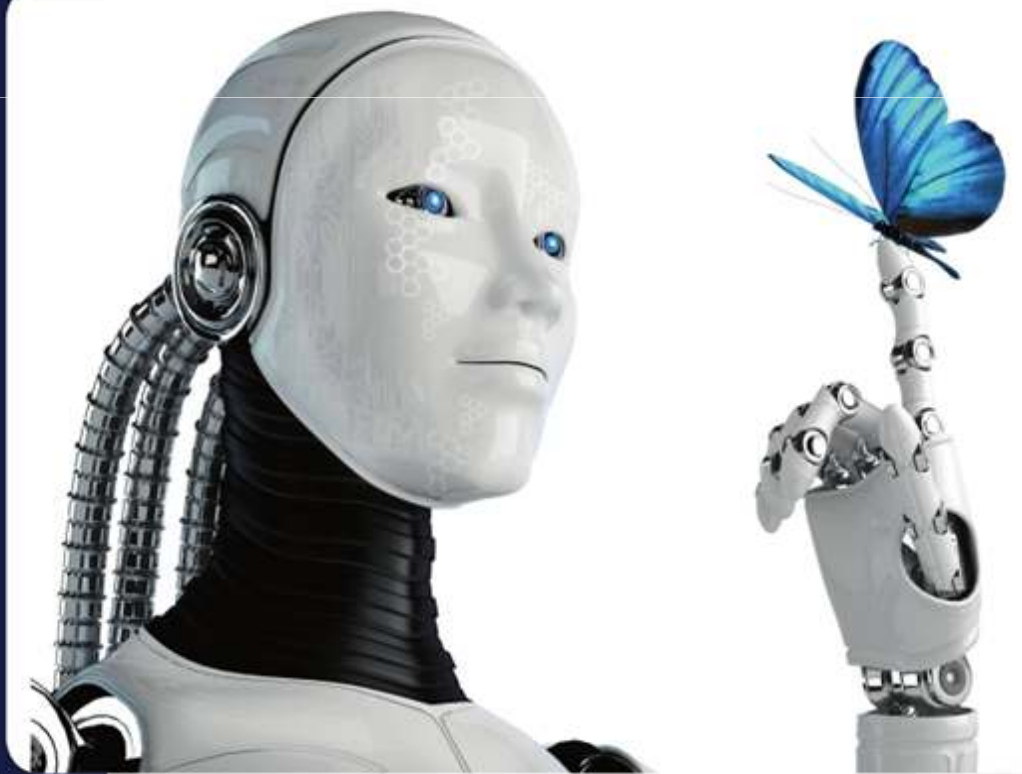


Newsletter October, 2017



ICR



Hot issue

- **Public Procurement Delegation for Poland Medical Equipment**
- **ISO 17021-2:2016 Published**
- **ISO 17021-2:2016 Gap Analysis**
- **SEMI E78**
- **KID Phones · Smart watch also displays the "Absorption Rate of Electromagnetic Wave" rating**
- **Biometrics in the Internet Age - Smart Sensor Technology and Research Trends**





Public Procurement Delegation for Poland Medical Equipment



On September 21st in Warsaw hotel Sheraton has taken place an conference dedicated EU medical devices legal requirements. Conference has been organized by KOTRA with support or Polish governmental authorities.

Among over 150 guests, representatives of Korean manufacturers of medical devices were majority.

We proudly inform, that ICR Polska as Notified Body 2703 was requested to give a speech about conformity assessment of medical devices according to EU legal requirements. Speech was given by ICR Polska Director – Mr. Rafal Kalinowski.

The speech was practical and provide guides and tips to the participants about their way to CE for medical devices.

ISO 17021-2:2016 Published



■ ISO 17021-2:2016

- In December 2016, ISO 17021-2:2012 is revised and published into ISO 17021-2:2016.
- ISO/IEC 17021-2:2016 specifies additional competence requirements for personnel involved in the audit and certification process for environmental management systems (EMS) and complements the existing requirements of ISO/IEC 17021-1.

ISO 17021-2:2016 Gap Analysis [1]



ISO 17021-2:2012	ISO 17021-2:2016	Changes
1. Scope	1. Scope	
2. Normative references	2. Normative references	
3. Terms and definitions	3. Terms and definitions	
3.1 EMS technical area	3.1 EMS technical area	area characterized by commonalities of processes relevant to an environmental management system and its intended results
4. Generic competence requirements	4. Generic competence requirements	
5. Competence requirements for EMS auditors		
	5.1 General	
5.1 EMS terminology	5.2 Environmental terminology	Environmental terms of ISO 14001:2015 is applied
5.3 Environmental monitoring and measuring techniques appropriate to the aspects and EMS technical area	5.4 Environmental monitoring and measuring techniques	Each EMS auditor shall have knowledge of environmental monitoring and measuring techniques and analytical methods.
5.4 Techniques for identification and evaluation	5.5 Environmental aspects and impacts	Each EMS auditor shall have knowledge of techniques for the identification of environmental aspects and impacts and the determination of their environmental significance.
5.5 Environmental aspects of design		Removed

ISO 17021-2:2016 Gap Analysis [2]



ISO 17021-2:2012	ISO 17021-2:2016	Changes
	5.6 Life cycle perspective	Each EMS auditor shall have knowledge of life cycle concepts and how an organization can apply a life cycle perspective to its products and services.
5.6 Environmental performance evaluation	5.7 Environmental performance evaluation	Each EMS auditor shall have knowledge of environmental performance evaluation methods, including indicators, sufficient to determine whether an organization's environmental performance is achieving the intended outcomes of an EMS.
5.7 Legal and other requirements	5.8 Compliance obligations	
5.8 Emergency preparedness and response	5.9 Emergency preparedness and response	5.9.1 Each EMS auditor shall have knowledge sufficient to determine whether an organization has identified potential emergency situations and planned relevant responses.
5.9 Operational control	5.10 Operational control	Each EMS auditor shall have knowledge of processes used for operational planning and control, including management of change related to an EMS.
5.10 Factors related to site	5.11 Factors related to site	Each EMS auditor shall have knowledge of site-related factors that might influence the potential impacts of an organization's aspects on the surrounding areas, ecosystems and communities.

ISO 17021-2:2016 Gap Analysis [3]



ISO 17021-2:2012	ISO 17021-2:2016	Changes
	5.12 Scope	Each EMS auditor shall have knowledge to determine that the scope of an EMS is appropriate within the context of an organization and its activities, products and services.
	5.14 Communicated information	Each EMS auditor shall have knowledge related to auditing of communicated information to enable the audit of the reliability of relevant environmental information related to the EMS.
	5.14 Context of the organization	Added requirements
	5.14.1	Each EMS auditor shall have knowledge to determine that an organization has identified the external and internal issues, including environmental conditions relevant to the context in which it operates that have the potential to affect the organization's ability to achieve the intended outcomes of its EMS.
	5.14.2	Each EMS auditor shall have knowledge to determine that an organization has identified the needs and expectations of interested parties relevant to an organization's EMS.
	5.15 Risks and opportunities	Added requirements

ISO 17021-2:2016 Gap Analysis [4]



ISO 17021-2:2012	ISO 17021-2:2016	Changes
	5.15.1	Each EMS auditor shall have knowledge of methods for determining risks and opportunities and how these methods can be applied in an organizational context.
	5.15.2	Each EMS auditor shall have knowledge to determine if an organization has appropriately identified and addressed the risks and opportunities related to its context, environmental aspects and compliance obligations.
6. Aspects=specific competence requirements for EMS auditing	6.1 General	An audit team shall be appointed that is composed of auditors (and technical experts, as necessary) having the collective competence to undertake the audit.
6.1 Emissions to air	6.2 Emissions to air / 6.2.1 General	Emissions to air occur from activities such as performing mechanical, chemical or biological processes, generating or using energy or through the provision of services requiring the use of fossil fuelled vehicles.
6.1.1 Gases and particulate matter	6.2.2 Gases, aerosols and particulate matter	Personnel on a team involved in EMS auditing shall have knowledge of types of emissions to air of gases, aerosols or particulate matter.

ISO 17021-2:2016 Gap Analysis [5]



ISO 17021-2:2012	ISO 17021-2:2016	Changes
6.1.2 Operational control	6.2.3 Operational control	Personnel on a team involved in EMS auditing shall have knowledge of the techniques used to control emissions to air such as filtering techniques, scrubbers, water mist control and thermal oxidizers.
6.1.3 Monitoring and measurement	6.2.4 Monitoring and measurement	Personnel on a team involved in EMS auditing shall have knowledge of the techniques used to monitor emissions to air, e.g. observation of stack emissions, continuous or sample-based stack monitoring, air sampling and analysis and calculation-based mass balance, microorganism counts, and odour testing.
6.2 Releases to land	6.3 Release to land / 6.3.1 General	Releases to land of solids or liquids may occur as waste from mechanical, chemical or biological processes, on the production or disposal of a product or the delivery of a service or as a result of a natural event or accidental situation.
6.2.1 Liquid or solid releases	6.3.2 Liquid or solid releases	Personnel on a team involved in EMS auditing shall have knowledge of releases to land.

ISO 17021-2:2016 Gap Analysis [6]



ISO 17021-2:2012	ISO 17021-2:2016	Changes
6.2.2 Operational control	6.3.3 Operational control	Personnel on a team involved in EMS auditing shall have knowledge of the techniques used to control releases to land such as primary or secondary containment and dispersion.
6.2.3 Monitoring and measurement	6.3.4 Monitoring and measurement	Personnel on a team involved in EMS auditing shall have knowledge of the techniques used to monitor, measure and analyse soil associated with releases to land.
6.3 Releases to water	6.4 Releases to water / 6.4.1 General	Releases to water are discharges which include effluents, sewage and diffuse runoffs. This water may be discharged for treatment; or directly to surface or ground water before or after treatment.
6.3.1 surface and ground water	6.4.2 Surface and ground water	Personnel on a team involved in EMS auditing shall have knowledge of surface and ground water flows and characteristics, including water columns, suspended and dissolved solids, sedimentation, effluent viscosity and density, evaporation, acidification and eutrophication.
6.3.2 Operational control	6.4.3 Operational control	Personnel on a team involved in EMS auditing shall have knowledge of the typical liquid waste streams and the techniques used to treat liquid waste.

ISO 17021-2:2016 Gap Analysis [7]



ISO 17021-2:2012	ISO 17021-2:2016	Changes
6.3.3 Monitoring and measurement	6.4.4 Monitoring and measurement	Personnel on a team involved in EMS auditing shall have knowledge of the parameters measured and the techniques used to monitor liquid waste treatment processes and/or other discharges.
6.4 Uses of raw materials, energy and natural resources	6.5 Uses of raw materials, energy and natural resources	
6.4.1 Upstream management – Use of natural resources	6.5.1 Upstream management	
	6.5.1.1	Personnel on a team involved in EMS auditing shall have knowledge of resource depletion issues including sourcing renewable and non-renewable materials, water scarcity, forest loss and soil degradation.
	6.5.1.2	Personnel on a team involved in EMS auditing shall have knowledge of renewable and non-renewable sources of energy, the techniques for converting them to useful energy and their environmental impacts, including climate change, impact on biodiversity and on ecosystems, and limitations in their application.
6.4.2 Downstream management	6.5.2 Downstream management	

ISO 17021-2:2016 Gap Analysis [8]



ISO 17021-2:2012	ISO 17021-2:2016	Changes
	6.5.2.1	Personnel on a team involved in EMS auditing shall have knowledge of technology and techniques related to source reduction, consumption, minimization, resource recovery and treatment practices and processes.
	6.5.2.2	Personnel on a team involved in EMS auditing shall have knowledge of the impact that the activities of an organization have on the environment including biodiversity and ecosystems.
6.4.3 Operational control	6.5.3 Operational control	Personnel on a team involved in EMS auditing shall have knowledge of the techniques to control efficient use of resources.
6.4.4 Monitoring and measurement	6.5.4 Monitoring and measurement	Personnel on a team involved in EMS auditing shall have knowledge of monitoring and measuring techniques related to the use of resources.
6.5 Energy emitted	6.6 Energy emitted / 6.6.1 Sources of energy emissions	Personnel on a team involved in EMS auditing shall have knowledge of sources of emissions of heat, light, electromagnetic and ionising radiation, noise and vibration, and their potential environmental impacts.

ISO 17021-2:2016 Gap Analysis [9]



ISO 17021-2:2012	ISO 17021-2:2016	Changes
6.5.1	6.6.2 Operational control	Personnel on a team involved in EMS auditing shall have knowledge of emissions management and control methods, including process management, and emissions reduction and abatement.
6.5.2	6.6.3 Monitoring and measurement	Personnel on a team involved in EMS auditing shall have knowledge of monitoring and measuring techniques related to the energy emissions.
6.6	6.7 Waste / 6.7.1 Sources of waste	Personnel on a team involved in EMS auditing shall have knowledge of the wastes generated by an organization's activities.
6.6.1 Sources of energy emissions / 6.6.2 Operational control	6.7.2 Operational control	
	6.7.2.1	Personnel on a team involved in EMS auditing shall have knowledge of methodologies for the elimination, source reduction and waste minimization, including reuse, segregation and recycling.
	6.7.2.2	Personnel on a team involved in EMS auditing shall have knowledge of handling, storage, transportation, treatment and disposal of waste.
	6.7.3	Personnel on a team involved in EMS auditing shall have knowledge of waste monitoring and measurements techniques

ISO 17021-2:2016 Gap Analysis [10]



ISO 17021-2:2012	ISO 17021-2:2016	Changes
	6.8 Use of space	
6.7 Physical attributes	6.8.1 Physical attributes	Personnel on a team involved in EMS auditing shall have knowledge of the interactions of the physical attributes of buildings, structures and equipment with the local environment.
	6.8.2 Operational control	Personnel on a team involved in EMS auditing shall have knowledge of techniques to manage physical attributes, such as planning and design, landscaping, use of colour to reduce intrusive impact on the environment.
	6.8.3 Monitoring and measurement	Personnel on a team involved in EMS auditing shall have knowledge of the monitoring of spatial planning, building and equipment requirements as well as maintenance systems and landscaping.
7. Competence requirements for other personnel	7. Competence requirements for other personnel / 7.1 General	The certification body shall define competence requirements for other personnel involved in the certification functions as given in 7.2 and 7.3. These functions can be fulfilled by one or more persons.

ISO 17021-2:2016 Gap Analysis [11]



ISO 17021-2:2012	ISO 17021-2:2016	Changes
7.1 Competence of personnel conducting the application review to determine the audit team competence required, to select the audit team members and to determine the audit time	7.2 Competence of personnel conducting the application review to determine the audit team competence required, to select the audit team members and to determine the audit time	
7.1.1 Environmental terminology	7.2.1 Environmental terminology	As appropriate for their function, personnel shall have knowledge of environmental terms and definitions.
7.1.2 Techniques for identification and evaluation of environmental aspects and impacts and their environmental significance	7.2.2 Environmental aspects and impacts	As appropriate for their function, personnel shall have knowledge of environmental aspects and associated impacts.
7.1.3 Factors related to site	7.2.3 Factors related to site	As appropriate for their function, personnel shall have knowledge of site-related factors, including proximity to sensitive environments that may be impacted by the organization's activities, sufficient to select a competent audit team.
	7.2.4 Scope	As appropriate for their function, personnel shall have knowledge to determine that the proposed scope of certification is appropriate to achieve the intended results of the application review.

ISO 17021-2:2016 Gap Analysis [12]



ISO 17021-2:2012	ISO 17021-2:2016	Changes
7.2 Competence of personnel reviewing audit reports and making certification decisions	7.3 Competence of personnel reviewing audit reports and making certification decisions	
7.2.1 Environmental terminology	7.3.1 Environmental terminology	Personnel reviewing audit reports and making certification decisions shall have knowledge of environmental terms and definitions.
7.2.2 Techniques for identification and evaluation of environmental aspects and impacts and their environmental significance	7.3.2 Environmental aspects and impacts	Personnel reviewing audit reports and making certification decisions shall have knowledge of environmental aspects and impacts.
7.2.3 Environmental performance evaluation	7.3.3 Environmental performance evaluation	Personnel reviewing audit reports and making certification decisions shall have knowledge of environmental performance evaluation.
7.2.4 Legal and other requirements	7.3.4 Compliance obligation	Personnel reviewing audit reports and making certification decisions shall have knowledge of applicable compliance obligations sufficient to make a decision on the basis of a certification audit report.
	7.3.5 Scope	Personnel reviewing audit reports and making certification decisions shall have knowledge to determine that the scope of certification is appropriate.



SEMI E78 [1]

Static electricity is the occurrence of transient electronic shocks caused by people or charged objects. It has tens of thousands of volts and is equivalent to lightning, but with little current, it is not fatal to the human body. However, static electricity can be fatal if the object is electronic and not human. Many equipment and parts are damaged by static electricity, and precision equipment such as semiconductor equipment is inevitably damaged. Disposal or rework of parts damaged by static electricity wastes valuable time and money.

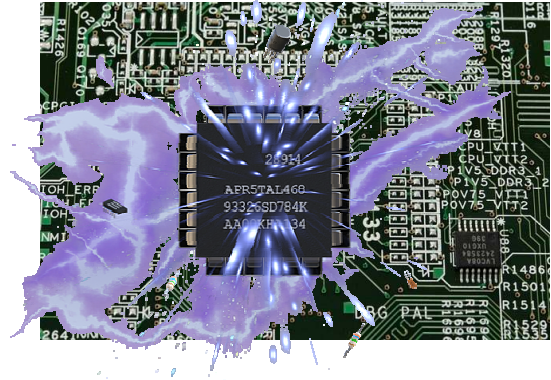
SEMI E78 is a standard to minimize the negative impact on the productivity caused by static electricity and electric field of semiconductor manufacturing equipment. **It is a guide to ensure the static resistance of equipment used in semiconductor**





SEMI E78 [2]

SEMI E78 can be used as a guide for equipment manufacturers during the design and testing of their equipment.



The test methods can also be used by semiconductor manufacturers to check the performance of equipment and to verify its conformance with procurement.

ICR provides **standard evaluation and evaluation service for SEMI E78**.

ICR, as a SEMI Member, provides the **SEMI service**, which is easier and more precise to customers' safety of semiconductor equipment and market entry, by taking full advantage of the networking, issue management, marketing, market and industry information provided by SEMI Association.

KID Phones · Smartwatch also displays the "Absorption Rate of Electromagnetic Wave" rating [1]



Kid phones and smart watches, such as wristwatches wearable devices, such as cell phones and tablets 'electromagnetic wave absorption rate' rating is displayed.

The Ministry of Science and Technology announced that the Ministry of Information and Communication announced the revised bill on the "Electromagnetic Wave Class Standard, Target of Display and Indication Method". Administrative notice will be available until October 10.

The Ministry of Science and Technology and the Ministry of Information and Communication explained that "not only mobile phones used in close contact with the ear but also wearable devices such as kids phones and smart watches that transmit and receive radio waves are displayed so that the SAR information can be easily known" .

According to the Notification of 'Equipment for Measurement of Electromagnetic Wave Intensity and Electromagnetic Wave Absorption Ratio', all portable radio equipment whose power exceeds 20mW and whose radiated emission center is within 20cm from the human body should be subjected to SAR measurement by government agencies.



KID Phones · Smartwatch also displays the "Absorption Rate of Electromagnetic Wave" rating [2]



In the case of smart phones, SAR ratings are displayed outside the package as "1st grade" or "2nd grade" so that consumers can see at a glance. However, wearable devices such as smart watches or kids phones are excluded from the "Rating" category, so the measured electromagnetic rating must be displayed outside the product.

This raises concerns about complaints and safety among consumers who use kids' phones that are often used by infants.

Accordingly, the government decided to revise the relevant provisions and to indicate the degree of absorption of electromagnetic waves of wearable appliances. The degree of absorption of the electromagnetic waves can be displayed on the removable film paper, and can also be displayed in a packaging box, a user's manual, an information menu in the apparatus, or the like.

In addition, wearable device manufacturers are obliged to inform consumers of the SAR rating or measurement value of their handset on the homepage.

According to an official from the Ministry of Science and Technology, "The number of users of wearable devices is steadily increasing in Korea," adding, "With the addition of smart watches and kids phones to the labeling requirement of electromagnetic waves, consumers can use safe products, said.

Biometrics in the Internet Age – Smart Sensor Technology and Research Trends [1]



■ Characteristics of biometric industry and domestic and overseas market trends

According to market research by the International Biometric Group, the biometric market grew at a CAGR of 23% annually, growing from \$ 3.4 billion in 2009 to \$ 7.8 billion in 2013, According to biometrics technology, fingerprint recognition market is leading the growth of biometrics industry, accounting for about 30% of total market with about 2.4 billion dollar market based on high convenience and security. Biometric market trends in North America accounted for 30.9% of the entire biometric market in 2013, making it the largest market in the US, followed by the Asia / Pacific market with 22.4%.

According to the Korea Institute of Science and Technology Information, the domestic biometric market is worth KRW 171.6 billion in 2012, and the fingerprint recognition market accounts for about 62.9% of the total. In 2017, domestic sales are expected to reach KRW 428.2 billion, and the annual growth rate is expected to reach 23%. The market size is expected to increase sharply due to the spread of smartphones and the widespread adoption of mobile device application services based on wireless communications, and the market will continue to grow as fingerprint recognition and various other biometric technologies combine with mobile devices

Division	2009	2010	2011	2012	2013	2014
South America	304.6	395.6	502.2	621.3	794.9	918.2
Asia	828.2	1035.2	1264.8	1505.8	1760.8	2061.2
Middle east/India	355.9	481	633.5	810.8	1016.9	1274.2
Europe	708.4	857.4	1012	1160.9	1304.1	1461.6
North America	1031.1	1320.1	1654.2	2020.4	2424.6	2913.7
Africa	195.1	267.5	356.9	462	585.4	740.1
Total	3422.3	4356.8	5423.6	6584.2	7369	9369

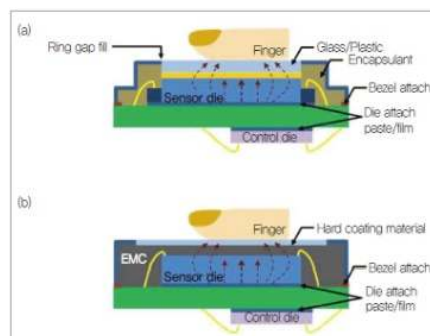
(Unit : Ten million dollars)

Biometrics in the Internet Age – Smart Sensor Technology and Research Trends [2]



■ Characteristics of biometric industry and domestic and overseas market trends

The mobile fingerprint sensor covers the sensor protection material because it is exposed on the surface of the device. Apple iPhone uses sapphire glass with a thickness of about 260 μm and most of the remaining companies use resin with about 20 μm . The UV coating material (about 1/7 of the sapphire material price) is applied to a thickness of 30 μm . Fingerprint sensor cover materials have recently been used to replace ceramics or tempered glass to replace the resin because it affects the sensing by scratching or delamination of the material when used about 10 million times. Panasonic has announced the commercialization of high-permittivity encapsulation materials suitable for mobile fingerprint sensor packages, enabling improvements in the performance of fingerprint sensors and package miniaturization. Sapphire glass, which has been widely used in the past, has a disadvantage in that it is difficult to miniaturize and slim down the sensor package, and the manufacturing process is complicated. However, Panasonic's high dielectric sealant can produce a relative dielectric constant of up to 20 at 1 MHz and a thickness of 50 μm , And it is possible to acquire excellent fingerprint images.



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