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Robotics — Application services provided by service robots — Safety management systems requirements

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The UK participation in its preparation was entrusted to Technical Committee AMT/10, Robotics.

A list of organizations represented on this committee can be obtained on request to its committee manager.

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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO document should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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This document was prepared by Technical Committee ISO/TC 299, *Robotics*.

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Introduction

When operating service robots that coexist with people, proper management of their residual safety risks is needed. To achieve this, in the same manner as with general machineries, application service providers, who intended to start application services provided by service robots, need to consider the safety in operation as well as the robot system providers need to consider the safety in design. For application service providers to safely operate service robots with residual safety risks, communication between the robot system providers and the application service provider is important. For example, the robot system providers provide appropriate information for use when application service providers operate robots based on the comprehension of this information for use communicated by the robot system providers of the service robot. The application service providers then give feedback to the robot system providers on the safety-related information obtained from actual operation.

For some service robots, the design safety requirements have already been standardized in ISO 13482. There have been application service providers that operate robots within the scope of these standards. Although these application service providers have operated their application services safely, based on a certain level of knowledge and experience, their methodology has not yet been systematized, nor have the terms been standardized. It is considered that by systemizing and documenting an optimal methodology to operate application services provided by service robots safely, the criteria to be satisfied by new application service providers would be clarified which would then promote sound development of the industry.

The purpose of this document is to provide application service providers using service robots with the safety management system requirements for application services provided by service robots as a safe operating framework.

The safety management system for the application services provided by service robots is based on the concept of Plan-Do-Check-Act (PDCA). The PDCA model provides an iterative process used by organizations to achieve continual improvement. It can be briefly described as follows:

— Plan: establish safety objectives and processes necessary to deliver results in accordance with the organization's safety policy

— Do: implement the processes as planned.

— Check: monitor and measure processes against the safety policy, including its commitments, safety objectives and operating criteria, and report the results.

— Act: take actions to continually improve.

In this document, the following verbal forms are used:

— “shall” indicates a requirement;

— “should” indicates a recommendation;

— “may” indicates a permission;

— “can” indicates a possibility or a capability.

Information marked as “Note” is intended to assist the understanding or use of the document.

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Robotics — Application services provided by service robots — Safety management systems requirements

1 Scope

This document specifies the requirements of safety management systems for application services provided by service robots [application service safety management system (hereafter ASSMS)] that an application service provider can use for the safety of its users and its third parties when it provides application service in unstructured human spaces with trained and untrained persons (e.g. giving directions for visitors in airport or shopping mall, carrying goods to patients in hospital, delivering food to customers in restaurant.)

This document is applicable to any organization that wishes to:

a) improve safety performance of application services provided by service robots,

b) establish, implement, maintain and improve safety management systems for application services provided by service robots,

c) assure itself of conformity with its stated application service safety policy, and

d) demonstrate conformity with this document.

The requirements of this document can be conformed to by integrating safety management systems for application services provided by service robots into, or making it compatible with, other management systems or processes within the organization.

The requirements of this document can be conformed to by multiple organizations without omission depending on what is done as an organization and safety management.

Although intended for application services provided by service robots, this document can also be applied to services using robots other than service robots.

This document is not intended to be used as a product safety standard.

NOTE There are cases where the safety management systems for application services provided by service robots established in accordance with the requirements of this document cannot apply directly when the service robots to be used, robot systems, contents of service, places of operation, users or so, differ.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 13482:2014, *Robots and robotic devices — Safety requirements for personal care robots*

ISO 12100:2010, *Safety of machinery — General principles for design — Risk assessment and risk reduction*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 13482 and the following apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

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— IEC Electropedia: available at https://www.electropedia.org/

3.1
organization
person or group of people that has its own functions with responsibilities, authorities and relationships to achieve its *objectives* (3.6)

Note 1 to entry: The concept of organization includes, but is not limited to, sole-trader, company, corporation, firm, enterprise, authority, partnership, association, charity or institution, or part or combination thereof, whether incorporated or not, public or private.

Note 2 to entry: If the organization is part of a larger entity, the term "organization" refers only to the part of the larger entity that is within the scope of the application service safety *management system* (3.4).

3.2
interested party
person or *organization* (3.1) that can affect, be affected by, or perceive itself to be affected by a decision or activity

Note 1 to entry: A robot system provider is an interested party related to ASSMS.

3.3
top management
person or group of people who directs and controls an *organization* (3.1) at the highest level

Note 1 to entry: Top management has the power to delegate authority and provide resources within the organization.

Note 2 to entry: If the scope of the *management system* (3.4) covers only part of an organization, then top management refers to those who direct and control that part of the organization.

3.4
management system
set of interrelated or interacting elements of an *organization* (3.1) to establish *policies* (3.5) and *objectives* (3.6), as well as *processes* (3.8) to achieve those objectives

Note 1 to entry: A management system can address a single discipline or several disciplines.

Note 2 to entry: The management system elements include the organization's structure, roles and responsibilities, planning and operation.

3.5
policy
intentions and direction of an *organization* (3.1) as formally expressed by its *top management* (3.3)

3.6
objective
result to be achieved

Note 1 to entry: An objective can be strategic, tactical, or operational.

Note 2 to entry: Objectives can relate to different disciplines (such as finance, health and safety, and environment). They can be, for example, organization-wide or specific to a project, product or *process* (3.8).

Note 3 to entry: An objective can be expressed in other ways, e.g. as an intended result, as a purpose, as an operational criterion, as an application service safety objective or by the use of other words with similar meaning (e.g. aim, goal, or target).

Note 4 to entry: In the context of application service safety *management systems* (3.4), application service safety objectives are set by the *organization* (3.1), consistent with the application service safety *policy* (3.5), to achieve specific results.

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3.7
risk
effect of uncertainty

Note 1 to entry: An effect is a deviation from the expected — positive or negative.

Note 2 to entry: Uncertainty is the state, even partial, of deficiency of information related to, understanding or knowledge of, an event, its consequence, or likelihood.

Note 3 to entry: Risk is often characterized by reference to potential events (as defined in ISO Guide 73) and consequences (as defined in ISO Guide 73), or a combination of these.

Note 4 to entry: Risk is often expressed in terms of a combination of the consequences of an event (including changes in circumstances) and the associated likelihood (as defined in ISO Guide 73) of occurrence.

Note 5 to entry: In this document, where the term "risks and opportunities" is used this means *safety risks* (3.39), *safety opportunities* (3.40) and other risks and other opportunities for the management system.

Note 6 to entry: This constitutes one of the common terms and core definitions for ISO management system standards given in Annex SL of the Consolidated ISO Supplement to the ISO/IEC Directives, Part 1. Note 5 to entry has been added to clarify the term "risks and opportunities" for its use within this document.

3.8
process
set of interrelated or interacting activities that uses or transforms inputs to deliver a result

Note 1 to entry: Whether the result of a process is called an output, a product or a service depends on the context of the reference.

3.9
competence
ability to apply knowledge and skills to achieve intended results

3.10
documented information
information required to be controlled and maintained by an *organization* (3.1) and the medium on which it is contained

Note 1 to entry: Documented information can be in any format and media and from any source.

Note 2 to entry: Documented information can refer to:

— the *management system* (3.4), including related *processes* (3.8);

— information created in order for the organization to operate (documentation);

— evidence of results achieved (records).

3.11
performance
measurable result

Note 1 to entry: Performance can relate either to quantitative or qualitative findings.

Note 2 to entry: Performance can relate to managing activities, *processes* (3.8), products, services, systems or *organizations* (3.1).

3.12
continual improvement
recurring activity to enhance *performance* (3.11)

3.13
effectiveness
extent to which planned activities are realized and planned results are achieved

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3.14
requirement
need or expectation that is stated, generally implied or obligatory

Note 1 to entry: "Generally implied" means that it is custom or common practice for the *organization* (3.1) and *interested parties* (3.2) that the need or expectation under consideration is implied.

Note 2 to entry: A specified requirement is one that is stated, e.g. in *documented information* (3.10).

3.15
conformity
fulfilment of a *requirement* (3.14)

3.16
nonconformity
non-fulfilment of a *requirement* (3.14)

3.17
corrective action
action to eliminate the cause(s) of a *nonconformity* (3.16) and to prevent recurrence

3.18
audit
systematic and independent *process* (3.8) for obtaining evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled

Note 1 to entry: An audit can be an internal audit (first party) or an external audit (second party or third party), and it can be a combined audit (combining two or more disciplines).

Note 2 to entry: An internal audit is conducted by the *organization* (3.1) itself, or by an external party on its behalf.

Note 3 to entry: "Audit evidence" and "audit criteria" are defined in ISO 19011.

3.19
measurement
process (3.8) to determine a value

3.20
monitoring
determining the status of a system, a *process* (3.8) or an activity

Note 1 to entry: To determine the status, there can be a need to check, supervise or critically observe.

3.21
application service safety performance
measurable result related to the safety of an *application service* (3.26)

Note 1 to entry: Examples of metrics to measure *performances* (3.11) relevant to the safety of an application service are:

— continuous operation time without an *accident* (3.43);

— the number of near-hits (generally known as an incident which is a *hazardous event* (3.41) but does not cause a *harm* (3.41) as a result);

— the number of improvement proposals;

— the number of persons with safety-related qualification;

— the number of emergency tests.

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3.22
outsource (verb)
make an arrangement where an external *organization* (3.1) performs part of an organization's function or *process* (3.8)

Note 1 to entry: An external organization is outside the scope of the *management system* (3.4), although the outsourced function or process is within the scope.

3.23
robot
programmed actuated mechanism with a degree of autonomy to perform locomotion, manipulation or positioning

[SOURCE: ISO 8373:2021, 3.1]

3.24
service robot
robot (3.23) in personal use or professional use that performs useful tasks for humans or equipment

[SOURCE: ISO 8373:2021, 3.7]

3.25
robot system
system constructed for an *application service* (3.26), including *service robots* (3.24), safeguarding and complementary protective measures independently installed by an *application service provider* (3.30), communication networks, and so on

3.26
application service
action to provide benefit to a *user* (3.27) by interaction between a *service robot* (3.24) or a *robot system* (3.25) and the *user* (3.27)

Note 1 to entry: Trials are regarded as an application service.

3.27
user
beneficiary, person who receives the benefit, of the *application services* (3.26) provided by the *service robot* (3.24)

Note 1 to entry: In some applications, a user could be both the operator and the beneficiary.

3.28
user limit
limit or condition to limit to be a *user* (3.27) by his/her category and/or characteristics

Note 1 to entry: Examples of user limit are body height, body mass, age, skill, disease, clinical history, body condition or so.

3.29
user's behaviour limit
limit or condition to limit the behaviour of a *user* (3.27)

Note 1 to entry: Examples of user's behaviour limit are acting in accordance with the operation procedure of a service robot specified by the *robot system provider* (3.33), putting on a protective equipment or so.

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3.30
application service provider
organization (3.1) that initiatively performs planning, implementation and providing *application service* (3.26) and has overall responsibility of *application service* (3.26) including safety. In the case of that application service provider *outsources* (3.22) operation task to *operator agency* (3.31), it provides a *robot system* (3.25) to an *operator agency* (3.31) for a defined use

Note 1 to entry: There are several cases in market to establish robot system for application service. The simplest case is using general-purpose robot system which robot system provider supply. However, in many cases, integration of robot system according to each application service are needed. When application service provider performs system integration by itself, it takes on the role and responsibilities of a *robot system provider* (3.33) including to certify that the robot system meets relevant safety standards if necessary. When application service provider outsourced system integration, outsourcing partner takes on these role and responsibilities depends on contract.

Note 2 to entry: When application service provider performs planning application service, it can apply organizational measures, and/or person-based measures to ensure the safety of application service.

3.31
operator agency
organization (3.1) that has the responsibility to manage and operate a *service robot* (3.24)

Note 1 to entry: *Operator agency* (3.31) can be a part of *application service provider* (3.30), otherwise can be a different *organization* (3.1) which outsourced by *application service provider* (3.30).

EXAMPLE 1 The application of a delivery robot for transporting food and food-related items between an *operator agency* (3.31) such as a restaurant, and a *user* (3.27) such as a restaurant customer. The restaurant, the *operator agency* (3.31), that manages a person, the *operator* (3.23), who programs the delivery destination and initiates the *service robot* (3.4) to accomplish the delivery task.

EXAMPLE 2 The application of an exoskeleton robot for personal mobility assistance by an *operator agency* (3.31) such as a rehabilitation facility, to aid a *user* (3.27) such as a rehabilitation client. The rehabilitation facility, *operator agency* (3.31), that manages a rehabilitation staff member, the *operator* (3.32), who provides rehabilitation services to clients, *users* (3.27).

Note 2 to entry: An *operator agency* (3.31) is responsible for the safe operation of the *service robot* (3.24) for the defined use of the *application service provider* (3.30). This responsibility can be identified in a contract between the *application service provider* (3.30) and the *operator agency* (3.31), or by safe operating instructions in an operating manual that is provided by the *application service provider* (3.30) to the *operator agency* (3.31).

3.32
operator
person or agency designated to make parameter and program changes, and to start, monitor, and stop the intended operation of the *service robot* (3.24)

[SOURCE: ISO 8373:2021, 2.17, modified]

3.33
robot system provider
organization that supplies robotic components, subsystems, or systems for *application service provider* (3.30). These include hardware for the physical system of a *robot* (3.23), and software for operation of the hardware and control interfaces

Note 1 to entry: A manufacturer can be regarded as a robot system provider.

Note 2 to entry: A system integrator can be regarded as a robot system provider.

Note 3 to entry: A seller can be regarded as a robot system provider.

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3.34
information for use
information that has a safety specification of a *robot* (3.23), a *robot use restriction* (3.35), a compliance matter to assure safe and proper operation of machines or a residual *safety risk* (3.39)

Note 1 to entry: In general, information for use is provided by a robot system provider as a user manual.

3.35
robot use restriction
condition of use intended by a *robot system provider* (3.33) during designing including an operational environment of *robot* (3.23), a *user limit* (3.28), a *user's behaviour limit* (3.29), *competence* (3.9) required to use, education and training contents to obtain the *competence* (3.9), a period for safety-related *performance* (3.11) to be maintained, and necessary maintenance and inspection

Note 1 to entry: Robot use restriction is equivalent to "limits of machinery" specified in 5.3 of ISO 12100:2010.

Note 2 to entry: "Machinery" and "machine" is changeable to "robot" in this document.

3.36
life cycle of application service
consecutive and interlinked stages of a *management system* (3.4) related to an *application service* (3.26), from transportation and installation of *service robots* (3.24) to final disposal

Note 1 to entry: The life cycle of application service stages include transportation of *service robots* (3.24), installation, use, change of contents of a service, inspection, maintenance, end-of-life treatment and final disposal.

Note 2 to entry: Adapted from ISO 14001:2015, 3.3.3.

3.37
third party of application service
person who is in the operation space of an *application service* (3.26) but is not *user* (3.27) nor in charge of the *application service* (3.26) as a member of the *application service provider* (3.30).

Note 1 to entry: In general, third party of application service do not have prior knowledge and information relevant to the safety of a specific *robot* (3.23).

3.38
third party who has special knowledge
person or *organization* (3.1) that can be regarded to have knowledge of machinery safety

Note 1 to entry: For example, a certifier or a person who has knowledge of machinery safety [e.g. system safety engineer, safety assessor (part), industrial safety consultant (part)].

Note 2 to entry: A member of an *application service provider* (3.30) can be a third party who has special knowledge.

3.39
safety risk
combination of the probability of occurrence of *harm* (3.41) and the severity of that *harm* (3.41)

3.40
safety opportunity
circumstance or set of circumstances that can lead to improvement of *application service safety performance* (3.21)

3.41
harm
injury or damage to the health of people, or damage to property or the environment

[SOURCE: ISO/IEC Guide 51:2014, 3.1]

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