Industrial Health 2015, **53**, 498–504

Original Article

Global harmonization of safety regulations for the use of industrial robots-permission of collaborative operation and a related study by JNIOSH

Tsuyoshi SAITO[1]*, Toshiro HOSHI[2], Hiroyasu IKEDA[1] and Kohei OKABE[1]

[1]National Institute of Occupational Safety and Health, Japan
[2]Nagaoka University of Technology, Japan

Received November 1, 2014 and accepted May 26, 2015

Abstract: In December 2013, the Japanese Ministry of Health, Labour and Welfare (MHLW) partially amended the safety regulations for use of industrial robots so that "collaborative operation" could be performed at Japanese worksites as allowed in the ISO standard for industrial robots. In order to show global harmonization of Japanese legislation on machinery safety and problems with applying ISO safety standards to Japanese worksites, this paper reports the progress of a research study which have been conducted in National Institute of Occupational Safety and Health, Japan from 2011 to the present at the request of MHLW to examine the necessity and effect of the amendment. In the first phase of this study, a questionnaire survey was conducted among domestic robot manufacturers and users. The obtained results revealed their potential demand for the collaborative operation and problems concerning their risk assessment and rule-based risk reduction. To solve the problems, we propose a method based on an investigation result of the regulatory framework for safety of machinery in the European Union. Furthermore, a model of robot system capable of demonstrating the collaborative operation and risk reduction measures which is being developed to support appropriate implementation of the amendment is also described.

Key words: Global harmonization, Ordinance on industrial safety and health, Machinery safety, Industrial robot, Collaborative operation, Risk reduction measures

Introduction

ISO standards for safety of machinery have been systematically taken into Japanese industrial standards after the signing of WTO Agreement on Technical Barriers to Trade in 1995 and more than 20 harmonized standards are published today. However, it has only just begun to reflect those standards in the Ordinance on Industrial Safety and Health (OISH) regarding the machinery safety in Japan. The partial amendment of the safety regulations for the use of industrial robots (i.e., the partial modification of illustrative rules for interpreting Article 150-4 of OISH) done in December 2013[1)] is a pioneering example.

The regulations were established as part of OISH in 1983, in response to a number of accidents occurred following the rapid spread in the use of the industrial robots at that time. The Research Institute of Industrial Safety (RIIS) which is the antecedent of the National Institute of Occupational Safety and Health, Japan (JNIOSH) contributed greatly to develop its technical aspects. The contents of the regulations were essential for preventing accidents, which means they were based on the principle of isolating

---

*To whom correspondence should be addressed.
E-mail: saitot@s.jniosh.go.jp

persons from robots during operation by using guards and interlocking devices. However, technical discrepancies between the regulations and an international standard for industrial robots, i.e., ISO 10218-1 were thought to be a serious problem. The first edition of the standard published in 1993 was drafted by referring to a Japanese industrial standard established based on the regulations. However, following the successive publication of ISO standards which deal with basic and general aspects of safety of machinery, ISO 10218 was drastically revised in 2006[2)] by introducing a risk-based approach. In particular, a special automatic operation mode called "collaborative operation" was newly defined to allow robots to perform intended tasks in cooperation with a person while sharing a workspace.

Under the circumstances, taking into account the second revision of ISO 10218-1 in 2011[3)] (and the subsequent publication of ISO 10218-2[4)]), the Japanese Ministry of Health, Labor and Welfare (MHLW) requested JNIOSH to conduct a research study to examine the necessity and effect of a partial amendment of the regulations, and then MHLW partially amended the regulations in December 2013. This paper reports an example of global harmonization of Japanese legislation on the machinery safety and problems with applying ISO safety standards to Japanese worksites through the progress and results of this research study which started in April 2011 and has been proceeded to the present by roughly dividing into three phases.

Definition and Requirements of the Collaborative Operation

"Collaborative operation" is defined as an operational state in which a purposely designed robot works in direct cooperation with a person(s) within a defined common workspace where they can perform tasks simultaneously. During the operation, physical contact is allowed between a robot and a worker. For instance, Fig. 1 shows an example of workpiece feeding operation by hand guiding[5)]. The operator conducts the robot arm to the workpiece position and makes the arm grasp the workpiece in the collaborative work space by using the hand guiding device. After this, he moves the arm to the automatic operation space, and once the arm has passed the boundary provided by the safeguards, the robot transits to automatic operation mode to carry out a programmed process. Other than this, assist operations for handling work pieces or tools in parts assembling or welding are expected as concrete applications of the collaborative operation.

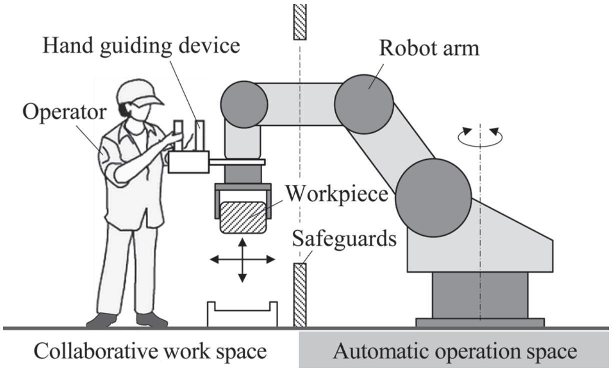


Fig. 1. Example of workpiece feeding operation by using hand guiding device[5)].

Although the collaborative operation was explicitly stated first in ISO 10218-1:2006[2)] and fundamental studies had been conducted before then[6, 7)], practical examination has only just begun in these last few years[8)]. For this reason, technical requirements for the collaborative operation are not yet well-developed. Table 1 shows risk reduction measures for collaborative operation listed in ISO 10218-1[3)] and 2[4)], which are achieved by rated safety-related functions or by inherently safe design of the robot. These standards require the safety of workers must be ensured by using one or more of the measures, however, concepts or outlines of the measures are merely stipulated as shown in Table 1. These standards also state that detailed specifications of the measures, such as speed limit, stopping accuracy and response time, need to be appropriately determined by the designer or the system integrator on the basis of either their risk assessments or other relevant ISO standards. This will be mentioned again later in the context of problems with introducing the requirements of ISO standards into OISH.

Results of Questionnaire Survey

For the first phase of this study, a questionnaire survey was conducted with the aim of understanding the actual situation of the use of industrial robots in Japanese worksites, including the potential demand for collaborative operation, between August and October in 2011[9)]. With the cooperation of the Japan Robot Association, survey responses were received from 36 domestic robot manufacturers and 14 domestic robot users (the response rate was 44.7%). The questionnaire was composed of 24 items on topics such as opinions on the regulations and the ISO standards. From the obtained results, some key issues for the amendment were revealed as detailed below.

Table 1. Risk reduction measures listed in ISO 10218-1 and 2 for collaborative operation

	Measures	Descriptions and requirements
A	Safety-rated monitored stop	When a person enters the collaborative workspace, the robot is compelled to stop and maintain its position. This standstill condition must be monitored by this safety function, and if a deviation of more than a defined amount is detected then power to drive the actuators is removed.
B	Limited speed monitoring	This safety function monitors the motion speed of the robot. If the speed exceeds the predefined limit, then this function stops all robot motions.
C	Power or force limiting	The power or force of the robot is limited by inherently safe design or monitored by a rated safety-related function during the collaborative operation.
D	Hand guiding device	When applied, an enabling device and an emergency stop device must be fitted and the motion speed of the robot must be monitored.
E	Separation distance monitoring	This safety function monitors whether a safe separation distance between the operator and the robot is maintained above the predefined amount.
F	Intrusion detection	Intrusion of any person other than the specified operators into the movable space of the robot must be detected, and this must causes all hazardous robot motion to stop.
G	Provision of appropriate clearance	The robot system should be installed so that a clearance of 500 mm or more is provided between its movable space and peripheral equipment, other machines and/or obstacles. Where this clearance cannot be provided, additional protective measures must be taken.
H	Personal protective equipment	If needed, any limitations to the operator caused by the use of the protective equipment must be taken into consideration.

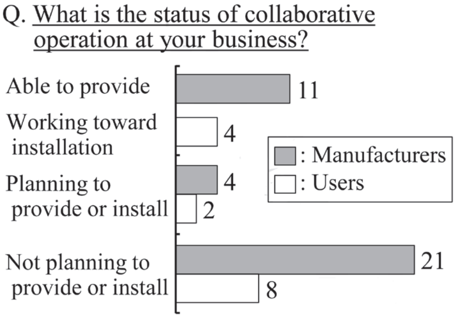


Fig. 2. Survey results on demand for collaborative operation.

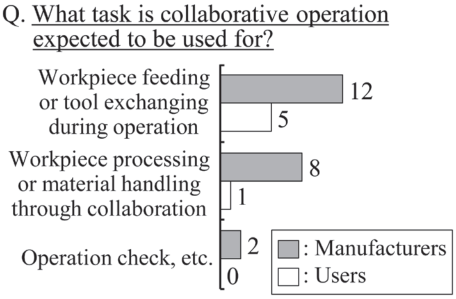


Fig. 3. Survey results on expected applications of collaborative operation.

Figure 2 shows their intention to produce or use robots which can perform the collaborative operation. 42% of respondents expected to permit the collaborative operation, and some users had already formed concrete implementation plans. Workpiece feeding or tool exchanging during operation was mentioned by the majority as an expected application (Fig. 3). On the basis of these results, MHLW formed a conclusion that the amendment of the regulations should be positively promoted.

However, as mentioned above, to introduce the requirements of ISO 10218-1 and 2 for the collaborative operation, there was an issue that the standard merely stipulated conceptual methods to reduce the possible risks during the collaborative operation that had not yet been developed and examined sufficiently as an actual operational state. Therefore, deliberated risk assessment and complete utilization of relevant standards are essential to ensure the safety of collaborating workers. However, our survey results showed a possibility that these requests might not be accomplished at Japanese worksites. First, a result of tallying whether the manufacturers and the users gather accident and incident information is shown in Fig. 4. Forty-four percent of manufacturers and 36% of users did not gather accident or incident information. This indicated that, even if they carried out risk assessments, these would be insufficient because the assessor might not have enough knowledge of prior accidents and incidents in order to list all possible hazardous situations during the risk assessment. Second, results of tallying whether they have design criteria for guards and color codes for indicator lights are shown in Figs. 5 and 6 respectively. Guards and fences are

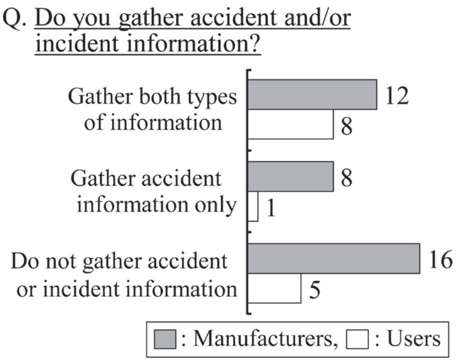


Fig. 4. Survey results on collection of accident and incident information.

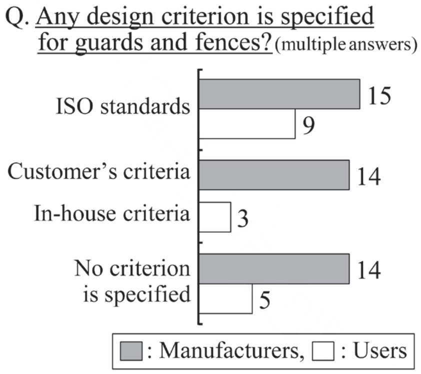


Fig. 5. Survey results on the presence of design criteria for guards.

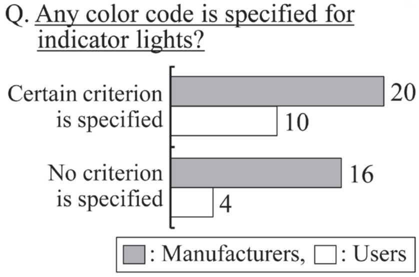


Fig. 6. Survey results on the presence of color codes for indicator lights.

fundamental measures for industrial robots regardless of whether the collaborative operation is performed, therefore, they must be designed and positioned properly based on related ISO standards. However, 39% of manufacturers and 36% of users answered that they had no criterion even without knowing the presence of these standards. Also 40% of respondents had no color code for indicator lights. The colors of indicator lights should be defined and used according as their respective meanings (i.e., to indicate the state or condition of the robot or production system) to avoid erroneous recognition by workers, and therefore a scheme for color coding which can be commonly applied to all kinds of machinery is specified in IEC 60204-1. Overall, these results showed the possibility that such international standards would not be referenced or searched adequately.

Proposals to the Ministry of Health, Labour and Welfare for Solving Problems

In order to solve the problems mentioned above, we proposed the following two actions to MHLW for the amendment as an interim conclusion of this research study:

1) To make the implementation of risk assessment including searching and referencing of relevant international standards mandatory,

2) To provide the information necessary to support adequate implementation of risk reduction, e.g., risk assessment methods, related standards, concrete risk reduction measures, etc.

In 1983, i.e., the same year when the regulations were enforced, a technical guideline was also published, which interprets mandatory requirements and concrete measures for the effective promotion of the regulations. RIIS was greatly involved in formulate it. Revision of the guideline was adopted as a concrete method for realizing the second action.

On the other hand, to find a practical way to achieve the first action, we investigated the regulatory framework regarding machinery safety in the European Union (EU) where ISO harmonized standards have already utilized to ensure a common safety level of products placed on the market and/or put into service, and we focused on the system of "technical file" in the Machinery Directive (Directive 2006/42/EC[10)]). In EU member states, all types of machines used at worksites must comply with the Machinery Directive, and the directive requires that a risk assessment for the machine and its outcome must be documented. This series of documents is referred to as "technical file". Manufacturers must prepare the technical file to demonstrate that their machines comply with the relevant essential health and safety requirements, and the technical file would be checked during market surveillance whenever inspectors have concerns about the safety of the machines, particularly for aspects that cannot be checked by visual inspection[11)].

Referring to the framework, we suggested to MHLW that a series of technical documents that includes risk assessment results and a list of the referenced safety standards also be required in the amendment. This was reflected in the amendment with partial modifications. Conclusively, the requirements of 10218-1 and 2 and the request for technical documentation were incorporated into the illustrative rules for interpreting Act 150-4 of OISH, and the collaborative operation was explicitly permitted in Japan.

Robot System Model to Demonstrate Necessary Technical Measures

As the third phase of this research study, we are now preparing a draft of new technical guideline to realize the second action mentioned above. For ensuring adequate implementation of risk reduction during the collaborative operations, we consider that at a minimum the guideline should cover:

- appropriate risk assessment methods and risk evaluation criteria,
- ISO/IEC safety standards related to various hazards,
- concrete examples of a robot system and risk reduction measures, and
- information on causes of prior accidents and incidents.

Of these items, a robot system model to demonstrate the collaborative operation and necessary technical measures is described in this paper (Fig. 7). The model is designed to simulate a collaborative operation by using a hand guiding device, and being developed by using a Scott Russell linkage type robot with 5 degrees of freedom (ASD-1100, SQUSE) which is generally used for pick and place operation involving small workpieces. Additionally, as concrete examples of risk reduction measures, standstill monitoring and limited speed monitoring are examined at this moment. Such safety functions are generally achieved by functional safety features implemented in the robot control system, such as the duplication of encoder signals and cross-checking of the progress of program processes. However, as part of the explanations in the guideline, the functions should preferably be visually understood. Thus, in the model, designs are adopted such that each function is realized separately by means of widely used commercial safety components. For example, the limited speed monitoring is executed by the subsystem shown in Fig. 8. It is composed of a cogged disk rotated at a speed according to the robot motion by means of a rack and pinion mechanism, proximity sensors (E2E-X1R5F1, OMRON) to detect the rotation of the cogged disk and a low-speed monitoring unit (9SX-LM, OMRON) to process the sensor signals. The low-speed monitoring unit is widely used to confirm that a rotational speed of a motor is below a preset level and to give an access permission signal to a guard locking device.

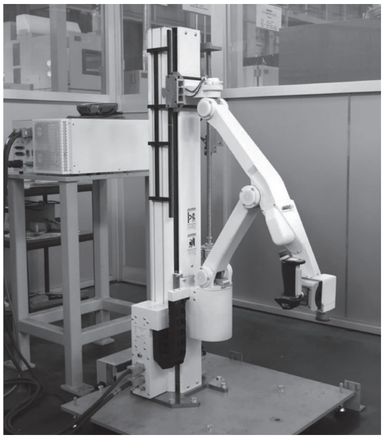


Fig. 7. Robot system model capable of demonstrating collaborative operation.

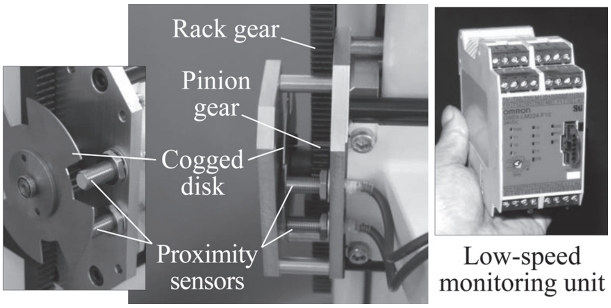


Fig. 8. Composition of limited speed monitoring device.

The safety-rated monitored stop is executed by another subsystem composed of three-position enabling switches (HE5B, IDEC), coil springs, a ball screw, non-excitation actuated type electromagnetic brakes (ERS-260l/FMF, SINFONIA TECHNOLOGY) and touch switches (D5B, OMRON) as shown in Fig. 9. The enabling switches and the springs are attached to the base of the second joint of the robot, but others are mounted on the main body. The drive nut is supported by the springs so that it moves according to the second joint while the brakes are disengaged and the feed screw can rotate freely.

The three-position enabling switch is a safety component with a structure such that it is in an ON state only when lightly pressed and held in the mid-position and turns to an OFF state when released or further depressed.

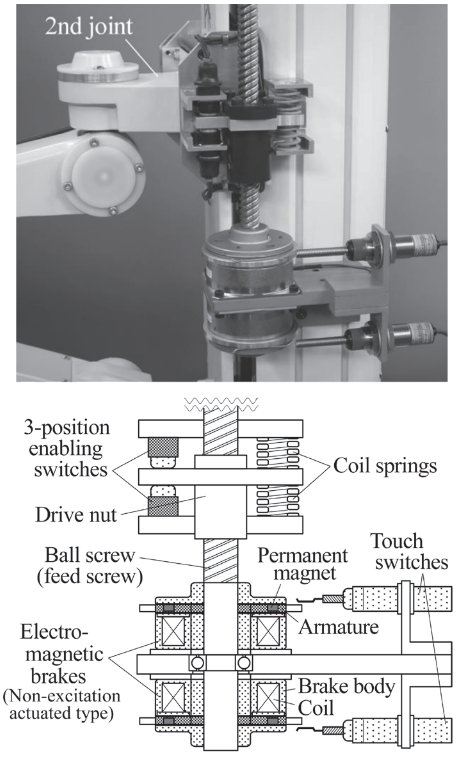
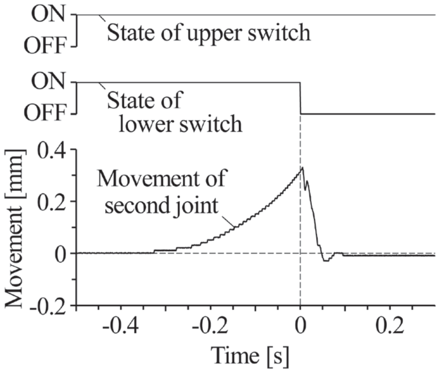
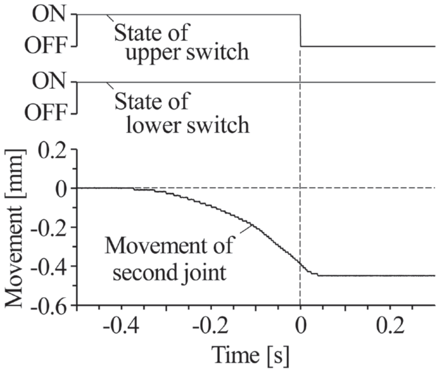


Fig. 9. Photographic and schematic views of standstill monitoring device.



(a) Detection of upward movement



(b) Detection of downward movement

Fig. 10 Examples of experimental results of standstill monitoring.

Such switches are commonly used in manual operating devices of machines but, in this subsystem, the enabling switches are attached to the base of the second joint. Their positions are adjusted by spacers so that they are in the ON state while the drive nut moves according to the second joint, and their outputs are connected to an emergency stop circuit of the robot.

The electromagnetic brakes are a non-excitation actuated type such that, when an exciting current of the coil is in a non-energized state (i.e., no exciting current), the armature is attracted to the brake body by magnetic force of permanent magnets embedded in the armature. In this subsystem, the exciting currents of the coils of the brakes are controlled according to the operational state of the robot. Therefore, when the robot has to stop and maintain a standstill condition (due to a release of the hand guiding device, for example), the exciting currents of the coils are cut, each armature is attracted to each brake body, and then the feed screw is locked. These normal operations of the brakes are checked by using the touch switches.

If any unintended motion of the second joint arises under the condition that the feed screw is locked, then the enabling switch on the upper or lower side is further depressed and turns to the OFF state which causes the derive power of the robot to be shut down. On the other hand, the enabling switches are in the ON state while they are appropriately pressed by the drive nut, that is, as long as the robot is moving and stopping normally. This fact demonstrates one of the configuration principles of a fail-safe interlocking system in which information indicating a safe and normal state is continuously confirmed by transmission of ON signals through a processing circuit of the interlock system$^{12)}$.

Figure 10 shows examples of experimental results of the standstill monitoring function. Both upward and downward movements of the second joint can be detected within 0.4 mm or less. Although this monitoring performance seems to be sufficient to avoid any hazardous situation due to an unintended start-up of the robot, its appropriateness must be evaluated in a risk assessment or previously specified by the risk assessment. The new technical guideline is drafted so that it will explain these issues and provide useful information.

Discussion

As an example of the global harmonization of OISH regarding the machinery safety, this paper described the process to apply the requirements of ISO 10218 to Japanese safety regulations for the use of industrial robots through the research study conducted by JNIOSH.

The amendment was the first case to apply the requirements of ISO standard to the parts of OISH dealing with safety of machinery, and more ISO standards would be introduced or reflected in the future, considering the globalization of safety standards. However, the following problems would make it difficult to ensure the validity of risk reduction measures implemented at actual worksites:

- The requirements of the present ISO standards related to safety of machinery are provided on the premise that the users of the standard will execute risk assessments. There are many cases in which the application of optional requirements and/or detailed specifications of risk reduction measures depend on the outcomes of risk assessment. Some standards give guidance in informative annexes, for example. There, however, are quite a few vague requirements.
- As a drafting rule, an ISO standard for individual machine does not deal with all relevant hazards that are identified as being present in, or associated with, the machine. Further hazards must be treated by following other basic and general standards. However, these standards are not always properly utilized. It must additionally be considered that these standards are revised frequently or newly established to reflect the state of the art.

One possible solution is that, in such amendments, the provision of a series of technical documents, which describe the involved issues, e.g., risk assessment results, referenced relevant standards and residual risks, is also obligated as proposed in the research study. The effectiveness of this approach could be verified by the future prevalence of safe collaborative operation in Japan.

References

1) Japanese Ministry of Health, Labour and Welfare (2013) About the partial revision of the notification for enforcement of Ordinance on industrial safety and health Act 150-4 relating to industrial robots, 24 December 2013. https://www.jaish.gr.jp/anzen/hor/ hombun/hor1-54/hor1-54-62-1-0.htm.

2) ISO 10218-1 (2006) Robots for industrial environments—Safety requirements—Part 1: Robots. International Organization for Standardization, Geneva.

3) ISO 10218-1 (2011) Robots and robotic devices—Safety requirements for industrial robots—Part 1: Robots. International Organization for Standardization, Geneva.

4) ISO 10218-2 (2011) Robots and robotic devices—Safety requirements for industrial robots—Part 2: Robot systems and integration. International Organization for Standardization, Geneva.

5) Fujii M, Ogura Y, Murakami H, Sonehara M (2011) Proposal of human-robot collaborative system using hand guiding. J IHI Technol **51**, 18–24.

6) Ikeda H, Saito T (2005) Proposal of inherently safe design method and safe design indexes for human-collaborative robots. Specific Research Reports of the National Institute of Industrial Safety. NIIS-SRR-No **33**, 5–14.

7) Saito T, Ikeda H (2005) Measurement of human pain tolerance to mechanical stimulus of human-collaborative robots. Specific Research Reports of the National Institute of Industrial Safety. NIIS-SRR-No **33**, 15–23.

8) Ottersbach HJ, Huelke M (2012) Kollaborierende Roboter. Tech Sicherheit **10**, 14–9 Springer-VDI-Verlag, Düsseldorf.

9) Hoshi T, Ikeda H, Okabe K, Saito T (2012) Proposal of revision of regulations based on labour accident analysis and questionnaire on industrial robots. J Occup Safety Health **5**, 3–15.

10) Directive 2006/42/EC on machinery, 17 May 2006. European Parliament and the Council of the European Union. Brussels. http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri =OJ:L:2006:157:0024:0086:EN:PDF.

11) European Commission (2010) Guide to application of the Machinery Directive 2006/42/EC, 2nd Ed., 355, Brussels.

12) Sugimoto N, Futsuhara K, Ikeda H (1990) Discussion and realization of safety device for stop-hold robot operation. Nihon Kikai Gakkai Ronbunshu C **56**, 2623–30 (in Japanese).