or liable to result in the exposure of an individual beyond the operational limits or conditions of operation specified in licensing requirements with regard to occupational or public exposure, or –for medical devices- as defined by the Medical device directives ~~authorities for medical exposure~~.

Why COCIR requests these amendments:
This requirement is already covered by the MDD. COCIR recommends exempting medical devices and refer to the MDD.

Article 55.2 - Optimisation

Text from the European Commission:
2. Member States shall ensure the establishment, regular review and use of diagnostic reference levels for radiodiagnostic examinations, and when appropriate, for interventional radiology procedures, and the availability of guidance for this purpose.

Alternative text suggested by COCIR:
2. Member States shall ensure the establishment, regular review and use of diagnostic reference levels for radio diagnostic examinations, and when appropriate, for interventional radiology procedures, by the means of a harmonized EN standard containing reference levels for radio diagnostic examinations, and where appropriate, for interventional radiology procedures.

Why COCIR requests these amendments:
EU Member States should not be allowed to introduce their own reference levels. We should avoid having different diagnostic reference levels in each EU Member States.

Article 59.2 (d) - Acceptance testing

Text from the European Commission:
2. Member States shall ensure that:
(d) acceptance testing, involving the medical physics expert, is carried out before the first use of the equipment for clinical purposes, and performance testing is carried out thereafter on a regular basis, and after any major maintenance procedure.

Alternative text suggested by COCIR:
2. Member States shall ensure that:
(d) acceptance testing, involving the medical physics expert, is carried out before the first use of the equipment for clinical purposes, and performance testing is carried out thereafter on a regular basis, and after any major maintenance procedure. The Member States should adopt European Commission guidelines (e.g. RP162), European or International standards currently developed by Standardization Organizations as acceptance criteria for medical radiological equipment (e.g., IEC TC62, IAEA standards, ICRP guidelines....).

Why COCIR requests these amendments:
Article 59 gives the possibility to EU Member States to generate their own acceptance testing. This would create additional burden and cost without bringing additional benefit. This will require equipment adjustment per country as each EU Member States could have different interpretations of the same internationally published standards or guidelines.

Article 62 (d) - Accidental and unintended exposures

Text from the European Commission:
Member States shall ensure that:
(d) the undertaking declares as soon as possible to the competent authorities the occurrence of significant events as defined by the authorities, including the results of the investigation and the corrective measures to avoid such events. The competent authorities shall share this information with the competent authorities for post-market surveillance established in Council Directive 93/42/EEC concerning medical devices;

Alternative text suggested by COCIR:
Member States shall ensure that:
(d) the undertaking declares as soon as possible to the competent authorities the occurrence of significant events as defined by the authorities, including the results of the investigation and the corrective measures to avoid such events. For medical devices, the undertaking declares this information as soon as possible to ~~The competent authorities shall share this information with~~ the competent authorities for post-market surveillance established in Council Directive 93/42/EEC ~~concerning medical devices~~;

Why COCIR requests these amendments:
A single competent authority should coordinate the investigation and the follow-up of the corrective action for both directives –MDD and BSS.

Article 63 - Estimates of population doses

Text from the European Commission:
Member States shall ensure that the distribution of individual dose estimates from medical exposure is determined and shall take into account the age distribution and the gender of the exposed population.

Alternative text suggested by COCIR:
Member States shall ensure that the distribution of individual dose estimates from medical exposure is determined and shall take into account the age and weight distribution and the gender of the exposed population.

Why COCIR requests these amendments:
Weight categories should also be determined. This would avoid patient selection based on weight to report the doses.

Annex III. A - Placing on the market of apparatus or products

Text from the European Commission:
A. Any undertaking intending to place on the market apparatus or products shall provide the competent authorities with all relevant information as to the:

Alternative text suggested by COCIR:
A. Any undertaking intending to place on the market apparatus or products shall ~~provide~~ keep at the disposal of ~~disposal of~~ the competent authority, for a period ending at least five years after the last product has been placed on the market, ~~with all relevant~~ the following information ~~as to the~~:

Why COCIR requests these amendments:
The information to be provided to the competent authorities is very extensive and does not seem justified. This will cause delays in placing new and innovative medical equipment on the market.

Annex III. A. (3) Placing on the market of apparatus or products

Text from the European Commission:
A. (3) dose rates at relevant distances for the use of the apparatus or product, including dose rates at a distance of 0.1 m from any accessible surface;

Alternative text suggested by COCIR:
COCIR recommends deleting this section or exempting medical devices.

Why COCIR requests these amendments:
Medical devices are subject to specific standards that define other method for measuring dose rates at different distances.

Annex III. A. (4) Placing on the market of apparatus or products

Text from the European Commission:
A. (4) intended use of the apparatus or product and information on the relative performance of the new apparatus or product compared to existing ones;

Alternative text suggested by COCIR:
A. (4) intended use of the apparatus or product and information on the relative performance of the new apparatus or product compared to existing ones where applicable;

Why COCIR requests these amendments:
Comparison is only possible between apparatus of the same manufacturer but not to all of them. Otherwise there is a need to have specified test methods for performance for each product family.

Annex III. A. (5) - Placing on the market of apparatus or products

Text from the European Commission:
A. (5) expected doses to regular users of the apparatus or product.

Alternative text suggested by COCIR:
COCIR recommends deleting this section or exempting medical devices.

Why COCIR requests these amendments:
This requirement is already covered by the MDD. The expected radiation dose to regular users of the apparatus or product depends on the use of protective devices and other precautions.

Annex III. B. - Placing on the market of apparatus or products

Text from the European Commission:
B. The competent authorities shall assess the information listed in Section A and in particular shall assess:
(1) whether the performance of the apparatus or product justifies its intended use;
(2) whether the design is adequate in order to reduce exposures in normal use and the likelihood and consequences of misuse or accidental exposures;
(3) in the case of a consumer product, whether the product is adequately designed to meet the exemption criteria and does not necessitate specific precautions for disposal when no longer in use;
(4) in the case of apparatus or products for use in practices exempted from authorisation, whether conditions for disposal are adequate;
(5) Whether the apparatus or product is appropriately labeled and suitable documentation is provided to the customer with instructions for proper use and disposal.

Alternative text suggested by COCIR:
COCIR recommends deleting this section.

Why COCIR requests these amendments:
The information to be provided to the competent authorities is very extensive and does not seem justified. This will cause delays in placing the new and innovative medical equipment on the market.