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ICRP PERSPECTIVE ON CRITERIA OF ACCEPTABILITY FOR MEDICAL RADIOLOGICAL EQUIPMENT

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The International Commission on Radiological Protection (ICRP) does not have a specific publication or recent detailed advice on acceptability criteria and suspension levels for medical radiological equipment. However, a number of the Commission's publications clearly stress the need to carry out acceptance testing of radiological equipment. Such general recommendations are frequent in earlier and recent reports related to external radiation therapy. Over 30 y ago, the ICRP even included some examples of parameter accuracies concerning acceptance levels in connection with radiotherapy units. Later more general advices related to acceptability tests as important parts of various quality assurance programs were formulated for radiation therapy as well as for radiodiagnostics without going into details to give values for specific parameters. In the radiodiagnostic field, there are such general recommendations in reports related to equipment for X-ray interventional procedures, digital radiology and computed tomography. The ICRP highly supports the elaboration of detailed and clear acceptability and suspension criteria for equipment used in medical radiology carried out by organisations like International Atomic Energy Agency, International Electrotechnical Commission, European Commission, National Electrical Manufacturers Association (NEMA, USA) and others and consider such criteria as important parts of the quality programmes to guarantee good radiation safety conditions for patients in radiation therapy as well as in radiodiagnostics.

INTRODUCTION

In 2007, the European Commission (EC) set up a group of experts to undertake the revision of Report Radiation Protection (RP) 91, written in 1997, on 'Criteria for acceptability of radiological (including radiotherapy) and nuclear medicine installations'[(1)]. The performance parameters for medical radiological equipment, with their stated acceptability/suspension levels, are intended to assist in the decision-making process regarding the equipment concerned. When the equipment no longer meets the required performance tolerance levels, it should be withdrawn from use, may be disposed of, and replaced (see, e.g. Article 8 (3) of Directive 97/43/Euratom[(2)]).

Before publication, the EC issued the document for public consultation to further improve the revised report. The EC intends to publish the final report under its Radiation Report Series with the number RP 162.

The International Commission on Radiological Protection (ICRP) welcomes a discussion about the acceptability criteria and the initiative of the EC to update the definition of parameters essential to the assessment of the performance of medical radiological equipment and to set up the criteria of acceptability for these parameters within which the equipment performance and safety standards of medical procedures are ensured.

The ICRP itself has not issued any specific publication or recent detailed advices on acceptability criteria for medical radiological equipment. However, a number of the Commission's publications clearly identify the two key elements in radiation protection in medicine: justification and optimisation. Key components in optimisation are quality control and quality assurance, which implicitly motivates acceptability and suspension criteria. The aim of this report is to review ICRP publications related to radiological protection in medicine to identify the aspects related to the criteria of acceptability of medical radiological equipment.

MATERIALS AND METHODOLOGY

Over the last decade, the Commission has published a number of documents, prepared (or in cooperation) by Committee 3, that provide detailed advice related to radiological protection and safety in the medical applications of ionising radiation. Each of these publications addresses a specific topic defined by the type of radiation source and the medical discipline in which the source is applied, and was written with the intent of communicating directly with the relevant physicians, medical physicists, nurses, radiographers and other clinical staff. These publications (in chronological order) are as follows:

– Publication 84[(3)]: Pregnancy and medical radiation (2000).

- Publication 85[4]: Avoidance of radiation injuries from medical intervention procedures (ICRP, 2000).
- Publication 86[5]: Prevention of accidental exposures to patients undergoing radiation therapy (ICRP, 2000c).
- Publication 87[6]: Managing patient dose in computed tomography (ICRP, 2000d).
- Supporting Guidance 2[7]: Radiation and your patient: a guide for medical practitioners (ICRP, 2001).
- Supporting Guidance[8]: Diagnostic reference levels in medical imaging—review and additional advice (ICRP, 2001).
- Publication 93[9]: Managing patient dose in digital radiology (ICRP, 2003a).
- Publication 94[10]: Release of patients after therapy with unsealed radionuclides (ICRP, 2004).
- Publication 97[11]: Prevention of high-dose-rate brachytherapy accidents (ICRP, 2005).
- Publication 98[12]: Radiation safety aspects of brachytherapy for prostate cancer using permanently implanted sources (ICRP, 2005).
- Publication 102[13]: Managing patient dose in multidetector computed tomography (ICRP, 2007).
- Publication 103[14]: The 2007 recommendations of the International Commission on Radiological Protection (ICRP, 2007).
- Publication 105[15]: Radiological protection in medicine (ICRP, 2007).
- Publication 112[16]: Preventing accidental exposures from new external beam radiation therapy technologies (ICRP, 2009).

Also, in 2008, the Commission issued Publication 106[17], entitled 'Radiation dose to patients from radiopharmaceuticals' (ICRP, 2008); a joint document of Committees 2 and 3 that presented biokinetic and dosimetric data on a number of radiopharmaceuticals, which together with the earlier ICRP publications on this subject, Publication 80[18] (ICRP, 1998) and Publication 53[19] (ICRP, 1988) forms an almost complete catalogue of the currently clinically used radiopharmaceuticals.

A number of new publications are in progress and the following are at an advanced stage:

- Radiological Protection in paediatric diagnostic and interventional radiology.
- Avoiding adverse radiation effects to doctors and patients in fluoroscopically guided procedures—practical guidelines.
- Patient and staff radiation protection in cardiology.

The above-mentioned printed publications have been reviewed with respect to the acceptability criteria and suspension levels for radiological equipment. Some older publications found to be of potential interest in relation to the aim have also been reviewed:

- Publication 33[20]: Protection against ionising radiation from external sources used in medicine (ICRP, 1982).
- Publication 44[21]: Protection of the patient in radiotherapy (ICRP, 1985).

RESULTS

For publications not mentioned in the following, no statements regarding the acceptance tests, etc. were found. Those with advice on acceptance testing/criteria are discussed below.

Medical radiology in general

In Publication 105 (Radiological protection in medicine, ICRP, 2007) is stated (paragraph 111, page 47): 'Quality assurance programmes are essential for maintaining the intended standards in all the functions of the undertaking (etc.). These programmes should include acceptance testing carried out before the first use of the equipment for clinical purposes, and thereafter performance testing on a regular basis and after any major maintenance procedure. Specific quality assurance programmes should be adapted to the new imaging technologies (e.g. digital) and radiation therapy procedures'. Further (in paragraph A 19, page 56): 'The complex equipment and techniques used in radiation therapy mandate that for accident prevention, there must be sound and risk-informed regulations, managerial commitment at the hospital level, an adequate number of trained staff, adequate resources, a functional implemented quality assurance programme, good communication, and continuing education'.

Radiation therapy

Already in Publication 44, there are advices of parameter accuracies that should be met by radiotherapy units (paragraphs 71–76, pages 16–18) with references to Publication 33 (ICRP, 1979). In Publication 86 (ICRP, 2000) 'Prevention of accidents to patients undergoing radiation therapy', there are a number of recommendations regarding acceptance tests and definition of acceptance criteria in general, but without any details given about acceptable values or accuracies for parameters. The same line is followed in Publication 112 (Preventing accidental exposures from new external beam radiation therapy technologies in which acceptance testing, etc. is mentioned in at least 12 of its paragraphs).

X-ray imaging

An example from the diagnostic field is the general recommendation given in Publication 93 (digital radiology, page 49): 'Quality control in digital radiology requires new procedures and protocols. Acceptance and constancy tests should include aspects concerning visualisation, transmission and archiving of the images'.

The first Publication stressing the importance of acceptance testing in the diagnostic fields is Publication 85[4] from 2000 (Avoidance of radiation injuries from medical interventional procedures) followed by Publication 87[6] (Managing patient dose in computed tomography) and the earlier mentioned Publication 93[9]. In the more recent Publication 102[13] [Managing patient dose in multidetector computed tomography (MDCT)], there is no specific discussion about the need for acceptance tests etc.

Nuclear medicine

No statement regarding the acceptability criteria neither for the older nor the evolving technologies was found.

DISCUSSION AND CONCLUSIONS

Thirty years ago, ICRP included some examples of parameter accuracies concerning acceptance levels in connection with radiotherapy units. Later more general advices related to quality assurance programmes were formulated for radiation therapy as well as for radiodiagnostics without going into details to give values or accuracies for parameters. However, the ICRP highly welcome the elaboration of clear suspension and acceptability criteria for equipment used in medical radiology by other organisations like International Atomic Energy Agency, International Electrotechnical Commission, EC, National Electrical Manufacturers Association (NEMA, USA) and others and the use of them as part of the quality programmes to guarantee good radiation safety conditions for patients in radiodiagnostics as well as in radiation therapy. The ICRP also welcomes a discussion about the experiences so far of the use of the acceptability criteria and the experimental basis on which these criteria is laid. It is important to stress that such criteria should not diminish the efforts of users to further optimise the equipment to get better image quality for lower doses or to implement better radiotherapy.

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