TECHNICAL REPORT

ISO/TR 23482-2

First edition
2019-03

Robotics — Application of ISO 13482 —

Part 2: Application guidelines

Robotique — Application de l'ISO 13482 —

Partie 2: Lignes directrices sur l'application

Reference number
ISO/TR 23482-2:2019(E)

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Published in Switzerland

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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 documents 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*.

A list of all parts in the ISO 23482 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

ISO 13482 is the first safety standard developed for the area of service robots. It allows close human-robot interaction, including human-robot contact. Although ISO 13482 follows well-established principles and practices from standards for industrial robots and machines in general, additional guidance can facilitate its rapid and successful adoption by manufacturers and other stakeholders.

This document clarifies which robots fall under the definition of personal care robots and what distinguishes personal care robots from robots in other areas, such as medical robots or industrial robots. This document also provides further guidance on the risk assessment and risk reduction process to be conducted for a personal care robot. It contains examples of risk assessments for different types of personal care robots that can serve as an example for the user of ISO 13482 for their own risk assessment.

Robotics — Application of ISO 13482 —

Part 2: Application guidelines

1 Scope

This document provides guidance on the use of ISO 13482 and is intended to facilitate the design of personal care robots in conformity with ISO 13482. Additional guidance is provided for users with limited experience of risk assessment and risk reduction. This document provides clarification and guidance on new terms and safety requirements introduced to allow close human-robot interaction and human-robot contact in personal care robot applications, including mobile servant robots, physical assistant robots and person carrier robots. This document considers the application of ISO 13482 to all service robots and includes related examples.

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 8373:2012, *Robots and robotic devices — Vocabulary*

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

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 8373:2012 and ISO 13482:2014 and the following apply.

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

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

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

3.1
service robot
robot that performs useful tasks for humans or equipment excluding industrial automation applications

[SOURCE: ISO 8373:2012, 2.10, modified — Notes to entry have been deleted.]

3.2
personal care robot
service robot (3.1) that performs actions contributing directly towards improvement in the quality of life of humans, excluding medical applications

[SOURCE: ISO 13482:2014, 3.13, modified — Notes to entry have been deleted.]

3.3
industrial robot
automatically controlled, reprogrammable multipurpose manipulator, programmable in three or more axes, which can be either fixed in place or mobile for use in industrial automation applications

[SOURCE: ISO 10218-1:2011, 3.10, modified — Notes to entry have been deleted.]

3.4
mobile servant robot
personal care robot (3.2) that is capable of travelling to perform serving tasks in interaction with humans, such as handling objects or exchanging information

[SOURCE: ISO 13482:2014, 3.14]

3.5
physical assistant robot
personal care robot (3.2) that physically assists a user to perform required tasks by providing supplementation or augmentation of personal capabilities

[SOURCE: ISO 13482:2014, 3.15]

3.6
person carrier robot
personal care robot (3.2) with the purpose of transporting humans to an intended destination

[SOURCE: ISO 13482:2014, 3.16, modified — Notes to entry have been deleted.]

3.7
medical robot
robot intended to be used as MEE or MES

Note 1 to entry: MEE (medical electrical equipment) and MES (medical electrical system) are defined in IEC 60601-1.

[SOURCE: IEC/TR 60601-4-1:2017, 3.20, modified — Note to entry has been added.]

3.8
household robot
actuated mechanism with a degree of autonomy, operating within the household and similar environment, to perform intended tasks

Note 1 to entry: Operating includes travel and/or robot body movement.

[SOURCE: IEC 62849:2016, 3.1]

4 Guidance on the scope of ISO 13482 and gaps or overlaps with other standards

4.1 General

This clause clarifies what robot types and applications are covered by the scope of ISO 13482. It also covers gaps and overlaps with standards for similar products, such as industrial robots, medical robots and light electric vehicles.

4.2 Guidance on the definition of service robots

Service robots include various robot categories performing useful tasks for humans or equipment. Figure 1 illustrates robot categories that are included in the definition of service robot and how they relate to other relevant areas.

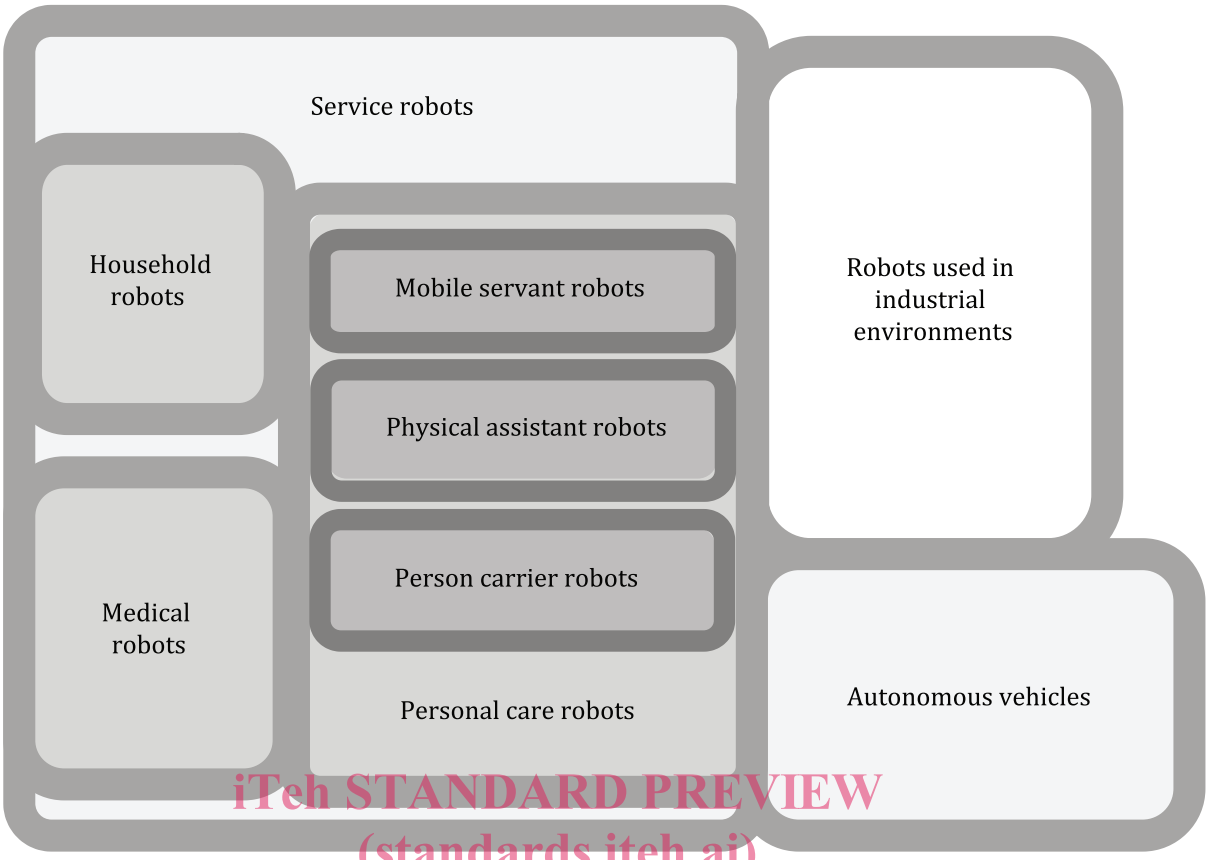

Figure 1 — Categorization of personal care robots and relation with other relevant areas

The term "service robot" contains most robot categories, except industrial robot, as illustrated in Figure 1. As different legal and regulatory requirements apply to different robot categories, one of the first tasks for the manufacturer in commercialization of a robot is to identify the robot category to which it belongs. Robot categories of particular interest to robot manufacturers at the time of publication of ISO 13482 are summarized in Table 1.

Table 1 — Summary of selected robot categories

Robot categories	Purpose	User	Examples
Personal care robot	Improvement of the quality of life of humans (on a non-medical basis)	Lay person (not a patient)	Autonomous mobile robot that takes objects at the request of its user Robot exoskeleton to enhance physical capability of healthy person in non-industrial environment Self-balancing type personal mobility robot
Medical robot	Diagnosis, treatment, or monitoring of a patient; or compensation or alleviation of disease, injury or disability	Patient Medical expert	Robot exoskeleton to compensate disability of affected limbs Surgery robot Self-transfer robot transferring a patient between bed and wheelchair
Household robot	Implementation of housework for humans	Lay person (not a patient)	Autonomous vacuum cleaner Mowing robot
Robot used in industrial environments	Implementation of tasks in industrial automation	Worker	Warehouse mobile robot Welding robot

ISO 10218 was the only International Standard dealing with safety for robots and robot systems prior to the publication of ISO 13482.

4.3 Guidance on the definition of personal care robots

Personal care robots are covered by ISO 13482. They are a subset of service robots that contribute to the quality of life of users through direct interaction.

ISO 13482 is intended to be applied to personal care robots that improve the quality of life of humans regardless of their attribute, age or gender (e.g. children, elderly persons, pregnant women). Since the area of personal care robots is broad, only a small portion thereof was relevant to the existing market at the time of publication of ISO 13482. With the market relevance in mind, ISO 13482 selects the three most commercialized types of personal care robot and specifies safety requirements particularly for these three robot types while allowing its application to any type of personal care robot. The three robot types are mobile servant robot, physical assistant robot and person carrier robot.

The improvement of the quality of life provided by each of the three robot types is as follows.

— Mobile servant robots provide services to their users. These include serving information as well as objects. The role of mobile servant robots can be compared to serving personnel, such as butlers, waiters, secretaries or receptionists.

— Physical assistant robots help the wearer to do a task by physically supporting movements. This includes supporting the user's weight, as well as amplifying the force of muscles.

— Person carrier robots transport users. Such robots can be designed to carry a single person or a small group of persons, at limited speed, normally in pedestrian areas.

Some personal care robots can adopt the attributes of two or more robot types specified in ISO 13482. This kind of hybrid personal care robots includes:

— person carrying exoskeleton (hybrid of physical assistant robot and person carrier robot);

— person carrier robot handling objects and interacting with humans (hybrid of mobile servant robot and person carrier robot).

For such hybrid personal care robots, it is important to identify all relevant safety requirements for the two or more robot types very carefully.

One feature of ISO 13482 compared to ISO 10218 is the physical range of risk of application (see ISO 13482:2014, 6.1.1). Industrial robot applications range from low to high risk, with more applications having high risk. As personal care robots tend to have more direct physical contact with humans than industrial robots, there was a tendency for manufacturers to produce more robots with low risk at the time of publication of ISO 13482. This trend in the personal care robot market is reflected by the intensive coverage of robots with low risk.

4.4 Guidance on the distinction between personal care robots and other robots

There are some known overlaps of scope between ISO 13482 and other standards. Such overlaps allow more than two interpretations of robot category applicable to one robot. To minimize double interpretations, the robot category can be identified based on the intended use of the robot in question. The purposes of the four most market-relevant robot categories are specified in Table 1. The following are examples of identifying robot category based on the purpose of the robot.

— A wearable robot for diagnosis, treatment, or monitoring of a patient, or for compensation or alleviation of diseases, injury or disability, is categorized as a “medical robot” (see IEC 60601-1). The same wearable robot can be categorized as a “physical assistant robot” (ISO 13482:2014, 3.15), if used otherwise, e.g. exoskeleton robot assisting medical worker to transfer a patient.

— A mobile robot for transporting parts for an assembly line can be categorized as a “robot used in industrial environments”. The same robot can be categorized as a “mobile servant robot” (ISO 13482:2014, 3.14) if used otherwise, e.g. a mobile robot for fetch and carry tasks in the household.

— A wearable robot assisting a factory worker in installing a door onto an automobile in manufacturing premises, can be categorized as a “robot used in industrial environments”. The same robot can be categorized as a “physical assistant robot” if used otherwise, e.g. to minimize factory worker’s fatigue when not performing tasks in factory automation.

It is usually in the interests of a robot manufacturer to identify one singular type to which a particular robot belongs. In this way, it is only necessary to fulfil the safety requirements for this type and contradicting requirements from different standards are avoided. When a particular robot can belong to more than one type, the manufacturer chooses the robot type, intended use, conditions for use and limitation for use.

If a robot is intended to be used for multiple purposes, the robot is normally considered to belong to multiple robot types. One such example is an autonomous mobile robot able to serve food and beverages (“mobile servant robot”) and also managing and dispensing medication to a patient (“medical robot”). In such a case, both applicable medical device standards and machinery standards should be considered.

NOTE 1 If a robot is designed in a way that software can be altered, it is important that the manufacturer specifies the limits of use and selects applicable safety standards accordingly for the risk assessment process. If the software is altered beyond the specified limits (e.g. using a non-medical robot for a medical task), a new risk assessment is conducted according to ISO 12100 (or another applicable standard) by the party responsible for the alteration.

In the following examples, the boundaries of the personal care robots and the other products need to be clarified:

— a driverless road vehicle can be classified as a person carrier robot if the speed is limited to 20 km/h; ISO 13482 applies;

— a person carrier robot is classified as a road vehicle if it is used on the public roads; regulations for road vehicles apply.

NOTE 2 To determine which standards to apply in case of conflicting requirements, the manufacturer can consult a third party qualified to provide advice until the boundaries are clarified. This can be from organizations accredited according to ISO/IEC 17025.

Reasonably foreseeable misuses are identified in the risk assessment, according to ISO 12100. The robot design can be changed to lessen the likelihood of foreseeable misuses. When these cannot be eliminated, they are used to determine the intended uses and limitations of use of the personal care robot.

5 Concepts in ISO 13482

5.1 General

ISO 13482 addresses safety issues that are distinct compared to medical and industrial robots. The following are some elemental differences between personal care robots and other existing machinery:

— personal care robots are usually mobile and work among humans without being separated by guards;

— interaction between human and robot, including physical contact, is often an essential part of the robot's task;

— personal care robots often have a certain degree of autonomy which enables them to act and decide without human intervention.

5.2 Interaction without guards

Personal care robots are usually designed to operate among humans, sharing their operational space with them. In addition, personal care robots are usually mobile. As a result, protective devices are usually attached to, or can be integrated with, the personal care robot, rather than being installed in the environment. Operating zones and zones safeguarded by protective devices and safety functions are defined relative to the mobile personal robot.

Due to the closer interaction with humans, the protective stop is not considered the only option to achieve a safe state. More flexibility can be reached when the robot adjusts its speed to the distance and the relative speed of obstacles. To guarantee safe interaction, safety functions such as safety-related speed control and obstacle avoidance can be applied. Requirements for the control system performance of such safety functions are provided in ISO 13482:2014, 6.4 and 6.5.

5.3 Intended physical contact

Physical contact with the user is often essential for the task of a personal care robot. This applies especially for physical assistant robots where force is directly applied to parts of the human body, but it is also important that person carrier robots are in permanent contact with their rider. Mobile servant robots establish temporary physical contact, e.g. when objects are handed over.

During robot design and risk assessment, it is important that a manufacturer distinguishes between intended and unintended forms of physical contact. For intended contact, it is important to limit contact forces and impacts to a level that allows interaction with the user without pain or discomfort. A strategy or process is usually developed for controlled engagement and disengagement into/from physical contact. It is important to avoid unintended contact, especially harm from collisions and clamping with high force and impact.

Requirements for the control system performance of a safety-related force control function that can be used to achieve acceptable physical interaction are provided in ISO 13482:2014, 6.6.

5.4 Autonomous functions

Personal care robots are in many cases equipped with autonomous functions. ISO 13482 distinguishes between autonomous and semi-autonomous operation (see ISO 13482:2014, 6.10). During autonomous mode, the frequency of human interaction is very low, e.g. when a mobile servant robot performs

household tasks like tidying up or preparing drinks on its own. In semi-autonomous mode, user and robot interact frequently, but the robot is only indirectly controlled by the human.

EXAMPLE When the human controls the general direction of motion of a person carrier robot while the robot performs obstacle avoidance and stability control on its own.

As the level of autonomy in personal care robots is still considerably low and often limited to simple autonomous decisions, ISO 13482 assumes that the manufacturer still carries the full responsibility for autonomous actions of the robot. The robot cannot be responsible itself for its actions, nor is the user responsible for harm originating from autonomous decisions when using the robot as intended. It is important that the manufacturer of a personal care robot judges carefully which actions and decisions can be executed autonomously by such a robot without any unacceptable risk of harm. Further guidance on this issue is provided in ISO 13482:2014, 5.12.

It is expected that the autonomy of personal care robots will increase in the future and will comprise more complex autonomous actions and decisions. The relevant clause of ISO 13482 is therefore likely to be expanded in future revisions.

6 Methodology

6.1 Risk reduction methodology of ISO 13482 in the context of other safety standards

The process of risk assessment and risk reduction is shown in Figure 2, which is adapted from ISO 12100:2010, Figure 1, and has been extended with additional information for users of ISO 13482, including priority of application order of the risk reduction measures.

As shown in Figure 2, as a first step, the limits of the robot are determined, and thereby the environment and the use context or application in which the robot operates. Based on these limits, hazard identification is performed and the risk associated with the identified hazards is estimated. Risk reduction is required if risk evaluation indicates that a risk has not been adequately reduced. It is the manufacturer's responsibility to determine the acceptable risk. Acceptable risk can be understood as the level of risk that is accepted in a given context based on the current values of society.

A risk reduction is performed according to the three-step method illustrated in Figure 2 for any risks which need risk reduction. The first step is to reduce the risk by applying inherently safe design measures. The second step (the reduction of the risk by applying safeguards or complementary protective measures) can only be applied when the first step is not applicable or the necessary risk reduction cannot be achieved by applying the first step. In the same way, the third step is not applicable without performing the first and the second step.

The process of risk reduction is always iterative. After measures have been applied, the residual risk is again assessed to determine if the risk is adequately reduced. These steps are repeated until finally all the remaining risks are adequately reduced.

For hazard identification, the list of significant hazards provided in ISO 13482:2014, Annex A, can be used as a checklist. This list is not exhaustive and does not necessarily cover all hazards of a particular personal care robot: as a supplement, the more general list of hazards provided in ISO 12100:2010, Annex B, can be used to identify less common hazards.

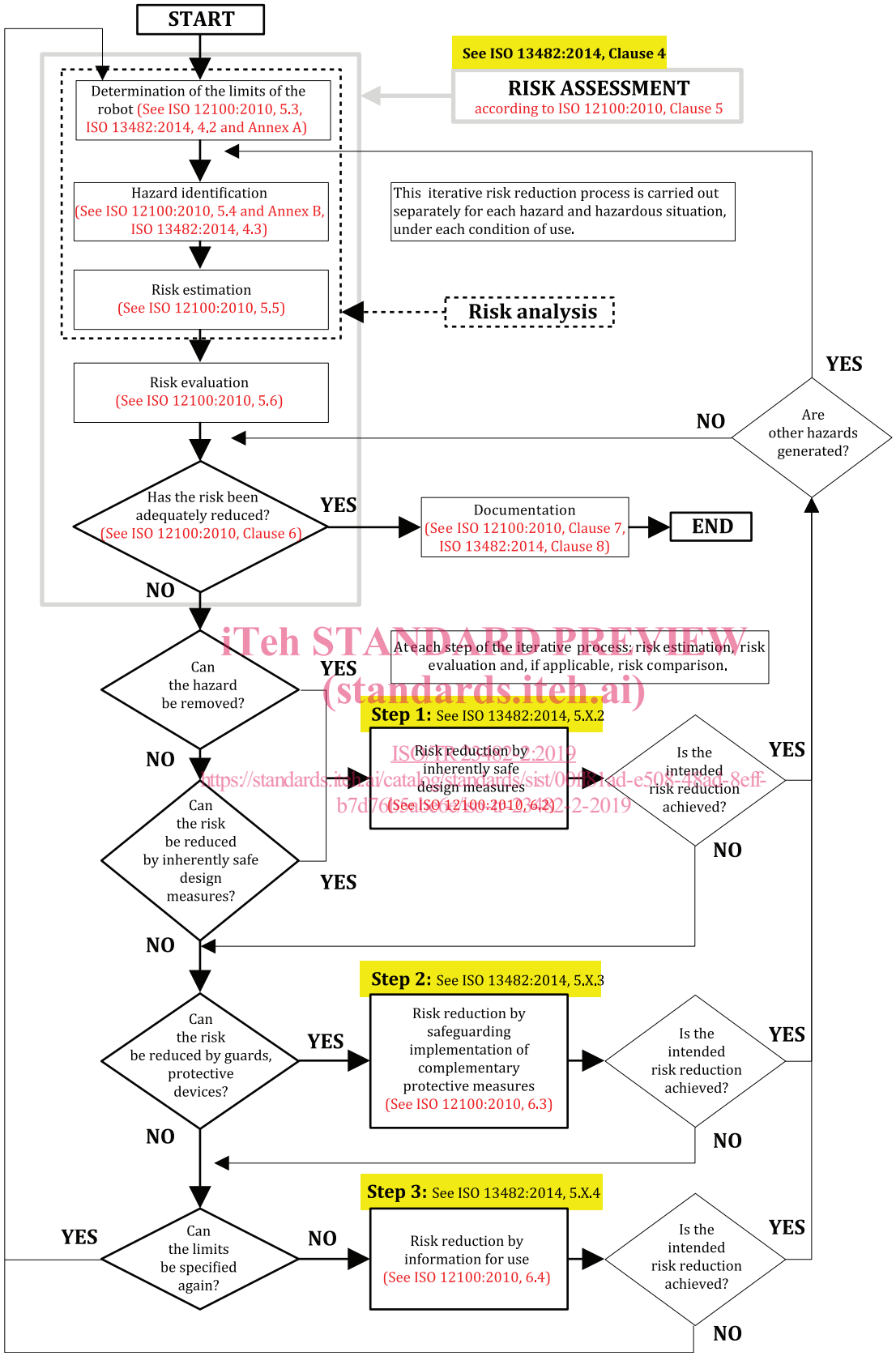

Figure 2 — Schematic representation of risk reduction process with extended information for users of ISO 13482

ISO 13482:2014, Clause 5, is structured in such a way that appropriate measures for the three steps of risk reduction are provided for each particular hazard in subsequent subclauses, as follows:

— 5.X.2 Inherently safe design;

— 5.X.3 Safeguarding and complementary protective measures;

— 5.X.4 Information for use.

This allows the user to take all possible measures for risk reduction into account and choose appropriate solutions according to the priorities defined in ISO 12100.

NOTE 1 Other measures than those mentioned in ISO 13482:2014, 5.X.2 to 5.X.4, can be chosen for risk reduction if they are considered to be appropriate.

When safety functions are implemented for risk reduction using the safety-related part of the control system, ISO 13482:2014, Clause 6, applies, with each safety function being realized with a sufficiently high safety performance level (PL). The definition of PL and categories of control architecture are described in ISO 13849-1. Before applying ISO 13482:2014, Clause 6, users are highly encouraged to familiarize themselves with the principles and methodology described in ISO 13849-1.

NOTE 2 This document uses PL for evaluation of safety related control circuit according to ISO 13849-1. However, safety integrity level (SIL) defined in IEC 62061 can also be applied for the same purpose.

ISO 13482 requires that the required performance level (PLr) for a certain safety function be determined by risk assessment, taking into account expected probability and severity of harm. ISO 13482:2014, Clause 6, contains recommendations for the PL of typical safety functions for typical robot types. However, the recommendations in ISO 13482 only serve as a guideline and are not a substitute for users to determine the PLr of their particular robot. Compared with the recommended PL, the PLr determined by the user can be higher or lower.

— Higher: In this case, the particular personal care robot has risks that are higher than the risks of typical examples of personal care robots illustrated in ISO 13482. The manufacturer needs to fulfil all the requirements of ISO 13849-1 to mitigate these higher risks.

— Lower: In this case, the particular personal care robot can have risks that are lower than the risks of typical examples of personal care robots illustrated in ISO 13482. However, it should be ensured that substantial reasons exist for this outcome of risk estimation. These reasons should be carefully documented in the technical documentation of the robot for later review.

Expected safety-related control functions of personal care robots are used as titles from ISO 13482:2014, 6.2 to 6.11. Each clause shows requirements for the safety-related control system with expected PL.

ISO 13482 subdivides each robot type into a high-risk sub-type and a low-risk sub-type of each example of a robot type. Choosing either sub-type results in different recommendations for the PLr, which are usually based on the choice of a high or low expected severity in the associated risk graph. This differentiation serves as an additional guideline for the user. However, it is not a substitute for performing a risk assessment to determine the PLr for each safety function. In practice, a robot that at first sight seems to correspond to the “low-risk” definition can prove to require safety functions with high PL after careful inspection. The robot sub-type can be changed by implementing inherently safe design measures.

6.2 Approach adopted for the working examples

Clause 7 comprises working examples to provide guidance on the following subjects:

— procedural steps for risk assessment and the generation of a risk assessment table;

— the application of the ISO 12100 risk reduction methodology;

— the application of safety PL for the safety-related control system function according to ISO 13849-1;