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TECHNICAL REPORT

Guidelines for the development and use of medical electrical equipment educational materials

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INTERNATIONAL
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COMMISSION

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

GUIDELINES FOR THE DEVELOPMENT AND USE OF MEDICAL ELECTRICAL EQUIPMENT EDUCATIONAL MATERIALS

FOREWORD

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IEC/TR 61258, which is a technical report, has been prepared by subcommittee 62A: Common aspects of electrical equipment used in medical practice, of IEC technical committee 62: Electrical equipment in medical practice.

This second edition cancels and replaces the first edition published in 1994. This edition constitutes a technical revision. This edition has been aligned with IEC 60601-1:2005 to include medical electrical systems within its scope. USABILITY ENGINEERING concepts from IEC 62366:2007 have also been added to this edition.

The text of this technical report is based on the following documents:

Enquiry draft	Report on voting
62A/615/DTR	62A/625/RVC

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

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

The committee has decided that the contents of this publication will remain unchanged until the maintenance result date indicated on the IEC web site under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

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- withdrawn,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

A bilingual version of this publication may be issued at a later date.

INTRODUCTION

The prevention and alleviation of public health problems arising from the use of medical electrical equipment and medical electrical systems are major concerns for many regulatory agencies, standards organizations, professional associations of health care personnel, and manufacturers. Incorrect use of medical electrical equipment or medical electrical systems can result in death or injury to patients, to health care personnel operating medical electrical equipment or medical electrical systems, or consumers using such equipment.

Government agencies often rely on regulatory approaches to solve problems related to the way the equipment is manufactured, marked, and described in the ACCOMPANYING DOCUMENTS, but many problems arise from erroneous use of medical electrical equipment or a medical electrical system. Errors in using equipment are made for a variety of reasons, including lack of knowledge about its proper use, impediments or lack of incentives for appropriate use. For these user problems, non-regulatory strategies might be necessary. These require an analysis of the problems and the development of EDUCATIONAL MATERIALS and programs to address misunderstandings and bad habits that can cause the problems.

The development and use of materials and programs are an essential part of the health care facilities' "quality system". For information on quality systems, see ISO 9001, ISO 9004 and ISO 13485.

GUIDELINES FOR THE DEVELOPMENT AND USE OF MEDICAL ELECTRICAL EQUIPMENT EDUCATIONAL MATERIALS

1 Scope

IEC/TR 61258, which is a technical report, outlines a generic process for developing materials for education and training of OPERATORS of medical electrical equipment or a medical electrical system, hereafter referred to collectively as equipment. It can be used by standards organizations, manufacturers, health care facility managers, clinical engineers, physician and nurse educators, and others involved directly or indirectly in education and training of OPERATORS.

In particular, manufacturers might find this process useful in preparing the necessary markings, ACCOMPANYING DOCUMENTS and other EDUCATIONAL MATERIALS which will provide necessary information to OPERATORS of the equipment and encourage them to employ safe and effective practices.

This technical report is not intended to be used for regulatory purposes.

2 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

2.1
ACCOMPANYING DOCUMENTS
documents accompanying medical electrical equipment, a medical electrical system, other equipment or an accessory and containing information for the responsible organization or OPERATOR, particularly regarding basic safety and essential performance

[IEC 60601-1:2005, definition 3.4, modified]

2.2
EDUCATIONAL MATERIALS
means used to disseminate information for the purpose of training, instruction, and education of OPERATORS of equipment

2.3
INTENDED USE
INTENDED PURPOSE
use of a product, process or service in accordance with the specifications, instructions and information provided by the manufacturer

[ISO 14971:2007, definition 2.5, modified]

2.4
OPERATOR
person handling equipment

[IEC 60601-1:2005, definition 3.73]