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CRITERIA FOR ACCEPTABILITY OF MEDICAL RADIOLOGICAL EQUIPMENT IN EURATOM LEGISLATION

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The treaty establishing the European Atomic Energy Community ('Euratom Treaty') is binding primary law for 27 member states of the European Union (EU) with about 500 million inhabitants. Council Directive 96/29/Euratom is a secondary EU law establishing the Basic Safety Standards (BSS) for protection of the health of workers and the general public. The BSS Directive is supplemented by other binding instruments, medical exposure being regulated under Council Directive 97/43/Euratom ('Medical Exposures Directive', MED). MED, Article 8 (3), stipulates that the EU member states shall adopt criteria of acceptability for medical radiological equipment in order to indicate when action is necessary, including taking the equipment out of service. A few years ago, the European Commission ('the Commission', EC) started a revision of the Euratom BSS encompassing, among others, a codification of similar legal acts including MED. The draft legal proposal contains a number of changes on medical exposure and, while no amendments have been made on the criteria for acceptability, some of them (e.g. those concerning the requirements for equipment in use and the involvement of the medical physics expert) may have a direct influence in this area. The Commission submitted the revised Directive to the Council of the European Union in September 2011; the adoption depends on the procedures in the Council. In order to facilitate the implementation of MED, Article 8 (3), in 1997 the Commission published '*Radiation Protection 91: Criteria for acceptability of radiological (including radiotherapy) and nuclear medicine installations*'; an update of RP 91 was launched in 2007 and planned for publication in early 2012 (as RP 162).

EURATOM LEGAL BASIS FOR RADIATION PROTECTION

In the field of nuclear energy, the treaty establishing the European Atomic Energy Community ('Euratom Treaty')[1] is binding primary law for 27 member states of the European Union with about 500 million inhabitants. Since its entry into force in 1958, the Euratom Treaty has provided the foundations on which the European institutions and member states share their competencies and discharge their respective responsibilities[2]. The main tasks under the Euratom Treaty are defined in its Article 2, among them to protect the health of the workers and the public against the dangers arising from ionising radiation.

Chapter III, Health and Safety, of the Euratom Treaty offers the legal framework for the establishment of Euratom Basic Safety Standards (BSS) for the health protection of workers and the general public. The first Euratom BSS date back to 1959, and the latest version, Council Directive 96/29/Euratom[3], was published as the Euratom secondary law in 1996. According to Article 31 of the Euratom Treaty, the Euratom BSS is worked out by the Commission after it has obtained the opinion of a group of public health experts.

The Euratom BSS has been supplemented by additional binding instruments, the relevant piece of legislation with regard to medical exposure being the Council Directive 97/43/Euratom ('Medical Exposures Directive', MED)[4]. The European Commission also issues documents of a non-binding nature, which have different status in the hierarchy of EU-instruments and include, for example, recommendations, communications and guidance.

CRITERIA FOR ACCEPTABILITY OF EQUIPMENT IN DIRECTIVE 97/43/EURATOM

Article 8 (3) of Council Directive 97/43/Euratom creates legally binding responsibility for the member states of the European Union to 'adopt specific *criteria of acceptability for equipment* in order to indicate when appropriate remedial action is necessary, including, if appropriate, taking the equipment out of service'. This shall be done as part of the competent authorities' responsibility to 'take steps to ensure that necessary measures are taken by the holder of the radiological installation to improve inadequate or defective features of the equipment'.

The MED requirements for acceptability criteria[1] are supported by several other legal provisions on testing and performance of medical radiological

[1]While the strict legal term in MED is 'criteria of acceptability for equipment', 'criteria for acceptability' or 'acceptability criteria' are also used in the text interchangeably.

equipment in use in the European Union. For example, article 8 (2) introduces requirements for 'quality assurance programmes including quality control measures', 'acceptance testing' before first clinical use of equipment and 'performance testing' on a regular basis and after major maintenance. It should be noted that MED's testing requirements apply to all individual pieces of equipment used in clinical practice and to the users of the equipment, which distinguishes them from the testing requirements of the Medical Devices Directive[5] applicable to new types (or models) of equipment and to the equipment manufacturers. Direct restrictions and prohibitions on the use of certain equipment are defined in MED, Article 8 (4–6).

MED contains several other requirements, which influence the way in which acceptability criteria are adopted and used in practice. For example, the requirements of Article 6 (3) regarding the level of involvement of the Medical Physics Expert (MPE) in different types of medical procedures will influence the acceptability criteria and testing procedures used for the corresponding equipment. Other important provisions regarding the special attention required for performance and testing of equipment used on children, in health screening or in procedures 'involving high doses' are defined in Article 9.

REVISION OF THE EURATOM BSS

In 2007, following the adoption of the latest recommendations of the International Commission for Radiological Protection[6], the European Commission launched a revision of the existing Euratom legislation on radiation protection. The revision aimed at updating the legislation in line with the latest knowledge and technological developments and at simplifying it by the integration of five current legal acts, BSS and MED among them, into a single Euratom Directive ('revised Euratom BSS'). In September 2011, the Commission adopted a formal legal proposal for a revised Euratom BSS[7].

Relevant changes in the revised Euratom BSS

Even though the MED has been widely recognised as one of the most advanced pieces of legislation on radiation protection in medical exposure, some changes in the current requirements have been proposed. These changes stem from the need to have a coherent text of the revised Euratom BSS, for incorporation of experience gained in the implementation of the legislation over the past 10 years and for taking into account developments in the medical area not foreseen back in the 1990s. These changes are mainly contained in Chapter VII of the draft revised Euratom BSS but some, for example, on education and training of medical staff, are found in other parts of the proposal. While the legal provisions on criteria for acceptability of equipment remain unchanged in the Commission's proposal, there are some other changes relevant to this area.

The medical physics expert

The proposed new definition and detailed description of MPEs' responsibilities seek to provide a link between her/his required competences and assigned responsibilities (in relation to medical exposure only). The requirements on involvement of the MPE in medical exposure procedures have been changed to strengthen her/his presence in high-dose radiological imaging examinations. It is now explicitly required that the MPE be involved in the acceptance testing of equipment.

New requirements for equipment

The revised Euratom BSS requires that any system used for interventional radiology and computed tomography shall have a device informing the practitioner of the quantity of radiation produced by the equipment during the medical radiological procedure. Any other medical radio-diagnostic equipment shall have such a device or equivalent means of determining the quantity of radiation produced. The radiation dose shall form part of the report on the examination.

Revised Euratom BSS adoption procedures

According to Article 31 of the Euratom Treaty Commission's proposal for a revised Euratom, BSS shall be first presented for the opinion of the European Economic and Social Committee (EESC). At the time of writing, April 2012, EESC issued a favourable opinion[8] not requesting any changes to the proposal. According to the Euratom Treaty procedures, the proposal, together with the EESC opinion, should be sent to the European Parliament for their (non-binding) opinion and to the Council of the EU. The Council has its own working procedures and the proposal may be discussed in one or more committees or working parties before being formally adopted. Only after adoption by the Council will the revised Euratom BSS become part of binding for the EU Member States legislation.

It should also be noted that since the revised Euratom BSS is a Council Directive, it is not directly implemented by the Member States, but transposed (within deadlines defined in the Directive) into national law. According to Article 33 of the Euratom Treaty, the draft national provisions shall be submitted to the Commission, who can issue recommendations on the correct transposition.

EUROPEAN GUIDANCE ON ACCEPTABILITY CRITERIA

In 1997, in order to facilitate the implementation of MED's Article 8 (3) the European Commission published '*Radiation Protection 91. Criteria for acceptability of radiological (including radiotherapy) and nuclear medicine installations*'[9] (RP91). According to the European Commission's foreword to RP91, the document contains 'a flavor of' non-binding criteria of acceptability 'prepared to assist competent authorities in their task to establish or to review criteria of acceptability, also called minimum criteria'. It is also clearly stated that the criteria in RP91 are different from, and should not be confused with, the requirements for design and construction of radiological and nuclear medicine equipment defined under the Medical Devices Directive. Finally, already at this early stage of the development of European criteria for acceptability, the Commission realised the need for their frequent update and declared that the RP91 report 'will be reviewed on a regular basis'. This document has been widely used in the EU Member States, and abroad, as a basis for establishing national criteria for acceptability of radiological equipment.

Revision of European Guidelines

In line with earlier commitments, in 2006 the Commission issued a call for tenders for updating of RP91 in accordance with the technological development in the past decade. The document had to be expanded to cover technologies that developed rapidly in the 1990s and 2000s, in particular digital radiography, multi-slice computed tomography and positron emission tomography systems as well as linear accelerators and treatment planning systems used in radiotherapy. The work on this project commenced in 2007 and was successfully finalised in October 2009 when the final draft was produced and presented to the Commission.

In line with its long-time practice, the Commission asked the advice of the group of experts created under Article 31 of the Euratom Treaty, who recommended that due to the technical complexity and compass of the document, it should be subject to public consultation and discussion before being adopted as European Guidelines and part of the EC Radiation Protection series of publications (http://ec.europa.eu/energy/nuclear/radiation_protection/publications_en.htm). Following this advice, from January to June 2010 the Commission carried out an open public consultation and collected more than 1800 comments on the draft (to which the RP162 number was assigned). Another EC tender was then issued to address public consultation comments on draft RP162, organise a workshop to discuss any remaining issues and finalise the publication. The workshop was actually a part of this project and a reworked draft RP162 was distributed prior to it. The final draft report should be produced several months after the workshop and the RP162 publication should be published in the Commission's Radiation Protection series in 2012.

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