

Newsletter

May, 2021



ICR



Hot Issue

1. Latest Medical Device Standard Status
2. Enforcement of Legislation on the Management of Conformity Evaluation, etc.
3. Partial Revision of the Enforcement Decree of the Occupational Safety and Health Act



Latest Medical Device Standard Status



- There was an **update to the medical device-related standard** in IECCE.
- As for the updated standard, **one auxiliary standard and two Prerelease versions** have been issued.

(New standard status)

Standard No.	Date	Standard	Status
IEC 60601-1-3 ed2.2	2021-01	Radiation protection in diagnostic X-ray equipment	Published
IEC 60601-2-63 ed1.2	-	essential performance of dental extra-oral X-ray equipment	Prerelease
IEC 60601-2-65 ed1.2	-	essential performance of dental extra-oral X-ray equipment	Prerelease

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Enforcement of Legislation on the Management of Conformity Evaluation, etc.



- **Ministry of Trade and Industry** enacted to implement the "Act on the Management of Conformity Evaluation, etc." to enhance the reliability of conformity evaluation and strengthen capabilities.
- **As of April 8, 2021**, the Act on the Management of Conformity Evaluation, Enforcement Decree, Enforcement Rules, and related operational guidelines **have been implemented**.
- The administrative notice of the enactment of the operational guidelines is carried out as follows.

= as follows =

■ **Announcement number**

1. Ministry of Trade and Industry Announcement No. 2021-156(Operational guidelines for investigation of conformity assessment cheating and the designation of a management system accreditation body)
 2. Korean Agency for Technology and Standards Announcement No. 062(Operational guidelines for conformity assessment management, etc.)
- Legal confirmation: Korean Law Information Center (<https://www.law.go.kr>)

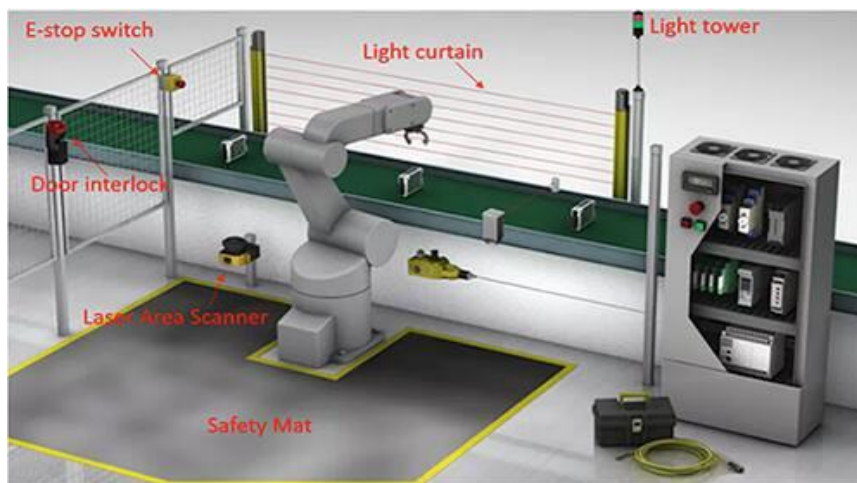
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Partial Revision of the Enforcement Decree of the Occupational Safety and Health Act



- The Enforcement Decree of the Industrial Safety and Health Act has been partially revised as of **March 11, 2021**.
- The notice on the **procedures for safety certification, self-safety confirmation report and the self-safety standard notice of protective devices** have been partially revised.
- The major revisions are as follows.
 - Regulations on the scope of application of machinery, etc. subject to safety certification and self-safety confirmation report
 - Classification of types and scope of the same type for industrial robot protection devices



(Source: <https://www.digikey.kr/en/articles/reducing-robot-risk-how-to-design-a-safe-industrial-environment>)

Partial Revision of the Enforcement Decree of the Occupational Safety and Health Act



- Changes in the notification of self-safety standards for protective devices
 - In the Enforcement Decree of the Industrial Safety and Health Act revised on December 24, 2019, **the definition of the safety mat and the self-safety standards were deleted as industrial robot safety mats** were excluded from the self-safety confirmation report.
- Changes in the notification on the procedures for safety certification and self-safety confirmation report
 - **The industrial robot protective device has been converted from the subject of the existing self-safety confirmation report to the subject of safety certification.**
 - The type of industrial robot protection device and the range of the same type are as follows.

Classification of types	Scope of the same type
1. Type (Safety mat, optoelectronic protective device) and classification.	1. Type of power supply (DC/AC)
2. Safety mat structure (control part, detector)	2. When the structure of the safety mat is the same and the shape of the detector is different in the same area.
3. Structure of optoelectronic protective device(control part, light-transmitting part, light-receiving part, output signal switching device) and detection performance.	3. When the structure of the optoelectronic protective device and the detection performance are the same, but the number of optical axes is different.

- ❖ More details, including the above revision, can be found at the **Korean Law Information Center.**

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