## COCIR contribution to the Draft European Basic Safety Standards (BSS) Directive

<table>
<thead>
<tr>
<th>Draft European BSS Directive</th>
<th>Previous text in Medical Directive 97/43/EURATOM or BSS Directive 96/29/EURATOM</th>
<th>Rationale</th>
<th>Proposed text</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>TITLE VI JUSTIFICATION AND REGULATORY CONTROL OF PLANNED EXPOSURE SITUATIONS</strong></td>
<td>New</td>
<td>There is a Risk of multiple authorization procedures in the different member states causing delays for placing new products on the market. The Information to be provided to the Competent Authorities is very extensive and does not seem justified.</td>
<td><strong>Article 47 - New types of apparatus or products</strong> 1. With regard to new types of apparatus or products:  (a) Any undertaking intending to place on the market in European Union a new type of apparatus or product, shall inform the competent authority of the Member State in which he has his registered place of business of the address of the registered place of business and the description of the device concerned. (b) the undertaking must keep at the disposal of the competent authority, for a period ending at least five years after the last product has been placed</td>
</tr>
<tr>
<td>Article 47 - New types of apparatus or products</td>
<td>1. With regard to new types of apparatus or products:  (a) Member States shall require any undertaking intending to place on the market a new type of apparatus or product to provide the competent authorities with relevant information such as listed in Annex 7a to enable the authorities, on the basis of national requirements such as listed in Annex 7b, to decide whether the intended use is justified, to grant the manufacturer or importer with a type approval for the apparatus or product, and where appropriate permit its use as a consumer product outside regulated practices.  (b) The competent authorities may review the</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

---

1. The aim of the EURATOM recast is to update the legal requirements, in the light of the new International Commission on Radiological Protection (ICRP) Recommendations published in 2007 (ICRP Publication 103), to take into account the experience gained by Member States and the Commission and to simplify the EURATOM radiation protection legislation (Basic Safety Standards (BSS) Directive (96/29/Euratom), Medical Directive (97/43/Euratom), Directive on High Activity Sealed Sources (2003/122/Euratom), Directive on Outside Workers (90/641/Euratom), Directive on Public Information (89/618/Euratom)).


existing authorisations and type approvals on a regular basis, and if necessary withdraw the authorisation when there is new and important evidence on the efficacy or potential consequences of the use of the apparatus or product.

(c) The competent authorities shall inform the competent authorities of other Member States of the type approvals that have been granted and of the underlying documentation and assessment; competent authorities shall allow for such received information, as well as applicable European and international standards, in making their own decisions with regard to authorising or exempting the use of such types of apparatus or product.

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

on the market, the information such as listed in Annex 7a
### Article 85 - Equipment
1. Member States shall take such steps as they may consider necessary with a view to avoiding unnecessary proliferation of medical radiological equipment.
2. Member States shall ensure that:
   - all medical radiological equipment in use is kept under strict surveillance regarding radiation protection,
   - an up-to-date inventory of medical radiological equipment for each medical radiological installation is available to the competent authorities,
   - appropriate quality assurance programmes including quality control measures and dose or administered activity assessments are implemented by the undertaking, and
   - acceptance testing, involving the medical physics expert, is carried out before the first use of the equipment for clinical purposes, and thereafter performance testing on a regular basis, and after any major maintenance procedure.
3. Competent authorities shall take steps to ensure that necessary measures are taken by the undertaking to improve inadequate or defective features of the equipment. They shall also 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.
4. The use of fluoroscopy equipment without a device to control the dose rate, or without an image intensifier or equivalent device, is not justified and shall therefore be prohibited.

### 97/43/EURATOM Article 8 - Equipment
1. Member States shall take such steps as they may consider necessary with a view to avoiding unnecessary proliferation of radiological equipment.
2. Member States shall ensure that:
   - all radiological equipment in use is kept under strict surveillance regarding radiation protection,
   - an up-to-date inventory of radiological equipment for each radiological installation is available to the competent authorities,
   - appropriate quality assurance programmes including quality control measures and patient dose or administered activity assessments are implemented by the holder of the radiological installation, and
   - acceptance testing is carried out before the first use of the equipment for clinical purposes, and thereafter performance testing on a regular basis, and after any major maintenance procedure.
3. Competent authorities shall 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. They shall also 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.
4. The use of fluoroscopy equipment without a device to control the dose rate, or without an image intensifier or equivalent device, is not justified and shall therefore be prohibited.

There is a need for European homogenous criteria for acceptance testing. COCIR strongly recommends the EC to define a uniform system for acceptance testing and common acceptability criteria.
5. 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 radiodiagnostic equipment brought into use after this Directive has been brought into force shall have such a device or equivalent means of determining the quantity of radiation produced. In this case the radiation dose shall form part of the report on the examination.

remedial action is necessary, including, if appropriate, taking the equipment out of service.

4. In the case of fluoroscopy, examinations without an image intensification or equivalent techniques are not justified and shall therefore be prohibited.

5. Fluoroscopic examinations without devices to control the dose rate shall be limited to justified circumstances.

6. If new radiodiagnostical equipment is used, it shall have, where practicable, a device informing the practitioner of the quantity of radiation produced by the equipment during the radiological procedure.

In order to inform practitioners about the quantity of radiation produced, it is not necessarily needed to equip already in use or new equipment with a “device”. The information requested is rather related to a function and the displaying of such information. Most accurately this is expressed by the word “feature”.

In addition, if this function can only be added via a new “device”, this may cause delay in the availability.

5. Any system used for interventional radiology and computed tomography shall have a feature informing the practitioner of the quantity of radiation produced by the equipment during the medical radiological procedure. Any other medical radiodiagnostic equipment brought into use after this Directive has been brought into force shall have such a feature or equivalent means of determining the quantity of radiation produced. In this case the radiation dose shall form part of the report on the examination.
**Article 88 - Accidental and unintended exposures**

Member States shall ensure that
(a) all reasonable steps to minimize the probability and the magnitude of accidental or unintended exposures of patients from all medical radiological procedures are taken, economic and social factors being taken into account.
(b) for radiotherapeutic practices the quality assurance programme includes a study of risk of accidental or unintended exposures.
(c) for all medical exposures the undertaking implements a registration and analysis system of events involving or potentially involving accidental or unintended exposures.
(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.
(e) arrangements are made to inform the referrer, the practitioner and the patient about an unintended or accidental exposure.

**97/43/EURATOM**

**Article 11 – Potential Exposure**

Member States shall ensure that all reasonable steps to reduce the probability and the magnitude of accidental or unintended doses of patients from radiological practices are taken, economic and social factors being taken into account. The main emphasis in accident prevention should be on the equipment and procedures in radiotherapy, but some attention should be paid to accidents with diagnostic equipment. Working instructions and written protocols as referred to in Article 6 (1) and quality assurance programmes as referred to in Article 8 (2) and the criteria referred to in Article 8 (3) are of particular relevance for this purpose.

COCIR recommends that this process of reporting accidental and unintended exposure to be consistent with European Vigilance System already in place in the framework the Directive 93/42/EEC. In particular a single Competent Authority should coordinate the investigation and the follow-up of the corrective action.

**Article 89 - Estimates of population doses**

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.

**97/43/EURATOM**

**Article 12 - Estimates of population doses**

Member States shall ensure that the distribution of individual dose estimates from medical exposure referred to in Article 1 (2) is determined for the population and for relevant reference groups of the population as may be deemed necessary by the Member State. COCIR recommends that weight categories should also be determined. This would avoid patient selection based on weight to report the doses.
### Annex 7 Placing on the market of apparatus or products

**a)** Any undertaking intending to place on the market apparatus or products provides the competent authorities with all relevant information as to the:
- technical characteristics of the apparatus
- in case of apparatus containing radioactive substances, information on the means of fixation of the source in a holder and on shielding
- dose rates at relevant distances for the use of the apparatus or product, including dose rates at a distance of 0.1 m of any accessible surface
- intended use of the apparatus or product, information on the relative performance of the new apparatus or product compared to existing ones
- expected doses to regular users of the apparatus.

**b)** The competent authorities will make an assessment of the above information and in particular assess:
- whether the performance of the apparatus or product justifies its intended use;
- whether the design is adequate in order to reduce the exposures in normal use and the likelihood and consequences of misuse or accidental exposures;
- in case of consumer products, whether the

<table>
<thead>
<tr>
<th>New. See Art 47</th>
<th>Same rationale as for Article 47 above.</th>
<th>Delete Annex 7b</th>
</tr>
</thead>
</table>
| a) Any undertaking intending to place on the market apparatus or products, shall keep at the disposal of the competent authority, for a period ending at least five years after the last product has been placed on the market, the following information:
- technical characteristics of the apparatus
- in case of apparatus containing radioactive substances, information on the means of fixation of the source in a holder and on shielding
- dose rates at relevant distances for the use of the apparatus or product, including dose rates at a distance of 0.1 m of any accessible surface
- intended use of the apparatus or product, information on the relative performance of the new apparatus or product compared to existing ones
- expected doses to regular users of the apparatus. | New. See Art 47 | Same rationale as for Article 47 above. | Delete Annex 7b |
product is adequately designed and does not necessitate specific precautions for disposal when it is no longer in use;
- in case of apparatus or products for use in practices, whether conditions for disposal are adequate;
- whether the apparatus or product is appropriately labelled and suitable documentation is provided to the customer with instructions for proper use and disposal.