Submit Comments

ENTERPRISE SINGAPORE CALLS FOR PUBLIC COMMENTS – 2 OCTOBER 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 – sterilisation of health care products and medical devices, medical device labels and labelling

Building and Construction – fire doors, energy efficiency standard for building services and equipment

Electrical and Electronic – electrical fire alarm systems, PVC insulated cables

Food – food waste management, peanut butter

Quality and safety – temporary edge protection systems, auditing management systems

For more information on viewing the documents, click here.

Closing date for comments: **3 December 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 – sterilisation of health care products

Manufacturing – additive manufacturing facility setup and operations

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

Closing date for comments: **3 November 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.

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Published Singapore Standards are reviewed to determine if they should be updated, confirmed or withdrawn (if they no longer serve the industry's needs) or classified as mature standards (no foreseeable changes; to be reviewed only upon request).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

Building and Construction – precast concrete slab and wall panels

The review is ongoing and new version/draft is not available at this juncture. Users can refer to the current standard to provide feedback. Click here to view and purchase the standard.

Closing date for comments: **3 November 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

New

1. *Sterilisation of health care products – Vocabulary of terms used in sterilisation and related equipment and process standards (Identical adoption of ISO 11139:2018)

This standard defines terms in the field of the sterilisation of health care products including related equipment and processes.

2. Sterilisation of health care products – Radiation

***Part 1: Requirements for development, validation and routine control of a sterilisation process for medical devices** (Identical adoption of ISO 11137-1:2006)

This standard specifies requirements for the development, validation and routine control of a radiation sterilisation process for medical devices. Although the scope is limited to medical devices, it specifies requirements and provides guidance that may be applicable to other products and equipment.

It covers radiation processes employing irradiators using:
a) the radionuclide ^{60}Co or ^{137}Cs,
b) a beam from an electron generator, or
c) a beam from an X-ray generator.

***Part 3: Guidance on dosimetric aspects of development, validation and routine control** (Identical adoption of ISO 11137-3:2017)

This standard gives guidance on meeting the requirements in ISO 11137-1 and ISO 11137-2 and in ISO/TS 13004 relating to dosimetry and its use in development, validation and routine control of a radiation sterilisation process.

3. *Sterilisation of health care products – Microbiological methods – Part 1: Determination of a population of microorganisms on products (Identical adoption of ISO 11737-1:2018)

This standard specifies requirements and provides guidance on the enumeration and microbial characterisation of the population of viable microorganisms on or in a health care product, component, raw material or package.

This standard does not apply to the enumeration or identification of viral, prion or protozoan contaminants. It also does not apply to the microbiological monitoring of the environment in which health care products are manufactured.

4. *Sterilisation of health care products – Biological indicators – Guidance for the selection, use and interpretation of results (Identical adoption of ISO 14161:2009)

This standard provides guidance for the selection, use and interpretation of results from application of biological indicators when used in the development, validation and routine monitoring of sterilisation processes.

This standard does not consider those processes that rely solely on physical removal of microorganisms, e.g. filtration.

It is not intended to apply to combination processes using, e.g. washer disinfectors or flushing and steaming of pipelines. It is also not intended to apply to liquid sterilisation processes.

5. *Sterilisation of health care products – Moist heat – Part 1: Requirements for the development, validation and routine control of a sterilisation process for medical devices (Identical adoption of ISO 17665-1:2006)

This standard specifies requirements for the development, validation and routine control of a moist heat sterilisation process for medical devices.

Moist heat sterilisation processes covered by this standard include but are not limited to:

a) saturated steam venting systems;
b) saturated steam active air removal systems;
c) air steam mixtures;
d) water spray;
e) water immersion.

This standard does not apply to those sterilisation processes that are based on a combination of moist heat with other biocidal agents (e.g. formaldehyde) as the sterilising agent. It also does not specify requirements for occupational safety associated with the design and operation of moist heat sterilisation facilities.

6. *Sterilisation of health care products – Dry heat – Requirements for the development, validation and routine control of a sterilisation process for medical devices (Identical adoption of ISO 20857:2010)

This standard specifies requirements for the development, validation and routine control of a dry heat sterilisation process for medical devices.

Although this standard primarily addresses dry heat sterilisation, it also specifies requirements and provides guidance in relation to depyrogenation processes using dry heat.

It does not apply to processes that use infrared or microwaves as the heating technique. It also does not specify requirements for occupational safety associated with the design and operation of dry heat sterilisation and/or depyrogenation facilities.

7. Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied

***Part 1: General requirements** (Identical adoption of ISO 15223-1:2016)

This standard identifies requirements for symbols used in medical device labelling that convey information on the safe and effective use of medical devices. It also lists symbols that satisfy the requirements of this standard.

This standard is applicable to symbols used in a broad spectrum of medical devices, which are marketed globally and therefore need to meet different regulatory requirements.

These symbols may be used on the medical device itself, on its packaging or in the associated documentation.

***Part 2: Symbol development, selection and validation** (Identical adoption of ISO 15223-2:2010)

This standard specifies a process for developing, selecting and validating symbols for inclusion in ISO 15223-1. Its purpose is to ensure that symbols included in ISO 15223-1 are readily understood by the target group.

This standard is not restricted to symbols intended to meet regulatory requirements or specified in regulatory guidelines on labelling.

Potential users of the above standards on medical devices and health care products may include healthcare sectors, manufacturers, developers and sterilisation service providers.

(II) Building and Construction

Revision

8. *Specification for fire doors (Revision of SS 332 : 2007)

This standard specifies requirements for the construction and installation of fire-resistant doorsets used to protect openings in walls and partitions which are required to resist the passage of fire. This standard also applies to transom panels over 0.5 h fire rated doors, where the panels are contained within the doorframe and form part of the doorset.

This standard does not apply to lift-landing doors.

Potential users of the standard may include architects, professional engineers, consultants, contractors, developers, testing/accreditation bodies and relevant regulatory/government agencies.

Amendment

9. Amendment No. 1 to Code of practice for energy efficiency standard for building services and equipment (SS 530 : 2014)

This amendment specifies the minimum efficiency level at IE3 regardless of the operating hours to align it with the requirements under the Minimum Energy Performance Standards (MEPS) for motors that will come into force in 1 October 2018. As MEPS covers motors of 2 poles to 6 poles, the formula and efficiencies of 6-pole motors have been included. The rated motor output has also been updated to include 375 kW since the MEPS for motors currently cover rated outputs ranging from 0.75 kW to 375 kW.

(Click here to download the amendment.)

(III) ***<u>Electrical and Electronic</u>***

<u>Revision</u>

10. ***Code of practice for installation and servicing of electrical fire alarm systems** (Revision of CP 10: 2005)

This standard applies to the installation and servicing of electrical fire alarm systems in buildings. It covers alarm systems using manual call points, heat detectors, smoke detectors, flame detectors and video image fire detectors.

Potential users of the standard may include testing laboratories, manufacturers, purchasers, suppliers, professional engineers, consultants, licensed electrical workers, building owners and relevant government agencies.

(NOTE: Instead of the prefix CP, the revised edition of CP 10 will carry the prefix 'SS', i.e. SS XXX, XXX representing the number that will be assigned when the standard is approved.)

11. **Polyvinyl chloride insulated cables of rated voltages up to and including 450/750 V**

***Part 3: Non-sheathed cables for fixed wiring** (Revision of SS 358 : Part 3) (Modified adoption of IEC 60227-3:1993+A1:1997)

This standard details the particular specifications for polyvinyl chloride insulated single-core non-sheathed cables for fixed wiring of rated voltages up to and including 450/750 V.

The modification was to replace the current Table 1 with a more comprehensive one covering additional data points (nominal cross-sectional area of conductors from 1.5 mm^2 to 1000 mm^2 instead of 1.5 mm^2 to 400 mm^2).

***Part 5: Flexible cables (cords)** (Revision of SS 358 : Part 5) (Identical adoption of IEC 60227-5:2011)

This standard details the particular specifications for polyvinyl chloride insulated flexible cables (cords), of rated voltages up to and including 300/500 V.

Potential users of the standards on cables may include testing laboratories, manufacturers, purchasers, suppliers, professional engineers, consultants, licensed electrical workers, building owners and relevant government agencies.

(IV) ***<u>Food</u>***

<u>New</u>

12. ***Code of practice for food waste management for food retail, wholesale and distribution establishments**

This standard sets out recommendations and guidelines for proper food waste management at various stages in the food value chain – receiving of materials, preparation, storage, packing, transportation/distribution, sales and disposal of food loss and waste (FLW).

The objective of this standard is to help food retail, wholesale and distribution establishments develop a food waste management plan with the goal of minimising food waste generated and move towards a zero waste nation, as set out in the Sustainable Singapore Blueprint 2015.

Potential users of the standard may include food retail, wholesale and distribution establishments, which include restaurants, caterers, coffee shops, food courts, cafes, takeaway kiosks, supermarkets, hawker stalls, food wholesalers, food distributers and other F&B establishments.

Mature standard

13. Specification for peanut butter (SS 179 : 1978)

This standard covers the requirements and methods of test for peanut butter.

It is proposed to classify this standard as a mature standard as there are no foreseeable changes to it. Hence, it will not be reviewed until a request is put forth to do so.

Users of the standard may include peanut butter manufacturers as well as retail, wholesale and distribution establishments.

(V) Quality and Safety

New

14. *Temporary edge protection systems – Product specification – Test methods (Identical adoption of EN 13374 : 2013)

This standard specifies the requirements and test methods for temporary edge protection systems for use during construction or maintenance of buildings and other structures. It applies to edge protection systems for flat and inclined surfaces and specifies the requirements for temporary edge protection. For edge protection systems with an arrest function (e.g. falling or sliding down a sloping roof) this standard specifies requirements for energy absorption. This standard also includes edge protection systems, some of which are fixed to the structure and others which rely on gravity and friction on flat surfaces.

This standard does not provide requirements for edge protection systems intended for protection against impact from vehicles or from other mobile equipment, protection from sliding down of bulk loose materials, and protection of areas accessible to the public. This standard does not apply to side protection on scaffolds.

Potential users of the standard may include manufacturers and suppliers, users, architects, professional engineers, safety officers, academic institutions, consultants, testing laboratories, contractors, industry associations and relevant government agencies.

Revised

15. *Guidelines for auditing management systems (Revision of SS ISO 19011 : 2011) (Identical adoption of ISO 19011:2018)

This standard provides guidance on auditing management systems, including the principles of auditing, managing an audit programme and conducting management system audits, as well as guidance on the evaluation of competence of individuals involved in the audit process. These activities include the individual(s) managing the audit programme, auditors and audit teams.

It is applicable to all organisations that need to plan and conduct internal or external audits of management systems or manage an audit programme.

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. Technical Reference – Sterilisation of health care products – Moist heat – Part 2: Guidance on the application of SS ISO 17665-1 (Identical adoption of ISO/TS 17665-2:2009)

This Technical Reference (TR) provides general guidance on the development, validation and routine control of moist heat sterilisation processes and is intended to explain the requirements set forth in SS ISO 17665-1 (see item 5 above). The guidance given in this TR is provided to promote good practice related to moist heat sterilisation processes and to assist those developing and validating a moist heat sterilisation process according to SS ISO 17665-1.

Potential users of the standard may include healthcare sectors, manufacturers, developers and sterilisation service providers.

(II) Manufacturing

2. Technical Reference – Safety requirements of additive manufacturing (AM) facility setup and operations

This Technical Reference specifies the safety requirements on designing, operating and maintaining an AM facility.

Potential users of the standard may include manufacturers, industry users, research institutions and institutes of higher learning.

B.2 Review of Singapore Standards

(I) Building and Construction

1. Code of practice for precast concrete slab and wall panels (CP 81 : 1999)

This standard gives recommendations and guidelines for the design, production and construction of precast slab and wall panels in buildings. It covers the following main areas:

a) Design and durability;
b) Water- and weather- tightness;
c) Production quality control;
d) Handling, storage, transportation and erection; and
e) Acceptance of precast units.

The standard is reviewed with the intention to update it.

Users of the standard include consultants, contractors, developers, professional engineers, suppliers / manufacturers, tertiary institutions, testing bodies, accreditation bodies and relevant government agencies.

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.