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ENTERPRISE SINGAPORE CALLS FOR PUBLIC COMMENTS ON SINGAPORE STANDARDS – 4 APRIL 2025

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 Standard for Publication

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

Biomedical and Health – edible bird's nest, data standards

Building and Construction - formwork

Closing date for comments: 5 June 2025 (except for SS on formwork which closes on 12 June 2025)

For more information on viewing the document, click here.

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

B) Notification of Work Item Proposals

B.1 Proposal for New Work Items

New Work Items (NWIs) are approved proposals to develop new Singapore Standards, or prestandards like Technical References and Workshop Agreements.

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 – <u>clinical investigation requirements</u>

The NWI is a work-in-progress, and the draft is not available at this juncture.

Closing date for comments: 5 May 2025

B.2 Proposal for the Review of Singapore Standards

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Singapore Standards and Technical References are reviewed to determine if they should be updated, confirmed or withdrawn (if they no longer serve the industry's needs) or classified as mature standards (no foreseeable changes; to be reviewed only upon request).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

Safety and Quality – rope access systems, personal fall-arrest systems

The reviews are ongoing, and the new version/drafts are not available at this juncture. Users can refer to the current standards to provide feedback. Click here to view or purchase the standards.

Closing date for comments: 5 May 2025

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

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

A) Notification of Draft Singapore Standard for Publication

(I) Biomedical and Health

New

1. Non-destructive authentication of edible bird's nest Using NIR

This standard specifies the test method for authentication of edible bird's nest (EBN) using a hand-held microNIR spectrometer. The method includes information such as instructions to run an authentication test with appropriate positive and negative controls, instructions/guidelines on how to differentiate authentic, fake and adulterated EBN based on distinctive "signature" spectrum, and instrument specifications and consumables.

Users of the standard include manufacturers and distributors, Traditional Chinese Medicine companies, research institutions, Testing, Inspection and Certification (TIC) bodies and relevant government agencies.

2. Guidelines for data standards (terminology) for interoperability – Definition, scope, structures, and requirements

This standard focuses exclusively on data standards for patients' data, ensuring the consistent use and management of the prescribed terminology and code-sets. It covers demographics data, laboratory test identity, drugs and vaccine data, supporting drug information and diagnosis data. It outlines licensing agreements required for patient health data summary and specifies required data elements and structures for information exchange including data maintenance, exchange formats, codes retirement management and mapping of local codes and data standards.

This standard does not address the healthcare interoperability standards or communication protocols (e.g. Health Level Seven, Fast Healthcare Interoperability Resources, Clinical Document Architecture, etc). It is also not meant to cover the technical aspects related to system integration.

Users of the standard include service providers that support companies needing to contribute clinical data to relevant national systems.

(II) Building and Construction

Amendment

1. Amendment No.1 to Code of practice for formwork (SS 580: 2020)

This amendment establishes guidelines for evaluating the traceability and reusability of formwork structures. These guidelines aim to ensure formwork structures are manufactured with quality materials, are produced with consistency, and would maintain their performance through repeated use.

Users of the standard may include architects, manufacturers, suppliers, contractors, TIC bodies and relevant government agencies.

(Click here to download the amendment.)

Comment period: 11 April 2025 to 12 June 2025

Copies of the draft are available at:

Viewing from Singapore Standards eShop

Login to Singapore Standards eShop at: www.singaporestandardseshop.sg

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Viewing Singapore Standards from Public Libraries

Singapore Standards are viewable multimedia stations at all Public Libraries via NLB databases "Singapore Standards Collection" at https://reference.nlb.gov.sg/guides/sci-tech/tech/standards-and-references/ Please refer to https://www.nlb.gov.sg/main/visit-us for address and viewing hours.

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NOTE – The viewing period of the draft and standard will expire on the closing of the public comment period and will no longer be available after this date.

B) Notification of the Work Item Proposals

B.1 Proposal for New Work Items

Biomedical and Health

Technical Reference (TR) - Guidelines for clinical investigation requirements for medical devices

This standard specifies how applicable ISO 14155 is in defining clinical investigation standards for investigational device studies.

For selected ISO14155 clauses, it provides further elaboration on:

- one or more recommended or mandated approaches or principles for implementation of the clause,
- a recommended or mandated minimum specification for a quantifiable standard which should be met to fulfil the requirement of the clause,
- other relevant standard(s) which are recommended or mandated to be adopted in fulfilment of the clause; and
- recommendations of best practices with given justification for implementation of the clause.

For medical devices to be used in investigational device studies, it will include minimum requirements on:

- Design controls
- Safety and/or efficacy testing
- Engineering risk management and mitigation
- Documentation

This standard does not apply to clinical trials involving medicinal products, therapeutic products, and cell, tissue, and gene therapy products.

Users of the standard include medical devices manufacturers and suppliers, healthcare professionals and medical device engineers, academic institutions, regulatory consultants, TIC bodies and relevant government agencies.

B.2 Proposal for the Review of Singapore Standards

Safety and Quality

1. Personal equipment for protection against falls - Rope access systems

Part 1: Fundamental principles for a system of work (SS 588-1:2013)

This standard sets out the fundamental principles for the use of rope access methods for work-at-height. It is applicable to situations where ropes are used as the primary means of access, egress or support and as the primary means of protection against a fall, on both man-made and natural features.

Part 2: Code of practice (SS 588-2:2013)

This standard provides requirements and recommendations on the use of rope access methods for work-at-height and expands on the fundamental principles given in SS 588-1, in conjunction with which it is intended to be used.

SS 588-1 and SS 588-2 will be reviewed with the intention to update and align with current industry practices. The updates may include technological advancements, hazard identification and risk assessment requirements, and training protocols to enhance worker safety and efficiency.

Users of the standard include work-at-height specialist/operators, site supervisors, project managers, safety professionals, contractors and property developers, training providers, industry associations, TIC bodies and relevant government agencies.

2. Personal fall-arrest systems

SS 528 consists of the following parts, under the general title, "Personal fall-arrest systems"

- Part 1: Full body harnesses (SS 528-1:2006(2014)) (Identical adoption of ISO 10333-1:2000(2016))
- Part 2: Lanyards and energy absorbers (SS 528-2:2006(2014)) (Identical adoption of ISO 10333-2:2000(2016))
- Part 3: Self- retracting lifelines (SS 528-3:2006(2014)) (Identical adoption of ISO 10333-3:2000(2016))
- Part 4: Vertical rails and vertical lifelines incorporating a sliding-type fall arrester (SS 528-4:2006(2014)) (Identical adoption of ISO 10333-4:2002(2023))
- Part 5: Connectors with self-closing and self-locking gates (SS 528-5:2006(2014))
 (Identical adoption of ISO 10333-5:2001(2024))
- Part 6: System performance tests (SS 528-6:2006(2014)) (Identical adoption of ISO 10333-6:2004(2024))

SS 528 Parts 1 to 5 specify the requirements, test methods, instructions for use, marking, labelling, packaging and maintenance for the components of personal fall-arrest systems.

The system performance tests will be based on the Part 6. It specifies tests and requirements for complete personal fall arrest systems made up from specific combinations of components and subsystems selected from those conforming to the other parts of SS 528, where it is both important and desirable to ascertain satisfactory system performance and interactive component compatibility.

Users of the standards include companies involved in work-at-height operations, personal protective equipment (PPE) suppliers & manufacturers, industry associations, professional institutions, training providers, TIC bodies and relevant government agencies.

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. Why are comments only accepted through the new public comment form provided by Enterprise Singapore?

We have developed a new public comment form which will enable users to submit their comments in a standardised and structured manner. The Working Group (WG) that will be reviewing the comments will have a better understanding of what the commenter has proposed, the rationale for the changes and where these changes will be made in the standard. This will assist the WG in addressing the comments more effectively.

5. What happens after I have submitted my comments?

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

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

Drafts will not be available after the public comment period.

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

You can propose the development of a new standard here.