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French health products safety agency

Medical Devices Evaluation Directorate

Market Surveillance Department

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NOTICE TO MANUFACTURERS OF RADIOTHERAPY MEDICAL DEVICES

Foreword:

Continuously evolving, increasingly precise and complex, radiotherapy uses ionizing radiation for therapeutic purposes in human being.

The safety and efficacy of radiotherapy largely depends on the conditions of acceptance-testing and use of various related systems, without disregarding other factors relating in particular to organization of the healthcare chain and staff training.

Afssaps initially intervened in the context of medical devices vigilance in order to evaluate incidents involving radiotherapy medical devices.

Under the agenda drawn up by the Ministry of Health subsequent to the Epinal accident, Afssaps engaged then a work to improve the enforcement of the essential requirements defined by directive 93/42/EEC on radiotherapy medical devices, pursuant to its market surveillance mission.

Afssaps' working program on this matter has been extended. It comprises:

- Controlling compliance with article R. 5211-20 of the French Public Health Code (which transposed article 4 of the directive in French law) requiring the availability of instruction of use in French,
- Examination of the safety and ergonomics of the software linking the key figures concerned,
- Strengthening quality control carried out by operating staff and independent quality control of radiotherapy installations,
- Drawing up recommendations to radiotherapy center staff for acceptance-testing of newly-acquired installations.

This document addresses the first two points, with respect to, firstly, the results of the language of instruction for use controls and, secondly, the conclusions of the reflection on product ergonomics and safety conducted in collaboration with the French Nuclear Safety Authority. Its aim is to draw up recommendations for manufacturers. Additional publications will be issued for the two other points.

Approach:

Subsequent to an initial meeting with the various key figures of the market in February 2007, Afssaps implemented a survey targeting manufacturers from February through March, 2007. The survey mainly investigated the availability of an instruction for use in French, the human-machine interface language used, the operator profile envisaged by the manufacturer and the training media.

In parallel, Afssaps conducted a review of the standards available to date and addressing the human-machine interface and ergonomics.

The results of these actions were presented to representatives of the radiotherapy medical devices' manufacturers operating on the French market (accelerators, radiotherapy treatment planning systems (TPS), radiotherapy record and verify systems, simulation software) on June 18, 2007.

The foregoing will lead Afssaps to take initiatives at the European and international levels.

1 General

It will be recalled that any instrument, apparatus, appliance, material or other article, including the software necessary for its proper application intended by the manufacturer to be used on human for the purpose of diagnosis or treatment of disease is defined as a medical device.

Medical devices are subject to European directive 93/42/EEC. CE marking denotes compliance with the provisions of that directive. The CE marking enables the free movement of the devices throughout the European Union.

The conformity assessment procedure is under the manufacturer's responsibility, and, whenever appropriate, intervention of a notified body is required.

Afssaps, in the context of its market surveillance activities, as a competent authority, may take all necessary measure to ensure that products placed on the market comply with the provisions of the directive.

The directive established the essential requirements providing the safety and health of the patients, users and third parties when the device is used. The manufacturer is required to demonstrate that those essential requirements have been fulfilled, in particular with respect to design, manufacture, and user information.

The "harmonized standards" constitute a special tool for demonstrating the required compliance. These standards are specifically intended to respond to the essential requirements. Products manufactured in compliance with harmonized standards benefit from a presumption of conformity with the corresponding essential requirements. However, the manufacturer may also opt for other reference systems provided that the notified body determines that they are equivalent. The competent authority may review the pertinence and adequacy of the manufacturer's demonstration in the course of market controls.

Medical devices are divided into four classes (I, IIa, IIb and III) on the basis of the degree of risk associated with device use.

Radiotherapy medical devices are in class IIb under rule 9 of Annex IX of the directive.

Irrespective of the class of the medical device, the manufacturer's approach is to be oriented by systematically reflecting on the risk analysis and minimization of the risks related to the intended purpose of the device compared to the expected benefits.

Articles L. 5211-4 and R. 5211-66 of the French Public Health Code, transposing article 14 of directive 93/42/EEC into French law, state that Afssaps must be informed of medical devices associated with a high potential risk for human health (medical devices of classes IIb and III, and active implantable medical devices) when they are put into service in France. This communication, since 2002 to be made by the manufacturer, authorised representative or distributor, includes all data allowing for identification of the devices together with the labelling and instruction for use.

The list of communications is available on the Afssaps' website at the following address: http://afssaps.sante.fr/hm/10/dm/sdm/ind_risque.htm

The survey results showed that all the radiotherapy medical devices, including the radiotherapy software packages have the CE marking of conformity in accordance with the procedure in the directive 93/42/EEC.

With regard to the classification rules to be applied to software, and more particularly treatment planning software (TPS), the recommendations compiled by the notified bodies for their own use (NB-MED/2.2/Rec 4 – <http://www.old.team-nb.org>) state that "software for dose planning with a view to control the setting of oncology treatment devices" are to be considered as software intended to control or influence the functioning of medical devices. In consequence, TPS are included in class IIb in accordance to paragraph two of rule 9 of Annex IX, which states that: 'All active devices intended to control or monitor the performance of active therapeutic devices in Class IIb' - in the present case linear accelerators – 'or intended directly to influence the performance of such devices are in Class IIb'.

The survey showed that TPS and treatment record and verify software, virtual simulation software or contouring software, with the exception of two TPS that are no longer marketed, have been classified in class IIb by their manufacturers.

Review of the manufacturer's obligations concerning medical devices vigilance on the French territory :

Pursuant to article L. 5212-2 of the French Public Health Code, any incident or risk of incident involving a medical device that lead or might have led to the death or serious deterioration of the state of health of a patient, user or third party is to be reported to Afssaps without delay.

The report form may be downloaded from the Afssaps website (www.afssaps.sante.fr), tabs: 'Infos pratiques / Signalement des vigilances'.

The reports are to be forwarded to Afssaps /Département des vigilances – Fax: +(33)1.55.87.37.02.

In the same time, any event (incident or accident) occurring in a radiotherapy installation and liable to compromise human health through exposure to ionizing radiation is to be reported without delay to the Prefect of the administrative district and the Nuclear Safety Authority (ASN) by the head of the installation involved (Article L. 1333-3 of the French Public Health Code). Guide ASN/DEU/03 relating to reporting modalities may be downloaded from the ASN website (www.asn.fr).

2 Linguistic requirements

2.1 Language of instruction for use

Article R. 5211-20 of the French Public Health Code provides for the following:

The medical device's labelling available for final user or patient, the instruction for use accompanying the device, and any other information relating to the operation of the device or its use, are to include a version in French.'

Thus, the instruction for use for a medical device is to be written in French by the manufacturer.

For the translation, the manufacturer is to have set up, in his quality assurance system, procedures to ensure accurate translation of the labelling and instruction for use (cf. Recommendations of notified bodies medical devices NB-MED/2.5.2/Rec3 – <http://www.old.team-nb.org>)

The survey showed that out of the approximately sixty medical devices (or versions of medical devices) available on the French market, only nine were not accompanied by instruction for use in French.

In consequence, the manufacturers of the medical devices involved undertook to:

- Either provide a instruction of use in French in the timeliest manner,
- Or replace the medical device involved by a more recent product (software) for which a instruction for use in French is available.

2.2 Human-machine interface language

The survey showed that for about half of the radiotherapy medical devices available in France the interface language was English.

Essential requirement 12.9 of the directive relating to the requirements for medical devices connected to or equipped with an energy source (e.g. a linear accelerator) states that: ' 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.'

The issue is therefore to be tackled by the manufacturer through risk management and, in consequence, through management of the usability of the device, and, in particular, the fit between the human-machine interface and the technical language usually used by the operator in his/her professional activities, the operator's skill profile and operator training in use of the device.

In particular, the fact that medical physicists are not the only users of, for example, a TPS, is to be taken into account

2.3 Training language

The survey showed that some training courses are only taught in English. That situation requires, as a minimum, use of the French instruction for use and the assistance of a person able to act as a translator in order to facilitate the interactive aspect of the training course and ensure that the operators successfully acquire the knowledge and know-how dispensed during the training course.

Afssaps would like to point out that the subject is to be tackled by the overall management of the risks associated with the medical device. Thus, the manufacturer is to supply training and teaching aids that have been adapted to the operator's profile and the interface language.

Further input with regard to that issue will be derived from the work of the Autorité de Sureté Nucléaire (Nuclear Safety Authority)' on the quality assurance of radiotherapy departments with respect to the requirements of user training and validation of achievement of this training.

Review of manufacturers' and distributors' obligations on French territory

Pursuant to article R. 5211-20 of the French Public Health Code, the labeling, instruction for use and all other information relating to the operation or use of a medical device is to include a French version.

The requirement is to be verified in the context of application of articles L. 5211-4 and R. 5211-66 of the French Public Health Code, which provide for medical devices associated with a high potential human health risk being reported to Afssaps when first put into service in France.

3 **Essential requirements relating to ergonomics and safety**

3.1 Ergonomics

'Ergonomics (or study of human factors) is the scientific discipline concerned with the understanding of interactions among humans and other elements of a system, and the profession that applies theory, principles, data and methods to design in order to optimize human well-being and overall system performance' (International Ergonomics Association's definition)

In general, during the design phases, the questions relating to safety are, most frequently, still addressed from the technical angle. The taking into account of human factors still remains inadequate both at the system design stage and with respect to the incorporation of feedback in the form of corrective measures based on the data acquired in the use of medical devices.

The integration of human factors in the design of radiotherapy systems is to enable reduction of the dysfunctions liable to compromise equipment efficacy, efficiency, safety or reliability.

The approach is to be incorporated in the risk management process that enables the manufacturer to determine whether the device has the required degree of safety, given the intended purpose, the recognized state of the art, and the benefits procured in the light of the risks incurred.

In order to identify the hazardous phenomena and situations associated with the manufacturer's medical device, estimate and evaluate the risks, control them and monitor the effectiveness of that control, it is advisable for the manufacturer to apply harmonized standard EN ISO 14971 (Application of risk management to medical devices – June 2007), which is currently very widely used.

The standard offers the manufacturer a working framework for the management of the risks related to his medical devices at all stages through the product's life cycle.

Insofar as application of the standard enables the manufacturer to demonstrate compliance with the essential requirements, the manufacturer is to 'document the list of all the qualitative and quantitative characteristics liable to affect the safety of the medical device' in his risk analysis.

In order to draw up the list, the manufacturer asks himself a series of questions. Annex C of the standard includes a list for guidance in that process.

The ergonomic aspect is mainly addressed through two questions:

- 'What is the intended use and how is the medical device to be used?'

In particular, the following are to be considered: Who is the intended user? What are his tasks? What skills and training does the user have? What are the ergonomic aspects? In what environment will the device be used and who is responsible for installing it?

- 'Is successful application of the medical device critically dependent on human factors such as the user interface?'

It is advisable for the characteristics of the user interface liable to contribute to erroneous use to be designed in a manner to prevent incorrect use. This concerns, for example, the device control, symbols used, ergonomic features, menus for software driven devices, etc.

If the medical device displays information, it is appropriate to consider the visibility, clarity of presented information and density of the information.

In order to evaluate the risks related to human factors, the manufacturer has standard instruments for the medical device sector and, more generally, other industrial sectors available.

With regard to the medical device sector, the manufacturer can consult the guidelines of the standards relating to usability:

- NF EN 60601-1-6 (April 2005) Medical electrical equipment – Part 1-6: General requirements for safety. Collateral standard: Usability
- Pr NF EN 62366 (October 2006) Medical devices – Application of usability engineering to medical devices

Those recent and pertinent standards specify a process enabling manufacturers to analyze, specify, design, verify and validate the usability with respect to the safety of a medical device. This process is intended to obtain a reasonable usability enabling minimization of improper use and the risks associated with use.

In conclusion, the manufacturer is to take the following, among other, components into account in his risk analysis:

- the operator's profile,
- the foreseeable use errors,
- the constraints related to the tasks,
- the context of use,
- the information on the known hazards for the existing operator-device interfaces for similar devices,
- the results of the operator-apparatus interface revue.

By way of information and in order to demonstrate the value of the standards for manufacturers, it is noteworthy that the usability requirements are included in the new editions of standards NF EN 60601-1 Medical Electrical Equipment – Part 1: General requirements for Basic Safety and Essential Performance (January 2007) and EN ISO 14971 (June 2007).

In order to implement that approach, the manufacturer may also draw on the numerous reference standards developed in the industrial sector. For example, the series of standards ISO 9241 may constitute an appropriate working framework with respect to the design of work stations and with regard to the various components of software ergonomics, such as: general design principles, on-screen information display, man-machine interaction modalities, and user guidance.

Standard ISO 13407 relates to the design process centered on the human operator for interactive systems, while standard ISO 16982 relates to design methods centered on the human operator.

One of the important general principles relating to the design of interactive systems is that of homogeneity, i.e., the stability of the design choices over all the system components, e.g., the consistency of information presentation, which presupposes that the information is displayed in the same manner throughout the application, or the fact that a given action consistently yields the same result.

At last, it should be noted that the revised directive relating to medical devices provides that, "where the relevant hazard exists, devices which are also machinery within the meaning of Article 2(a) of Directive 2006/42/EC must also meet the essential health and safety requirements set out in Annex I of that Directive to the extent to which those essential health and safety requirements are more specific than the essential requirements set out in Annex I of this Directive".

Thus, the ergonomic requirements for machines will soon be applicable to radiotherapy medical devices.

3.2 Standards relating to safety

In the various investigations conducted, Afssaps observed that some reference standards relating to safety requirements, sometimes recent, were not yet being implanted by manufacturers.

In the meeting on June 18, 2007, Afssaps addressed the subject and stressed the value of applying certain international standards that would doubtless reduce the number of incidents.

For example:

- Standard NF EN 62304 – Medical device software – Software life-cycle processes (October 2006) would undoubtedly enable a reduction in software dysfunctions.
- Standard NF EN 62274 - Safety of radiotherapy record and verify systems (November 2005)
- Standard NF EN 62083 – Requirements for the safety of radiotherapy treatment planning systems (September 2001)

Recommendation

Afssaps asks manufacturers to take into account the existing standards relating to safety and ergonomics in product design, but also to take them into account, as early as possible, in the context of the evolution of existing products.

The application of that recommendation will be verified in the context of application of articles L. 5211-4 and R. 5211-66 of the French Public Health Code, which provides for medical devices associated with a high potential human-health risk being reported to Afssaps when they are first put into service in France.

The claimed standards are to be made public at the time of those reports.