SS IEC 60601-1-9:2018+A1:2020

IEC 60601-1-9:2007+AMD2:2020, IDT

(ICS 11.040; 13.020)

SINGAPORE STANDARD

Medical electrical equipment

– Part 1-9 : General requirements for basic safety and essential performance – Collateral standard: Requirements for environmentally conscious design

Incorporating Amendment No. 1

Singapore Standards Council

SS IEC 60601-1-9 :2018+A1:2020

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– Part 1-9 : General requirements for basic safety and essential performance

– Collateral standard: Requirements for environmentally conscious design

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The content of this Singapore Standard was approved on 15 November 2018 by the Biomedical and Health Standards Committee (BHSC) under the purview of the Singapore Standards Council.

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National Foreword

This Singapore Standard was prepared by the National Mirror Working Group on IEC SC62D MT20 set up by the Technical Committee on Medical Devices under the purview of BHSC.

This standard is identical with IEC 60601-1-9:2007, “Medical electrical equipment – Part 1-9: General requirements for basic safety and essential performance – Collateral standard: Requirements for environmentally conscious design”, including the amendments to this edition, published by the International Electrotechnical Commission.

NOTE 1 – Where appropriate, the words “International Standard” are read as “Singapore Standard”.

NOTE 2 – Reference to International/Overseas Standards are replaced by applicable Singapore Standards or Technical References.

Attention is drawn to the possibility that some of the elements of this Singapore Standard may be the subject of patent rights. Enterprise Singapore shall not be held responsible for identifying any or all of such patent rights.

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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This consolidated version of the official IEC Standard and its amendments has been prepared for user convenience.

IEC 60601-1-9 edition 1.2 contains the first edition (2007-07) [documents 62A/571/FDIS and 62A/575/RVD], its amendment 1 (2013-06) [documents 62A/874/FDIS and 62A/881/RVD] and its amendment 2 (2020-07) [documents 62A/1393/FDIS and 62A/1408/RVD].

This Final version does not show where the technical content is modified by amendments 1 and 2. A separate Redline version with all changes highlighted is available in this publication.

International standard IEC 60601-1-9 has been prepared by IEC subcommittee 62A: Common aspects of electrical equipment used in medical practice, of IEC technical committee 62: Electrical equipment in medical practice.

The first edition of this publication constitutes a collateral standard to IEC 60601-1: *Medical electrical equipment – Part 1: General requirements for safety and essential performance* hereafter referred to as the general standard.

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

In the 60601 series of publications, collateral standards specify general requirements for safety applicable to:

– a subgroup of MEDICAL ELECTRICAL EQUIPMENT (e.g. radiological equipment); or
– a specific characteristic of all MEDICAL ELECTRICAL EQUIPMENT, not fully addressed in the general standard (e.g. alarm systems).

In this collateral standard, the following print types are used:

– Requirements and definitions: roman type.
– *Test specifications: italic type.*
– Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.
– TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS COLLATERAL STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this standard, the term

– “clause” means one of the four numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 4 includes subclauses 4.1, 4.2, etc.);
– “subclause” means a numbered subdivision of a clause (e.g. 4.1, 4.5 and 4.5.1 are all subclauses of Clause 4).

References to clauses within this standard are preceded by the term “Clause” followed by the clause number. References to subclauses within this standard are by number only.

In this standard, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

– “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;
– “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;
– “may” is used to describe a permissible way to achieve compliance with a requirement or test.

Clauses, subclauses and definitions for which a rationale is provided in informative Annex A are marked with an asterisk (*).

A list of all parts of the IEC 60601 series, published under the general title *Medical electrical equipment,* can be found on the IEC website.

The committee has decided that the contents of the base publication and its amendments will remain unchanged until the stability 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.

NOTE The attention of National Committees is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised IEC or ISO publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this publication be adopted for mandatory implementation nationally not earlier than 3 years from the date of publication.

INTRODUCTION

The objective of this collateral standard is to improve the ENVIRONMENTAL IMPACT for the entire range of MEDICAL ELECTRICAL EQUIPMENT, taking into account all stages of the product LIFE CYCLE:

– product specification;
– design;
– manufacturing;
– sales, logistics, installation;
– use;
– END OF LIFE management.

This means protecting the ENVIRONMENT and human health from HAZARDOUS SUBSTANCES, conserving raw materials and energy, minimizing the generation of WASTE, as well as minimizing the adverse ENVIRONMENTAL IMPACTS associated with WASTE. The criteria needed to reach this goal must be integrated into all stages of the MEDICAL ELECTRICAL EQUIPMENT LIFE CYCLE from the specification stage to END OF LIFE management.

The ENVIRONMENTAL IMPACTS of ME EQUIPMENT through all LIFE-CYCLE stages are determined from the MEDICAL ELECTRICAL EQUIPMENT'S ENVIRONMENTAL ASPECTS defined during the identification of need, product planning, and design stages (see Table A.1). Consideration of ENVIRONMENTAL ASPECTS as early as possible in these stages can produce numerous benefits that might include lower costs, stimulation of innovation and creativity, and increased knowledge about the product. It can also provide new business opportunities, and improved product quality as well as reduction of adverse ENVIRONMENTAL IMPACTS. The assessment of the ENVIRONMENTAL ASPECTS and IMPACTS of MEDICAL ELECTRICAL EQUIPMENT is a developing science and it is anticipated that this collateral standard will require periodic updating as the science develops.

The requirements given in this collateral standard do not replace national or international laws and regulations.

Environmental protection is one element of the overall RISK MANAGEMENT PROCESS as required by the general standard.

The acceptability of MEDICAL ELECTRICAL EQUIPMENT'S ENVIRONMENTAL IMPACTS are balanced against other factors, such as the product's intended function, performance, safety, cost, marketability, quality, legal and regulatory requirements. This balance can differ depending on the intended function of the MEDICAL ELECTRICAL EQUIPMENT. For example, a solution appropriate for life-saving or life-supporting MEDICAL ELECTRICAL EQUIPMENT might not be appropriate for a device intended to correct a minor ailment. A MANUFACTURER of MEDICAL ELECTRICAL EQUIPMENT might have to justify, as a result of RISK MANAGEMENT, that a medical benefit outweighs the associated adverse ENVIRONMENTAL IMPACTS.

INTRODUCTION to Amendment 1

The first edition of IEC 60601-1-9 was published in 2007. This amendment is intended to update the references to IEC 60601-1:2005 to include Amendment 1:2012 and to make a few minor editorial updates.

INTRODUCTION to Amendment 2

The first edition of IEC 60601-1-9 was published in 2007 and amended in 2013. Since the publication of IEC 60601-1-9:2007+A1:2013, the IEC Subcommittee (SC) 62A Secretariat has been collecting issues from a variety of sources including comments from National Committees. At the November 2015 meeting of IEC/SC 62A in Kobe, Japan, the subcommittee initiated a process to identify high-priority issues that need to be considered in an amendment and should not wait until the second edition of IEC 60601-1-9, which is presently targeted for publication sometime after 2024.

As directed in item 1 of Kobe Resolution 1, the IEC/SC 62A Chairman Advisory Group (CAG) considered the 7 issues collected by the SC/62A Secretariat for IEC 60601-1-9:2007 and determined that none met the selection criteria stated in Kobe Resolution 1.

However, an amendment is needed to update the reference to IEC 60601-1:2005+A1:2012 +A2:2020. In London in 2018, SC 62A approved the development of an administrative amendment to IEC 60601-1-9:2007+A1:2013.

Because this is an amendment to IEC 60601-1-9:2007, the style in force at the time of publication of IEC 60601-1-9 has been applied to this amendment. The specified in ISO/IEC Directives Part 2:2018 has only been applied when implementing the new style guidance would not result in additional editorial changes.

Users of this document should note that when constructing the dated references to specific elements in a standard, such as definitions, amendments are only referenced if they modified the text being cited. For example, if a reference is made to a definition that has not been modified by an amendment, then the reference to the amendment is not included in the dated reference.

MEDICAL ELECTRICAL EQUIPMENT –

Part 1-9: General requirements for basic safety and essential performance – Collateral Standard: Requirements for environmentally conscious design

Scope, object and related standards

1.1 * Scope

This International Standard applies to the reduction of adverse ENVIRONMENTAL IMPACTS of MEDICAL ELECTRICAL EQUIPMENT, hereafter referred to as ME EQUIPMENT.

MEDICAL ELECTRICAL SYSTEMS are excluded from the scope of this collateral standard.

1.2 Object

The object of this collateral standard is to specify general requirements, in addition to those of the general standard, for the reduction of the adverse ENVIRONMENTAL IMPACT of ME EQUIPMENT, and to serve as the basis for particular standards.

1.3 Related standards

1.3.1 IEC 60601-1

For ME EQUIPMENT, this collateral standard complements IEC 60601-1.

When referring to IEC 60601-1 or to this collateral standard, either individually or in combination, the following conventions are used:

– "the general standard" designates IEC 60601-1 alone, including any amendments;

– "this collateral standard" designates IEC 60601-1-9 alone, including any amendments;

– "this standard" designates the combination of the general standard and this collateral standard.

1.3.2 Particular standards

A requirement in a particular standard takes priority over the corresponding requirement in this collateral standard.

1.3.3 Environmental standards

This standard takes into account the ISO 14000 series of environmental standards with particular emphasis on ISO 14062 [8][1)].

1) Figures in square brackets refer to the Bibliography.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
Amendment 1:2012
Amendment 2:2020

3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005+A1:2012+A2:2020 and the following definitions apply.

NOTE An index of defined terms is found beginning on page 30.

3.1
DESIGN AND DEVELOPMENT
set of PROCESSES that transforms requirements into specified characteristics or into the specification of a product, PROCESS or system

NOTE 1 The terms “design” and “development” are sometimes used synonymously and sometimes used to define different stages of the overall PROCESS of turning an idea into a product.

NOTE 2 Product development is the PROCESS of taking a product idea from planning to market launch and post-market review of the product, in which business strategies, marketing considerations, research methods and design aspects are used to take a product to a point of practical use. It includes improvements or modifications to existing products or PROCESSES

NOTE 3 The integration of ENVIRONMENTAL ASPECTS into product DESIGN AND DEVELOPMENT can also be termed design for the ENVIRONMENT (DFE), eco-design, the environmental part of product stewardship, etc.

[ISO/TR 14062:2002, definition 3.3]

3.2
END OF LIFE
EOL
state of a ME EQUIPMENT when it is finally removed from its INTENDED USE

NOTE Adapted from IEC Guide 109:2003, Definition 3.1.

3.3
ENVIRONMENT
surroundings in which an ORGANIZATION operates, including air, water, land, natural resources, flora, fauna, humans and their interrelation

NOTE Surroundings in this context extend from within an ORGANIZATION to the global system.

[ISO 14001:2004, definition 3.5]

3.4
*** ENVIRONMENTAL ASPECT**
element of an ORGANIZATION’S activities, products or services that can interact with the ENVIRONMENT

NOTE A significant ENVIRONMENTAL ASPECT has or can have a significant ENVIRONMENTAL IMPACT.

[ISO 14001:2004, definition 3.6]

3.5
*** ENVIRONMENTAL IMPACT**
any change to the ENVIRONMENT, whether adverse or beneficial, wholly or partially resulting from an ORGANIZATION'S ENVIRONMENTAL ASPECTS

[ISO 14001:2004, definition 3.7]

3.6
HAZARDOUS SUBSTANCE
substance which can affect human health or the ENVIRONMENT with an immediate or retarded effect

[IEC Guide 109: 2003, definition 3.6, modified]

3.7
LIFE CYCLE
consecutive and interlinked stages of a product system, from raw material acquisition or generation from natural resources to final disposal

[ISO 14040:2006, definition 3.1]

3.8
LIFE-CYCLE ASSESSMENT
LCA
compilation and evaluation of the inputs, outputs and the potential ENVIRONMENTAL IMPACTS of a product system throughout its LIFE CYCLE

[ISO 14040:2006, definition 3.2]

3.9
ORGANIZATION
company, corporation, firm, enterprise, authority or institution, or part or combination thereof, whether incorporated or not, public or private, that has its own functions and administration

NOTE For ORGANIZATIONS with more than one operating unit, a single operating unit may be defined as an ORGANIZATION.

[ISO 14001:2004, definition 3.16]

3.10
PACKAGING
material that is used to protect or contain a product during transportation, storage and marketing

NOTE 1 For the purposes of this standard, the term PACKAGING also includes any item that is physically attached to, or included with, a product or its container for the purpose of marketing the product.

NOTE 2 Adapted from ISO 14021:1999, definition 3.1.10.

3.11
RECYCLING
reprocessing in a production PROCESS of the WASTE materials for the original purpose or for other purposes but excluding energy recovery

[IEC Guide 109:2003, definition 3.16]

3.12
REUSE
utilization of ME EQUIPMENT or a part of ME EQUIPMENT, after it has been disposed of by the RESPONSIBLE ORGANIZATION as WASTE, for a similar purpose to that for which it was originally intended by the MANUFACTURER

3.13
SUPPLY CHAIN
those involved, through upstream and downstream linkages, in PROCESSES and activities delivering value in the form of products to the MANUFACTURER

NOTE 1 In practice, the expression “interlinked chain” applies from suppliers to those involved in END OF LIFE processing.

NOTE 2 In practice, the expressions “product chain”, “value chain” are often used.

NOTE 3 Adapted from ISO/TR 14062:2002, definition 3.9.

3.14
WASTE
substance or object which the holder disposes of, or is required to dispose of, pursuant to the provisions of national law in force

[IEC Guide 109:2003, definition 3.18]

4 Protection of the ENVIRONMENT

4.1 * Identification of ENVIRONMENTAL ASPECTS

THE MANUFACTURER shall establish, implement and maintain a PROCESS to identify and document the relevant ENVIRONMENTAL ASPECTS of ME EQUIPMENT across all LIFE-CYCLE stages. Examples of ENVIRONMENTAL ASPECTS are:

– use of HAZARDOUS SUBSTANCES;
– emissions to air;
– releases to surface water and ground water;
– WASTE, especially HAZARDOUS SUBSTANCES;
– use of natural resources, energy and raw materials;
– noise, vibration, odour, dust, electromagnetic fields etc.;
– transport (both for goods and services and employees);
– RISKS from environmental accidents and ENVIRONMENTAL IMPACTS arising, or likely to arise, as consequences of incidents, accidents and potential emergency situations; and
– use and contamination of the biosphere.

Compliance is checked by inspection of the relevant design documents and PROCESS description.

4.2 * Determination of significant ENVIRONMENTAL ASPECTS

The MANUFACTURER shall establish, implement and maintain a PROCESS to qualitatively or quantitatively determine and document the ENVIRONMENTAL ASPECTS that can have significant ENVIRONMENTAL IMPACTS (i.e. significant ENVIRONMENTAL ASPECTS) during all LIFE-CYCLE stages of the ME EQUIPMENT.

Compliance is checked by inspection of the relevant design documents and PROCESS description.

4.3 * Information from the SUPPLY CHAIN

The MANUFACTURER shall establish, implement and maintain PROCESSES to:

– identify those suppliers (including services) that are likely to contribute significant ENVIRONMENTAL ASPECTS to the ME EQUIPMENT; and

– obtain from those SUPPLIERS the information necessary to assist the MANUFACTURER in identifying and assessing the ENVIRONMENTAL ASPECTS of the ME EQUIPMENT as required in 4.1 and 4.2.

If, despite the MANUFACTURER'S efforts, ORGANIZATIONS within the SUPPLY CHAIN fail to provide the information requested by the MANUFACTURER, the MANUFACTURER shall provide an estimation of the missing information and document the rationale.

NOTE To fully assess the ENVIRONMENTAL ASPECTS across the entire life of the ME EQUIPMENT it is necessary for the MANUFACTURER to gather information and involve the environmentally significant SUPPLIERS during the concept and design stage.

Compliance is checked by inspection of the relevant design documents and PROCESS description.

4.4 * Reduction of adverse ENVIRONMENTAL IMPACTS

The MANUFACTURER shall establish and document targets for the significant ENVIRONMENTAL ASPECTS of the ME EQUIPMENT to minimize as far as reasonable the adverse ENVIRONMENTAL IMPACTS across all LIFE-CYCLE stages. The documented targets shall be based on functional as well as environmental requirements, and, when available, previous product designs.

During the ME EQUIPMENT concept and specification setting stage, the MANUFACTURER shall consider, as far as reasonable, novel emerging or alternative technologies and/or solutions for the ME EQUIPMENT that reduce significant adverse ENVIRONMENTAL IMPACTS.

The MANUFACTURER shall assess and document the actual significant ENVIRONMENTAL ASPECTS across all LIFE-CYCLE stages of a representative prototype of the final design of the ME EQUIPMENT. Any deviations from the targets shall be assessed and documented for consideration in future designs.

Compliance is checked by inspection of the relevant design documents.

4.5 Environmental information

4.5.1 * PACKAGING of ME EQUIPMENT

The MANUFACTURER shall make available information on the type and mass of PACKAGING material(s).

NOTE 'Type' of PACKAGING refers, as a minimum, to the generic description (e.g. cardboard, plastic, wood, glass etc).

Compliance is checked by verifying the availability of the information.

4.5.2 * Instructions for minimizing ENVIRONMENTAL IMPACT during NORMAL USE

The MANUFACTURER shall provide instructions for minimizing the ENVIRONMENTAL IMPACT of the ME EQUIPMENT during NORMAL USE in the ACCOMPANYING DOCUMENTS.

The instructions shall cover the following items where applicable:

- instructions on how to install the ME EQUIPMENT in order to minimize the ENVIRONMENTAL IMPACT during its EXPECTED SERVICE LIFE;
- instructions on how to use and maintain the ME EQUIPMENT in order to minimize the ENVIRONMENTAL IMPACT during its EXPECTED SERVICE LIFE;
- consumption during NORMAL USE (e.g. energy, consumable materials/parts, disposables, water, gasses, chemicals/reagents etc.);
- emissions during NORMAL USE (e.g. WASTE water, WASTE consumable materials, acoustic energy, heat, gasses, vapours, particulates, HAZARDOUS SUBSTANCES and other WASTE); and
- information on the location within the ME EQUIPMENT of HAZARDOUS SUBSTANCES, radioactive sources and induced radioactive materials.

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS.

4.5.3 * Information for END OF LIFE management

The MANUFACTURER shall provide the RESPONSIBLE ORGANIZATION with information for the proper disposal of the ME EQUIPMENT at END OF LIFE.

The MANUFACTURER shall make available information to WASTE treatment facilities necessary for the environmentally responsible management of END OF LIFE ME EQUIPMENT. The information shall contain:

- the location of components and parts within the ME EQUIPMENT that contain stored energy or pose other HAZARDS that can result in an unacceptable RISK to disassemblers or others and methods for controlling such RISKS;
- the identity and location of HAZARDOUS SUBSTANCES requiring special handling and treatment; and
- disassembly instructions sufficient for the safe removal of these HAZARDOUS SUBSTANCES including radioactive sources and induced radioactive materials within the ME EQUIPMENT.

Compliance is checked by verifying the availability of the information.

Annex A
(informative)

General guidance and rationale

A.1 General guidance

In the future, MANUFACTURERS and RESPONSIBLE ORGANIZATIONS will be required to holistically meet enhanced environmental criteria and to further improve product quality and safety. ME EQUIPMENT is intended to have beneficial effects on humans. However if the damage to the ENVIRONMENT caused by the ME EQUIPMENT outweighs the medical benefits, this is counter-productive to the intended function of the ME EQUIPMENT. ME EQUIPMENT should be designed, manufactured, used and discarded in a manner that is environmentally responsible.

The objective of this collateral standard is to reduce the ENVIRONMENTAL IMPACTS of the ME EQUIPMENT taking into account all the ME EQUIPMENT LIFE-CYCLE stages. Benefits of implementing this collateral standard include, for example, the reduction of potential sources of HARM, HAZARDOUS SUBSTANCES and WASTE, and savings of natural resources, raw materials and energy. Benefits can be grouped into transportation reduction, cost reduction and a positive public perception of the MANUFACTURER as a good corporate citizen.

LIFE-CYCLE ASSESSMENT is a tool that can be used to reduce the ENVIRONMENTAL IMPACT of ME EQUIPMENT. The principle and framework for LIFE-CYCLE ASSESSMENT is described in ISO 14040 [7]. MANUFACTURERS undertaking LIFE-CYCLE ASSESSMENT will have to select or develop their own PROCESSES and assessment tools to achieve product-related environmental improvements.

The ENVIRONMENTAL IMPACTS of ME EQUIPMENT are largely determined during the DESIGN AND DEVELOPMENT stage. Therefore, in order to reduce the adverse ENVIRONMENTAL IMPACTS of the new ME EQUIPMENT:

– adverse ENVIRONMENTAL IMPACT reduction should be seen as starting at the identification of need and flowing throughout DESIGN AND DEVELOPMENT;
– it is highly desirable to start the ENVIRONMENTAL ASPECT/IMPACT assessment as early as possible in product planning.

Typically the ME EQUIPMENT LIFE CYCLE includes the stages in Table A.1. Table A.1 contains both environmental considerations and, where applicable, examples of ENVIRONMENTAL ASPECTS for each LIFE-CYCLE stage.

Environmental protection is not a subject that is covered in all engineering training. Consequently this rationale is more detailed than normal for a standard of this type.

The following is one of many examples of the LIFE-CYCLE stages of ME EQUIPMENT.

Table A.1 – Example product LIFE-CYCLE stages

Stage	Activity	Characteristics	Environmental considerations
Identification of need	Exploration, identification of opportunities and management decision	Identification of a market need (including environmental expectations). For example, market needs can be defined from direct customer demand or market feedback.	It might be possible to meet the identified need by solutions not requiring the production of a new product. The ENVIRONMENTAL ASPECTS of adapting existing products or non-physical product solutions (e.g. a time counter can be replaced by a software module or hardware can be replaced by a service solution) should be explored.
Planning	Requirement specification	A solution requiring a product has been identified. Comparison of the expected ENVIRONMENTAL IMPACTS of the proposed product against previous or competitive products is appropriate. Legal and other normative information needs to be considered. The Requirement specification is created. The requirement specification should detail required performance and not propose specific solutions, so as to allow innovative and novel approaches. The project is formalized.	Define and assess ENVIRONMENT-related targets. Identify requirements that result from these targets. Establish these requirements in the requirement specification (e.g. reduce energy consumption over the product LIFE CYCLE by 20%).
	Product concept	The point at which preliminary solutions to the need are explored. Ideas will be documented informally; the design will be very fluid. Up to this point, there has been little commitment of time or materials. Communications with suppliers are informal and exploratory.	The optimal stage at which to consider creative solutions to reduce adverse ENVIRONMENTAL IMPACTS. e.g. consideration can be given to: – modifying, upgrading, refurbishing existing products – novel technologies – creative design solutions – alternative material choice (Including reduction/removal of HAZARDOUS SUBSTANCES) – use of recycled materials – use of recovered components/assemblies – new production PROCESSES – alternative energy sources – PACKAGING – Reduction/elimination of consumables – Service and maintenance – Extended durability – Marketing and promotional materials – END OF LIFE REUSE/RECYCLING and material recovery There might be experimentation with different configurations so that the design solution with the optimum balance between product benefit, performance and ENVIRONMENTAL IMPACT can be easily and cost-effectively established. Most appropriate point at which the assessment of product ENVIRONMENTAL ASPECTS and ENVIRONMENTAL IMPACTS can be determined. Strategic suppliers become involved in the design solutions and start to become important to the environmental profile of the ME EQUIPMENT.

Table A.1 – Example product LIFE-CYCLE stages *(continued)*

Stage	Activity	Characteristics	Environmental considerations
Design	DESIGN AND DEVELOPMENT	Design solution now becoming established. Information necessary to turn the concept into a formal product is gathered. Components and assemblies are developed or sourced. Although changes to the specification can be made, this now starts to incur costs.	Establish environmental targets and requirements for the design, considering all LIFE-CYCLE stages, in the design specification. The design is refined and incremental environmentally beneficial changes can usually be made, especially in the areas of material reduction and component selection. Appropriate production PROCESSES should be considered as these can be a significant source of adverse ENVIRONMENTAL IMPACTS. All suppliers start to become integrated into the development PROCESS and their environmental performance will have effects on the overall ENVIRONMENTAL IMPACT of the ME EQUIPMENT. Consideration must be given to limiting the amount and number of materials used in the ME EQUIPMENT. (As a general rule the smaller and lighter the better, as this has a subsequent benefit on PACKAGING, transportation and END OF LIFE as well.) Efforts should be made to eliminate HAZARDOUS SUBSTANCES both in the product and during the production PROCESS. Where the use of HAZARDOUS SUBSTANCES is unavoidable ME EQUIPMENT construction and operation should consider RISKS.
Testing	Prototype testing including TYPE TESTING	Design now established and major changes now only possible at great expense. A physical model exists. Testing against the specification will have commenced and design will be validated against original need. Representative sample(s) can be submitted for TYPE TESTING.	The ENVIRONMENTAL IMPACT of the ME EQUIPMENT design should be confirmed against the assessment documented at the product concept stage. Significant deviations from expected results should be investigated.
	Product testing	Manufactured ME EQUIPMENT subjected to final testing to ensure quality and confirm conformance with standards.	Consideration should be given to ENVIRONMENTAL ASPECTS resulting from extreme operating conditions (e.g. as a result of safety factor / margin).
Production	Product manufacturing	The design of the ME EQUIPMENT is now fixed and is being manufactured to revision controlled drawings and assembly method sheets.	Production PROCESS ENVIRONMENTAL ASPECTS (e.g. production WASTE, water usage, energy consumption, component logistics, HAZARDOUS SUBSTANCES) should be considered. SUPPLY CHAIN PROCESSES and work sub-contracted out should also be considered.

Table A.1 – Example product LIFE-CYCLE stages *(continued)*

Stage	Activity	Characteristics	Environmental considerations
Distribution	Storage	ME EQUIPMENT can be in final PACKAGING and is stored pending shipment to RESPONSIBLE ORGANIZATIONS.	Consideration needs to be given to adverse ENVIRONMENTAL IMPACTS caused by failure of the ME EQUIPMENT when stored outside the specified storage conditions, e.g. by bursting a container that leaks corrosive materials.
	Product transport	ME EQUIPMENT being shipped to designated sites.	Consideration needs to be given to type and reusability of PACKAGING, transportation method, weight of ME EQUIPMENT and whether the ME EQUIPMENT can be assembled on site or shipped assembled. Logistical efficiency can be enhanced by: – contracting suppliers / subcontractors to deliver directly to the RESPONSIBLE ORGANIZATION / distributor if possible – by ensuring that packaged ME EQUIPMENT can stack efficiently in standard generic transportation containers. – collecting old products for REUSE, recovery or RECYCLING.
	Installation	New ME EQUIPMENT is installed at site prior to being used.	Although installation is not normally environmentally significant, should the product require substantial quantities of HAZARDOUS SUBSTANCES (e.g. transformer oil) consideration has to be given to ease of transportation and handling of these substances, as well as the disposal of any excess at the end of the installation PROCESS. The use of specialized mechanical handling or assembly tools should be avoided where possible.

Table A.1 – Example product LIFE-CYCLE stages *(continued)*

Stage	Activity	Characteristics	Environmental considerations
Use	NORMAL USE	INTENDED USE of ME EQUIPMENT	Examples of ENVIRONMENTAL ASPECTS during NORMAL USE include: – energy – consumables (including batteries) – chemicals (especially HAZARDOUS SUBSTANCES) – natural resources, e.g. water – smoke or gasses – WASTE (including contaminated material) – heat (e.g. ME EQUIPMENT could make substantial demands on air-conditioning) The consumption of energy during NORMAL USE can be a major ENVIRONMENTAL ASPECT of ME EQUIPMENT and should not be overlooked.

	Repair and maintenance	ME EQUIPMENT is maintained or repaired to ensure continued operation to specification.	Examples of ENVIRONMENTAL ASPECTS to be considered are:
			– WASTE (service materials, spare parts)
			– transportation (technical staff / spare parts)
			– HAZARDOUS SUBSTANCES (used in technical maintenance)
			– PACKAGING WASTE (spare parts)
			– energy use (testing and calibration)
			– emissions to:
			  – air
			  – soil
			  – ground water/rivers
			  – sewer
			– water usage:
			  – ground (water extraction)
			  – purchased / purified
			Service and maintenance can be very important in ensuring that ME EQUIPMENT works at peak efficiency.

END OF LIFE (EOL)	Removal from service	RESPONSIBLE ORGANIZATION has no further use for the ME EQUIPMENT.	RESPONSIBLE ORGANIZATION decides whether to:
			– sell second hand [a]
			– transfer to the MANUFACTURER or other authorized ORGANIZATION [b]
			  – The ME EQUIPMENT is refurbished and resold
			  – The ME EQUIPMENT is disassembled and parts / components are incorporated into new products or used as spare parts
			  – The ME EQUIPMENT is disassembled and parts/components recycled (EOL)
			  – The ME EQUIPMENT is put to landfill / incineration (EOL)
			– disposed of as WASTE. (EOL)
			  – send to treatment centre for RECYCLING
			  – THE ME EQUIPMENT is landfilled /incinerated [c]

Table A.1 – Example product LIFE-CYCLE stages *(continued)*

Stage	Activity	Characteristics	Environmental considerations
END OF LIFE (EOL)	END OF LIFE (EOL) management	The ME EQUIPMENT is disassembled and parts / components reused or recycled.	Consideration must be given to the following. – MANUFACTURERS can gain new product development information from the examination of EOL components. – It should generally be easy and safe for people to remove HAZARDOUS SUBSTANCES (e.g., consumable parts such as batteries and oil) from the EOL ME EQUIPMENT. Full instructions must be available to enable RESPONSIBLE ORGANIZATIONS or others to undertake these tasks. The MANUFACTURER should provide guidance if trained personnel are required to remove the HAZARDOUS SUBSTANCES (e.g. radioactive material) – HAZARDS that can result in an unacceptable RISK to disassemblers or others (e.g. retained energy sources) should be detailed. This is particularly important if there is a possibility of those working on the ME EQUIPMENT being exposed to a biohazard. – All HAZARDOUS SUBSTANCES with the potential for leaching or which could continue to present long-term RISK to health or the ENVIRONMENT should be removed from ME EQUIPMENT prior to landfill. All local laws and regulations controlling landfill disposal and incineration should be complied with. – In the case of the REUSE of components of ME EQUIPMENT, consideration needs to be made of the ENVIRONMENTAL ASPECTS associated with the REUSE, in comparison to the ENVIRONMENTAL ASPECTS of producing a new (and possibly more efficient) component with lower ENVIRONMENTAL IMPACTS. – Recovered materials must be channelled into the appropriate recovery stream – Transportation can have a significant effect on the viability of any recovery operation.
		The ME EQUIPMENT (or parts / components) are landfilled/incinerated.	Landfilling or incinerating WASTE ME EQUIPMENT / components / parts is the least environmentally desirable route of disposal. Landfill or incineration should only be considered when all other options have been explored, and found to be unfeasible. Many countries have very strict laws on what may or may not be landfilled.

[a] Continued use of equipment can have significant environmental advantages, however the continued use of ME EQUIPMENT in a clinical application can carry higher PATIENT RISK.

[b] "Authorized ORGANIZATION" is an ORGANIZATION authorised by the MANUFACTURER and/or national authorities, to manage EOL ME EQUIPMENT.

[c] Disposal to landfill or incineration is not a recommended disposal route.

A.2 Rationale for particular clauses and subclauses

The following are rationales for specific clauses and subclause in this collateral standard, with clause and subclause numbers parallel to those in the body of the document.

Clause 0 – Scope

This collateral standard recognises that avoiding damage to the ENVIRONMENT is part of BASIC SAFETY and ESSENTIAL PERFORMANCE.

Substantial benefits are likely when considering ENVIRONMENTAL ASPECTS of ME EQUIPMENT DESIGN AND DEVELOPMENT. In addition to reducing the ENVIRONMENTAL IMPACTS of the ME EQUIPMENT, these benefits can include business risk reduction, lower costs, stimulation of innovation, new business opportunities, and improved ME EQUIPMENT quality.

An ME SYSTEM consists of items of equipment, at least one of which must be ME EQUIPMENT, connected together to form a system. The ME EQUIPMENT will fall within the scope of this collateral standard; however the non-ME EQUIPMENT (e.g. a video recorder or monitor used with an endoscope), will fall outside the scope of the general standard. It is therefore impossible to apply this collateral standard to an ME SYSTEM that can contain both ME EQUIPMENT and non-ME EQUIPMENT.

Definition 3.4 – ENVIRONMENTAL ASPECT

The ENVIRONMENTAL ASPECTS are those interactions with the ENVIRONMENT that result from a MANUFACTURER'S product. For example, if a component of a product is a plastic tray then the aspects of that component will be:

– the use of raw material, for example oil to make plastic (use of natural resources);
– the use of energy, for example electricity to manufacture the plastic and form the tray, and oil for transporting raw materials and the finished product (use of natural resources);
– the disposal of any WASTE material from the manufacturing PROCESS (WASTE);
– the disposal of the tray at END OF LIFE (WASTE).

For example, if the energy to form the tray comes from renewable resources then the ENVIRONMENTAL IMPACTS will be lower than if the energy comes from the burning of fossil fuels. This is why ENVIRONMENTAL IMPACTS should be considered when determining the significance of ENVIRONMENTAL ASPECTS. However, it is ENVIRONMENTAL ASPECTS that can be quantified and controlled by the ME EQUIPMENT MANUFACTURER.

Definition 3.5 – ENVIRONMENTAL IMPACT

There are two types of adverse ENVIRONMENTAL IMPACTS:

a) the depletion of natural resources (e.g. the use of fossil fuels or minerals);
b) the contamination of the natural ENVIRONMENT (e.g. from air emissions, WASTE water or WASTE).

For example, if we identify an ENVIRONMENTAL ASPECT of a product as production of WASTE plastic from a cutting operation, then the ENVIRONMENTAL IMPACT will be land pollution and

ground water pollution due to landfill disposal or air pollution (if WASTE is incinerated) with consequent damage to flora/fauna. See Table A.2 for some examples of ENVIRONMENTAL IMPACTS and their causes.

Table A.2 – Examples of ENVIRONMENTAL IMPACTS and their cause

Impact type	Impact example	Cause (Aspect)
1) Depletion	Depletion of resources	Quarrying, mining, drilling (for oil), fishing, tree felling etc
	Alteration of habitats	Tree felling, peat digging, water abstraction, urbanisation
	Reduction of biological diversity	Urbanisation, agriculture, pollution, foreign species introduction
2) Contamination	Ozone depletion	Chlorofluorocarbon (CFC) release
	Smog formation	Volatile organic compound (VOC) release
	Eutrophication	Agriculture
	Climate change	Transportation, energy generation, domestic/industrial heating
	Alteration of habitats	Landfilling, transport pollution, accidental spills etc
	Acidification	Energy generation
	Reduction of biological diversity	Urbanisation, agriculture
	Air, water and soil pollution	Smoke emissions, landfill, air emissions, WASTE water discharges, chemical spills etc

Subclause 4.1 – Identification of ENVIRONMENTAL ASPECTS

An effective ENVIRONMENTAL ASPECT assessment PROCESS catalogues ME EQUIPMENT-related ENVIRONMENTAL ASPECTS as a first step. One must be able to identify those ENVIRONMENTAL ASPECTS that are most important and can have the greatest opportunities for improvement. For example, it is important to know which environmentally HAZARDOUS SUBSTANCES there are in ME EQUIPMENT. The World Health Organization (WHO) provides information on possible environmentally HAZARDOUS SUBSTANCES. There can be regulatory restrictions on the use of some HAZARDOUS SUBSTANCES in particular markets. For example, some types of batteries contain environmentally HAZARDOUS SUBSTANCES and their disposal is regulated in many countries.

The MANUFACTURER needs to quantify, as far as is practicable, the actual ENVIRONMENTAL ASPECTS (e.g. 1 kWh of electricity per operational cycle) and should then allocate resources to those ENVIRONMENTAL ASPECTS over which the MANUFACTURER can have the most significant effect based on the ranking of ENVIRONMENTAL IMPACTS. It is important that the assessment includes ENVIRONMENTAL ASPECTS across all LIFE-CYCLE stages. If activities are performed by subcontractors or suppliers, the assessment of those activities needs to be included since they can affect the ENVIRONMENTAL ASPECTS of the MANUFACTURER'S ME EQUIPMENT. Realistic boundaries need to be set for the investigation. For example, it might be relevant to list the use of RAW MATERIAL, but not the energy used by the ship to bring the RAW MATERIAL in bulk from its source.

It is not necessary to catalogue every small ENVIRONMENTAL ASPECT or to have exact information. In many cases, the ME EQUIPMENT MANUFACTURER purchases subsystems and components from suppliers that in turn purchase their components and materials. It might not

be possible or practical to obtain exact material information from complex SUPPLY CHAINS. Estimates based on reasonable assumptions are sufficient to allow the MANUFACTURER to determine what ENVIRONMENTAL ASPECTS are most important (the relevant ENVIRONMENTAL ASPECTS). To differentiate between an ENVIRONMENTAL ASPECT and an ENVIRONMENTAL IMPACT, an ENVIRONMENTAL ASPECT of energy usage could be the emission of 1 kg/day of CO_2 to air and the associated ENVIRONMENTAL IMPACT will be global warming. Note that ENVIRONMENTAL IMPACTS can be positive as well as negative.

Examples of ENVIRONMENTAL ASPECTS that can be considered are as follows.

– Emissions to air; (e.g. fumes, smoke, gasses, vapours, exhausts)

  Some PROCESSES throughout the life of the product (manufacturing as well as use or disposal) will involve the disposal of material to air, for example a painting PROCESS can involve the release of volatile organic compounds (VOC), the use of vehicles and heaters can generate carbon dioxide, and soldering will release fumes.

– Releases to water; (e.g. liquids, detergents, suspended solids)

  Cleaning PROCESSES involving water will almost inevitably mean contaminants are being washed into the drainage system or into water courses directly. Cooling plants can also be problematic due to the chemicals used (to prevent corrosion and improve thermal performance).

– Avoidance, RECYCLING, REUSE, transportation and disposal of solid and other WASTES, particularly hazardous WASTES.

  The hierarchy of WASTE management is as follows.

  – Reduce (eliminate) – The best option is to avoid the generation of WASTE if at all possible and a WASTE audit is one tool that can be used to accomplish this.
  – REUSE – If WASTE cannot be avoided then recovery is the next best option with a view to reusing in an alternative application.
  – Recycle – If it is not possible to REUSE then RECYCLING will need to be considered.
  – Incinerate – Incineration with energy recovery is possible, but has its own significant ENVIRONMENTAL IMPACTS and should be seen as only slightly better than landfill.
  – Landfill – The placing of WASTE to landfill is to be avoided if at all possible. Landfill sites are potential sources of pollution to water supplies and also a potential source of a significant greenhouse gas (methane) emission and contamination of land (e.g. spills).

    Land is a precious resource and contamination should be avoided (e.g. by spills). The contamination of land will almost inevitably have legal consequences. Cleaning up after land contamination can be very expensive.

– Use of natural resources and raw materials (including energy)

  The use of natural resources, especially if non-renewable (e.g. fossil fuel) should be limited to what is absolutely necessary.

– Aspects as a result of the MANUFACTURER'S facilities / PROCESSES (noise, vibration, odour, dust, visual appearance, etc.)

  Apart from a global obligation, ORGANIZATIONS have a local obligation. It is important that ORGANIZATIONS manage the effect they are having on their locality and ensure they are not causing inconvenience to others in the same area.

– Transportation issues (related to manufacture, distribution, maintenance and service)

  Transportation is very energy intensive, and can have significant ENVIRONMENTAL IMPACTS especially in the area of global warming, and should therefore be managed to ensure it is used only when necessary and with maximum efficiency.

– RISKS of environmental accidents and impacts arising, or likely to arise, as consequences of incidents, accidents and potential emergency situations

  Managing the environmental sensitivity of ORGANIZATIONS and products can be negated by a single accident. ORGANIZATIONS should undertake a periodic environmental RISK ASSESSMENT of their activities and make appropriate provision to reduce the likelihood of accidents compromising the ENVIRONMENT. For example, installing secondary containment devices where chemicals are unloaded from a truck, so that if a chemical container is dropped and breaks, the chemical spill is contained and not allowed to contaminate drains or soil.

It is desirable that the assessment of ENVIRONMENTAL ASPECTS be consistent for ME EQUIPMENT of the same type and undertaken according to a documented PROCESS.

The PROCESS should be reviewed periodically to take into account best practice.

Table A.3 contains some examples of ENVIRONMENTAL ASPECTS and typical ENVIRONMENTAL IMPACTS associated with those ENVIRONMENTAL ASPECTS. It should be noted that this table is not exhaustive and is intended only to illustrate the difference between ENVIRONMENTAL ASPECTS and ENVIRONMENTAL IMPACTS.

Table A.3 – ENVIRONMENTAL ASPECTS and typical ENVIRONMENTAL IMPACTS

ENVIRONMENTAL ASPECTS			ENVIRONMENTAL IMPACT
Aspect type (All LIFE-CYCLE stages)	**Substance or description**	**Unit of measure examples**	
Emissions to air	CO_2	Mass per product	Climate change
	Methane	Mass per product	Climate change
	Particulates	Mass per product	Respiratory disease
	Volatile organic compounds	Mass per product	Local ozone Air pollution Smog formation
Releases to water	Detergents	Mass per product Mass per product operational cycle	Water pollution Alteration of habitats Reduction in aquatic life Reduction of biological diversity
	Sterilization agents	Mass per product operational cycle	
	Heavy metals	Mass per product operational cycle	Water pollution Absorption by living organisms Alteration of habitats Reduction of biological diversity
WASTE, especially HAZARDOUS SUBSTANCES	Manufacturing offcuts (plastic)	Mass per product	Depletion of natural resources Air, water and soil pollution
	Manufacturing offcuts (aluminium)	Mass per product	
	Lubricating oil for machine tools	Mass per product	
	Cardboard PACKAGING (internal transportation)	Mass per product	
	Paint overspray	Mass per product	
	Etching acid	Mass per product	Air, water and soil pollution
	Plating WASTE	Mass per product	Air, water and soil pollution
Use of natural resources and raw materials (including energy)	Electricity	Watt	Depletion of natural resources
	Oil	Watt	
	Town gas	Watt	
	Water	Volume per time	
	Steel	Mass per product	
	Aluminium	Mass per product	
	Bismuth	Mass per product	
	Platinum	Mass per product	
	Gold	Mass per product	
	Wood pallets	Mass per product	Depletion of natural resources Loss of habitat

Table A.3 – ENVIRONMENTAL ASPECTS and typical ENVIRONMENTAL IMPACTS *(continued)*

ENVIRONMENTAL ASPECTS			ENVIRONMENTAL IMPACT
Aspect type (All LIFE-CYCLE stages)	**Substance or description**	**Unit of measure examples**	
Noise, vibration, odour, dust.	Noise (metal forming)	Decibel	Local nuisance
	Vibration (truck movements)	Force or frequency	Local nuisance
	Odour (plating PROCESS)	ppm	Air pollution
	Particulates (delivery trucks-10 tonne)	Mass per km	Respiratory disease
Transportation (related to manufacture, distribution, maintenance and service)	Diesel fuel (delivery trucks – 10 tonne)	Volume per km	Depletion of natural resources Climate change
	Petrol fuel (car)	Volume per km	Depletion of natural resources Climate change
	Natural gas (car)	Volume per km	Depletion of natural resources Climate change
	Electricity (rail)	Kilowatt-hours, weight in tonne and distance in km	Depletion of natural resources Climate change
Probability of HARM from environmental accidents	Surface water contamination	Concentration in ppm or mg per litre	Water Pollution
Use and contamination of the biosphere	Fish enzyme (reagent)	Mass per test	Depletion of natural resources
	Landfilled material	Mass per product	Air, water and soil pollution
	Land use for new warehousing	Area lost	Loss of habitat

Subclause 4.2 – Determination of significant ENVIRONMENTAL ASPECTS

An ORGANIZATION can have many ENVIRONMENTAL ASPECTS for its ME EQUIPMENT. It is important to note the most significant ENVIRONMENTAL ASPECTS in order to prioritize those for which targets will be established and improvements made. In determining the most significant ENVIRONMENTAL ASPECTS of ME EQUIPMENT, the ORGANIZATION should take into consideration legal requirements, business strategies, technological developments, scientific opinion and concerns of customers and other interested parties. Determination of significant ENVIRONMENTAL ASPECTS should focus on those factors that can be most influenced through product design and have the greatest improvement on ENVIRONMENTAL IMPACTS.

The MANUFACTURER should ensure that relevant ENVIRONMENTAL IMPACTS are identified and assessed consistently as far as reasonable from the list of ENVIRONMENTAL ASPECTS.

The importance of any ENVIRONMENTAL IMPACT will depend upon the product, operating ENVIRONMENT, geographic location, etc. As scientific understanding improves, the number and importance of possible ENVIRONMENTAL IMPACTS can change. It is the MANUFACTURER'S responsibility to determine the environmental acceptability of one ENVIRONMENTAL IMPACT over another, for example the use of renewable resources is usually preferable to the use of non-renewable resources.

Subclause 4.3 – Information from the SUPPLY CHAIN

During the whole LIFE-CYCLE of ME EQUIPMENT the role of the SUPPLY CHAIN is becoming increasingly important to the environmental profile of the MANUFACTURER'S ME EQUIPMENT. Assessment of the ENVIRONMENTAL ASPECTS of ME EQUIPMENT across the entire life of the ME EQUIPMENT requires the MANUFACTURER to gather information and involve the SUPPLY CHAIN. Additionally, ORGANIZATIONS external to the MANUFACTURER can have expertise that will assist the MANUFACTURER in minimizing the ENVIRONMENTAL IMPACT of the ME EQUIPMENT.

MANUFACTURERS should therefore contact suppliers to request information, for example:

– the materials contained within suppliers' products;
– the manufacturing PROCESSES used to make suppliers' products;
– the PROCESSES and PROCEDURES suppliers employ to ensure they are managing their own ENVIRONMENTAL IMPACT.

Because considering ENVIRONMENTAL ASPECTS during the design of products is a relatively new and developing concept, many suppliers might not be equipped to provide the information to the MANUFACTURER.

Because the amount of data to be obtained could be large, it is desirable that a standardized format for the request of information be used. MANUFACTURERS can also define the criteria for the type and amount of data to be obtained.

In some cases it will not be possible to obtain the necessary information from suppliers, in which case a MANUFACTURER should estimate to the best of his ability, the likely environmental implications of the missing information. The MANUFACTURER should document the rationale for his estimate so it can be reviewed at a later date.

IEC/PAS 61906 [4] and IEC Guide 113 [2] can be useful in obtaining data from the SUPPLY CHAIN.

Subclause 4.4 – Reduction of adverse ENVIRONMENTAL IMPACTS

The reduction of adverse ENVIRONMENTAL IMPACTS should begin as early as possible in the design stage since it is more effective and cost efficient to make changes while the product exists only in theory or as a drawing. This is also the appropriate stage to consider the complete elimination of some ENVIRONMENTAL ASPECTS (e.g. some HAZARDOUS SUBSTANCES if possible). ENVIRONMENTAL IMPACT improvement must be balanced against the ME EQUIPMENT'S functional requirements, performance, safety, cost, marketability, quality and regulatory requirements. A MANUFACTURER can use a RISK ANALYSIS to help decide on environmental improvement targets.

ENVIRONMENTAL IMPACT reductions need only be made to the extent technically and economically feasible. MANUFACTURERS should endeavour to make ENVIRONMENTAL IMPACT improvements across all LIFE-CYCLE stages. It is acceptable for ME EQUIPMENT to have increased ENVIRONMENTAL IMPACTS provided that it can be justified by an impact / benefit analysis of ME EQUIPMENT performance or medical benefit. MANUFACTURERS should set challenging targets. Significant reductions to product costs can be achieved (less is better and cheaper). A reappraisal of how a product functions, is produced, used and disposed of, can yield significant ENVIRONMENTAL IMPACT reductions as well as cost advantages.

Creative solutions to reduce adverse ENVIRONMENTAL IMPACTS should be considered as early in the project as possible. Consideration should be given to:

a) modifying / upgrading existing products;
b) novel technologies;
c) creative design solutions;
d) alternative material choice;
e) use of recycled materials;
f) use of recovered components or assemblies;
g) new production PROCESSES;
h) alternative energy sources;
i) PACKAGING reduction;
j) reduction / elimination of consumables;
k) service and maintenance reduction;
l) extended durability;
m) REUSE / RECYCLING and material recovery at END OF LIFE.

There can be experimentation with different configurations so that the design solution with the optimum balance between product benefit, performance and ENVIRONMENTAL IMPACTS can be easily and cost effectively established. It is necessary for the MANUFACTURER to understand the environmental profile of its ME EQUIPMENT. It is inevitable that at some point trade-offs will need to be made between various ENVIRONMENTAL IMPACTS in order to arrive at the best compromise.

IEC Guide 114 [3] identifies three types of trade-offs:

– Trade-offs between different ENVIRONMENTAL ASPECTS; for example, optimizing a product for weight reduction might negatively affect its recyclability. The comparison of potential ENVIRONMENTAL IMPACTS associated with each option can help decision-makers find the best solution.
– Trade-offs between environmental, economic and social benefits. These can be tangible (e.g. lower cost, WASTE reduction), intangible (e.g. convenience) and emotional (e.g. image). For example, making a product more robust increases the lifetime and, as a result, might benefit the ENVIRONMENT by reducing long-term resource use and WASTE, but might also increase initial costs. This can have social as well as economic effects.
– Trade-offs between environmental, technical and/or quality aspects; for example, design decision related to the use of a particular material might negatively affect the reliability and durability of a product, even though this produces environmental benefits.

The MANUFACTURER should check a prototype of the ME EQUIPMENT'S final design against the ENVIRONMENTAL ASPECT reduction targets that were set and document the results. This check serves to assess the degree to which implementation of the targets is achieved and can be used to improve future product design, improve production PROCESSES, or serve as a basis of comparison in the DESIGN AND DEVELOPMENT of future ME EQUIPMENT.

Subclause 4.5.1 – PACKAGING of ME EQUIPMENT

PACKAGING of ME EQUIPMENT will usually be disposed of as soon as the ME EQUIPMENT is installed or commissioned unless the PACKAGING is intended to be reused. PACKAGING is a significant WASTE stream and it is therefore logical that MANUFACTURERS provide sufficient information to permit it to be recovered or disposed of in a proper manner.

Subclause 4.5.2 – Instructions for minimizing ENVIRONMENTAL IMPACT during NORMAL USE

The ENVIRONMENTAL IMPACT of ME EQUIPMENT can be greatly influenced by how it is used. It is necessary, therefore, for MANUFACTURERS to provide sufficient information to enable RESPONSIBLE ORGANIZATIONS to operate the ME EQUIPMENT in the most environmentally responsible manner.

RESPONSIBLE ORGANIZATIONS can require and use product environmental information during their supplier and equipment selection PROCESS. MANUFACTURERS might be expected to publish environmental information in their promotional material.

Subclause 4.5.3 – Information for END OF LIFE management

It is necessary for MANUFACTURERS to provide information as required to ensure that ME EQUIPMENT is recovered at END OF LIFE in the most safe and environmentally responsible manner.

ORGANIZATIONS involved in END OF LIFE management will need to know the correct way to treat the ME EQUIPMENT at END OF LIFE and the location of any HAZARDOUS SUBSTANCES as well as any potential sources of HARM to the disassembler if not handled in the correct manner (e.g. sources of stored energy in high tension circuits, capacitors and springs in compression or tension). Refer to IEC Guide 109 [1] for disassembly information.

It should be noted that ACCOMPANYING DOCUMENTS rarely stay with ME EQUIPMENT throughout its life, so MANUFACTURERS should take this into consideration when deciding the best method of ensuring that the END OF LIFE information is readily available to those who will require it.

In order to reduce adverse ENVIRONMENTAL IMPACT and to minimize the cost of END OF LIFE MANAGEMENT of the ME EQUIPMENT, it is beneficial for MANUFACTURERS to provide information on the amount of useful material that can be recovered from ME EQUIPMENT at END OF LIFE.

Annex B
(informative)

Guide to marking and labelling requirements for ME EQUIPMENT

The requirements for general information to be included in the ACCOMPANYING DOCUMENTS are found in subclause 7.9.1 and Table C.4 of the general standard. Additional requirements for general information to be included in the ACCOMPANYING DOCUMENTS are found in the subclauses listed in Table B.1.

Table B.1 – ACCOMPANYING DOCUMENTS, General

Description of requirement	Clause or subclause
Instructions for minimizing ENVIRONMENTAL IMPACT during NORMAL USE	4.5.2

This collateral standard includes requirements for the MANUFACTURER to provide information to third-parties such as WASTE treatment facilities who are not normally an audience for ACCOMPANYING DOCUMENTS. The subclauses listed in Table B.2 contain requirements for information to be provided by the MANUFACTURER. It can be included in the ACCOMPANYING DOCUMENTS, but it can also be provided in other ways such as internet sites or technical bulletins.

Table B.2 – Other information

Description of requirement	Clause or subclause
PACKAGING of ME EQUIPMENT, information on the type and mass of PACKAGING material(s)	4.5.1
END OF LIFE management, information for the proper disposal	4.5.3
END OF LIFE management, information for WASTE treatment facilities	4.5.3

Bibliography

[1] IEC Guide 109:2003, *Environmental aspects – Inclusion in electrotechnical product standards*

[2] IEC Guide 113:2000, *Materials declaration questionnaires – Basic guidelines*

[3] IEC Guide 114:2005, *Environmentally conscious design – Integrating environmental aspects into design and development of electrotechnical products*

[4] IEC/PAS 61906, *Procedure for the declaration of materials in products of the electrotechnical and electronic industry*

[5] ISO 14001:2004, *Environmental management systems – Requirements with guidance for use*

[6] ISO 14021:1999, *Environmental labels and declarations – Self-declared environmental claims (Type II environmental labelling)*

[7] ISO 14040:2006, *Environmental management – Life cycle assessment – Principles and framework*

[8] ISO/TR 14062:2002, *Environmental management – Integrating environmental aspects into product design and development*

Index of defined terms used in this collateral standard

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BASIC SAFETY ..... IEC 60601-1:2005, 3.10
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ESSENTIAL PERFORMANCE ..... IEC 60601-1:2005++A2:2020, 3.27
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