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TECHNICAL REPORT

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

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INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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

FOREWORD

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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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]

2.5
QUALITY ASSURANCE
part of quality management focused on providing confidence that quality requirements will be fulfilled

[ISO 9000:2005, definition 3.2.11]

NOTE 1 Unless given requirements fully reflect the needs of the responsible organization, QUALITY ASSURANCE will not be complete.

NOTE 2 For effectiveness, QUALITY ASSURANCE requires a continuing evaluation of factors that affect the adequacy of the design or specification for intended applications as well as verifications and audits of production, installation and inspection operations. Providing confidence can involve producing evidence.

NOTE 3 Within an organization, QUALITY ASSURANCE also serves to provide confidence in the supplier.

2.6
USABILITY ENGINEERING
application of knowledge about human behaviour, abilities, limitations, and other characteristics related to the design of tools, devices, systems, tasks, jobs, and environments to achieve adequate usability

[IEC 62366:2007, definition 3.18]

3 General aspects

Assuring the safety and performance of equipment not only requires attention to the design, testing, review and manufacture of the equipment itself, but it also requires OPERATORS with the know-how to use the equipment safely for its INTENDED PURPOSE and the motivation to apply that knowledge.

There are a number of ways in which OPERATORS might gain information about the appropriate use of equipment. These sources include theory, training and over-the-shoulder learning gained from experienced personnel, and from the information supplied by marking and in the ACCOMPANYING DOCUMENTS.

Some equipment can be incorrectly used due to inadequate marking and instructions for use. Because this information is important to the OPERATOR, it should be written in the appropriate language and reading level. Knowledge of equipment or ability that is not typical for the lay person is not to be presumed.

Inadequate marking and ACCOMPANYING DOCUMENTS are not the only cause of erroneous use by the OPERATOR. Other reasons, such as lack of motivation, inadequate experience or training, and environment variables such as an overcrowded work situation, can cause OPERATORS to use the equipment in a manner contrary to the instructions for use. For example, the use of anaesthesia equipment without performing a complete pre-use check-out procedure illustrates the point that adequate information itself does not guarantee a particular OPERATOR behaviour. This can happen despite the fact that the marking and instructions for use of most anaesthesia systems include such pre-use procedures

Because problems with equipment can be due to several contributing factors, some of which might not be obvious or easy to discover, a comprehensive analysis of a problem related either to the equipment itself or to its use, is a prerequisite for the implementation of effective measures to resolve it. Limiting the analysis can cause lengthy delays in resolving the problem. Likewise, limiting the analysis can result in selecting solution strategies that are unnecessarily costly. Therefore, before developing an educational strategy to address an equipment problem area, the following two logical steps should be taken:

a) Perform a full analysis of the problem of use by:
   – determining the extent of the problem and its immediate causes;

  - identifying particular OPERATOR behaviour (actions, omissions) involved;
  - identifying incentives and disincentives to desired behaviours.

b) identify solution strategies to address the performance of OPERATORS by:
  - design changes;
  - changes in marking and ACCOMPANYING DOCUMENTS;
  - training or educational changes;
  - motivational solutions;
  - environmental changes.

The development of effective educational programs for OPERATORS is a task shared by the manufacturer and those responsible for deployment of the equipment in the health care facility,

The manufacturer has a responsibility to provide markings on the equipment. In addition, training on the specific equipment is required for the safe and effective use by the intended OPERATOR. The MANUFACTURER should do at least one of the following:

– provide the necessary instructional materials;
– ensure that these materials are available; or
– provide the training.

Health care facility managers should offer a comprehensive educational program to prepare the OPERATORS to use the equipment safely for its INTENDED PURPOSE. The program should cover both the initial training and periodic retraining, as appropriate.

The EDUCATIONAL MATERIALS should be based on the materials provided by the manufacturer, i.e. the ACCOMPANYING DOCUMENTS and, when available, instructional materials or training provided by the manufacturer, Those responsible for deployment of the equipment might want to develop their own EDUCATIONAL MATERIALS based on the materials provided by the manufacturer in order to account for individual circumstances or the special needs of the OPERATORS.

It should be kept in mind that educational approaches to alleviating equipment problems are most likely to be effective when they are developed by collaboration between all parties who have experience with and interest in the problem and its solutions. These parties can include OPERATORS, health care facility managers, clinical engineers, manufacturers, health care and technical personnel educators and standards-setting organizations. All of these parties are encouraged to incorporate the steps listed later in this technical report.

4 Development and use of educational programs and materials

4.1 Program goals

An educational program directed to the OPERATORS of any equipment should have one or more of the following goals:

a) develop proper attitude by providing information that will motivate the OPERATOR to use the equipment safely;
b) encourage appropriate behaviour by providing information and motivation that leads to the development of new skills or behaviour;
c) provide adequate knowledge by providing information that will enable the OPERATOR to understand the function and use of the equipment, and that will train the OPERATOR in the recommended procedures for operation and maintenance for safe use of the equipment; and
d) develop skills necessary for operation by providing the OPERATOR with guidance and practice opportunities to operate the equipment or perform tests as recommended.

4.2 Division of tasks for information development

It is important to decide who should be involved at each step of the process. The emphasis is on developing materials with assigned and appropriate parties.

NOTE Health care facilities that continue to use equipment from manufacturers who no longer exist will need to take on the additional task of maintaining the instructional materials for the equipment.

4.2.1 Manufacturers

Basic education regarding proper use of the equipment begins with its manufacturer. As a minimum, manufacturers and/or the manufacturer's representatives should:

a) Provide written instructions for use, maintenance, etc. that are clear, concise, easily understood by the intended OPERATOR, and are well illustrated, with important messages highlighted.

   NOTE The patient or a relative can, in some cases, be the intended OPERATOR. See Clause 5.

b) Use good educational and USABILITY ENGINEERING principles when developing instructional materials, courses, etc.

c) Make certain that instructional materials are developed with, and tested on, target OPERATORS of the equipment to validate the understandability and effectiveness of the materials. Medical and paramedical staff, clinical engineers and educators can also provide their expertise in the development of instructional materials. When appropriate to the INTENDED USE of the equipment, lay persons could be involved in the development and testing of EDUCATIONAL MATERIALS.

d) Recommend in-service training and propose a training plan.

e) Assure that appropriate documentation (e.g. short form instructions for use, checklists) are available to remind OPERATORS of important information including the OPERATOR-performed maintenance necessary to maintain the basic safety and essential performance of the equipment.

f) Revise instructional materials promptly when necessary and disseminate to existing facilities and operators of the equipment.

4.2.2 Health care facility managers

4.2.2.1 Educational program implementation

Health care facilities should have a comprehensive educational program to help assure that equipment is used safely for its INTENDED PURPOSE. To accomplish this objective, health care facilities should provide training for the OPERATORS to assure that they have the proper skills, experience and theoretical background to understand the operation and proper use of the assigned equipment. Only those who demonstrate proficiency should be allowed to use the equipment. The comprehensive educational program should include the following general and specific elements:

a) there are written criteria for the training of all personnel who use, maintain, calibrate, or are otherwise concerned with any equipment. Training should be tailored to the OPERATOR'S responsibilities and the specific equipment;

b) training and instructional materials are developed in accordance with good educational and USABILITY ENGINEERING principles;

c) training is conducted by qualified persons;

d) initial training of all OPERATORS is documented;

e) there is an established program for periodic retraining of OPERATORS to ensure that skills are maintained. Successful completion of training is documented;

f) the initial training and the periodic retraining of OPERATORS should include testing of the OPERATORS' knowledge and skills. Skills are tested by observers who are qualified to test OPERATORS, and will observe the OPERATORS under simulated conditions including various patient conditions, environments, and models of the equipment.

The education program should stress the OPERATORS' responsibility to help identify when specific training is needed and to call for that education when necessary.

4.2.2.2 Training elements

Specific tasks on which personnel might be trained and tested on particular equipment can include, as appropriate:

a) recognition of conditions for which the equipment should be used;
b) how the equipment operates;
c) how to check the equipment before use and before delivery to a patient;
d) how to set up and use the equipment;
e) how to avoid injury to both patients and OPERATORS;
f) how to assess problems;
g) how to maintain or service the equipment and record the service history;
h) how to calibrate the equipment;
i) how to test for constancy of results;
j) how to document and report malfunctions, accidents and injuries associated with equipment use;
k) where and how to obtain assistance with the equipment;
l) how to store the equipment.

4.2.2.3 Availability of information

Health care facility management should ensure that all EDUCATIONAL MATERIAL, especially accompanying material supplied by the manufacturer, is complete and readily available to the OPERATOR.

4.2.2.4 Record maintenance

Health care facility management should establish and maintain records that document that the tasks listed above have been performed.

4.2.2.5 Auditing

Health care facility management should establish procedures to ensure that their educational procedures are reviewed at periodic intervals.

4.2.3 Medical, paramedical and clinical engineering personnel

Medical, paramedical and clinical engineering personnel often develop information concerning equipment for use within their medical practice or for use with health education programs. This information should incorporate USABILITY ENGINEERING principles involving information development and OPERATOR considerations. Medical, paramedical and clinical engineering personnel should also provide their expertise to manufacturers in the development of marking and ACCOMPANYING DOCUMENTS provided with the equipment.

Equipment OPERATORS should be involved in the testing and validation of the EDUCATIONAL MATERIALs that are developed by manufacturers, health care facility managers, medical and paramedical staff, clinical engineers and educators.

4.2.4 Educators

Educators should be aware of USABILITY ENGINEERING principles in the development of supplementary materials for health education programs and lend expertise to the development process for equipment information by manufacturers and medical staff.

4.2.5 Standards-writing organizations

Standards-writing organizations should incorporate USABILITY ENGINEERING principles into standards dealing with equipment and include in those standards the elements of the process outlined in this report.

4.3 Data collection

Data and information regarding the use of the selected equipment should be gathered by means of theoretical or technical evaluation, focus groups or clinical evaluation in view of putting together the educational program.

4.3.1 Information to consider concerning equipment

Information to consider concerning equipment includes the following:

a) manufacturer(s) of the equipment;

b) model(s) available;

c) INTENDED PURPOSE of the equipment;

d) intended for single or multiple use;

e) operational procedures that accomplish purpose of the equipment;

f) intended OPERATOR (e.g. health professional, lay person);

g) OPERATOR responsibilities (what is expected to be done by the OPERATOR):
   - correctly operate the equipment;
   - properly maintain the equipment;
   - identify malfunctions and take appropriate action.

h) physical and clinical fundamentals on which operational procedures are based (e.g. infusion pump therapy incorporating patient physiological parameters and volume flow rate);

i) interaction of the equipment, patient, OPERATOR, facility, and environment;

j) problems associated with the equipment and its use;

k) equipment design and manufacture:
   - human interface design;
   - QUALITY ASSURANCE systems;
   - information supplied by the manufacturer.

   NOTE See the future IEC 60601-1-11 for specific requirements beyond those in IEC 60601-1 for equipment intended by its manufacturer to be used in the environment in which a patient lives or other environments that patients can occupy, excluding professional healthcare facility environments.

l) environment:
   - organization of the OPERATOR work area;
   - supervisory and administrative support;
   - support systems for handicapped, elderly, impaired lay OPERATORS;
   - atmosphere (heat, light, sound);
   - electromagnetic compatibility;
   - decontamination (e.g. cleaning, sterilization);
   - types of other equipment used with or in the vicinity of the equipment in question;
   - maintenance of equipment.

m) Choice of accessories:
   - recommended;
   - third party.

n) information and training programs provided.

4.3.2 Information to consider about the audience(s) for the EDUCATIONAL MATERIALS

Information to consider about the audience(s) for the EDUCATIONAL MATERIALS includes:

a) audience:
   - direct audiences: nurses, medical doctors, technicians, non-technically trained persons including patients;
   - indirect audiences: teachers, supervisors and managers, biomedical or clinical engineers or physicists, trainers, and auxiliary health care personnel such as pharmacists;

b) individual characteristics of the OPERATOR, for instance:
   - physical characteristics (e.g. colour blindness);
   - dexterity;
   - illnesses;
   - use of medications;
   - personality;
   - socio–economic factors;
   - OPERATOR knowledge and skill;
   - quality and timeliness of training and follow–up proficiency checks;
   - motivation;
   - experience.

NOTE 1 The patient or a relative can, in some cases, be the OPERATOR.

NOTE 2 The equipment OPERATOR as well as the patient can have a handicapping condition.

4.4 Selection of media and formats

Determine which media (or combination) and their formats most effectively reach the audience and meet the selected goal(s) of developing proper attitudes, encouraging appropriate behaviour, providing adequate knowledge, and developing skills necessary for operation or performance of the medical electrical equipment.

a) Written media:
   - ACCOMPANYING DOCUMENTS;
   - marking on the equipment;
   - brochures;
   - manuals;
   - patient package inserts;
   - checklists/sheet form instructions for use/instruction cards;
   - posters–text;
   - training packages;
   - standards;
   - journal articles.

b) Audio:
   - cassettes;
   - audio conferences;
   - voice synthesizers;
   - radio networks.

c) Audio-visual:
   – slides and tapes;
   – videotapes;
   – television networks;
   – interactive video;
   – computers;
   – simulators.
d) Instructions:
   – demonstrations;
   – lectures;
   – seminars;
   – in-service training;
   – college courses;
   – on-the-job training;
   – simulation.
e) dummy or training devices.

   EXAMPLE Training defibrillator.

4.5 Development and presentation of messages and materials

In developing the educational messages and materials, it is recommended that they be presented in a manner that is:

– interesting, motivating, targeted at OPERATOR interests;
– logically presented, simple, clearly stated text;
– liberal in the use of illustrations;
– attractive (colour, form, shape, etc.) in its presentation and packaging;
– reinforcing (repeat, and highlight important messages);
– up-to-date in its information content;
– easy to use;
– in a language understandable by the user;
– affordable and accessible;
– appropriate in print size;
– appropriate in its use of the selected educational modality(ies);
– appropriate in length and level of detail.

4.6 Validation of information content and presentation

4.6.1 Testing of EDUCATIONAL MATERIAL during product development

The following are examples of methods to assess the information content and presentation mode for the intended OPERATORS of the equipment:

a) OPERATOR surveys to determine informational needs;
b) focus group testing by interviews to obtain insights into the target audience's perceptions and beliefs prior to material development and/or after drafting of the materials;
c) readability testing to determine reading grade level of draft manuscripts;

d) individual in-depth interviews probing the target audience's attitudes, beliefs, and emotions about the use of the equipment or their health related to the use of such equipment;

e) interviews to obtain the target audience's reactions to concepts and messages;

f) questionnaires to obtain the target audience's reactions to draft materials;

g) review of draft materials prior to final production by intermediary organizations such as professional associations of health care personnel;

h) OPERATOR studies that use the proposed materials and the equipment to determine the adequacy of instructions and performance of the equipment in the hands of the target OPERATORS.

4.6.2 Testing of EDUCATIONAL MATERIAL during equipment use

EDUCATIONAL MATERIALS might need to be revised once the equipment is in use. Some examples of the sources of change that could require revising the EDUCATIONAL MATERIALS are the results of clinical trials, engineering design testing and feedback from students on the EDUCATIONAL MATERIAL. The following methods can also be used as a further assessment of the revised EDUCATIONAL MATERIALS:

a) marking, ACCOMPANYING DOCUMENTS, and EDUCATIONAL MATERIALS evaluation;

b) OPERATOR studies.

4.7 Distribution and use

a) Decide how the EDUCATIONAL MATERIAL will be distributed to the target audience:
   - direct mail;
   - delivered with the equipment;
   - health fairs;
   - the offices of health care personnel and biomedical or clinical engineers;
   - professional seminars.

b) Consider how the EDUCATIONAL MATERIAL will be used once it arrives at the destination:
   - incorporated in educational program for the use of the equipment;
   - interactive education.

c) Determine optimum material location to assure correct use, (e.g. checklist affixed to the equipment).

4.8 Follow-up of EDUCATIONAL MATERIAL

Health care facilities should report to the manufacturer incidents that can be directly attributed to deficiencies or other shortcomings in the instructional materials provided by the manufacturer. Such feedback is important so that manufacturers can revise and improve their instructional materials.

Manufacturers should include this feedback in their risk management process.

5 Patients and lay OPERATORS

Those developing the instructions for use, instructional materials, and education programs for patients or lay OPERATORS need to consider the mental, physical and demographic traits of the intended patient or lay OPERATOR population. These can include:

– age, condition and general state of health;

– reading level and comprehension;

– decrements in vision, hearing, strength, manual dexterity and memory;

– inexperience and lack of medical training.

EDUCATIONAL MATERIALS developed for patients or lay OPERATORS should be validated using patients or lay OPERATORS who are representative of the mental, physical and demographic traits of the intended population.

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1) Under consideration.

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