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**Requirements for safety management
system of robot service using service
robots**

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Foreword

This Japanese Industrial Standard has been established by the Minister of Economy, Trade and Industry, through deliberations at the Japanese Industrial Standards Committee in accordance with the Industrial Standardization Act.

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Attention is drawn to the possibility that some parts of this Standard may conflict with patent rights, published patent application or utility model rights. The relevant Minister and the Japanese Industrial Standards Committee are not responsible for identifying any of such patent rights, published patent application or utility model rights.

NOTE This Standard has been established based on the provisions of Article 2, Article 11, Article 13 and Article 19 of the Industrial Standardization Act, which are applied under the provisions of Article 6, paragraph (3) of the Supplementary Provisions to the Unfair Competition Prevention Act etc.

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Requirements for safety management system of robot service using service robots

Introduction

0.1 Background

When operating service robots that coexists with humans, appropriate management of residual risk is required. In order to pursue this objective, consideration is essential in the aspect of operations performed by robot service providers that use the service robots, in addition to consideration in terms of design performed by the manufacturers, as is the case of general machinery. For the safe operation of the service robot with residual risk performed by the robot service provider, communication between the manufacturer and robot service provider is critical, e.g., the manufacturer provides appropriate information for use; the robot service provider operates the service robot after understanding unclear points among information for use via inquiries to the manufacturer; and the robot service provider provides feedback to the manufacturer regarding safety-related information obtained through actual operation.

For some service robots, safety requirements in terms of design have already been specified in **JIS B 8445**, **JIS B 8446-1** through **JIS B 8446-3** and **JIS B 8456-1**, based on which robot service providers operate the service robots. While these robot service providers safely operate their robot services using knowledge exceeding a certain level and expertise based on experiences, terms has not been organized or systematized for the methodology. This Standard stipulates and systematizes optimum solutions in safe operations of robot services so as to clarify the criteria that robot service providers newly joining the market should fulfil and to promote sound development of the industry.

0.2 Objective of this Standard

The objective of this Standard is to provide service providers using service robots with essential requirements for a robot service safety management system, which is a framework for safety operation in implementation of robot services.

This Standard is not intended to increase or change legal requirements for the organization.

0.3 Contents of this Standard

The robot service safety management system is based on the concept, “Plan-Do-Check-Act (PDCA)”. A PDCA model shows a repetitive process used by an organization to achieve continual improvements. A PDCA model can be briefly described as follows :

- Plan : establish safety objectives and processes necessary to bring results that are consistent with safety policy of the organization;
- Do : perform the process as planned;
- Check : in light of safety policies including commitments, safety objectives, and

operational criteria, monitor the process, perform measurements and report the results;

- Act : take actions for continual improvements.

An organization can demonstrate conformity to this Standard by any of the following methods :

- make a self-determination and a self-declaration;
- for conformity, ask a person or group who has an interest in the organization, e.g., client, for verification;
- for self-declaration, ask a person or a group outside the organization for verification;
- request certification and registration of the robot service safety management system by an external agency.

The following expressions are used in this Standard :

- “shall”, “is to” and “is required to” indicate requirements;
- “should” indicates recommendations;
- “may” indicates permissions;
- “can”, “be able to” and “there is a possibility of” indicate possibilities or abilities.

Information described in “NOTE” is intended to facilitate understanding or use of this Standard.

1 Scope

This Standard specifies requirements for the safety management system, which the robot service provider using service robots can use for safety of a beneficiary and a third party in robot services.

This Standard is applicable to any organizations that perform the following items :

- a) improve robot service safety performance;
- b) establish, implement, maintain, and improve a robot service safety management system;
- c) assure by itself the conformity to the presented robot service safety policy;
- d) demonstrate conformity with this Standard.

Requirements in this Standard may be integrated into the existing management system or work process of the organization or may be satisfied as a part of them.

Requirements in this Standard may cover and be enforced over multiple organizations, depending on the contents to be implemented for the organization and safety management.

This Standard may be applied to services using robots other than service robots and robotic devices.

NOTE It should be noted that the robot service safety management system established according to the requirements in this Standard may not be applicable as it is if the service robots and robot service system to be used, operational contents of the service, place of implementation, targeted beneficiaries of the service, etc., are different.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this Standard. The most recent editions of the standards (including amendments) indicated below shall be applied.

- JIS B 0134 *Robots and robotic devices — Vocabulary*
- JIS B 8445 *Robots and robotic devices — Safety requirements for personal care robots*
- JIS B 8446-1 *Safety requirements for personal care robots — Part 1 : Static stable mobile servant robot with no manipulator*
- JIS B 9700 *Safety of machinery — General principles for design — Risk assessment and risk reduction*
- JIS Q 9000 *Quality management systems — Fundamentals and vocabulary*
- JIS Q 9001 *Quality management systems — Requirements*
- JIS Z 8051 *Safety aspects — Guidelines for their inclusion in standards*

3 Terms and Definitions

For the purpose of this Standard, the terms and definitions given in **JIS B 8445**, and the following apply.

3.1

organization

person or group of people that has its own functions with responsibilities, authorities and interrelationships to achieve its objectives

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

(Modification of 3.2.1 of JIS Q 9000)

3.2

interested party

person or organization that can affect, be affected by, or perceive itself to be affected by a decision or activity

NOTE Manufacturer is included in interested party associated with the robot service safety management system.

(See 3.2.3 of JIS Q 9000)

3.3

requirement

need or expectation that is stated, generally implied or obligatory

NOTE 1 “Generally implied” means that it is custom or common practice for the organization and interested parties that the need or expectation under consideration is implied.

NOTE 2 A specified requirement is one that is stated, for example in documented information.

(See 3.6.4 of JIS Q 9000)

3.4

management system

set of interrelated or interacting elements of an organization to establish policies and objectives, and processes to achieve those objectives

NOTE 1 A management system can address a single discipline or several disciplines.

NOTE 2 The management system elements establish the organization's structure, roles and responsibilities, planning, operation, and performance evaluation and improvement.

NOTE 3 The scope of a management system can include the whole of the organization, specific and identified functions of the organization, specific and identified sections of the organization, or one or more functions across a group of multiple organizations.

(See 3.5.3 of JIS Q 9000)

3.5

robot service safety management system

part of the management system related to the robot service safety policy

3.6

top management

person or group of people who directs and controls an organization at the highest level

NOTE 1 Top management has the power to delegate authority and provide resources within the organization.

NOTE 2 If the scope of the management system covers only part of an organization, then top management refers to those who direct and control that part of the organization.

(Modification of 3.1.1 of JIS Q 9000)

3.7

effectiveness

extent to which planned activities are realized and planned results are achieved (see 3.7.11 of JIS Q 9000)

3.8

policy

intentions and direction of an organization as formally expressed by its top management (see 3.5.8 of JIS Q 9000)

3.9

robot service safety policy

policy related to robot service safety

3.10

objective

result to be achieved

NOTE 1 An objective can be strategic, tactical, or operational.

NOTE 2 Objectives can relate to different disciplines (such as financial, health and safety, and environmental goals) and can apply at different levels (such as strategic, tactical, organization-wide, project, product and process).

NOTE 3 An objective can be expressed in other ways, e.g. as an intended outcome, a purpose, an operational criterion, as a robot service safety objective or by the use of other words with similar meaning (e.g. aim or goal).

NOTE 4 In the context of robot service safety management systems, robot service safety objectives are sometimes set by the organization, consistent with the robot service safety policy, to achieve specific results.

(Modification of 3.7.1 of JIS Q 9000)

3.11

harm

injury or damage to the health of people, or damage to property or the environment (see 3.1 of JIS Z 8051)

3.12

risk

combination of the probability of occurrence of harm and the severity of that harm (see 3.7 of JIS B 8445)

3.13

competence

ability to apply knowledge and skills to achieve intended results (see 3.10.4 of JIS Q 9000)

3.14

documented information

information required to be controlled and maintained by an organization and the medium on which it is contained

NOTE 1 Documented information can be in any format and media and from any source.

NOTE 2 Documented information can refer to :

- the management system, including related processes;
- information created in order for the organization to operate (documentation);
- evidence of results achieved (records).

(See 3.8.6 of JIS Q 9000)

3.15

process

set of interrelated or interacting activities that convert inputs to outputs (modification of 3.4.1 of JIS Q 9000)

3.16

performance

measurable results

NOTE 1 Performance can relate to either quantitative or qualitative findings.

NOTE 2 Performance can relate to the management of activities, processes, services, systems or organizations.

(See 3.7.8 of JIS Q 9000)

3.17

robot service safety performance

measurable results related to robot service safety

NOTE Scales to measure performance related to robot service safety include the following :

- continuous operation time without accident;
- number of near-miss;

A “near-miss” is generally considered as a hazardous event that has not resulted in any harm.

- number of proposals for improvement;
- number of people having safety-related qualifications;
- number of emergency response drills performed.

3.18

outsource (verb)

make an arrangement where an external organization performs part of an organization's function or process

NOTE An external organization is outside the scope of the management system, although the outsourced function or process is within the scope.

(See 3.4.6 of JIS Q 9000)

3.19

monitoring

clarifying the status of a system, a process or an activity

NOTE For the clarification of the status, there can be a need to check, supervise or critically observe.

(Modification of 3.11.3 of JIS Q 9000)

3.20

measurement

process to determine a value (see 3.11.4 of JIS Q 9000)

3.21

audit

systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled

NOTE 1 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 (combination of multiple disciplines).

NOTE 2 Internal audits are conducted by the organization itself, or by external parties on behalf of the organization.

NOTE 3 Definitions of audit evidence and audit criteria are provided in JIS Q 19011.

(Modification of 3.13.1 of JIS Q 9000)

3.22

conformity

fulfilment of a requirement (see 3.6.11 of JIS Q 9000)

3.23

nonconformity

non-fulfilment of a requirement (see 3.6.9 of JIS Q 9000)

3.24

corrective action

action to eliminate the cause of a nonconformity and to prevent recurrence (see **3.12.2** of **JIS Q 9000**)

3.25

continual improvement

recurring activity to enhance performance (see **3.3.2** of **JIS Q 9000**)

3.26

autonomy

ability to perform intended tasks based on current state and sensing, without human intervention (see **3.1** of **JIS B 8445**)

3.27

robot

actuated mechanism programmable in two or more axes with a degree of autonomy moving within its environment, to perform intended tasks (see **3.2** of **JIS B 8445**)

3.28

robotic device

actuated mechanism fulfilling the characteristics of an industrial robot or a service robot, but lacking either the number of programmable axes or the degree of autonomy (see **3.3** of **JIS B 8445**)

3.29

service robot

robot that performs useful tasks for humans or equipment excluding industrial automation applications (see **3.4** of **JIS B 8445**)

3.30

robot service system

sets of systems developed for robot services, which includes service robots, safeguarding separately installed by a robot service provider, additional protective measures and communication networks

3.31

robot service

action to provide a beneficiary with benefit by interaction between service robot or robot service system and a beneficiary

NOTE Demonstration experiments are included in robot service.

3.32

beneficiary

person who receives the benefit of robot service (modification of **2.19** of **JIS B 0134**)

3.33

beneficiary limit

limitation or conditions for limitation for being a beneficiary according to category and/or characteristic

NOTE Examples of beneficiary limit are height, body weight, age, skills, disease, medical history, and physical condition.

3.34

beneficiary's behavior limit

limitation of beneficiary's behavior or conditions for limitation of beneficiary's behavior

NOTE Examples of beneficiary's behavior limit are compliance with operational procedures for a service robot specified by the manufacturer and wearing protective equipment.

3.35

robot service provider

organization that provides robot services (and system integration of robot service systems) for a beneficiary and takes general responsibility including safety

3.36

field provider

person or an organization that provides a facility or a place to perform robot service for a robot service provider

3.37

manufacturer

person or an organization that designs and produces a robot

NOTE A system integrator may be a manufacturer in some cases.

(See 3.7 of JIS B 8446-1)

3.38

seller

person or an organization that sells or lends a robot as a business

3.39

information for use

information containing robot safety specifications, use restrictions, operational compliance items necessary to ensure safe and correct use of a machine, and residual risks

NOTE Information for use is generally provided by a manufacturer as an instruction manual.

3.40

use restriction

use conditions for service robots, intended by the manufacturer in design, containing use environment, beneficiary limits, beneficiary's behavior limits, competence required for use, and contents of education and training to acquire the competence, period to maintain safety-related performance and required maintenance and inspection

NOTE The term "use restriction" is equivalent to the contents of limits of machinery specified in 5.3 of **JIS B 9700**.

3.41

life cycle

consecutive and interlinked stages of a robot service management system from transportation and installation to final disposal of a service robot

NOTE The life cycle stages include transportation, installation and use of a service robot, changes in service items, inspection and maintenance, end-of-life treatment and final disposal.

(Modification of 3.3.3 of **JIS Q 14001**)

3.42

safety standards

standards specifying safety requirement for service robots

NOTE Representative standards include **JIS B 8445**, **JIS B 8446-1**, **JIS B 8446-2**, **JIS B 8446-3** and **JIS B 8456-1**.

3.43

third party of robot service

person in the robot service implementation space, other than a beneficiary and a person who engages in operations as a robot service provider

NOTE Third party of robot service is generally not considered to have knowledge and expertise beforehand on the safety of a particular robot.

(Modification of 3.6 of **JIS B 8446-1**)

3.44

third party who has special knowledge

person or an organization deemed to have knowledge of machinery safety

NOTE 1 Third party who has special knowledge includes a certification body or person or an organization deemed to have knowledge of machinery safety [system safety engineer, safety assessor (in part), and industrial safety and health consultant (in part)] as indicated in Matters to be Noted Regarding Education on Machinery Safety for a Design Engineer and an Production Engineering Manager (Circular 0415 No. 1 issued by the manager of Safety Division, Industrial Safety and Health Department, Labour Standards Bureau, Ministry of Health, Labour and Welfare, dated 15 April 2014).

NOTE 2 A person who belongs to a service provider may be a third party who has special knowledge, in some cases.

3.45

hazardous event

event that can cause harm (see 3.9 of JIS B 9700)

3.46

accident

hazardous event that has resulted in causing harm

4 Context of the organization

4.1 General

When any of the requirements of this Standards are not applicable because of the nature of the organization and the service, such requirements may be excluded; however, the matters to be excluded and reasons for the exclusions shall be documented. When such exclusion is performed, conformity to this Standard can be declared only if the exclusion will not affect the ability of the organization to successfully establish, implement, maintain, and improve a robot service safety management system.

4.2 Understanding the organization and its context

The organization shall determine external and internal issues that are relevant to its purpose and that affect its ability to achieve the intended results of its robot service safety management system.

The organization shall monitor and review information about these external and internal issues (modification of 4.1 of JIS Q 9001).

NOTE 1 External issues include the following items :

- status of cultural, social, legal, technological, economic, natural and competitive environments, whether international, national, regional or local;
- status of competitors;
- relationship with external interested parties;
- changes related to any of the above.

NOTE 2 Internal tasks include the following items :

- organizational activities, strategic direction, culture and ability (capital, time, human resource, process);
- relationship with internal interested parties;
- changes related to any of the above.

4.3 Understanding of needs and expectations of interested parties

The organization shall determine the following items :

- interested parties related to the robot service safety management system;
- requirements relevant to those interested parties.

An organization shall consider the following items upon determining interested parties related to the robot service safety management system :

- owner of a robot;
- field provider;
- relevant administrative body;
- relevant outsourcing contractor;
- manufacturer;
- seller or leasing/rental company;
- beneficiary.

NOTE 1 The instructions in the information for use designated by a manufacturer are included in relevant requirements for the interested parties.

NOTE 2 When the position of robot service changes from a demonstration experiment to business, the interested parties related to the robot service safety management system and relevant requirements for the interested parties may change in some cases.

The term “demonstration experiment” means an action to provide a beneficiary with benefit while using the robot in actual situations and verifying issues (e.g., safety and/or values) for practical use.

NOTE 3 Even when the seller and leasing/rental company provides it for free of charge, they are considered to take the responsibility equivalent to that when providing it for a fee.

4.4 Determination of scope of robot service safety management system

In order to determine the scope of robot service safety management system, the organization shall determine its boundaries and applicability.

For determination of the scope, the organization shall consider the following items :

- external and internal issues specified in 4.2;
- requirements specified in 4.3;
- operational contents of robot services to be performed (see 6.1.2.2).

The scope of robot service safety management system shall be maintained as documented information and be made available to interested parties.

4.5 Robot service safety management system

In accordance with requirements in this Standard, the organization shall establish, implement, maintain, and continually improve the robot service safety management system, including processes necessary to ensure the robot service safety performance