Submit Comments

ENTERPRISE SINGAPORE CALLS FOR PUBLIC COMMENTS – 14 SEPTEMBER 2018

Under the National Standardisation Programme, the public comment period is an important stage of standards development. Members of the public are invited to provide feedback on draft Singapore Standards for publication and work item proposals for development and review of Singapore Standards and Technical References. The establishment of Singapore Standards is done in accordance with the World Trade Organisation's requirements for the development of national standards.

A) Notification of Draft Singapore Standards for Publication

Members of the public are invited to comment on the following Singapore Standards documents:

Biomedical and Health – medical electrical equipment, medical devices

Building and Construction – portable fire extinguishers

Chemical – fire safety for laboratories using chemicals, bunker mass flow metering, bunkering

Environment and Resources – pneumatic waste conveyance system, energy management systems

Manufacturing – network and system security, security for industrial automation and control systems

For more information on viewing the documents, click here.

Closing date for comments: **15 October 2018** for fire safety for laboratories using chemicals, bunker mass flow metering, bunkering, as they had undergone an earlier round of public comment.

Closing date for all other documents above: **15 November 2018**.

Please submit comments to: kay_chua@enterprisesg.gov.sg.

B) Notification of New Work Item Proposals

B.1 Proposal for New Work Items

New Work Items (NWIs) are approved proposals to develop new Singapore Standards or Technical References (pre-standards).

Members of the public are invited to comment on the scope of the new standards and contents that can be included into the following proposals:

Biomedical and Health – medical devices

Manufacturing – network and system security, security for industrial automation and control systems

Safety – water safety for swimming pools

The NWIs are works-in-progress and the drafts are not available at this juncture.

Closing date for comments: **15 October 2018**.

Members of the public are invited to join as standards partners, resource members or co-opted members subject to the approval of relevant committees and working groups.

To comment or to join in the development of standards, please write to: standards@enterprisesg.gov.sg

B.2 Proposal for the Review of Singapore Standards

Published Singapore Standards are reviewed to determine if they should be updated, confirmed or withdrawn (if they no longer serve the industry's needs) or classified as mature standards (no foreseeable changes; to be reviewed only upon request).

Members of the public are invited to comment on the scope and contents of the following standards to be reviewed:

> Building and Construction – Cleaning performance for commercial premises, central chilled water system energy efficiency, uPVC pipes and fittings

The review is ongoing and new versions/drafts are not available at this juncture. Users can refer to the current standards to provide feedback. Click here to view and purchase these standards.

Closing date for comments: **15 October 2018**.

Members of the public are invited to join as standards partners, resource members or co-opted members subject to the approval of relevant committees and working groups.

To comment or to join in the development of standards, please write to kay_chua@enterprisesg.gov.sg.

A) Notification of draft Singapore Standards for Publication

(I) Biomedical and Health

1. Medical electrical equipment

***Part 1: General requirements for basic safety and essential performance** (Identical adoption of IEC 60601-1:2005+A1:2012)

This standard applies to the basic safety and essential performance of medical electrical equipment and medical electrical systems.

This series of standards does not apply to:

- in vitro diagnostic equipment that does not fall within the definition of medical electrical equipment, which is covered by the IEC 61010 series;
- implantable parts of active implantable medical devices covered by the ISO 14708 series;
- medical gas pipeline systems covered by ISO 7396-1.

***Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests** (Identical adoption of IEC 60601-1-2:2014)

This collateral standard applies to the basic safety and essential performance of medical electrical equipment and medical electrical systems in the presence of electromagnetic disturbances and to electromagnetic disturbances emitted by medical electrical equipment and medical electrical systems.

Basic safety with regard to electromagnetic disturbances is applicable to all medical electrical equipment and medical electrical systems.

***Part 1-3: General requirements for basic safety and essential performance – Collateral standard: Radiation protection in diagnostic X-ray equipment** (Identical adoption of IEC 60601-1-3:2008+ A1:2013)

This collateral standard applies to X-ray equipment and to subassemblies of such equipment, where radiological images of a human patient are used for diagnosis, planning or guidance of medical procedures.

***Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability** (Identical adoption of IEC 60601-1-6:2010+A1:2013)

This standard specifies a process for a manufacturer to analyse, specify, design, verify and validate usability, as it relates to basic safety and essential performance of medical electrical equipment.

This usability engineering process assesses and mitigates risks caused by usability problems associated with correct use and use errors, i.e., normal use. It can be used to identify but does not assess or mitigate risks associated with abnormal use.

***Part 1-8: General requirements for basic safety and essential performance – Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems** (Identical adoption of IEC 60601-1-8:2006+A1:2012)

This collateral standard specifies requirements for alarm systems and alarm signals in medical electrical equipment and medical electrical systems.

It also provides guidance for the application of alarm systems.

***Part 1-9: General requirements for basic safety and essential performance – Collateral standard: Requirements for environmentally conscious design** (Identical adoption of IEC 60601-1-9:2007+A1:2013)

This standard applies to the reduction of adverse environmental impacts of medical electrical equipment.
Medical electrical systems are excluded from the scope of this collateral standard.

***Part 1-10: General requirements for basic safety and essential performance – Collateral standard: Requirements for the development of physiologic closed-loop controllers** (Identical adoption of IEC 60601-1-10:2007+A1:2013)

This collateral standard specifies requirements for the development (analysis, design, verification and validation) of a physiologic closed-loop controller (PCLC) as part of a physiologic closed-loop control system (PCLCS) in medical electrical equipment and medical electrical systems to control a physiologic variable.

It applies to various types of PCLC, e.g. linear and non-linear, adaptive, fuzzy, neural networks.

It does not specify additional mechanical requirements or additional electrical requirements.

This collateral standard applies to a closed-loop controller that sets the controller output variable in order to adjust (i.e. change or maintain) the measured physiologic variable by relating it to the reference variable.

A closed-loop controller that maintains a physical or chemical variable, using feedback that is not measured from a patient, is outside the scope of this standard.

***Part 1-11: General requirements for basic safety and essential performance – Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment** (Identical adoption of IEC 60601-1-11:2015)

This standard applies to the basic safety and essential performance of medical electrical equipment and medical electrical systems for use in the home healthcare environment and specified by the manufacturer in the instructions for use. It applies regardless of whether the medical electrical equipment or medical electrical system is intended for use by a lay operator or by trained healthcare personnel.

***Part 1-12: General requirements for basic safety and essential performance – Collateral standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment** (Identical adoption of IEC 60601-1-12:2014)

This standard applies to the basic safety and essential performance of medical electrical equipment and medical electrical systems, which are intended, as indicated in the instructions for use by their manufacturer, for use in the emergency medical services (EMS) environment.

The EMS environment includes:

- responding to and providing life support at the scene of an emergency to a patient reported as experiencing injury or illness in a pre-hospital setting, and transporting the patient, while continuing such life support care, to an appropriate professional healthcare facility for further care.
- providing monitoring, treatment or diagnosis during transport between professional healthcare facilities.

2. *Medical devices – Part 1: Application of usability engineering to medical devices (Identical adoption of IEC 62366-1:2015)

This standard specifies a process for a manufacturer to analyse, specify, develop and evaluate the usability of a medical device as it relates to safety. This usability engineering (human factors engineering) process permits the manufacturer to assess and mitigate risks associated with correct use and use errors, i.e. normal use. It can be used to identify but does not assess or mitigate risks associated with abnormal use.

If the usability engineering process detailed in this International Standard has been complied with, then the usability of a medical device as it relates to safety is presumed to be acceptable, unless there is objective evidence to the contrary.

Potential users of the above standards (items 1 and 2) may include developers and manufacturers of medical electrical equipment and medical electrical systems.

(II) Building and Construction

3. *Code of practice for use and maintenance of portable fire extinguishers (Revision of SS 578 : 2012)

This standard covers the selection, installation, inspection, testing and maintenance of portable fire extinguishers.

Users of the standard may include fire safety managers, facility managers, building owners, contractors, manufacturers, suppliers and testing bodies.

(III) Chemical

New

4. *Code of practice for fire safety for laboratories using chemicals

This standard sets out requirements and recommendations for the fire safety of laboratories using chemicals. It is intended to encompass laboratory unit design and construction, fire protection, explosion hazard protection, ventilating system requirements as well as the storage, handling and disposal of flammable chemicals. Toxic and hazardous chemicals are also included due to their potential impact related to fires.

This standard is applicable to laboratories located within manufacturing facilities (e.g. petrochemical, pharmaceutical, gas manufacturing), institutes of higher learning, research entities, commercial entities and the healthcare sector. Other potential users are laboratory

equipment suppliers, fire safety managers, health and safety professionals, facility managers and consultants (e.g. QP, M&E engineers, fire safety engineers).

The draft standard was released for public comment from 15 December 2017 to 16 February 2018. The Working Group had since deliberated and addressed the comments received. New definitions were added and there were significant changes in Clause 8 (Laboratory ventilation system), Clause 9 (Compressed and liquefied gases) and Annex C (Ventilation risk assessment flowchart for occupied laboratories) of the standard.

Closing date for comment: **15 October 2018**.

Amendment

5. Amendment No. 2 to Technical Reference for bunker mass flow metering (TR 48 : 2015)

This amendment included the changes to Annex P (Bunker delivery note) to align with the latest sulphur requirements in MARPOL Annex VI and changes to the Master's / Chief Engineers Acknowledgement section of the bunker delivery note.

(Click here to download the amendment.)

6. Amendment No. 1 to Code of practice for bunkering (SS 600 : 2014)

This amendment is to update Annex G (Example of bunker delivery note) to align it with the latest sulphur requirements in MARPOL Annex VI and changes to the Master's / Chief Engineers Acknowledgement section of the bunker delivery note.

(Click here to download the amendment.)

The two amendments were released for public comment from 15 May to 16 July 2018. Feedback from the public comment was considered and the changes indicated above were made.

Those interested in the Amendments include bunker suppliers, bunker tanker operators/owners, shipping lines, ship owners, bunker surveyors, bunkering associations/institutes, relevant government agencies and service providers.

Closing date for comment for the Amendments: **15 October 2018**.

(IV) Environment and Resources

New

7. *Code of practice for pneumatic waste conveyance system (PWCS)

This standard specifies the requirements for the design, construction, installation, testing and commissioning, and maintenance of pneumatic waste conveyance system (PWCS) that serves gravity chutes for general waste and recyclables generated from residential, commercial and mixed-use developments.

It covers specifications and performance of the feeding and discharge system, conveyance system and collection station but excludes the requirements for waste collection vehicles and driveway design.

This standard does not include the requirements for:

- waste conveyance using pipeline intervention gadget (PIG) concept;
- full vacuum system; and
- conveyance of pure food waste from food establishments.

Potential users of the standard may include real estate developers, consultants, designers, professional engineers, architects, PWCS providers and relevant government agencies.

Revision

8. *Energy management systems – Requirements with guidance for use (Revision of SS ISO 50001 : 2011) (Identical adoption of SS ISO 50001:2018)

This standard specifies requirements for establishing, implementing, maintaining and improving an energy management system (EnMS). The intended outcome is to enable an organisation to follow a systematic approach in achieving continual improvement of energy performance and the EnMS.

This standard:

- is applicable to any organisation;
- is applicable to activities affecting energy performance that are managed and controlled by the organisation;
- is applicable irrespective of the quantity, use, or types of energy consumed;
- requires demonstration of continual energy performance improvement but does not define levels of energy performance improvement to be achieved;
- can be used independently, or be aligned or integrated with other management systems.

Potential users of the standard may include energy managers, energy services companies (ESCOs), energy system auditors and energy management professionals/consultants and relevant government agencies.

(V) Manufacturing

New

9. Industrial communication networks – Network and system security

***Part 2-1: Establishing an industrial automation and control system security program** (Identical adoption of IEC 62443-2-1:2010)

This standard defines the elements necessary to establish a cyber security management system (CSMS) for industrial automation and control systems (IACS) and provides guidance on how to develop those elements. This standard uses the broad definition and scope of what constitutes an IACS described in IEC/TS 62443-1-1.

The elements of a CSMS described in this standard are mostly policy, procedure, practice and personnel related, describing what shall or should be included in the final CSMS for the organisation.

***Part 3-3: System security requirements and security levels** (Identical adoption of IEC 62443-3-3:2013)

This standard provides detailed technical control system requirements (SRs) associated with the seven foundational requirements (FRs) described in IEC/TS 62443-1-1 including defining the requirements for control system capability security levels, SL-C(control system). These requirements would be used by various members of the IACS community along with the defined zones and conduits for the system under consideration while developing the appropriate control system target SL, SL-T(control system), for a specific asset.

As defined in IEC 62443-1-1 there are a total of seven FRs:

a) Identification and authentication control,
b) Use control,
c) System integrity,
d) Data confidentiality,
e) Restricted data flow,
f) Timely response to events, and
g) Resource availability.

These seven requirements are the foundation for control system capability SLs, SL-C (control system). Defining security capability at the control system level is the goal and objective of this standard as opposed to target SLs, SL-T, or achieved SLs, SL-A, which are out of scope.

10. Security for industrial automation and control systems

***Part 2-4: Security program requirements for IACS service providers** (Identical adoption of IEC 62443-2-4:2015+A1:2017)

This standard specifies a comprehensive set of requirements for security capabilities for IACS service providers that they can offer to the asset owner during integration and maintenance activities of an automation solution. Because not all requirements apply to all industry groups and organisations, this standard provides for the development of Profiles that allow for the subsetting of these requirements. Profiles are used to adapt this document to specific environments, including environments not based on an IACS.

***Part 4-1: Secure product development lifecycle requirements** (Identical adoption of IEC 62443-4-1:2018)

This standard specifies process requirements for the secure development of products used in industrial automation and control systems. It defines a secure development life-cycle for the purpose of developing and maintaining secure products. This life-cycle includes security requirements definition, secure design, secure implementation (including coding guidelines), verification and validation, defect management, patch management and product end-of-life. These requirements can be applied to new or existing processes for developing, maintaining and retiring hardware, software or firmware for new or existing products. These requirements apply to the developer and maintainer of the product, but not to the integrator or user of the product.

Potential users of the standards on cyber security may include asset owners of IACS, service providers, system integrators, and product suppliers. End users and stakeholders from industrial environments (e.g. factories) and government agencies may also be interested in these standards.

Copies of drafts and standards are available at:

*For drafts (Viewing only)
Login to Singapore Standards eShop at: www.singaporestandardseshop.sg
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NOTE – The viewing period of the drafts will expire on the closing of the 2-month public comment period. Drafts will no longer be available after this date.

B) Notification of New Work Item Proposals

B.1 Proposed New Work Items

(I) Biomedical and Health

1. Medical devices – Part 2: Guidance on the application of usability engineering to medical devices (Identical adoption of IEC/TR 62366-2:2016)

This Technical Reference (TR) contains background information and provides guidance that addresses specific areas that experience suggests can be helpful for those implementing a usability engineering (human factors engineering) process both as defined in IEC 62366-1:2015 (see item 2 above) and as supporting goals other than safety.

This TR has two main themes:

- information about efficient ways to implement elements required by IEC 62366-1:2015;
- additional information, in particular how usability relates to attributes such as task efficient and user satisfaction, which can enhance a medical device's commercial success.

This TR discusses the business benefits of usability engineering, the basics of applicable analysis and design techniques, medical device usability evaluation approaches, efficient ways to address usability engineering project implementation issues (e.g. integration into a quality management system) and provides a list of useful usability engineering resources.
This TR also can be useful for other healthcare products (e.g. drug packaging and drug labelling, drug-medical device combination products and health IT software).

Potential users of the standard may include developers and manufacturers of medical electrical equipment and medical electrical systems.

(II) Manufacturing

2. Industrial communication networks – Network and system security

Part 1-1: Terminology, concepts and models (Identical adoption of IEC/TS 62443-1-1:2009)

This Technical Reference defines the terminology, concepts and models for industrial automation and control systems (IACS) security. It establishes the basis for the remaining standards in the IEC 62443 series.

To fully articulate the systems and components the IEC 62443 series address, the range of coverage may be defined and understood from several perspectives, including the following:

a) range of included functionality;
b) specific systems and interfaces;
c) criteria for selecting included activities;
d) criteria for selecting included assets.

Part 3-1: Security technologies for industrial automation and control systems (Identical adoption of IEC TR 62443-3-1:2009)

This Technical Reference provides a current assessment of various cybersecurity tools, mitigation countermeasures, and technologies that may effectively apply to the modern electronically based IACSs regulating and monitoring numerous industries and critical infrastructures. It describes several categories of control system-centric cybersecurity technologies, the types of products available in those categories, the pros and cons of using those products in the automated IACS environments, relative to the expected threats and known cyber vulnerabilities, and, most important, the preliminary recommendations and guidance for using these cybersecurity technology products and/or countermeasures.

3. Security for industrial automation and control systems – Part 2-3: Patch management in the IACS environment (Identical adoption of IEC/TR 62443-2-3:2015)

This Technical Reference (TR) describes requirements for asset owners and IACS product suppliers that have established and are now maintaining an IACS patch management program.

This TR recommends a defined format for the distribution of information about security patches from asset owners to IACS product suppliers, a definition of some of the activities associated with the development of the patch information by IACS product suppliers and deployment and installation of the patches by asset owners. The exchange format and activities are defined for use in security related patches; however, it may also be applicable for non-security related patches or updates.

The TR does not differentiate between patches made available for the operating systems, applications or devices. It does not differentiate between the product suppliers that supply the infrastructure components or the IACS applications; it provides guidance for all patches applicable to the IACS. Additionally, the type of patch can be for the resolution of bugs, reliability issues, operability issues or security vulnerabilities.

Potential users of the standards on cyber security may include asset owners of IACS, service providers, system integrators, and product suppliers. End users and stakeholders from industrial environments (e.g. factories) and government agencies may also be interested in these standards.

(III) Safety

4. Code of practice for water safety – Swimming pools

The standard will cover the general safety requirements for swimming pools and safety requirements for water sports or activities. It will also cover the roles and responsibilities of event organisers, coaches, operators, hirers, users, event participants, volunteers, technical officials, lifeguards, spotters and rescuers.

The standard will include areas like sudden cardiac death or heat injuries in sports, fundamental principles of sports safety, pre-participating screening, training and education in sports safety, exercise and training facilities, event medical support plan and surveillance, evaluation and follow up.

Potential users of the standard may include condominiums MCST, property developers, swimming pool operators (including their staff and managing agents), home owners, private and public schools and educational institutions, social clubs, swim clubs, fitness clubs, hotels, users, hirers, event participants and organised groups of swimming pools, relevant government agencies and any other organisations, associations or agencies with swimming pools.

B.2 Review of Singapore Standards

(I) Building and Construction

1. Cleaning service industry – Cleaning performance for commercial premises [SS 499 : 2002 (2015)]

The standard applies to the quality of cleaning services in commercial premises.

The standard is reviewed with the intention to update it.

Users of the standard may include service providers, suppliers and manufacturers in the cleaning performance trade, as well as service buyers including facility managers and managing agents.

2. Code of practice for long term measurement of central chilled water system energy efficiency (SS 591 : 2013)

This standard specifies the requirements for sensors and instruments in capturing relevant process parameters, their installation, commissioning, operational monitoring and maintenance, in order to perform continuous, long term measurement of central chilled water system energy efficiency.

The standard is reviewed with the intention to update it.

Users of the standard may include facility owners, energy services companies, consultants, chiller manufacturers/suppliers, control and instrumentation systems suppliers as well as academics from universities and polytechnics.

3. Specification for unplasticised PVC pipes and fittings for soil, waste and vent applications (SS 213 : 1998)

This standard specifies requirements for unplasticised polyvinyl chloride (uPVC) pipes, fittings and accessories for soil, waste and vent applications above ground.

The standard is reviewed with the intention to update it.

Users of the standard may include plumbers, suppliers and manufacturers in the sanitary and plumbing trade.

Submit Comments

Frequently asked questions about public comment on Singapore Standards:

1. What is the public comment on Singapore Standards?

Singapore Standards are established based on an open system which is also in accordance with the requirements of the World Trade Organisation. These documents are issued as part of a consultation process before any standards are introduced or reviewed. The public comment period is an important stage in the development of Singapore Standards. This mechanism helps industry, companies and other stakeholders to be aware of forthcoming changes to Singapore Standards and provides them with an opportunity to influence, before their publication, the standards that have been developed by their industry and for their industry.

2. How does public comment on Singapore Standards benefit me?

This mechanism:

- ensures that your views are considered and gives you the opportunity to influence the content of the standards in your area of expertise and in your industry;
- enables you to be familiar with the content of the standards before they are published and you stand to gain a competitive advantage with this prior knowledge of the standards.

3. Why do I have to pay for the standards which are proposed for review or withdrawal?

These standards are available for ***free viewing*** at Toppan Leefung Pte Ltd and all public libraries. However, the normal price of the standard will be charged for those who wish to purchase a copy. At the stage where we propose to review or withdraw the standards, the standards are still current and in use. We seek comments for these standards so as to:

- provide an opportunity for the industry to provide inputs for the review of the standard that would make the standard suitable for the industry's use,
- provide feedback on the continued need for the standard so that it will not be withdrawn,

4. What happens after I have submitted my comments?

The comments will be channelled to the relevant standards committee for consideration and you will be informed of the outcome of the committee's decision and you may be invited to meet the committee if clarification is required on your feedback.

5. Can I view drafts after the public comment period?

Drafts will not be available after the public comment period.

6. How do I request for the development of a new standard?

You can propose the development of a new standard here.