NEW WORK ITEM PROPOSAL	
Date of presentation dd, mm, 2011	Reference number (to be given by the Secretariat)
Proposer Kazuo TORIIZUKA	ISO/TC 215 / SC /WG3 N
Secretariat Patricia Village	

A proposal for a new work item within the scope of an existing committee shall be submitted to the secretariat of that committee with a copy to the Central Secretariat and, in the case of a subcommittee, a copy to the secretariat of the parent technical committee. Proposals not within the scope of an existing committee shall be submitted to the secretariat of the ISO Technical Management Board.

The proposer of a new work item may be a member body of ISO, the secretariat itself, another technical committee or subcommittee, or organization in liaison, the Technical Management Board or one of the advisory groups, or the Secretary-General.

The proposal will be circulated to the P-members of the technical committee or subcommittee for voting, and to the O-members for information.

See overleaf for guidance on when to use this form.

IMPORTANT NOTE: Proposals without adequate justification risk rejection or referral to originator.
Guidelines for proposing and justifying a new work item are given overleaf.

Proposal (to be completed by the proposer)

Title of proposal (in the case of an amendment, revision or a new part of an existing document, show the reference number and current title)

English title: Health Informatics: Categorial structures for representation of herbal medicaments - Part 1: Single natural material

French title (if available): to be supplied

Scope of proposed project

The purpose of this Technical Specification is to specify categorial structures in the subject field of the herbal medicaments of single natural material, by defining a set of constraints for use within terminological resources.

This Technical Specification does not define any information models for drug products from herbal materials and/or the combinations of herbal materials and modern drugs. It also does not define any process models of drug product manufacturing and specifications of each ingredient captured in modern western medicine either, although they may be referred as values if needed.

Concerns known patented items (see ISO/IEC Directives Part 1 for important guidance)

☐ Yes ☒ No If "Yes", provide full information as annex

Envisaged publication type (indicate one of the following, if possible)

☐ International Standard ☒ Technical Specification ☐ Publicly Available Specification ☐ Technical Report

Purpose and justification (attach a separate page as annex, if necessary)

The purpose of this Technical Specification is to specify categorial structures in the subject field of herbal medicaments by defining a set of domain constraints for representation of the herbal medicaments which are derived from single natural material within terminological resources.

For centuries past, natural materials have provided mankind with medicinal effects. In this Technical Specification, natural materials include not only herbs but also animals and minerals since all of those materials have been historically used as medicinal. Today natural medicaments are reevaluated, so they are used extensively both in medicines and in supplements.

However, because of historical and vernacular reasons, single specific name frequently designates different materials or natural medicaments, or different names often designate same natural medicament. Such situation often causes confusion in international trading and serious health hazards occur in consequence. These problems should be resolved by standardization of the relations between terms and concepts by following the standardization of terminological resources.

This Technical Specification describes a concept system detailing a domain constraint of sanctioned characteristics each composed of a semantic link and an applicable characterizing category.

The potential uses of this categorial structure are to:
1) support developers of new terminology systems concerning herbal medicaments;
2) support developers of new detailed content areas of existing terminology systems concerning herbal medicaments to ensure conformance;
3) facilitate the representation of herbal medicaments using a standard core model in a manner suitable for computer processing;
4) provide the monitoring system for adverse events and adverse reactions;
5) provide the characterization of clinical research intervention of herbal medicaments;
6) permit physicians to compare herbal formulations with prescriptions on the component(s) which perform(s) same effect and exclude failures in dosages or incompatibilities;
7) promote smooth exchange of the information and prevent patients from adverse reactions and risks affected by the toxicity of herbal medicaments;
8) provide the characterization of clinical research intervention of herbal medicaments.
9) clarify the polysemy across different clinical specialties and the one sometimes subsisted in themselves internally.

Target date for availability (date by which publication is considered to be necessary)

Proposed development track ☐ 1 (24 months) ☒ 2 (36 months - default) ☐ 3 (48 months)

Relevant documents to be considered

Standards produced by TC215

Relationship of project to activities of other international bodies

WHO International Standard Terminology on Traditional Medicine in the Western Pacific Region, WHO monographs on selected medicinal plants (volume 1-4), WHO monographs on medicinal plants commonly used in the newly independent states

Liaison organizations	**Need for coordination with:**
WHO/HQ, WHO/WPRO, FHH (Forum for the Harmonization of Herbal Medicines)	☐ IEC ☐ CEN ☐ Other (please specify)

Preparatory work (at a minimum an outline should be included with the proposal)

☐ A draft is attached ☒ An outline is attached. It is possible to supply a draft by **Nov 30, 2011**

The proposer or the proposer's organization is prepared to undertake the preparatory work required ☒ Yes ☐ No

Proposed Project Leader (name and address)

Yasuyuki HIROSE
Medical Informatics, University of the Ryukyus
207 Uehara, Nishihara, Okinawa 903-0215, JAPAN
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Fax: +81(98)895-1475

Name and signature of the Proposer (include contact information)

Kazuo TORIIZUKA
School of Pharmacy, Showa University
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Fax: +81(3)3784-8191

Comments of the TC or SC Secretariat

Supplementary information relating to the proposal

☒ This proposal relates to a new ISO document;

☐ This proposal relates to the amendment/revision of an existing ISO document;

☐ This proposal relates to the adoption as an active project of an item currently registered as a Preliminary Work Item;

☐ This proposal relates to the re-establishment of a cancelled project as an active project.

Other:

Voting information

The ballot associated with this proposal comprises a vote on:

☒ Adoption of the proposal as a new project

☐ Adoption of the associated draft as a committee draft (CD)

☐ Adoption of the associated draft for submission for the enquiry vote (DIS or equivalent)

Other:

Annex(es) are included with this proposal (give details)

☐

Date of circulation	Closing date for voting	Signature of the TC or SC Secretary

Use this form to propose:

a) a new ISO document (including a new part to an existing document), or the amendment/revision of an existing ISO document;
b) the establishment as an active project of a preliminary work item, or the re-establishment of a cancelled project;
c) the change in the type of an existing document, e.g. conversion of a Technical Specification into an International Standard.

This form is not intended for use to propose an action following a systematic review - use ISO Form 21 for that purpose.
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Guidelines on the completion of a proposal for a new work item
(see also the ISO/IEC Directives Part 1)

a) Title: Indicate the subject of the proposed new work item.

b) Scope: Give a clear indication of the coverage of the proposed new work item. Indicate, for example, if this is a proposal for a new document, or a proposed change (amendment/revision). It is often helpful to indicate what is not covered (exclusions).

c) Envisaged publication type: Details of the types of ISO deliverable available are given in the ISO/IEC Directives, Part 1 and/or the associated ISO Supplement.

d) Purpose and justification: Give details based on a critical study of the following elements wherever practicable. *Wherever possible reference should be made to information contained in the related TC Business Plan.*

1) The specific aims and reason for the standardization activity, with particular emphasis on the aspects of standardization to be covered, the problems it is expected to solve or the difficulties it is intended to overcome.

2) The main interests that might benefit from or be affected by the activity, such as industry, consumers, trade, governments, distributors.

3) Feasibility of the activity: Are there factors that could hinder the successful establishment or global application of the standard?

4) Timeliness of the standard to be produced: Is the technology reasonably stabilized? If not, how much time is likely to be available before advances in technology may render the proposed standard outdated? Is the proposed standard required as a basis for the future development of the technology in question?

5) Urgency of the activity, considering the needs of other fields or organizations. Indicate target date and, when a series of standards is proposed, suggest priorities.

6) The benefits to be gained by the implementation of the proposed standard; alternatively, the loss or disadvantage(s) if no standard is established within a reasonable time. Data such as product volume or value of trade should be included and quantified.

7) If the standardization activity is, or is likely to be, the subject of regulations or to require the harmonization of existing regulations, this should be indicated.

If a series of new work items is proposed having a common purpose and justification, a common proposal may be drafted including all elements to be clarified and enumerating the titles and scopes of each individual item.

e) Relevant documents and their effects on global relevancy: List any known relevant documents (such as standards and regulations), regardless of their source. When the proposer considers that an existing well-established document may be acceptable as a standard (with or without amendment), indicate this with appropriate justification and attach a copy to the proposal.

f) Cooperation and liaison: List relevant organizations or bodies with which cooperation and liaison should exist.

NEW WORK ITEM PROPOSAL	
Date of presentation dd, mm, 2011	Reference number (to be given by the Secretariat)
Proposer Kazuo TORIIZUKA	ISO/TC 215 / SC /WG3 **N**
Secretariat Patricia Village	

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Proposal (to be completed by the proposer)

Title of proposal (in the case of an amendment, revision or a new part of an existing document, show the reference number and current title)

English title: Health Informatics: Categorial structures for representation of herbal medicaments - Part 2: Formula of single natural materials

French title (if available): to be supplied

Scope of proposed project

The purpose of this Technical Specification is to specify categorial structures of the formula with single natural materials in the subject field of the herbal medicaments, by defining a set of constraints for use within terminological resources.

This Technical Specification does not define any information models for drug products from herbal materials and/or the combination of herbal materials and modern drugs. It also does not define any process models of drug product manufacturing and specifications of each ingredient captured in modern western medicine either, although they may be referred as values if needed.

Concerns known patented items (see ISO/IEC Directives Part 1 for important guidance)

☐ Yes ☒ No If "Yes", provide full information as annex

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Purpose and justification (attach a separate page as annex, if necessary)

The purpose of this Technical Specification is to specify categorial structures in the subject field of herbal medicaments by defining a set of domain constraints for representation of the herbal medicaments which are the formulas with single natural materials within terminological resources.

For centuries past, natural materials have provided mankind with medicinal effects. In this Technical Specification, natural materials include not only herbs but also animals and minerals since all of those materials have been historically used as medicinal. Today natural medicaments are reevaluated, so they are used extensively both in medicines and in supplements.

However, because of historical and vernacular reasons, single specific name frequently designates different natural medicament formulas. Such situation often causes confusion in international trading and serious health hazards occur in consequence. These problems should be resolved by standardization of the relations between terms and concepts by following the standardization of terminological resources.

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☐ A draft is attached ☒ An outline is attached. It is possible to supply a draft by **Nov 30, 2011**

The proposer or the proposer's organization is prepared to undertake the preparatory work required ☒ Yes ☐ No

Proposed Project Leader (name and address)	**Name and signature of the Proposer** (include contact information)
Yasuyuki HIROSE Medical Informatics, University of the Ryukyus 207 Uehara, Nishihara, Okinawa 903-0215, JAPAN E-mail: hirose@m.hosp.u-ryukyu.ac.jp Vox: +81(98)895-1343 Fax: +81(98)895-1475	Kazuo TORIIZUKA School of Pharmacy, Showa University 1-5-8, Hatanodai, Shinagawa-ku, Tokyo 142-8555, JAPAN E-mail: k-tori@pharm.showa-u.ac.jp Vox: +81(3)3784-8189 Fax: +81(3)3784-8191

Comments of the TC or SC Secretariat

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f) Cooperation and liaison: List relevant organizations or bodies with which cooperation and liaison should exist.

Categorial Structures for representation of Herbal Medicaments

Prof. Kazuo Toriizuka (Showa University)
Prof. Yasuyuki Hirose (Univ. of the Ryukyus)

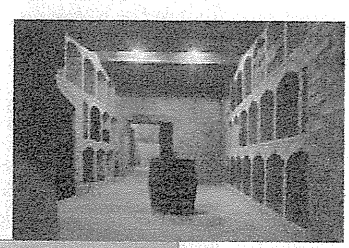
ISO / TC 215 / WG3 and TM-TF

19th, 20th November, 2011
HolidayInnMartPlaza, Chicago, IL, USA

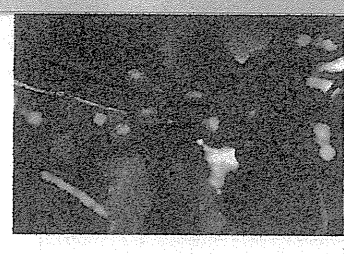
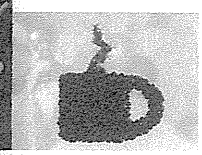
Outline

- Introduction
- Needs and Purpose (Justification)
- Core structure
  - Essences
  - Abstract level
- Title and Scope
  - Scope and Out of Scope
- No confliction /w IDMPs in WG6

Imagine Natural Products

As like those

Natural materials

- Species
- Area/District of harvest/gather
  - different flavors and taste
- Timing/Condition of harvest/gather
  - first flush tea, grapes with noble rot
- Processing
  - press, squeeze, fermentation
  - drying w/wo sunlight, cut, crumple, fermentation
- Evaluation of trading quality

Gentian

Root
Fermentation
Dry

Digitalis
(Fox glove)

Leaves
Dry
(in the shade)

Saffron

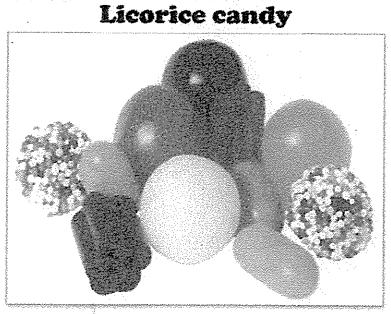
Pistil
Dry

Needs and Purpose

Polysemy

- Because of historical and vernacular reasons, single specific name frequently designates different natural materials or medicament formulas.
- Such situation often causes confusion in international trading and serious health hazards occur in consequence.
- These problems should be resolved by standardization of the relations between terms and concepts by the standardization of terminological resources.

Licorice candy



Three kind of *Glycyrhiza spp.*

~~Leaves~~

~~Seeds~~

Root

G. uralensis *G. glabra* *G. inflata*

Core structure

Core of the Categorial Structure for Herbal Medicaments - Single herb (Part I)

- Origin (part/whole of source material)
- Processing (w/wo supplement)
- Effect(s) on health issues(s)
- Designator

recognized in a medical domain

Each elements are able to be decompose into many child/grandchild elements. Categorial structure is minimum set of domain constraints, and a small framework helps better conformity.

In progress

Origin — Species, Area/District of harvest/gather, Timing/ Condition of harvest/gather, Part of use, Scientific name

Processing — Press, Squeeze, Fermentation, Drying, Cut, Crumple, Fermentation…

Effect(s) on health issues(s) — recognized in a medical domain
Uses described in pharmacopoeias
Uses described in traditional medicine
a certain TM specific characteristics

Designator

Each elements are able to be decompose into many child/grandchild elements. Categorial structure is minimum set of domain constraints, and a small framework helps better conformity.

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Core of the Categorial Structure for Herbal Medicaments – Formula (Part 2)

Single herbal medicament — Not name But "concept"

Amount in a formula

Effect(s) on health issues(s) — recognized in a medical domain

Designator

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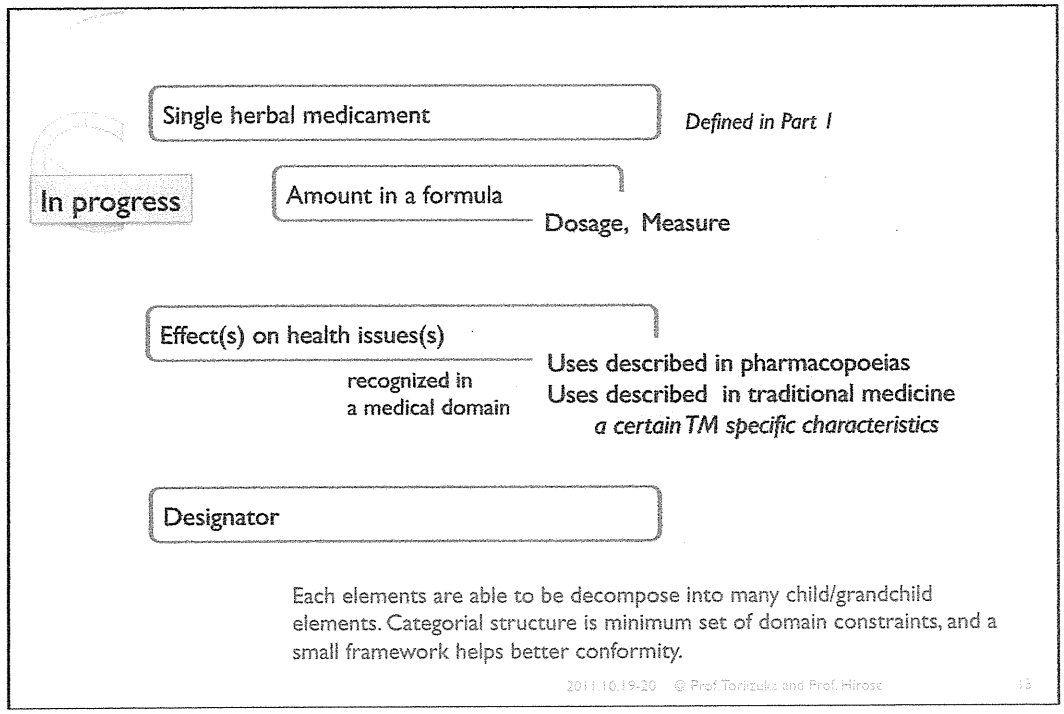
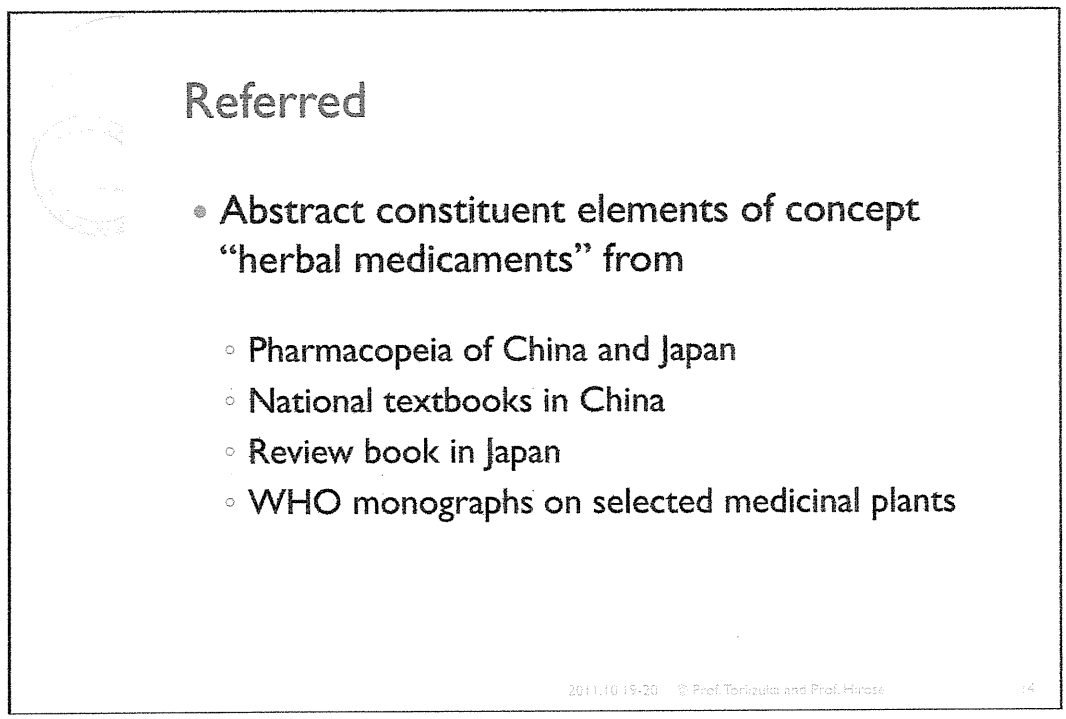

Single herbal medicament
Defined in Part I
In progress
Amount in a formula
Dosage, Measure
Effect(s) on health issues(s)
recognized in
a medical domain
Uses described in pharmacopoeias
Uses described in traditional medicine
a certain TM specific characteristics
Designator
Each elements are able to be decompose into many child/grandchild elements. Categorial structure is minimum set of domain constraints, and a small framework helps better conformity.
2011.10.19-20 © Prof. Toriizuka and Prof. Hirose 13


Referred
Abstract constituent elements of concept "herbal medicaments" from
Pharmacopeia of China and Japan
National textbooks in China
Review book in Japan
WHO monographs on selected medicinal plants
2011.10.19-20 © Prof. Toriizuka and Prof. Hirose 14

Title and Scope

Title

Part 1 • Health Informatics: Categorial structures for representation of herbal medicaments - Part 1: Single natural material

Part 2 • Health Informatics: Categorial structures for representation of herbal medicaments - Part 2: Formula of single natural materials

Scope

Part 1

- To specify categorial structures in the subject field of the herbal medicaments of single natural material, by defining a set of constraints for use within terminological resources

Part 2

- To specify categorial structures of the formula with single natural materials in the subject field of the herbal medicaments, by defining a set of constraints for use within terminological resources.

Out of scope #1

- define any information models for drug products from herbal materials and/or the combinations of herbal materials and modern drugs
- define any process models of drug product manufacturing and specifications of each ingredient captured in modern western medicine either, although they may be referred as values if needed.

Out of scope #2

- define any models or frameworks for quality control of (i) cultivation of natural materials and (ii) drug products from herbal materials and/or the combinations of herbal materials and modern drugs

The potential uses of this categorial structure are to: #1

- support developers of new terminology systems concerning herbal medicaments;
- support developers of new detailed content areas of existing terminology systems concerning herbal medicaments to ensure conformance;
- facilitate the representation of herbal medicaments using a standard core model in a manner suitable for computer processing;
- provide the monitoring system for adverse events and adverse reactions;
- provide the characterization of clinical research intervention of herbal medicaments;

The potential uses of this categorial structure are to: #2

- permit physicians to compare herbal formulations with prescriptions on the component(s) which perform(s) same effect and exclude failures in dosages or incompatibilities;
- promote smooth exchange of the information and prevent patients from adverse reactions and risks affected by the toxicity of herbal medicaments;
- provide the characterization of clinical research intervention of herbal medicaments.
- clarify the polysemy across different clinical specialties and the one sometimes subsisted in themselves internally.

No confliction /w IDMPs in WG6

- IDMPs:
  - Identification of drug products
  - Information models for the identifiers of drug products
- Herbal Medicaments
  - Identification of concepts of herbal medicaments
  - Categorial structures for use within terminological resources
  - Support IDMPs

NEW WORK ITEM PROPOSAL	
Date of presentation 20 December 2011	Reference number (to be given by the Secretariat)
Proposer Kazuo TORIIZUKA	ISO/TC 215 / SC **N** 934
Secretariat ANSI	

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Proposal (to be completed by the proposer)

Title of proposal (in the case of an amendment, revision or a new part of an existing document, show the reference number and current title)

English title: Health Informatics: Categorial structures for representation of herbal medicaments in terminological systems

French title (if available): to be supplied

Scope of proposed project

To specify categorial structures in the subject field of the herbal medicaments [A] herbal medicaments made of single natural material with or without adjuvant material(s) and [B] herbal medicaments that are made with the herbal medicaments made of single natural material, by defining a set of constraints for use within terminological resources.

This work will not include content of herbal medicament concept representation that would represent concepts of herbal medicaments, but it specifies the structural model in which such content can be developed and maintained with consistency and interoperability.

Out of scope:

This Technical Specification does not focus on chemical and physical characteristics of ingredients, although they may be referred to. N.B. Ingredients are not always active substances, but are considered as chemical markers.

This Technical Specification does not define (1) any information models for drug products from herbal medicament(s), and (2) the combinations of modern drug(s) and herbal medicament(s) or natural material(s). It also does not define (3) any process models of drug production or manufacturing, and (4) any models or frameworks for quality control of (i) cultivation of natural materials, and (ii) drug products from herbal medicaments, natural materials, or the combinations of modern drug(s) and herbal medicament(s) or natural material(s).

This Technical Specification does not include formulas of products that have already been formulated; therefore the scope of [B] is restricted to first order formulas that combine single herbal medicaments with or without adjuvant material(s).

Concerns known patented items (see ISO/IEC Directives Part 1 for important guidance)

☐ Yes ☒ No If "Yes", provide full information as annex

Envisaged publication type (indicate one of the following, if possible)

☐ International Standard ☒ Technical Specification ☐ Publicly Available Specification ☐ Technical Report