

# INTERNATIONAL STANDARD

# IEC 60601-2-1

1998

AMENDMENT 1  
2002-05

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Amendment 1

**Medical electrical equipment –**

**Part 2-1:  
Particular requirements for the safety  
of electron accelerators in the range  
1 MeV to 50 MeV**

*Amendement 1*

*Appareils électromédicaux –*

*Partie 2-1:  
Règles particulières de sécurité pour les accélérateurs  
d'électrons dans la gamme de 1 MeV à 50 MeV*

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International Electrotechnical Commission, 3, rue de Varembé, PO Box 131, CH-1211 Geneva 20, Switzerland  
Telephone: +41 22 919 02 11 Telefax: +41 22 919 03 00 E-mail: [inmail@iec.ch](mailto:inmail@iec.ch) Web: [www.iec.ch](http://www.iec.ch)



Commission Electrotechnique Internationale  
International Electrotechnical Commission  
Международная Электротехническая Комиссия

PRICE CODE

**D**

*For price, see current catalogue*

## FOREWORD

This amendment has been prepared by subcommittee 62C: Equipment for radiotherapy, nuclear medicine and radiation dosimetry, of IEC technical committee 62: Electrical equipment in medical practice.

The text of this amendment is based on the following documents:

FDIS	Report on voting
62C/329/FDIS	62C/334/RVD

Full information on the voting for the approval of this amendment can be found in the report on voting indicated in the above table.

The committee has decided that the contents of the base publication and its amendment will remain unchanged until 2005. At this date, the publication will be

- reconfirmed;
- withdrawn;
- replaced by a revised edition, or
- amended.

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## INTRODUCTION

Subclause 29.3.1.1 of IEC 60601-2-1:1998 sets limits to X-ray leakage radiation through beam limiting devices (BLDs) in the patient plane in order to reduce the detrimental effects on the patient due to leakage radiation. This clause restricts leakage through the main X and Y BLDs to a maximum of 2 % and an average of 0,5 %. Multi-element BLDs were assumed to replace a beam shielding block which attenuated the beam to about 5 %, and this was the upper limit applied to multi-element BLDs.

With the growth of techniques such as conformal therapy and IMRT, multi-element BLDs (which allow higher leakage levels) are being used to shield more of the radiation field area than was the case with conventional techniques using beam blocks. It is now proposed in the replacement subclause 29.3.1.1 to set a leakage tolerance on the total beam limiting system (the X and Y BLDs themselves may be single element, multi-element, or a combination of both) and to limit the leakage to an average of 0,75 %.