REPORT

Working Group:
"Safety of medical devices emitting ionising radiation"

November 2010

Articulation of basic requirements of Directive 97/43/ EURATOM and IAEA recommendations shared with the essential requirements of Directive 93/42/EEC concerning medical devices used in external radiotherapy

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SUMMARY

After the initial dysfunctions or events reported between the beginning of 2007 and mid-2008, in particular in radiotherapy, the AFSSAPS and the ASN[1] created a working group. This was done to determine the consistency between safety and radiation protection requirements with essential requirements applicable to medical devices (MD) emitting ionising radiation. Work of the group clarified consistency between European regulations involving the placing on the market of MD emitting ionising radiation and radiation protection, as well as required paths for progress.

In general, the working group did not detect any shortfall in the existing system concerning CE marking of MD. It also believes that the new provisions proposed in the draft Euratom Directive represent genuine progress compared to those of Directive 97/43.

The working group nevertheless issued the following recommendations:

1. Concerning requirements and recommendations of the IAEA[2], the working group would like more precise details on the respective responsibilities of equipment manufacturers and operators, concerning defence in depth, the assessment of safety and feedback from precursor events and incidents. At this occasion and in cooperation with the IEC[3], the IAEA should be able to determine relevant international standards pertaining to both methodology or organisation, and the safety of equipment and any possible additional needs; in particular this concerns the protection of software used for linear accelerators.

2. Concerning the requirements for CE marking, the working group proposes:
   a. reclassifying the following MD in class III: MD emitting ionising radiation for therapeutic use, treatment planning software, and radiotherapy record and verify systems (see appendix IX of Directive 93/42/EEC concerning medical devices);
   b. the preparation of a European MEDDEV guide to interpret Directive 93/42/EEC (MDD) devoted to the safety of medical devices used in external radiotherapy, in particular to deal with aspects related to including the measurement function in basic requirements, usability, installations acceptance, compatibility among the different medical devices in the chain of preparation and treatment and user training;
   c. verification by the European Commission of the thoroughness of the list of existing harmonised standards (EN[4]), which give a presumption of conformity with essential requirements (ER) applicable to medical devices emitting ionising radiation and their completeness with respect to requirements and recommendations of the IAEA.

3. Concerning new radioprotection and safety requirements in the draft Euratom Directive, the working group:
   a. has remarked that, in compliance with the requirements of the IAEA, the analysis of radiotherapy risks limited to the radiation protection of patients should be extended to risks to staff and the public, and that in-house collating and analysing significant events should also be included as precursor events;
   b. believes that more details should be added to the European guide planned by the Commission in order to clarify the links between defence in depth, risk analysis and feedback, and to highlight the value of including the results of the risk analysis conducted by the manufacturer in the framework of CE marking;
   c. also proposes to require in the draft Directive that personnel using equipment or maintaining it in correct operating condition benefit from a programme of training and qualification in the context of their continuous (on the job) training.

[1] AFSSAPS: French health products safety agency; ASN: French Nuclear Safety Authority
[2] International Atomic Energy Agency
[3] International Electrotechnical Commission
[4] European Standardization

INTRODUCTION

After the initial dysfunctions or events reported between the beginning of 2007 and mid-2008, in particular in radiotherapy, the AFSSAPS and the ASN created a working group. This was done to determine the consistency between safety and radiation protection requirements with essential requirements (ER) applicable to medical devices emitting ionising radiation. This concerns requirements to consider or useful recommendations when placing on the market this equipment in Europe and during its operation, in particular linear accelerators used in radiotherapy. The major goal of this work is the better understanding of all regulatory requirements arising from European Directives[5] and to place them in perspective with international recommendations arising from either IEC/ISO standards or stipulations of the IAEA. This working group whose composition is shown in appendix 6 was composed of representatives of competent authorities in France, Belgium and Switzerland regulating medical devices and radioprotection, one representative of a French standards body for the electrotechnical field and representatives of French users. The work done under the auspices of the working group involved:

- questioning manufacturers of medical devices used in radiotherapy (linear accelerators, treatment planning systems (TPS), record and verify systems (R&V) on the standards they apply to claim compliance of their medical devices with essential requirements that could have an impact on radiation protection (see appendix 1 for the list of basic requirements concerned);
- inventory horizontal and vertical harmonised European standards ("product" standard) applicable to one of the types of medical devices emitting ionising radiation, linear accelerators;
- inventory radiation protection requirements arising from regulations and international recommendations applicable to medical devices emitting ionising radiation, especially radiotherapy linear accelerators;
- compare radiation protection requirements and basic requirements applicable to medical devices emitting ionising radiation, especially radiotherapy linear accelerators.

This document is a report on this work. It contains a summary below and 6 appendices.

Appendix 1 contains the mains essential requirements applicable to medical devices emitting ionising radiation, especially those used in radiotherapy (pages 12 to 14).
Appendix 2 contains the results of a survey involved the manufacturers of medical devices used in radiotherapy (linear accelerators, TPS, R&V) (pages 15 to 21).
Appendix 3 contains the main European regulatory requirements and recommendations in international standards of the IAEA (pages 22 to 45).
Appendix 4 presents the bibliography of references examined (page 46).
Appendix 5 introduces a reference from the IRSN[6] report dealing with the safety of radiotherapy treatments and defence in depth (page 47).
Appendix 6 gives the list of members of the working group (page 48).

I SUMMARY OF THE STUDY

The placing on the market of medical devices (MD) are based on a European regulatory framework, governed by so-called "new approach" Directives. They require manufacturers of medical devices to affix CE marking to their product before it is placed on the market. This CE marking symbolises the conformity of their devices with essential requirements described in Appendix I of Directive 93/42/EEC. Some requirements are specific to medical devices emitting ionising radiation, in particular medical devices used in external radiotherapy. This Directive mentions that it shall not affect the application of Directive 96/29/Euratom or that of Directive 97/43/Euratom (see article 1.8). These two Directives concern the protection of populations, workers and patients from the dangers of ionising radiation. As a result, medical devices using ionising radiation must comply with the provisions of the new approach Directive 93/42/EEC and those of Euratom Directives. For purposes of simplification, Directive 96/29/Euratom was not included in the study since is deals more with the protection of patients.

[5] Directive 97/43/Euratom and Directive 93/42/EEC, modified in particular by Directive 2007/47/EC
[6] IRSN: French Institute of Radioprotection and Nuclear Safety

I.1. Survey of manufacturers of medical devices used in external radiotherapy

The March 2009 survey of manufacturers of medical devices used in radiotherapy (see Appendix 2, p. 13) first showed that checking the conformity with the essential requirements in relation with the radiation protection of patients or workers, manufacturers in general referred practically exclusively to international standards for medical devices. It was also noted that the times required for spreading and application of the latest versions of international standards are undoubtedly too long.

Standard EN ISO 14971 on the application of risk management to medical devices is a major reference used by manufacturers for the assessment of radiation-related risks. This standard requires the manufacturer to determine the compatibility of his device with other equipment used in the chain of radiotherapy. The responses to the survey, however, showed that all manufacturers do not systematically consider that their device is one of the links in this chain.

Most manufacturers of accelerators and TPS believe that essential requirements for devices with measuring function are not applicable to their medical devices. In this case, it is to be assured that the design of medical devices addresses the question of the precision of measurements necessary for their correct operation.

I.2. Study of regulations governing the marketing of medical devices and radioprotection

After this survey conducted on R&V, TPS and accelerators, the working group inventoried radiation protection requirements arising from regulations and standards of the IAEA[7] that are applicable to these medical devices.

This study examined European provisions (Directive 97/43/Euratom[8] and Directive 93/42/EC) and IAEA safety requirements. The goal was to identify requirements that are or could be applicable to manufacturers of medical devices used in radiotherapy, but also to radiation protection. Harmonised European standards applicable to medical devices were then included in this work with respect to the radiation protection topics dealt with. This last phase was submitted to a manufacturer of linear accelerators for an opinion and no comments were received.

This first part of this study initially involved examining basic requirements of Directive 97/43/Euratom and essential requirements of Directive 93/42/EEC in an attempt to determine how they interact. It was found that the requirements set by Directive 97/43/Euratom concerned the user or operator of equipment emitting ionising radiation and did not address the responsibility of manufacturers, especially concerning design. It can be noted, however, that except two requirements in Directive 97/43/Euratom concern design, manufacture and installation of medical devices and involve manufacturers:

1. the obligation of having a device to measure the dose delivered during a radiology procedure (applicable only to manufacturers);
2. the obligation for formal acceptance of medical devices emitting ionising radiation that requires acceptance controls (applicable to manufacturers and operators).

Work on these two Directives has enabled table 1 of appendix 3 to be prepared.

The working group pointed out the value of improvements to essential requirements provide by Directive 2007/47/EC which can contribute to radiation protection principles (justification and optimisation) in Directive 97/43/Euratom. Concerning the notion of usability, the following are requested:

- reducing, as far as possible, the risk of use error due to the ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety),
- consideration of the technical knowledge, experience, education and training of intended users

[7] Standard of the IAEA: they are consensus international recommendations prepared in the context of work by representatives of IAEA member states not part of IEC or ISO international standards organisations.

[8] Directive 97/43/Euratom, applicable at the time this document was prepared, is being revised by the European Commission whose drafts (Draft Euratom Basic Safety Standards Directive) are available on the Commission Web site: http://ec.europa.eu/energy/nuclear/radiation_protection/article_31_en.htm. Since these documents are still provisional, the study was conducted with respect to a officially adopted text.

I.3. Study of IAEA requirements and recommendations

It was decided to study IAEA requirements to extend the study of regulatory aspects. This part of the study involved collating international safety and radiation protection recommendations, applicable in particular to operators of linear accelerators used for radiotherapy (see table 2 of Appendix 3).

The first finding of this work is that IAEA requirements should address the responsibilities of operators, without directly addressing those of equipment manufacturers. These requirements envisage the possibility of including the manufacturer but not naming him as principal responsible party, in particular for making sure the equipment complies with required standards (see BSS 115, points II.13 and II.15), or to conduct safety assessments or ensure that the devices are tested to demonstrate that they comply with relevant specifications, (see RS-G-10, points 3.3 and 4.3). The role of manufacturers of medical devices emitting ionising radiation is thus undoubtedly underestimated. If this position is adapted to industrial installations, it nevertheless remains relatively incompatible with the responsibilities that can really be assumed by users of medical devices emitting ionising radiation for medical purposes. Operators of medical installations do not participate in the design of the equipment they use, delivered after ordering from the catalogue of manufacturers' equipment. Most of these devices are thus standard equipment with variable numbers of options selected by a customer. In rare cases, the equipment is developed for a specific customer need (case of hadron therapy) as a result the state of medical research, a small target population and the existence of a marginal number of partnerships between manufacturers and users.

The second finding of the examination of IAEA requirements is that in the context of the clinical use of ionising radiation, some major principles of international standards have not been included in European requirements involving radiation protection and the safety of installations. Even though the principle of justification and the principle of optimisation are contained in Directive 97/43/Euratom/EC, some principles applicable to the safety of installations using ionising radiation are not mentioned. We may cite:

1. The principle of 'defence in depth', in particular mentioned in basic safety principles arising from points 3.31 and 3.32 of SF-1 of the IAEA basic safety requirements and in basic standards of the IAEA, and point 2.35 of BSS 115, currently being revised.
2. The safety assessment, cited in point 2.37 of BSS and in basic safety principles arising from point 3.15 of basic safety requirements SF-1 and developed in detail in guide RS-G-1.10 defining the safety of radiation generators and sealed radioactive sources, and in guide GSR-Part 4 concerning the assessment of safety of installations and of activities totally devoted to this subject.
   Guide RS-G-1.10 concerning the safety of radiation generators and sealed radioactive sources proposes that manufacturers evaluate the generic safety of irradiation equipment for radiotherapy to make this information available to users before on-site reception (points 3.3 3.6 and 3.14). It is also recommended to consider ergonomics and human factors in risks of error, as well as the abusive use of equipment in points 3.8 and 3.12. This document also contains these safety evaluations in point 3.7 IV.4.
   Guide GSR-Part 4 also stipulates, in addition to conducting a safety assessment (points 1.7, 1.8, 2.3, 2.6, 3.2, 4.5, 4.6, 4.13) and applying the principle of defence in depth (point 4.12), an independent verification of how the assessment of safety was conducted, including an overall examination (document examination) and a spot verification (tests of equipment) (see point 4.67). Independent verification is conducted by sufficiently qualified and experienced people or a group, other than those who conducted the safety assessment. Its purpose is to determine if the safety assessment was acceptably conducted.
3. Feedback of precursor events and incidents cited in point 3.16 of SF-1 basic safety requirements and in point 4.3 IV.9 b) of guide RS-G-1.10 defining the safety of radiation generators and sealed radioactive sources.

I.4. Study of harmonised standards (EN) for linear accelerators

After the study of IAEA requirements and those of Directive 97/43/Euratom, it was decided to compare them to harmonised European standards (EN) requirements that can be applied to linear accelerators for the demonstration of compliance with the essential requirements of Directive 93/42/EEC, to determine to what extent international radiation protection requirements have been considered and implemented.
These standards involve primarily general safety requirements (EN 60601-1, EN 60601-1-1), risk management (EN 14971), usability (EN 60601-1-6), and finally particular requirements for electron accelerators (EN 60601-2-1).
Remark: The EN are often used by manufacturers for the demonstration of compliance with the essential requirements of Directive 93/42/EEC, the EN).

The conclusion; This study shows in particular that the EN 60601-2-1 concerning particular requirements for the safety for electron accelerators could be enriched by such (Table No. 2 – Appendix 3, p. 20 to 44) :

i. a signal to indicate in the facilities, the presence of a beam (irradiation under way) mentioned in point II.13 d) of BSS 115 of the IAEA;
ii. more precise requirements concerning characteristics and details of beams used in radiotherapy and indicated in points e) , f) d) of BS 115 and in points b) and c) of the guide defining the safety of radiation generators and sealed radioactive sources RS-G-1.10;
iii. design instructions concerning irradiation installations used for radiotherapy and in particular the selection, display and confirmation of operating parameters;
iv. requirements for suppliers to communicate information on the use of radiotherapy medical devices (ex: compatibility among the different medical devices used for example in stereotaxic radiotherapy) and their maintenance mentioned in point 4.3 IV.8 b) of the guide RS-G-1.10 defining the safety of radiation generators and sealed radioactive sources

II DISCUSSIONS AND RECOMMENDATIONS OF THE WORKING GROUP

At the end of these studies and survey, the working group proposed areas for further thought, based on the analysis of differences observed between international radiation protection requirements of the IAEA, basic requirements of Directive 97/43/Euratom, essential requirements of CE marking and requirements of standards (EN, IEC, ISO). Clarifications on these topics could enable manufacturers to place more emphasis on the safety of equipment and to clarify the sharing of responsibilities between manufacturers and operators concerning the analysis and management of risks to patients, defence in depth, the assessment of safety and feedback from precursor events and incidents.

II.1. Concerning requirements and recommendations of the IAEA

The working group would like more precise details on the respective responsibilities of facility operators and equipment manufacturers concerning defence in depth, and the assessment of safety and feedback from precursor events and incidents. The working group thinks that in cooperation with the IEC, the IAEA should be able to determine relevant international standards pertaining to both methodology or organisation, and the safety of equipment and any possible additional needs; in particular these concerns the protection of software used for particle accelerators.

II.2. Concerning the requirements for CE marking

1. Reclassify medical devices used in external radiotherapy.

   The IAEA requirements (GSR Part 4 points 4.66 and 4.71) provide firstly that the manufacturers have to carry out an independent verification of the safety assessment and secondly that the regulatory authority must conduct an independent verification of the installation to determine if the safety assessment is acceptable. All requirements of Directive 93/42/EEC applicable to therapeutic medical devices emitting ionising radiation, and those for manufacturers related to radiation protection, must undergo a design control before the placing on the market. This overall reinforcement of provisions concerning design evaluation could be improved by making them systematic and confiding this role to the notify body. To do this, it will be necessary to reclassify medical devices emitting ionising radiation for therapeutic use and treatment planning software, as well as radiotherapy record and verify systems in class III. Independent control would be a means of introducing an evaluation of requirements for usability (ergonomics) and software development (design and maintainability), among other things.

   This reclassification would also require the manufacturer to conduct clinical investigations, except if the use of existing clinical data can be duly justified (see I.2). This is especially true for medical devices with innovative functions. In this context, the manufacturer will confirm that the performance levels claimed for his medical device have been reached, at the same time as maximally reducing risks.

   This reclassification will require a modification of Directive 93/42/EEC by a special committee, by applying article 7 of this Directive.

2. Prepare a European MEDDEV guide for the interpretation of Directive 93/42/EEC devoted to the safety of medical devices used in external radiotherapy.

   This guide should enhance the clarity of interactions among essential requirements, harmonised standards and radiation protection principles in Euratom Directives, and in particular to deal with the following points:

   a. Usability:

      Requirements of the IAEA (GSR Part 4 point 5.7) stipulate that the results of the safety assessment of an installation must be used to define the skill set required of the operator and of his staff. Directive 2007/47/EEC, modifying Directive 93/42/EC, effective since March 2010, introduces requirements concerning usability. This must lead the manufacturer of a radiation-generating device to include this new notion in his risk management and to take it into account when designing the device. It is to be noted that a harmonised standard dedicated to usability of medical devices exists (NF EN 62366 (2006) Application of usability engineering to medical devices). When this principle is applied, it is seen that manufacturers of radiation-emitting therapeutic medical devices should supply alert and error messages in French because of potentially urgent situations.

   b. Reception – Compatibility:

      Requirements of the IAEA (BSS 115 point 2.38) stipulate conducting acceptance tests of installations. The manufacturer should provide the user with precise and detailed elements for acceptance tests of the installation. He should also inform the latter of requirements for compatibility among the different medical devices used in the treatment chain, including their accessories, and also on the consequences of upgrades of one of the links in the treatment chain, in particular software upgrades.

   c. Training:

      Requirements of the IAEA (BSS No. 115 point 2.30 and GSR Part 4 point 5.7) stipulate that the results of the safety assessment of the installation must be used to guide staff training and that measures shall be taken reduce the contribution of human error. The manufacturer of radiotherapy instruments should provide the user with precise and detailed elements on required training conditions so that users have relevant tools available for both initial and on the

job training in order to reduce human errors. These training programmes must be conducted contractually between manufacturers and operators.

3. Identify needs for standards

   The working group has noted that there exist international standards edited primarily by the IEC but also by the ISO. They are transversal or particular to a type of medical device, some of which are harmonised for Europe (EN) and that contain certain radiation protection requirements.

   In light of IAEA requirements and recommendations in the domain of safety and radiation protection applicable to medical devices, the group proposes that the Commission ensures that existing harmonised standards (EN) responding to the essential requirements updated in 2007 and applicable to medical devices are emitting ionising radiation:

   1. are harmonised to be claimed in order to give a presumption of conformity of products with essential requirements;
   2. cover all IAEA requirements and recommendations.

   Finally, since the time for approval of new harmonised European standards for these high risk medical devices is too long, the group proposed inciting manufacturers to more rapidly apply new standards for high risk devices.

II.3. Concerning radiation protection requirements of Euratom Directives

The group found that the three underlying principles (defence in depth, safety assessment, feedback of precursor events and incidents) of IAEA safety requirements are not found in European radiation protection rules (Directives 96/29 and 97/43).

It also found that although the absence of the principle of safety assessment is partly compensated by Directive 93/42/EEC, requiring risk management by manufacturers before marketing and throughout the lifetime of equipment, the obligation of conducting a risk assessment of each radiotherapy installation in Europe would augment safety in care with respect to incidents having been reported over the past several years. These provisions should increase the sharing of manufacturers' risk analysis data with users, and thus exchanges of information. As a result of users' understanding of the operational procedures adopted in each radiotherapy centre, they could more easily conduct a risk assessment specific to their installation by incorporating both risks from equipment an those resulting from organisational and human factors (see point 4.5 GSR Part 4 and points 3.3 and 3.14 of RS-G-1.10).
There is an advantage from sharing data on risk analyses of equipment between the manufacturer and the user that must include the prevention of abnormal operating conditions. It will formalise the principle of defence in depth that in case of failure of one safety feature ensures there is a backup of a different type in order to prevent the failure, and limit or attenuate these effects (see point 3.31 of SF-1). This principle would in fact be easier to implement by users who could then adapt their organisation in order to reinforce a measure of protection taken by a manufacturer against a given failure (see point 2.35 of BSS No. 115 and point 4.15 of GSR Part 4).

1. Extend new provisions of the draft Euratom Directive concerning risk analysis and management, and facilitate their implementation.

   a. Analysis of "a priori" risks

      It should be mentioned that the current project to totally revise Directive 97/43/Euratom introduces the obligation of operators to conduct an analysis of radiotherapy risks to patients, (article 88 of the draft Euratom Directive of 24 February, 2010). With reference to IAEA requirements, however, this analysis should not be limited to risks for to patient but should include risks to workers and the public, and be kept up to date.

      With respect to this type of obligation, the group is encouraging the preparation of a European methodology guide for analysing risks to radiotherapy patients[9]. Since the draft Euratom

[9] In France, the ASN has prepared a guide for self-assessment of risks to external radiotherapy patients. It extends the first guide by preparing a second guide for self-assessment of risks to radioisotope therapy patients. This work could be used for European work.

Directive does not contain specific regulatory restrictions, in order to carry out the analysis of a priori risks, the guide should recommend using results of the manufacturer's risk analysis in the framework of CE marking. The group also found it of interest that these analyses provide feedback to manufacturers that would be useful to them in the context of the post-marketing follow-up stipulated in appendix X of Directive 93/42/EEC.

b. Feedback ("a posteriori" analysis)

Finally, it is possible to create the obligation for users to provide feedback (see point 3.17 of SF-1) concerning difficulties encountered during the commissioning, operation and maintenance of various medical devices of the treatment chain (see point 4.3 - IV.9 a) and b) of RS-G-1.10). This would also be useful for the concrete implementation of the principle of defence in depth and for enhanced understanding of different installations by users and manufacturers.

For this point, the working group has also noted that the draft Euratom Directive introduces the obligation for operators to implement a system for recording events for all medical exposures that could cause accidental or unexpected exposures and to analyse their causes (article 89). In line with the requirements of the IAEA, the groups pointed out that this feedback should have been extended to precursor events.

The consideration of user feedback (a posteriori analysis of causes of events) should be used as input for the periodic update of the risk analysis (a priori). This point should be dealt with in the methodology guide for risk analyses in preparation.

In general, the future risk analysis guide prepared by the Commission should clarify the relationships between risk analysis and the principle of defence in depth, and between the obligation of feedback and updating the risk analysis.

2. Reinforce obligations for user training

The draft Directive should require that staff using equipment or maintaining benefits from a programme of training and qualification, with the obligation of periodic verification of this qualification.

In addition, the European Commission is currently preparing has a call for tenders, seeking a bid for developing the methodology of these analyses.

CONCLUSION

Work by the group has clarified the interactions between European regulations involving the placing on the market of MD emitting ionising radiation and radioprotection, as well as the required paths for progress.

In general, the working group did not find a shortfall in the system implemented for the CE marking of MD. It also believes that new provisions proposed in the draft Euratom Directive are genuine progress compared to those of Directive 97/43.

It nevertheless seems necessary to better consider the requirements of the IAEA in European regulation. This involves better cooperation between the Commission and the IAEA, with the objectives or reinforcing provisions of the Euratom Directive and extending it if necessary, harmonised European standards and to reclassify MD used in external radiotherapy in class III, including software.

The group recommends initially the preparation of a MEDDEV guide for the placing on the market and putting into service of MD used in external radiotherapy and the inclusion of links between risk analysis and the principle of defence in depth and feedback and updating the risk analysis in the draft Commission guide for radiation protection.

Appendix 1

Extract from the main essential requirements (ER) of Directive 93/42/EEC in relation to radiation protection requirements for medical devices used in radiotherapy

ER	DESCRIPTION	PROBLEMATIC
1. Essential requirements I – General requirements 1		
1	The devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their intended use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety. This shall include: — reducing, as far as possible, the risk of use error due to the ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety), and — consideration of the technical knowledge, experience, education and training and where applicable the medical and physical conditions of intended users (design for lay, professional, disabled or other users).)	Reducing risk to the patient of utilisation error (importance of ergonomics) and taking into account the technical knowledge, experience and training of users.
9. Construction and environmental properties		
9.1	If the device is intended for use in combination with other devices or equipment, the whole combination, including the connection system must be safe and must not impair the specified performances of the devices. Any restrictions on use must be indicated on the label or in the instructions for use.	Compatible accessories Software compatibility
9.2	Devices must be designed and manufactured in such a way as to remove or minimize as far as is possible: — the risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional and where appropriate ergonomic features,	Beam characteristics
10. Devices with a measuring function		
10.1	Devices with a measuring function must be designed and manufactured in such a way as to provide sufficient accuracy and stability within appropriate limits of accuracy and taking account of the intended purpose of the device. The limits of accuracy must be indicated by the manufacturer.	Beam characteristics
10.2	The measurement, monitoring and display scale must be designed in line with ergonomic principles, taking account of the intended purpose of the device.	Beam characteristics Ergonomics

ER	DESCRIPTION	PROBLEMATIC
11. **Protection against radiation** 11.1 *General*		
11.1.1	Devices shall be designed and manufactured in such a way that exposure of patients, users and other persons to radiation shall be reduced as far as possible compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes.	Beam characteristics
11.2 **Intended radiation**		
11.2.1	Where devices are designed to emit hazardous levels of radiation necessary for a specific medical purpose the benefit of which is considered to outweigh the risks inherent in the emission, it must be possible for the user to control the emissions. Such devices shall be designed and manufactured to ensure reproducibility and tolerance of relevant variable parameters.	Beam characteristics
11.3 **Unintended radiation**		
11.3.1	Devices shall be designed and manufactured in such a way that exposure of patients, users and other persons to the emission of unintended, stray or scattered radiation is reduced as far as possible.	Beam characteristics
11.4 **Instructions**		
11.4.1	The operating instructions for devices emitting radiation must give detailed information as to the nature of the emitted radiation, means of protecting the patient and the user and on ways of avoiding misuse and of eliminating the risks inherent in installation.	Beam characteristics
11.5 **Ionizing radiation**		
11.5.1	Devices intended to emit ionizing radiation must be designed and manufactured in such a way as to ensure that, where practicable, the quantity, geometry and quality of radiation emitted can be varied and controlled taking into account the intended use.	Beam characteristics Software compatibility
11.5.3	Devices emitting ionizing radiation, intended for therapeutic radiology shall be designed and manufactured in such a way as to enable reliable monitoring and control of the delivered dose, the beam type and energy and where appropriate the quality of radiation	Beam characteristics
12. **Requirements for medical devices connected to or equipped with an energy source** 12.8 *Protection against the risks posed to the patient by energy supplies or substances*		
12.8.1	Devices for supplying the patient with energy or substances must be designed and constructed in such a way that the flow-rate can be set and maintained accurately enough to guarantee the safety of the patient and of the user.	Beam characteristics
12.8.2	Devices must be fitted with the means of preventing and/or indicating any inadequacies in the flow-rate which could pose a danger. Devices must incorporate suitable means to prevent, as far as possible, the accidental release of dangerous levels of energy from an energy and/or substance source.	Beam characteristics Ergonomics
12.9	The function of the controls and indicators must be clearly specified on the devices. Where a device bears instructions required for its operation or indicates operating or adjustment parameters by means of a visual system, such information must be understandable to the user and, as appropriate, the patient.	Ergonomics

ER	DESCRIPTION	PROBLEMATIC
13. **Information supplied by the manufacturer** 13.6 *Where appropriate, the instructions for use must contain the fallowing particulars:*		
13.6.b	the performances referred to in Section 3 and any undesirable side-effects;	Beam characteristics
13.6.c	if the device must be installed with or connected to other medical devices or equipment in order to operate as required for its intended purpose, sufficient details of its characteristics to identify the correct devices or equipment to use in order to obtain a safe combination.	Compatible accessories Software compatibility
13.6.d	all the information needed to verify whether the device is properly installed and can operate correctly and safely, plus details of the nature and frequency of the maintenance and calibration needed to ensure that the devices operate properly and safely at all times;	Beam characteristics
13.6.j	In the case of devices emitting radiation for medical purposes, details of the nature, type, intensity and distribution of this radiation.	Beam characteristics
13.6.k	Precautions to be taken in the event of changes in the performance of the device.	Beam characteristics

Appendix 2

Safety and radiation protection of medical devices emitting ionising radiation - Summary of the survey

I- Context: reminder of the procedure

At the last meeting of the working group of safety and radiation protection of medical devices (MD) held on 14 October 2008, it was decided to conduct a survey of manufacturers of radiation-generating medical devices concerning their considerations of and compliance with essential requirements of Appendix I of Directive 93/42/EEC with respect to protection from ionising radiation.

The goal of this survey was to create an inventory of the solutions adopted by manufacturers to comply with essential requirements (ER) of design (Appendix I part 2 of Directive 93/42/EEC concerning medical devices) that could have an impact on radiation protection of patients, users and third parties.

In order to best meet this goal, the choice of MD and manufacturers concerned by the survey was modified. After giving thought to the issue, if was found of interest to be able to compare the responses of different manufacturers for the same type of MD.

The survey conducted in March 2009 thus involved the following MD:

- Linear accelerators:
  - Artiste (Siemens)
  - Clinac Trilogy (Varian)
  - Synergy (Elekta)
- Treatment planning systems (TPS):
  - Isogray (Dosisoft)
  - Monaco (CMS)
  - Pinnacle (Philips)
- Radiotherapy recording and verification systems (R&V):
  - Aria (Varian)
  - Lantis (Siemens*)
  - Sequencer (Impac)

For each ER (see Appendix 1), manufacturers were asked to precisely provide the references used and their justification.

The results of this survey are presented below.

II- Result of the AFSSAPS/ASN survey

The first finding is that all manufacturers responded.

Concerning the solutions adopted to respond to essential requirements (ER) that could have an impact on radiation protection of patients, users and third parties, manufacturers generally responded to the survey by referring to international standards, although without precisely indicating the relevant part(s) of these standards used to comply with the ER in question.
The vast majority of responses indicated the standard or reference with no further details on the solutions adopted to comply with ER
There were differences among manufacturers concerning the number of standards or other references applied to respond to the ER of the survey. The manufacturers thus did not automatically mention the same standards to comply with the same ER, resulting is some heterogeneity in the list of standards applied.
In the preface of the questionnaire, all the standards indicated by manufacturers as being applied were subsequently not used to justify the compliance of the medical devices in question with ER of the survey.
Some manufacturers use international ISO or IEC standards and European standards, whether or not harmonised.
There are also differences between manufacturers in terms of their use of versions of standards so that the most recent versions that may be known to manufacturers at the time of development of their medical devices are not always used, e.g. EN 60601-1-2:2007 not used by one manufacturer using standard EN 14971: 2007 or EN 14971: 2007, in turn not used by a manufacturer using standard EN 60601-1-2: 2007).

As a complement to international standards for the quality management (EN ISO 13485/EN ISO 9001) and risk management systems (EN ISO 14971), manufacturers practically exclusively applied international standards in the health sector.
In addition to general safety standards applicable to the MD concerned by the survey, manufacturers also use specific standards of safety proper to each MD: EN 60601-2-1 (accelerator), EN 62083 (TPS), EN 62274 (R&V) for only one of the manufacturers.

Concerning ER of chemical, physical and biological properties (ER 7.1), a point that concerns only accelerators, manufacturers did not address the issue of the choice of material with respect to its susceptibility to be activated by ionising radiation or exposure to radiation emitted by activation products accounting for more than 50% of the total effective dose (source: IRNS report, reference DRPH/SDE No. 2007-034)

Concerning manufacturing and environment properties (ER 9.1, 13.6.c, other information), most manufacturers claimed the application of risk management standard EN 14971 to justify compliance with compatibility requirements between their medical device and accessories. The responses did not show that all of them considered the fact that their medical device is one of the links in a chain of medical devices, e.g. for an accelerator, solutions implemented so it is compatible with an imaging medical device or an R&V is not clearly stated. The manufacturer must thus plan on the use of his MD in this environment, in particular by risk management. Nevertheless, simply using the risk management standard is not sufficient to justify claims of compatibility of the device in the radiotherapy treatment chain. Similarly, not applying a requirement for compatibility is not valid since these MD never function on a stand-alone basis.
In the same vein, simply referring to "compliance" with the DICOM[10] reference does not guarantee the safe operation of the MD in its environment.

Concerning the latter, is would undoubtedly be of value for all manufacturers to apply DICOM references (IEC 61852, IEC/TR 62266) and extend their approaches if necessary with health informatics standards, e.g. EN 12052 (Digital imaging – Communication, workflow and data management).

[10] Digital Information and COmmunication in Medicine

Most manufacturers of accelerators and TPS consider that ER for devices with a measurement function (ER 10.1 and 10.2) are not applicable to their MD because the primary purpose of these devices is probably not to make measurements. Even so, all of these MD conduct measurements (doses, rotation angles, distances on anatomical images, etc.). In this context, all manufacturers could use these ER and indicate the solutions adopted to comply with them. With this in mind, the fact that some manufacturers claim, for instance, compliance with standard EN 61217 (radiotherapy equipment, coordinates, movements and scales) is insufficient.

Furthermore, ER 10.1 and 10.2 also refer to ergonomic principles. In this area, manufacturers could use standard ISO 1000 (SI units and recommendations for the use of their multiples and of certain other units) or other ergonomic references.
This aspect is also related to usability and one of the two manufacturers of accelerators claimed using standard EN 60601-1-6.
Among the manufacturers of TPS and R&V, only one applied a standard for this subject (EN 62366).

For the part directly related to radiation (ER 11.1 to 12.8), most manufacturers of TPS and R&V considered that their MD did not emit radiation. Only two manufacturers of R&V indicated that the risk of unwanted exposure was included in the evaluation of effects of the medical device on the entire chain, without offering more details.

In general it can also be pointed out that almost all manufacturers did not claim using standard EN 60601-1-8: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems.

Only one accelerator manufacturer stated applying standard EN 60976, not harmonised, concerning functional performance characteristics of the machine. This standard specifies test methods for determining and declaring functional characteristics in accompanying documents and harmonisation of this standard could be of use in the industry.
On the contrary, only one manufacturer used standard EN 62304 concerning software life cycle processes, even though this standard is harmonised. As a result and in the absence of equivalent solutions adopted, the demand to harmonise existing and relevant European standards could also be extended by recommendations to manufacturers to consider applying standards that currently are seen as relevant by only some of them.

Finally, it is difficult to reach a conclusion on the responses by accelerator manufacturers, in particular on aspects directly related to the protection of patients from unintentional ionising radiation (application of the principle of optimisation). For example, no response was precise enough to determine if unintentional irradiation due to activation products resulted in closing the collimation system after each treatment. As a result, these details may be sought in the standards used, and work on the analysis of standards with respect to radiation protection requirements is undoubtedly required to extend this analysis.

The following tables list the references mentioned in this survey. The standards that manufacturers had declared to be applied in a 2007 survey are also given for the record.

		Accelerator 1 (2007)	Accelerator 1 (2009)	Accelerator 2 (2007)	Accelerator 2 (2009)	Accelerator 3 (2007)	Accelerator 3 (2009)
EN 980	Graphical symbols for use in the labelling of medical devices (2003)	_	_	A[11]	_	_	A
ISO 1000	SI units and recommendations for the use of their multiples and of certain other units (1992)	_	_	_	_	_	A
EN 1041	Information supplied by the manufacturer of medical devices (1998)	_	_	_	_	_	A
EN 1252	Standard Practice for General Techniques for Obtaining Infrared Spectra for Qualitative Analysis (2004)	_	_	_	_	_	A
EN ISO 10993-1	Biological evaluation of medical devices – Part. 1: Evaluation and testing (2003)	_	_	A	A	_	_
EN ISO 13485	Medical devices – Quality management systems – Requirements for regulatory purposes (2003)	_	A	A	A	_	A
EN ISO 14971	Medical devices – Application of risk management to medical devices (2000 New edition ISO in 2007)	A	A	A	A	_	A
EN 46001	Quality systems -- Medical devices -- Particular requirements for the application of ISO 9001 (1996)	_	_	_	_	A	_
IEC 60417	Graphical symbols for use on equipment (new ed. en 2007)	_	_	A	_	_	_
EN 60601-1	Medical electrical equipment -- Part 1- General requirements for basic safety (1990 New ed. in 2007)	A	A	A	A	A	A
EN 60601-1-1	Medical electrical equipment – Part. 1-1 General requirements - Collateral standard: General requirements for medical electrical systems (2001)	_	_	A	A	_	A
EN 60601-1-2	Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests (2001)	A	A	A	A	A	A
EN 60601-1-3	Medical electrical equipment -Part .1 General requirements for basic. safety Collateral Standard: General requirements for Radiation protection in diagnostic X-ray equipment (1994).	P	P	_	_	_	_
EN 60601-1-4	Medical electrical equipment –Part 1: General requirements for safety – Collateral Standard: Programmable electrical medical systems (1996)	A	A	A	A	_	A
EN 60601-1-6	Medical electrical equipment - Part 1-6: General requirements for safety - Collateral standard: Usability (2004)	_	A	_	A	_	_
EN 60601-1-8	Medical electrical equipment – Part. 1-8: General requirements for basic safety and essential performance – Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems (2004)	_	A	_	_	_	_
EN 60601-2-1	Medical electrical equipment -Part 2-1: Particular requirements for the safety of electron accelerators in the range of 1 to 50 MeV; Amendment 1 (2002)	A	A	A	A	A	A
EN 60601-2-11	Medical electrical equipment -Part 2-11: Particular requirements for the safety of gamma-beam therapy equipment (1997)	_	_	_	_	_	A
EN 60601-2-29	Medical electrical equipment - Part 2-29: Particular requirements for the safety of radiotherapy simulators.(1999)	P	P	_	_	_	_

[11] *A: Applied standard*
P: Partially applied standard

EN 60601-2-32	Medical electrical equipment – Part 2-: Particular requirements for the safety of associated equipment of x-ray equipment (1994)	P	P	_	_	_	_
EN 60601-2-44	Medical electrical equipment. Particular requirements for safety. Particular requirements for the safety of X-ray equipment for computed tomography (2001)	P	P	_	_	_	_
EN 60825-1	Safety of laser products – Part. 1: Equipment classification, requirements and user's guide (1993)	_	_	_	A	_	_
IEC 60878	Graphical symbols for electrical equipment in medical practice (2003)	_	_	A	_	_	_
EN 60950-1	Information technology equipment. Safety. General requirements	_	A	_	_	_	_
EN 60976	Medical electrical equipment. Medical electron accelerators. Functional performance characteristics (1999)	_	_	A	_	_	A
IEC 60977	Medical electrical equipment. Medical electron accelerators within the 1 Mev to 50 Mev range. Guidelines for functional performance characteristics (1989)	_	_	A	_	_	A
EN 61217	Radiotherapy equipment - Coordinates, movements and scales (1996 – edition IEC 2002, = IEC 1217)	_	A	A	A	_	A
IEC 61852	Technical Report (TR 3) - Medical electrical equipment - Digital imaging and communications in medicine (DICOM) - Radiotherapy objects (1998)	_	A	A	_	_	A
EN 62274	Medical electrical equipment – Safety of radiotherapy record and verify systems (2005)	_	_	_	_	_	A
NEMA: PS3	Digital Imaging and Communications in Medicine (DICOM)	_	A	A	_	_	_
IEC/TR 62226 (2002)	Medical electrical equipment - Guidelines for implementation of DICOM in radiotherapy	_	A	_	_	_	_
UL 187	UL Standard for Safety for X-Ray Equipment	_	_	_	_	A	_
UL 60601-1	General safety requirements for medical electrical equipment	_	_	A	_	A	_
CAN/CSA-C22.2 No. 601.1-M90	Medical electrical equipment – Part. 1: General requirements for basic safety.		_	_	_	A	_
CAN/CSA-C22.2 No. 114-M90	Diagnostic Imaging and Radiation Therapy Equipment	_	_	_	_	A	_

A: Applied standard
P: Partially applied standard

		TPS1 (2007)	TPS1 (2009)		TPS2 (2007)	TPS2 (2009)		TPS3 (2007)	TPS3 (2009)
EN 980	Graphical symbols for use in the labelling of medical devices (2003)	_	_		_	_		A	A
EN 1041	information supplied by the manufacturer with medical devices (1998)	_	_		_	_		A	A
EN ISO 9001	Quality management systems – Requirements (2000)	A	A		A	_		_	_
EN ISO 13485	Medical devices -- Quality management systems -- requirements for regulatory purposes (2003)	A	A		A	A		A	A
EN ISO 14971	Medical devices -- Application of risk management to medical devices (2000 – rd: new ed. ISO in 2007)	A	A		A	A		A	A
EN 60601-1	Medical electrical equipment. Part. 1: General requirements for basic safety (1990 – new ed. in 2007)	_	_		_	_		_	A
EN 60601-1-1	Medical electrical equipment. Part. 1-1: General requirements for safety. Collateral standard. Safety requirements for medical electrical systems (2001)	_	_		_	_		A	_
EN 60601-1-2	Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests (2001)	_	_		_	_		_	A
EN 60601-1-4	Medical electrical equipment – Part 1-4: General requirements for safety – Collateral Standard: Programmable electrical medical systems (1996)	_	_		A	A		_	_
EN 60601-1-6	Medical electrical equipment. General requirements for basic safety and essential performance. Collateral Standard. Usability	_	_		_	_		_	A
EN 60950-1	Information technology equipment - Safety - Part 1: General requirements (2006)	_	_		_	_		A	A
EN 61217	Radiotherapy equipment - Coordinates, movements and scales (1996 or ed. IEC 2002 = IEC 1217°	_	A		A	A		_	_
EN 62083	Medical electrical equipment - Requirements for the safety of radiotherapy treatment planning systems (2001)	A	A		A	A		_	_
EN 62304	Medical device software -- Software life cycle processes (2006)	_	_		_	_		_	A
EN 62366	Medical devices -- Application of usability engineering to medical devices (2008)	_	_		_	_		_	A
NEMA PS 3 DICOM	Digital Imaging and Communications in Medicine (DICOM)	_	_		_	A		_	A
IAEA TECDOC 1540	Standard - Specification and acceptance testing of radiotherapy treatment planning systems	_	_		_	_		_	A

A: Applied standard
P: Partially applied standard

		R&V1 (2007)	R&V1 (2009)		R&V2 (2007)	R&V2 (2009)		R&V3 (2007)	R&V3 (2009)
ISO 1000	SI units and recommendations for the use of their multiples and of certain other units (1992)	–	–		–	–		–	A
EN 1041	Information supplied by the manufacturer with medical devices (1998)	–	–		–	–		A	A
EN ISO 9001	Quality management systems – Requirements (2000)	A	A		–	A		–	–
EN ISO 13485	Medical devices – Quality management systems requirements for regula purposes (2003)	A	A		A	A		A	A
EN ISO 14971	Medical devices -- Application of risk management to medical devices (2000 – New ed. ISO in 2007)	A	A		A	A		A	A
EN 60601-1-4	Medical electrical equipment –Part 1-4: General requirements for safety – Collateral Standard: Programmable electrical medical systems (1996)	A	A		A	A		A	A
EN 61217	Radiotherapy equipment - Coordinates, movements and scales (1996 or ed. IEC 2002 = IEC 1217)	–	–		A	–		A	A
EN 62274	Medical electrical equipment - Safety of radiotherapy record and verify systems (2005)	–	–		–	–		A	A
NEMA: PS3.1-PS3.12	Digital Imaging and Communications in Medicine (DICOM)	–	–		A	–		–	–
IEC 61852	Technical Report (TR 3) - Medical electrical equipment - Digital imaging and communications in medicine (DICOM) - Radiotherapy objects (1998)	–	–		–	–		–	A
EN 1252	Health informatics – Digital imaging – Communication workflow and data management (2004).	–	–		–	–		–	A

A: Applied standard
P: Partially applied standard

Appendix 3

Generals guidelines of requirements and recommendations on radiation protection with essential requirements (ER) (directive 93/42/EEC)

Table 1 – Comparison with Directive 97/43 and Directive 93/42

Reference articles of directive 97/43	Thematic	Description	Topics	Observations in regarding the essential requirements (ER)
Article 3	General principle	Medical exposure referred to in Article 1 (2) shall show a sufficient net benefit, weighing the total potential diagnostic or therapeutic benefits it produces, including the direct health benefits to an individual and the benefits to society, against the individual detriment that the exposure might cause, taking into account the efficacy, benefits and risks of available alternative techniques having the same objective but involving no or less exposure to ionizing radiation.	Justification	More general principle ER 1 states that: The devices must be designed and manufactured in such a way that, when used in the intended conditions and for purposes intended, they will not compromise the clinical condition or the safety of patients or the safety and health of users or, if applicable, of other persons, provided that any risks which may be associated with their intended use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.
Article 4	General principle	All doses due to medical exposure for radiological purposes except radiotherapeutic procedures referred to in Article 1 (2) shall be kept as low as reasonably achievable consistent with obtaining the required diagnostic information, taking into account economic and social factors. For all medical exposure of individuals for radiotherapeutic purposes, as mentioned in Article 1 (2) (a), exposures of target volumes shall be individually planned; taking into account that doses of non-target volumes and tissues shall be as low as reasonably achievable and consistent with the intended radiotherapeutic purpose of the exposure.	Optimization	Concept similar to that of optimisation in ER 11.1.1 and ER 11.2.1 (not specific to ionising radiation)

Reference articles of directive 97/43	Thematic	Description	Topics	Observations in regarding the essential requirements (ER)
Article 8	General principle	Obligation testing out before the first use of the equipment.	Equipment	Not considered in ER There nevertheless exists IEC standard 60976 concerning tests to describe the functional characteristics of the accelerator.
Article 8	General principle	Obligation to equip the facilities of a device for measuring dose as far as practicable.	Equipment	Not considered as such in ER ER 11.5.1 requires adjustment and the control of quantity, geometry and quality of ionising radiation to the extent possible. A specific French measure has been added to the Public Health Code to require all medical devices emitting ionising radiation to also measure the dose delivered to the patient. (Art. 1 of decree No. 2004-547 of 15 June, 2004 modifying Appendix I of Volume V a)
Article 11	General principle	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.	Potential exposure	Concept of reduction of risks of error in ER 1 modified by Directive 2007/47/EC, of risks of lesions in ER 9.2 and unintentional exposure to irradiation in ER 11.3.1

Table 2 – Comparison of international standard of safety and radiation protection and the essential requirements (ER) health and safety applied for linear accelerators.

Reference recommendation	Thematic	Description	Topics	Possible links with essential requirements (ER)	Possible links with EN standards	Comments
BSS No. 115	Main requirements for practises - Scope	2.1. The practices to which the Standards shall apply include: (a) The production of sources […] 2.2. The sources within any practice to which the requirements for practices of the Standards shall apply include: a) […] radioactive substances and devices that contain radioactive substances or produce radiation, including consumer products, sealed sources, unsealed sources, and radiation generators, including mobile radiography equipment; […]	Manufacture of medical devices emitting ionizing radiation Use of medical devices emitting ionizing radiation			BSS are composed primarily of principal instructions and appendices containing complements. The principal instructions define what is essential if the objectives set down in the preface to BSS are to be reached. The resulting subsidiary detailed instructions are explained in the appendices. Instructions in Appendix II are considered to be complements to applicable instructions for optimising protection that are stated in the principal instructions.

Reference recommendation	Thematic	Description	Topics	Possible links with essential requirements (ER)	Possible links with EN standards	Comments
BSS No. 115	Main requirements for practises – Requirements management	2.30 Provision shall be made for reducing as far as practicable the contribution of human error to accidents and other events that could give rise to exposures, by ensuring that:				
		a) all personnel on whom protection and safety depend be appropriately trained and qualified so that they understand their responsibilities and perform their duties with appropriate judgement and according to defined procedures;	a) Training personnel In terms of protection and safety a) Qualification personnel In terms of protection and safety	a) ER 1	EN 14971	a) is more detailed than the 2nd paragraph of ER 1 modified by Directive 2007/47/EC.
		b) sound ergonomic principles be followed as appropriate in designing equipment and operating procedures, so as to facilitate the safe operation or use of equipment, to minimize the possibility that operating errors will lead to accidents, and to reduce the possibility of misinterpreting indications of normal and abnormal conditions;	b) Safe use b) Ergonomic equipment	b) ER 1, ER 12.8.2 and ER 12.9.	EN 60601-1-6 EN 62366	b) is more detailed than the 1st paragraph of ER 1 modified by Directive 2007/47/EC and than ER 12.8.2 and 12.9.
		c) appropriate equipment, safety systems, and procedural requirements be provided and other necessary provisions be made: i) to reduce, as far as practicable, the possibility that human error will lead to inadvertent or unintentional exposure of any person;;	c) Equipment characteristics security systems and Procedures ▪ Reducing the possibility of occurrence of errors ▪ Error detection ▪ Facilitate intervention in case of failure	c) ER 1, ER 9.2 and ER 11.3.1. ER 1.2	EN 60601-1-6 EN 62366	c) is more detailed than the 1st paragraph of ER 1 modified by Directive 2007/47/EC and than ER 9.2 and 11.3.1.

Reference recommendation	Thematic	Description	Topics	Possible links with essential requirements (ER)	Possible links with EN standards	Comments
		ii) to provide means for detecting human errors and for correcting or compensating for them; and iii) to facilitate intervention in the event of failure of safety systems or of other protective measures..				
BSS No. 115	Main requirements for practices – Technical requirements	2.35 A multilayer (defence in depth) system of provisions for protection and safety commensurate with the magnitude and likelihood of the potential exposures involved shall be applied to sources such that a failure at one layer is compensated for or corrected by subsequent layers, for the purposes of: a) preventing accidents that may cause exposure; b) mitigating the consequences of any such accident that does occur; and; c) restoring sources to safe conditions after any such accident..	Defence in depth: Subsequent layers for: ▪ Preventing accidents ▪ Mitigating the consequences of any accident ▪ Restoring sources to safe	Directive 93/42/EC implements a risk management system for general compliance with ER The main purposes of this risk management used in the design of a medical device are: a) to prevent dysfunctions from occurring; b) to attenuate the consequences of a dangerous situation if it arises.	EN 14971	The concept of successive multilayer defence (defence in depth) is applied to the operator. The purpose of this principle is to ensure that activities related to safety are subjected to partly overlapping regulations and generally organised in 5 levels. Thus, if one level fails, the next level comes into play to provide the expected protection. The 1st level prevents abnormal operating conditions and failures by selecting suitable requirements for: - design, manufacture (risk management required by Directive 93/42 EEC), - commissioning (recommendations have been made by French authorities (AFSSAPS and ASN) to avoid part of abnormal operating conditions and failures at the time of commissioning) - operation and maintenance of

Reference recommendation	Thematic	Description	Topics	Possible links with essential requirements (ER)	Possible links with EN standards	Comments
						the installation. As a result, part of the requirements of the 1st level are now taken into account, but what is expected from operation and maintenance and from other levels? Similarly, what is the situation on the 2nd and 3rd levels of the principle of defence in depth, in particular used to control abnormal operating conditions or accidental situations? As a result, the principle of defence in depth is insufficiently developed.
BSS No. 115	Main requirements for practices – Radiological monitoring and verifying compliance with requirements.	2.38. Monitoring and measurements shall be conducted of the parameters necessary for verification of compliance with the requirements of the Standards. 2.40 Records shall be maintained of the results of monitoring and verification of compliance, including records of the tests and calibrations carried out in accordance with the Standards.	Obligation to test for verify compliance with standards Obligation to deposit the result of monitoring and verification of compliance in accordance with the standards		EN 60601-2-1 EN 60976	Article 8 of Directive 97/43/Euratom introduces the obligation to conduct reception tests of equipment. It remains to be determined if outside quality controls of medical devices and technical radiation protection controls required in French regulations by the Public Health Code and the Labour Code are included in the spot verification to conduct during reception tests at the European level. Directive 93/42/EC does not require tests to verify compliance with standards. There nevertheless exists standard ISO EN 60976 enabling manufacturers who so desire to demonstrate the

Reference recommendation	Thematic	Description	Topics	Possible links with essential requirements (ER)	Possible links with EN standards	Comments
						functional characteristics of an accelerator
BSS No. 115 Appendices : II detailed requirements	Medicals exposures - Design considerations	II.11 The requirements for the safety of sources specified in other parts of the Standards shall also apply to sources used in medical exposure, where relevant, and, in particular, equipment used in medical exposure shall be so designed that: (a) failure of a single component of the system be promptly detectable so that any unplanned medical exposure of patients is minimized; and (b) the incidence of human error in the delivery of unplanned medical exposure be minimized.	Design feature of medical devices in terms of safety. ▪ Identifying the causes of failures; ▪ Prevision dosimetric consequences; ▪ Diminution risk of unintended exposure of a patient due to human error	Detection of the failure of a component and reduction of risk from human error is explained in ER 1 ER 11.3.1 deals in particular with unintentional exposure	EN 14971 EN 60601-2-1 EN 60601-1-6	
BSS No. 115 Appendices : II detailed requirements	Medicals exposures - Design considerations	II.13. Registrants and licensees, in specific co-operation with suppliers, shall ensure that, with regard to equipment consisting of radiation generators and that containing sealed sources used for medical exposures: a) whether imported into or manufactured in the country where it is used, the equipment conform to applicable standards of the International Electrotechnical Commission (IEC) and the ISO or to equivalent national standards; b) performance specifications and	Characteristics and specifications of equipment emitting ionising radiation in terms of safety: a) Obligations to require manufacturers to have a medical device compliant with IEC standards b) Language used for	For a), Directive 93/42/EC stipulates only the application of standards to presume compliance of medical devices with ER. For b), ER 13.1 to 6 are	EN 60601-1-1 to 1-6 are also IEC, just as EN 60601-2-1 b) EN 1041	Characteristics and specifications of equipment emitting ionising radiation in terms of safety: a) is even contrary to the principle of the so-called "new approach" Directives that call for the use of harmonised standards but without this being an obligation. MD that comply with harmonised standards are presumed to also comply with ER. The level of precision of b) is

Reference recommendation	Thematic	Description	Topics	Possible links with essential requirements (ER)	Possible links with EN standards	Comments
		operating and maintenance instructions, including protection and safety instructions, be provided in a major world language understandable to the users and in compliance with the relevant IEC or ISO standards with regard to 'accompanying documents', and that this information be translated into local languages when appropriate;	functional specifications and instructions for use and maintenance must be understandable by users.	applicable. ER 12.9 is also applied even if it is less precise.		more detailed than ER 12.9
		c) where practicable, the operating terminology (or its abbreviations) and operating values be displayed on operating consoles in a major world language acceptable to the user;	c) Operating parameters and abbreviations displayed on the control panels in a language acceptable for the user	For c), ER 12.9 is used even if it is less precise d) is more precise than ER 11.1.1	c) EN 60601-2-1 point 29.1.10 EN60601-1-6	The level of precision of c) is not included in ER.
		d) radiation beam control mechanisms be provided, including devices that indicate clearly and in a fail-safe manner whether the beam is 'on' or 'off';	d) Indication of the presence of the beam	ER 11.3.1 g) is more precise than ER 11.1.1, 11.5.3 and 12.8.1	d) EN 60601-2-1 point 29.1.1.10	The level of precision of d) is not included in ER.
		g) Exposure rates outside the examination or treatment area due to radiation leakage or scattering be kept as low as reasonably achievable.	g) Reduction of doses resulting from leaks or diffusion to the lowest possible level.		EN 60601-2-1	The level of precision of g) is not included in ER.
BSS No. 115 Appendices : II detailed requirements	Medicals exposures - Design considerations - Requirements for radiation generators and irradiation installations for radiotherapy	II.15. Registrants and licensees, in specific co-operation with suppliers, shall ensure that::	Features and specifications of devices transmitting ionizing radiations (IR) in terms of safety:	Characteristics and specifications of equipment emitting ionising radiation in terms of safety:		
		a) radiation generators and irradiation installations include provisions for selection, reliable indication and confirmation (when	a) Selection and reliable display of operating parameters (type of IR, energy, beam modification	For a) ER 11.1.1, 11.2.1, 11.5.1 to 11.5.3 concerning radiation and ER 12.8.1 and	a) EN 60601-2-1 Points 29.1	The level of precision of a) is not as detailed in ER. ER 11.1.1, 11.2.1, 11.5.1 to 11.5.3 concerning radiation or

Reference recommendation	Thematic	Description	Topics	Possible links with essential requirements (ER)	Possible links with EN standards	Comments
		appropriate and to the extent feasible) of operational parameters such as type of radiation, indication of energy, beam modifiers (such as filters), treatment distance, field size, beam orientation and either treatment time or preset dose;	device, duration of treatment and dose predefined)	12.8.2 concerning energy delivered to patients are applicable.		in ER 12.8.1 and 12.8.2 concerning energy delivered to patients.
		c) high energy radiotherapy equipment : i) have at least two independent 'fail to safety' systems for terminating the irradiation; and ii) be provided with safety interlocks or other means designed to prevent the clinical use of the machine in conditions other than those selected at the control panel;	c) Obligation of certain safety devices on the high energy radiotherapy.	For c) ER 11.1.1, 11.2.1, 11.5.1 to 11.5.3 concerning radiation and ER 12.8.1 and 12.8.2 concerning energy delivered to patients are applicable.	c) EN 60601-2-1 Points 29.1.1	The level of precision of c) is not included in ER 11.1.1, 11.2.1, 11.5.1 to 11.5.3 concerning radiation or in ER 12.8.1 and 12.8.2 concerning energy delivered to patients.
		d) the design of safety interlocks be such that operation of the installation during maintenance procedures, if interlocks are bypassed, could be performed only under direct control of the maintenance personnel using appropriate devices, codes or keys;	d) Obligation to requiring controlled access to the control system of the facility during his interview	For d) no ER to apply	d) EN60601-2-1 Points 29.1.10	d) is not in ER 11.1.1, 11.2.1, 11.5.1 to 11.5.3 concerning radiation or in ER12.8.1 and 12.8.2 concerning energy delivered to patients.
IAEA Safety Standards SF-1	Fundamental Safety Principles	3.3. The person or organization responsible for any facility or activity that gives rise to radiation risks or for carrying out a programme of actions to reduce radiation exposure has the prime responsibility for safety.	Principle of responsibility, which implements a nuclear activity			For medical devices emitting ionising radiation the responsibility of manufacturers for safety is not part of radiation protection standards. Nevertheless, manufacturers are fully responsible for aspects

Reference recommendation	Thematic	Description	Topics	Possible links with essential requirements (ER)	Possible links with EN standards	Comments
						of marketing authorisations as stipulated by Directive 93/42/EC. In addition, in the context of adopting the draft revision of BSS 115, France has requested the IAEA to review the part dealing with responsibilities of manufacturers and suppliers to strength forthcoming requirements. This work is under way and was scheduled to terminate in November 2010
IAEA Safety Standards SF-1	Fundamental Safety Principles	3.17. Despite all measures taken, accidents may occur. The precursors to accidents have to be identified and analysed, and measures have to be taken to prevent the recurrence of accidents. The feedback of operating experience from facilities and activities — and, where relevant, from elsewhere — is a key means of enhancing safety. Processes must be put in place for the feedback and analysis of operating experience, including initiating events, accident precursors, near misses, accidents and unauthorized acts, so that lessons may be learned, shared and acted upon.	Requirements of identification and analyze events leading to accidents and organization of a feedback of operating experience of the medical device.	Article 10 of Directive 93/42 stipulates the exchange of information on post-marketing incidents. Refer to the ASN decision	EN 14971 stipulates that information acquired while using medical devices is to be considered in terms of the appearance of a new risk or the discovery of a new consequence	The obligation to identify and analyse precursor events is in neither Directive 97/43/Euratom, nor in ER 1, 11.1.1, 11.2.1, 11.5.1 to 11.5.3 concerning radiation or in ER 12.8.1 and 12.8.2 concerning energy delivered to patients. Feedback from the occurrence of precursor events is absent from both Directive 97/43/Euratom and Directive 93/42/EC whereas it could be a complement to radiovigilance notifications (also absent from Directive 97/43) or material vigilance (introduced by Directive 93/42/EEC). In France, the Ministerial decree of 22 January, 2009 that approved decision No. 2008-DC-0103 of the Nuclear Safety Authority of 1 July, 2008

Reference recommendation	Thematic	Description	Topics	Possible links with essential requirements (ER)	Possible links with EN standards	Comments
						setting down radiotherapy quality assurance obligations defined in article R. 1333-59 of the Public Health Code requires the declaration and handling of precursor events within radiotherapy departments. In addition, the new Euratom Directive arising from the draft Euratom Basic Safety Standards Directive should include the requirement to declare events and their analysis with one part dealt with in-house and one part to be communicated to the competent authority with respect to certain criteria. French requirements will thus be extended to the European level.
IAEA Safety Standards SF-1	Fundamental Safety Principles	3.31. The primary means of preventing and mitigating the consequences of accidents is 'defence in depth'. Defence in depth is implemented primarily through the combination of a number of consecutive and independent levels of protection that would have to fail before harmful effects could be caused to people or to the environment. If one level of protection or barrier were to fail, the subsequent level or barrier would be available. When properly implemented, defence in depth	Introduction of the principle of defence in depth (Groups levels protection).	Obligation to conduct a risk analysis ER 1 ER 2	EN 14971	See point 2.35 of BSS (page 12) The concept of successive multilayer defence (defence in depth) does not exist as such in ER. Nevertheless, a part of the 1st level of the concept is included in Directive 93/42/EEC for design- and manufacturing-related aspects. For aspects related to commissioning, Directive 93/42/EEC does not address this subject; recommendations

Reference recommendation	Thematic	Description	Topics	Possible links with essential requirements (ER)	Possible links with EN standards	Comments
		ensures that no single technical, human or organizational failure could lead to harmful effects, and that the combinations of failures that could give rise to significant harmful effects are of very low probability. The independent effectiveness of the different levels of defence is a necessary element of defence in depth.				have nonetheless been made in France. Nothing exists for operation and maintenance, and for other levels.
IAEA safety standard - GSR Part 4	Safety assessment for facilities and activities - Scope	1.7. Safety assessment plays an important role throughout the lifetime of the facility or activity whenever decisions on safety issues are made by the designers, the constructors, the manufacturers, the operating organization or the regulatory body. The initial development and use of the safety assessment provides the framework for the acquisition of the necessary information to demonstrate compliance with the relevant safety requirements, and for the development and maintenance of the safety assessment over the lifetime of the facility or activity.	Requirements to conduct a risk analysis including manufacturers of medical devices but not conducting security assessment.	Obligation to conduct a risk analysis ER 1 ER 2	EN 14971	The principle of safety assessment is not included in Directive 97/43/Euratom. Nor is this principle included in Directive 93/42/EEC as such, but a risk analysis prior to marketing is nevertheless required. The application of standard EN 14971 is voluntary. It contains the obligation to enrich risk analysis for the entire lifetime of the medical device. This requirement 1.7 of GSR Part 4 is not easily understandable and must be clarified to know how to provide a precise response.
IAEA safety standard - GSR Part 4	Safety assessment for facilities and activities – Objective of the safety assessment	4.5. The safety assessment has to address all radiation risks that arise from normal operation (that is, when the facility is operating normally or the activity is being carried out normally) and from anticipated operational occurrences and accident conditions (in which	Responsibility for carrying out the safety assessment of all the radiation risks from the normal execution of the activity and the anticipated operational occurrences and accident conditions	Obligation to conduct a risk analysis ER 1 ER 2	EN 14971	The principle of safety assessment is not included in Directive 97/43/Euratom. Nor is this principle included in Directive 93/42/EEC as such, but a risk analysis prior to marketing is nevertheless required.

Reference recommendation	Thematic	Description	Topics	Possible links with essential requirements (ER)	Possible links with EN standards	Comments
		failures or internal or external events have occurred that challenge the safety of the facility or activity). The safety assessment for anticipated operational occurrences and accident conditions also has to address failures that might occur and the consequences of any failures.				
IAEA safety standard - GSR Part 4	Safety assessment for facilities and activities – Objective of the safety assessment	4.6. A Safety assessment has to be carried out at the design stage for a new facility or activity, or as early as possible in the lifetime of an existing facility or activity. For facilities and activities that continue over long periods of time, the safety assessment needs to be updated as necessary through the stages of the lifetime of the facility or activity, so as to take into account possible changes in circumstances (such as the application of new standards or new scientific and technological developments), changes in site characteristics, and modifications to the design or operation, and also the effects of ageing.	Requirement to conduct a safety assessment	Obligation to conduct a risk analysis ER 1 ER 2. Article 10: Information on post-marketing incidents with medical devices	EN 14971	Article 10 of Directive 93/42/EEC contains the obligation of post-marketing coordination of vigilance of medical devices that requires manufacturers to analyse the causes of an incident. The obligation to review the risk analysis, however, is required by the execution of commitments made by the manufacturers when the device was initially marketed. The Appendix states in point 3.1 " … a commitment by the manufacturer to implement and keep up to date a systematic procedure for examining data acquired by the device since its production, including the stipulations of Appendix X, and to implement suitable means to apply the necessary corrective measures. This commitment requires the manufacturer to inform competent authorities of the following incidents of which

Reference recommendation	Thematic	Description	Topics	Possible links with essential requirements (ER)	Possible links with EN standards	Comments
						it is aware: i) any dysfunction or any deterioration of the characteristics and/or performance of a device, as well as any unsuitability of labelling or in the instruction manual that could cause or have caused the death or serious degradation of the health of a patient or a user; ii) any technical or medical reason related to the characteristics or performances of a device and having caused, for the reasons stated in point i), the systematic recall of the same type of devices by the manufacturer." In addition, standard EN 14971, applied on a voluntary basis, stipulates the inclusion of new risks for the entire lifetime of medical devices.
IAEA safety standard - GSR Part 4	Safety assessment for facilities and activities – Objective of the safety assessment	4.15. The results of the safety assessment are used to determine appropriate safety related improvements to the design and operation of the facility or the conduct of the activity. The results will allow assessment of the safety significance of unremedied shortcomings or of planned modifications and may be used to determine priorities for	Safety improvements at the design stage through the results of the safety assessment.	Point 3.2 of Appendix II stipulates that documentation shall include design specifications, including standards that will be applied and the results of the risk analysis, as well as the description of solutions chosen to comply with basic	EN 14971	Directive 93/42/EEC stipulates that when carrying out procedures to determine the compliance of medical devices with requirements of directives, that the risk analysis results are included in the design of medical devices.

Reference recommendation	Thematic	Description	Topics	Possible links with essential requirements (ER)	Possible links with EN standards	Comments
		modifications. They may also be used to provide the basis for permitting the continued operation of the facility or conduct of the activity.		requirements applicable to the products when applicable harmonised European standards applicable are not fully applied.		
IAEA safety standard - GSR Part 4	Safety assessment for facilities and activities - Assessment of safety functions	4.20. All safety functions associated with a facility or activity are to be specified and assessed. This includes the safety functions associated with the engineered structures, systems and components, any physical or natural barriers and inherent safety features as applicable, and any human actions necessary to ensure the safety of the facility or activity. This is a key aspect of assessment, and is vital to the assessment of the application of defence in depth (see paras 4.45–4.48). An assessment is undertaken to determine whether the safety functions can be fulfilled for all normal operational modes (including startup and shutdown where appropriate), all anticipated operational occurrences and the accident conditions to be taken into account; these include design basis accidents and beyond design basis accidents (including severe accidents).	Assessment of safety functions to determine whether the safety functions can be fulfilled in the normal operating modes and fault.	ER 1 ER 2	EN 14971 EN 60601-2-1	Application of standard EN 60601-2-1 covers the technical aspects of design. The standard does not address organisational and human aspects.
IAEA safety standard - GSR Part 4	Safety assessment for facilities and activities – Evaluation of human factors	4.29. Where innovative improvements beyond current practices have been incorporated into the design, it has to be	Safety assessment particularly recommended for innovative improvements.	ER 1 ER 2 and ER 6 bis: demonstration of compliance with basic	EN 14791 EN 10993-1 PR NF EN ISO 14155	

Reference recommendation	Thematic	Description	Topics	Possible links with essential requirements (ER)	Possible links with EN standards	Comments
		determined in the safety assessment whether compliance with the safety requirements has been demonstrated by an appropriate programme of research, analysis and testing complemented by a subsequent programme of monitoring during operation.		requirements must include a clinical evaluation as stipulated in Appendix X		
IAEA safety standard - GSR Part 4	Safety assessment for facilities and activities – Evaluation of human factors	4.30. It has to be determined in the safety assessment whether a suitable safety classification scheme has been formulated and applied to structures, systems and components. It has to be determined whether the safety classification scheme adequately reflects the importance to safety of structures, systems and components, the severity of the consequences of their failure, the requirement for them to be available in anticipated operational occurrences and accident conditions, and the need for them to be adequately qualified. It also has to be determined in the safety assessment whether the scheme identifies the appropriate industry codes and standards and the regulatory requirements that need to be applied in the design, manufacturing, construction and inspection of engineered features, in the development of procedures and in the management system for the facility or activity.	Assessing safety systems is a basic principle of the assessment of safety that is to be adapted for all chains of medical devices used in radiotherapy from different manufacturers, requiring an overall integration of safety of the installation.	Point 3.2 of Appendix II stipulates that documentation shall include design specifications, including standards that will be applied and the results of the risk analysis, as well as the description of solutions chosen to comply with basic requirements applicable to the products when applicable harmonised European standards applicable are not fully applied. ER 13.6 state in point d) that the instruction manual contains all information required to verify if the device is correctly installed and can operate within specifications and in maximal safety, as well as indications on the nature and frequency of maintenance and	EN 14971 Point 6.8 of standard EN 60601-2-1 for certain technical information.	European directives (Euratom 97/43 and new approach 93/42/EEC) are not precise enough as this requirement to conduct a safety assessment for manufacturers of medical devices emitting ionising radiation. It is desired: 1. to know what "backup device" means; 2. to adapt the assessment of safety devices with respect to the chain of equipment used in radiotherapy and that may be produced by different manufacturers.

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				calibration operations required to permanently ensure the correct operation and safety of the devices.		
IAEA safety standard - GSR Part 4	Safety assessment for facilities and activities – Evaluation of human factors	4.40. It has to be determined in the safety assessment whether requirements relating to human factors were addressed in the design and operation of a facility or in the way in which an activity is conducted. This includes those human factors relating to ergonomic design in all areas and to human–machine interfaces where activities are carried out.	Determination of design requirements and use human factors including usability of interfaces	ER 1 It is in particular a question of reducing, to the extent possible, the risk of a utilisation error resulting from the ergonomic features of the device and from the environment in which the device is used.	EN 14971 Appendix C point C.2.29 EN 60601-1-6	European directive 93/42/EEC includes this requirement, although it remains general.
IAEA safety standard - GSR Part 4	Safety assessment for facilities and activities – Independent verification	4.66. The operating organization is to carry out an independent verification to increase the level of confidence in the safety assessment before it is used by the operating organization or submitted to the regulatory body.	Obligation to an independent audit of how the security assessment was operated.	N.A.	N.A.	European directives do not include this requirement to conduct a safety assessment for manufacturers of medical devices emitting ionising radiation. There is no obligation to have the relevance of the safety assessment verified by an independent third party or a safety authority
IAEA safety standard - GSR Part 4	Safety assessment for facilities and activities – Independent verification	4.71.13 In addition, the regulatory body has to carry out a separate independent verification to satisfy itself that the safety assessment is acceptable and to determine whether it provides an adequate demonstration of whether the legal and regulatory requirements are met. The verification by the regulatory body is not part of the	Obligation of the regulation authority to conduct a combination of a spot verification and an overall verification of the safety assessment, both independent of the operator.	N.A.	N.A.	Article 8 of Directive 97/43/Euratom contains the obligation to conduct reception tests of equipment. It nevertheless remains to be determined if outside quality controls of medical devices and technical controls of radiation protection are included in the spot verification to conduct

Reference recommendation	Thematic	Description	Topics	Possible links with essential requirements (ER)	Possible links with EN standards	Comments
		operating organization's process and is not to be used or claimed by the operating organization as part of its independent verification.				during reception tests. If this is the case, it should be pointed out that the regulation stipulates only: 1. that outside quality controls are conducted systematically before the first clinical use, 2. that technical radiation protection controls are conducted by a party independent of the operator.
IAEA safety standard - GSR Part 4	Safety assessment for facilities and activities – Update the safety assessment	5.7. The results of the safety assessment are to be used to specify the necessary competences for the staff involved in the facility or activity, which are used to inform their training, control and supervision.	Definition of the skill set required to use the installation and guide training and control on the basis of the results of the safety assessment.	ER 1 requires considering the technical understanding, experience, education and user training for medical devices such that utilisation shall not compromise the clinical status and safety of patients or the safety and health of users or, if applicable, of other persons.	EN 14971 Appendix C (for the record). Point C.2.26 requires determining if the installation or use of the medical device requires special training. Point C.2.27 requires considering if the new training or certification of operators or maintenance staff is necessary. EN60601-1-6	In particular at the moment of design review, European directives do not stipulate this requirement for determining the skill set of staff, required for the use and preparation of associated training programmes and minimum numbers of personnel needed to maintain the safety of medical devices throughout their lifetime.
IAEA safety standard -	Safety of radiation generators and sealed	3.3. The BSS (Ref. [17], para. 2.13 c)) require the legal person	Safety assessment by the operator with the possibility of	ER 1 and ER 2	EN 14971 EN 60601-2-1	European directives do not require the manufacturer to

Reference recommendation	Thematic	Description	Topics	Possible links with essential requirements (ER)	Possible links with EN standards	Comments
RS-G-1.10	radioactive sources - - Safety assessment	(principal party) applying for authorization from a regulatory body to "make an assessment of the nature, magnitude and likelihood of the exposures attributed to the source and take all necessary steps for the protection and safety of both workers and the public". Such an assessment should always be made by the principal party, even when considering the safety of sources in the lower risk categories and in commonplace applications. Safety assessments may be specific or generic. Generic safety assessments are not specific to a particular facility but cover all sources and/or devices of a particular design. They may be used for types of sources with a high degree of uniformity in design and may be available to the registrant or licensee from the manufacturer or supplier (further guidance on manufacture is given in Section 4). Such an assessment is likely to be available, for example, for a particular design of industrial gauge. However, the generic safety assessment may need to be supplemented by a site specific safety assessment covering, for example, the location of the source and the suitability of local shielding. In circumstances where no generic safety assessment is available, a full specific safety assessment should	generic study carried out either by himself or by the manufacturer.		Table 102 sets down information provided by the various ancillary documents.	transmit typical test data to the operator to help the safety assessment of his installation; The standard governing accelerators, however, is more stringent even though its application is voluntary. The idea of requiring a generic safety assessment study to extend locally by each operator for the specificities of his installation should be further explored.

Reference recommendation	Thematic	Description	Topics	Possible links with essential requirements (ER)	Possible links with EN standards	Comments
		be carried out.				
IAEA safety standard - RS-G-1.10	Safety of radiation generators and sealed radioactive sources - Safety assessment	3.12. For X ray generators and particle accelerators, there is no formal international system of categorization in relation to hazard. X ray generators have an inherent protection against misuse to the extent that they do not produce X rays when witched off (see, however, footnote 15). The principal misuse that may need to be addressed in a safety assessment is likely to be unauthorized activation of a generator that is left unattended by the operator. Adherence to the use of approved generator designs and safety procedures that include locks and key codes for access and activation should minimize the possibility of harm. However, there is a wide variation in generator power and control systems, and the scale of hazard appropriate to the circumstances should be taken into account in the safety assessment.	Risk Integration of use abuse in the safety assessment.	N.A.	EN 60601-2-1	This requirement has been included in the "zoning" decree of 15 May, 2006 concerning steps to take before being able to classify a zone as an intermittent control zone and downgrade its classification.
IAEA safety standard - RS-G-1.10	Safety of radiation generators and sealed radioactive sources - Safety assessment	3.14. A comprehensive safety assessment should be carried out for sources that produce high radiation fields, such as industrial radiography sources, other Category 1, 2 and 3 sources and particle accelerators, as these sources have a high potential for high exposures with severe or fatal consequences. The assessment	Conduct a complete safety assessment, especially for particle accelerators for medical use.	ER 1 and ER 2	EN 14971 EN 60601-2-1	The principle of safety assessment is not included in Directive 97/43/Euratom. Nor is this principle included in Directive 93/42/EEC as such, but a risk analysis prior to marketing is nevertheless required. Applying standard EN 60601-2-1 covers technical aspects of

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		should include an examination of postulated scenarios for exposure in order to ensure that safety features such as barriers and interlocks are adequate. The approach and the tools used to perform a safety assessment can range from straightforward qualitative assessments to the use of deterministic and probabilistic assessments. The level of detail and rigour applied to a safety assessment for a source should be commensurate with the potential hazard posed by the source. Probabilistic or other assessments of the likelihood of equipment failures should be supplemented with appropriate assessment of the likelihood of human error.				design. Organisational and human aspects are not dealt with in this standard.
IAEA safety standard - RS-G-1.10	Safety of radiation generators and sealed radioactive sources - - Design Manufacture and use of sources and design and operation of facilities	4.3. Good design and a high manufacturing quality of radiation sources are essential for optimum safety. The BSS [17] state the following in Appendix IV: "IV.8. Registrants and licensees, in specific co-operation with suppliers, shall ensure that the following responsibilities be discharged, if applicable: a) to provide a well designed and constructed source that: (i) provides for protection and safety in compliance with the Standards [i.e. the BSS];	Requirements for design, manufacture and utilisation of sources and design and operation of installations.	For IV.8) ER 1 and ER 2	For IV.8) EN 14971 EN 60601-2-1	Characteristics and specifications of sources: For VI.8 a) complies with the principle of so-called "new approach" directives that stipulate the use

Reference recommendation	Thematic	Description	Topics	Possible links with essential requirements (ER)	Possible links with EN standards	Comments
		(ii) meets engineering, performance and functional specifications; (iii) meets quality norms commensurate with the protection and safety significance of components and systems; (b) to ensure that sources be tested to demonstrate compliance with the appropriate specifications; and (c) to make available information in a major world language acceptable to the user concerning the proper installation and use of the source and its associated risks. "IV.9. In addition, and where applicable, registrants and licensees shall make suitable arrangements with suppliers of sources: (a) to establish and maintain mechanisms for suppliers to obtain information from the registrants and licensees or other users on the use, maintenance, operating experience, dismantling and disposal of sources, and any particular normal or abnormal operating conditions that may be important for the protection of individuals or the safety of the source; (b) to establish and maintain a mechanism to feed back to		For IV.9 a) European directives contain no obligation. For IV.9 b) Article 10 of Directive	For IV.9) EN 14971 point 9	of standards to demonstrate the compliance of medical devices with ER. b) is compliant with point c) of point 3 of Appendix II which is the procedure for determining the compliance of those medical devices most extensively monitored by manufacturers The level of precision of c) is included in ER. For IV.9) At the fringe of ongoing work by the working group on radiation protection of medical devices using ionising radiation, the question should be posed on the usefulness of creating a mechanism of information so that suppliers can obtain information from users on the use of medical devices using ionising radiation, their maintenance, operating experiences, retirement and removal, as well as in all special operating conditions, whether normal or abnormal, that could be important for the protection of persons and the

Reference recommendation	Thematic	Description	Topics	Possible links with essential requirements (ER)	Possible links with EN standards	Comments
		registrants and licensees information that may have implications for protection or safety affecting other registrants or licensees, or that may have implications for future improvements in protection or safety in the design of their products.		93/42/EC creates the obligation for a centralised inventory and assessment by Member States, especially dysfunctions, inadequate labelling or an incomplete instruction manual that could at least cause or have caused a severe degradation of the health of a patient or a user and requires that the manufacturer of the device in question, or his representative in the EC shall also be informed of the incident.		safety of sources
IAEA safety standard - RS-G-1.10	Safety of radiation generators and sealed radioactive sources - - Design Manufacture and use of sources and design and operation of facilities	4.5. Sealed sources and containment devices and radiation sources are normally designed and manufactured in accordance with national or international standards that specify, among other things, the nature of the encapsulation and the required performance characteristics [35, 36]. These standards include performance and safety requirements that are designed to ensure safe and effective operation.	Design and manufacturing requirement to reach essential performances required to ensure safe and effective operation.	Article 3 of Directive 93/42/EC requires that medical devices comply with applicable basic requirements by taking into account the destination of the devices concerned that may constitute minimal performances.	EN 60601-1: 2007 Definition of basic performance	The concept of essential performance requires further definition, in particular concerning the fact that standard 60601-2-1 does not include essential performances that can be modified, replaced, eliminated or reinforced by other basic safety requirements and essential performances contained in particular of the IEC 60601 series. Standard 60601-2-1, however, does not contain them since it is older. Standard IEC 60601-2-1 2009 (not yet EN) includes the concept of essential

Reference recommendation	Thematic	Description	Topics	Possible links with essential requirements (ER)	Possible links with EN standards	Comments
						performances
IAEA safety standard - RS-G-1.10	Safety of radiation generators and sealed radioactive sources - - Design Manufacture and use of sources and design and operation of facilities	4.17. Radiation generators normally include shielding to limit radiation exposure and do not present a radiation hazard until they are assembled to a point where power can be connected. Once the unit is able to generate radiation, provisions for safe use should include, as appropriate: (a) Measures to control access to the generator and controls, such as a key system, to ensure that the device cannot be operated unintentionally or by an unauthorized person; (b) Measures to identify the presence of a radiation source, typically by means of signs; (c) Warning signals (visual and audible) to indicate when the device is activated;	Integration of access control, notification of the presence of a source and signalling that the device operates within design requirements.	European directives contain no explicit requirements for the manufacturer to consider installation requirements involving: a) access control b) signalling the presence of a source c) warning signal (visual and audible) of equipment operation [..]	EN 14971 EN 61859: Directive for the design of treatment rooms	It is of use to question the value of including certain requirements in the design of medical devices, in particular to enable the user to subsequently comply with installation or safety requirements arising from application of standards or regulatory provisions.

Appendix 4

Bibliography

I - Requirements in terms of radiation protection:

Documents of the European Commission

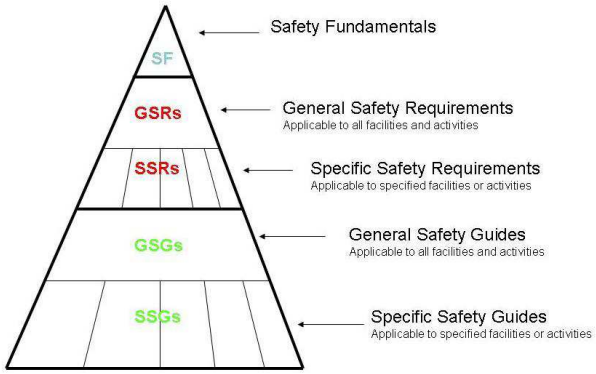
- **European guidelines on radiation protection**
  - Directive 96/29 Euratom (population & workers)
  - Directive 97/43/Euratom (patient)
  - CE-Draft Euratom Basic Safety Standards Directive - Version 24 February 2010 (final)

- **Documents of IAEA** (in the hierarchical order of publications)
  - **International Basic Safety Requirements**
    - SF1-Basic safety principle
  - **Basic Standard International Protection against Ionizing Radiation and for Safety of Radiation Sources**
    - BSS 115 Parts I, II, V and Appendices I-II-III setting down detailed instructions

- **International guides and recommendations**

GSR-Part 3: General safety requirements of installation management system and nuclear activities
GSR-Part 4: General safety requirements concerning the safety assessment of installations and nuclear activities
RS-G-1.10: General safety guide concerning the safety of radiation generators and sealed radioactive sources

The documents produced by IAEA are prioritised according to the principle below:



II - Requirements in terms of marketing of medical devices:

Documents of the European Commission

- **European directives on the marketing of medical devices**

Directive 93/42/EEC of the Council, 14 June, 1993, concerning medical devices.
Directive 2007/47/EC of the European Parliament and Council of 5 September, 2007 modifying Directive 90/385/EEC of the Council concerning the harmonisation of Member State legislation governing active implantable medical devices, Directive 93/42/EEC of the Council concerning medical devices and Directive 98/8/EC concerning the marketing of biocidal products.

Appendix 5

Excerpt of IRSN report N°2008-02 – Improving the s afety of radiotherapy treatments by developing a safety culture

The principle of defence in depth

The goals of nuclear safety are to protect individuals, society and the environment by establishing and maintaining an effective defence against radiological risks in nuclear facilities, including the dispersion of radioactive materials or the irradiation of persons.

In this context, all activities related to safety, whether conducted by man or machine, are subjected to requirements that partly and generally cover five levels. If one level fails, the next comes into play to ensure the expected protection.

- Level 1: prevent conditions of abnormal operation and failures by selecting suitable requirements for design, manufacture, construction, commissioning, operation and maintenance of the facility.
- Level 2: control abnormal operating conditions and detect failures to return the installation to normal operating conditions as soon as possible to prevent the recurrence of accident situations.
- Level 3: control accident situations to guarantee the effectiveness of physical barriers between radioactive products and persons and/or the environment.
- Level 4: control accident situations with considerable damage of physical barriers, in particular by keeping their probabilities and consequences at the lowest levels that can reasonably be reached.
- Level 5: attenuate important radiological consequences of radioactive discharge to the exterior of the facility.

Level 3 of defence in depth refers to the existence of physical barriers between radioactive products and persons and/or the environment. This concept can be applied in a broad sense and cover all material and organisational dispositions (devices and procedures) interposed between sources of risk and the target to be protected.

This approach, called *defence* in depth, is implemented in the design and operation of nuclear installations in order to provide graduated protection against a broad range of events resulting from material or human failures, whether inside the installation or resulting from outside aggressions to it.

Appendix 6

List of members of the working group convened by AFSSAPS and ASN

FIRST/LAST NAME		ORGANIZATION	REPRESENTATIVE
Mr.	Patrick DROESCH	FACN	Federal authority for nuclear control (Belgium)
Mr.	Michel BIERNAUX	FACN	Federal authority for nuclear control (Belgium)
Mr.	Philippe BAUWIN	FAMHP	Federal Agency for Medicines and Health Products (Belgium)
Ms.	Frédérique MEULDERS	FAMHP	Federal Agency for Medicines and Health Products (Belgium)
Dr.	Gérard BERTHIER	AFSSAPS	French health products safety agency
Mr.	Pascal DI DONATO	AFSSAPS	French health products safety agency
Mr.	Nicolas THEVENET	AFSSAPS	French health products safety agency
Mr.	Jean-Luc GODET	ASN	French nuclear safety authority
Mr.	David KREMBEL	ASN	French nuclear safety authority
Ms	Carole MARCHAL	ASN	French nuclear safety authority
Mr.	Marc VALERO	ASN	French nuclear safety authority
Mr.	Vincent FRANCHI	ASN	French nuclear safety authority
Ms.	Katia KERAUDY	Centre hospitalier de Tenon Groupement hospitalier universitaire Est	Representative of French users
Mr.	Albert LISBONA	CLCC Nantes-Atlantique René GAUDUCHEAU	Representative of French users
Mr.	Maurice PAGE	Biomedical engineer Haute-Savoie Departement	Representative of French users
Mr.	Bernard AUBERT	IRSN	French Institute of Radioprotection and Nuclear Safety
Mr.	Roland LANDIS	FOPH	Federal office of public health (Swiss land)
Mr.	Daniel REUSSEL	Swissmedic	Swiss agency for therapeutic products
Mr.	Philippe LARTIGUE	UTE UF 62	French standards body for the electrotechnical field

French health products safety agency

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Réf SIV2 ASN : DVS-DIS-ATR-021459-2011

The working group jointly led by the AFSSAPS and the ASN has convened representatives of the French standards body for the electrotechnical field and competent Belgian and Swiss authorities governing radioprotection or the marketing of medical devices, as well as representatives of French users.

This report describes the results of work started in October 2008 and terminated in October 2010. It contains proposals concerning:

- IAEA requirements and recommendations,
- requirements of CE marking,
- radiation protection requirements of Euratom Directives.

The report can be consulted on the ASN Web site:

www.asn.fr