HERCA Multi-Stakeholder Workshop (MSW)

How can CE Marking contribute to the justification process of new types of practices?

24-26 October 2016

CE MARKING CAN CONTRIBUTE TO THE JUSTIFICATION PROCESS

European and International standards used for demonstrating the conformity of devices with the MDD detail requirements that mitigate inter alia also the risks related to ionization radiation. For example:

- EN/IEC60601-1-3: Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment
- EN/IEC 60601-2-1: Medical electrical equipment - Part 2-1: Particular requirements for the basic safety and essential performance of electron accelerators in the range 1 MeV to 50 MeV
- EN/IEC 60601-2-64: Particular requirements for the basic safety and essential performance of light ion beam medical electrical equipment

Risk management:

- ISO 14971 gives requirement to put in place a risk management process ensuring identification and mitigation of risks relted to medical devices. Manufacturers of MDs must be conform to this standard in order to CE mark their equipment. The risk managemen tfile resulting from this process is part of the technical dossier evaluated in the CE marking process

Clinical evaluation:

- MDD Guidance MEDDEV 2.7/1 gives detailed requirements on how to perform an appropriate clinical evaluaiton both based on clinical trials or on evaluaiton of existing scientific literature.

Risk benefit evaluation

- MDD requires that the results of the risk managent process and of the clinical evaluaiton be analyzed together to derive a risk benefit analysisthat can justify the use of the device insofar the benefit overweight the residual risks of hte device.

REQUIREMENTS IN IEC STANDARDS (→ CE MARKING)

- Examples can be found in
  Medical electrical equipment –
  Part 1-3: General requirements for basic safety and essential performance –
  Collateral Standard: Radiation protection in diagnostic X-ray equipment
  (IEC 60601-1-3:2008)

EXAMPLE:
HELP USERS KNOW THE DOSE LEVEL THEY DELIVER

5.2.4.2 Quantitative information

For each INTENDED USE of the EQUIPMENT, the following information shall be provided:

– the RADIATION QUANTITY (or quantities) used for describing the RADIATION dose to the PATIENT. This quantity must be useful for assessing the RADIATION RISK to the PATIENT.

NOTE Such quantities are, for example, the ENTRANCE SURFACE dose (or dose rate), the DOSE AREA PRODUCT or the CTDIvol.

– the description of a specified test object representative of an average PATIENT;

– the specified procedure allowing measurement of the RADIATION QUANTITY (or quantities) for the specified test object;

– the value of the specified RADIATION QUANTITY (or quantities) when the specified test object is used to simulate a PATIENT when performing a procedure typical of this INTENDED USE;

– the influence of the main adjustments or selections available to the OPERATOR on the value of the specified RADIATION QUANTITY.

NOTE Examples of such adjustments or selections are MODES OF OPERATION, LOADING FACTORS, FOCAL SPOT selection and FOCAL SPOT TO IMAGE RECEPTOR DISTANCE. INTENDED USE should not be confused with NORMAL USE.

While both include the concept of use as intended by the MANUFACTURER, INTENDED USE focusses on the medical purpose. NORMAL USE incorporates not only the medical purpose, but maintenance, service, transport etc..

Compliance is checked by inspection of the instructions for use.

CE MARKING CAN CONTRIBUTE TO THE JUSTIFICATION PROCESS

ARTICLE 78.2

- COCIR Members agree that the information held by the manufacturer about the risk assessment and the clinical evaluation, related to ionizing radiation, can be made available for the application of Art. 78.2 Directive 2013/59/Euratom
- This information is suited for the justification process related to new classes of medical practices (see next slide).
- COCIR agrees to cooperate with HERCA to identify the relevant information and to work for the definition of an harmonized format which can be made available. It is important the effort is coordinated by HERCA.
- Already existing standards providing an important guidance on how to select relevant information should be recognized.

CE MARKING CAN CONTRIBUTE TO THE JUSTIFICATION PROCESS

CE MARKING

- The CE marking process implies:
  - Risk minimization based on conformity to safety standards
  - Risk minimization supported by risk management adressing residual risks remaining after the conformity to standards is implemented
  - Clinical evaluation
  - Final risk-benefit evaluation resulting from both the results of the risk management process and of the clinical evaluation
- COCIR recommends:
  - That implementation of article 55 is supported by the content of the CE marking technical file that refers to risks related to ionization radiation: conformity to standards, risk management file and clinical evaluation with the final risk benefit evaluation.

LIMITATIONS OF CE MARKING

- COCIR agrees with point V of the HERCA "discussion paper" concerning the lack of compatibility between CE marking/MDD and BSS
  - "Member State may not allow the use of a MD put on the market, considering for instance that the risk for patient is too high in comparison with the expected benefit, or taking into account *"information about other techniques and technologies"* (Art.19.2 Council Directive 2013/59/Euratom). ", even if "it meets the general safety and performance requirements which apply to it (set out in Annex I of the Medical Device Regulation, including specific requirements for MD using Ionizing Radiation).
- This creates a barrier to the free circulation of goods