Form 4: New Work Item Proposal

Circulation date: 2019-03-27 Closing date for voting: 2019-06-19	Reference number: ISO/NP 19609-3 (to be given by Central Secretariat) ISO/TC 249 **N 1070**
Proposer (e.g. ISO member body or A liaison organization) SAC	
Secretariat SAC	

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, an 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.

☒ The proposer has considered the guidance given in the Annex C during the preparation of the NWIP.

Proposal (to be completed by the proposer)

Title of the proposed deliverable.

English title:

Traditional Chinese medicine -- Quality and safety of natural materials and manufacturing products made with natural materials -- Part 3: Part 3: Testing of the absence of contaminants

French title:

Titre manque

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

Scope of the proposed deliverable.

This standard applies to the testing of the absence of contaminants within a quality control framework for starting materials and finished products, used in and as traditional Chinese medicine (TCM), and the comparison between the starting materials and the finished products if necessary. Starting materials are any incoming materials to be commercially processed, manufactured or packaged. Finished products are commercial products intended for sale and use, including decoction pieces.

Purpose and justification of the proposal*

The World Health Organization estimates that 80 percent of the populations in some Asian and African countries rely on traditional medicine for their primary health care, and that 70-80 percent of the populations in developed countries have used some form of alternative or complementary medicine. Systems of traditional medicine have developed over many centuries and include the use of natural materials of plant, animal, and mineral source and the application of documented diagnostic and therapeutic practices. Traditional medicine can be contrasted with contemporary conventional medicine, which relies on more recently developed practices and the use of modern drug therapies. One such system of traditional medicine that is identified here as traditional Chinese medicine (TCM) has spread from China, Japan and Korea to other Asian regions over thousands years as well as to Europe, Africa, and the Americas. Contemporary TCM includes treatment methods such as acupuncture, moxibustion, massage, and therapeutic use of herbs and other natural materials.
It is estimated that more than 2000 natural materials are known in TCM as therapeutic agents and of these about 500 drugs are used worldwide.
The purpose of the proposed project is to provide a standard for use in ensuring the quality and safety of the natural materials that fall within the scope of the proposed project.
There are many reasons why the quality and safety of natural materials and manufacturing products made with natural materials is important.
The integration of TCM into Western medicine and the spread of TCM in the world are only possible if the quality of medical drugs and derived products is secured. It would be unfortunate if this project fails because of a lack of quality.
Reinforced by the application of this medicine, there is an increased attention of stakeholders and quality criteria are necessary. Especially, patients will demand information such as what risks there are. It should be noted that medical drugs are products which are directly related to the consumer and all involved stakeholder in the process also have an ethical responsibility.
Especially in Europe, there are very strict laws and regulations and safety hazards are not tolerated. Without quality and safety of medical drugs an application of this medicine is not possible. For clinical trials, which are the prerequisite for approval of drugs, high-quality materials are also necessary. Last but not least, the market opportunities increase significantly if the quality of medical drugs and derived products is secured.
This proposal corresponds to the ideas of the WHO to Quality and Safety of TCM.
This proposal relates on the already confirmed as PWI within the work programme of ISO/TC 249/WG 2.

Consider the following: Is there a verified market need for the proposal? What problem does this standard solve? What value will the document bring to end-users? See Annex C of the ISO/IEC Directives part 1 for more information. See the following guidance on justification statements on ISO Connect:
https://connect.iso.org/pages/viewpage.action?pageId=27590861

Sustainable Development Goals (SDGs)

Goal 3: Good Health and Well-Being for People

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

☒ A draft is attached ☐ An outline is attached ☐ An existing document to serve as initial basis

The proposer or the proposer's organization is prepared to undertake the preparatory work required:

☒ Yes ☐ No

If a draft is attached to this proposal:

Please select from one of the following options (note that if no option is selected, the default will be the first option):

☒ Draft document will be registered as new project in the committee's work programme (stage 20.00)

☐ Draft document can be registered as a Working Draft (WD – stage 20.20)

☐ Draft document can be registered as a Committee Draft (CD – stage 30.00)

☐ Draft document can be registered as a Draft International Standard (DIS – stage 40.00)

If the attached document is copyrighted or includes copyrighted content:

☐ The proposer confirms that appropriate permissions have been granted in writing for ISO or IEC to use that copyrighted content.

Is this a Management Systems Standard (MSS)?

☐ Yes ☒ No

NOTE: if Yes, the NWIP along with the Justification study (see Annex SL of the Consolidated ISO Supplement) must be sent to the MSS Task Force secretariat (tmb@iso.org) for approval before the NWIP ballot can be launched.

Indication(s) of the preferred type to be produced under the proposal.

☒ International Standard ☐ Technical Specification

☐ Publicly Available Specification

Proposed development track

☐ 18 months* ☐ 24 months ☒ 36 months ☐ 48 months

Note: Good project management is essential to meeting deadlines. A committee may be granted only one extension of up to 9 months for the total project duration (to be approved by the ISO/TMB).

*DIS ballot must be successfully completed within 13 months of the project's registration in order to be elligible for the direct publication process

Draft project plan (as discussed with committee leadership)

Proposed date for first meeting:

Dates for key milestones: DIS submission

Publication

Known patented items (see ISO/IEC Directives, Part 1 for important guidance)

☐ Yes ☒ No

If "Yes", provide full information as annex

Co-ordination of work: To the best of your knowledge, has this or a similar proposal been submitted to another standards development organization?

☐ Yes ☒ No

If "Yes", please specify which one(s):

A statement from the proposer as to how the proposed work may relate to or impact on existing work, especially existing ISO and IEC deliverables.
The proposer should explain how the work differs from apparently similar work, or explain how duplication and conflict will be minimized.

There is no existing ISO and IEC deliverables related to the proposed work.

A listing of relevant existing documents at the international, regional and national levels.

National standards
Different Pharmacopeias
Pharmacological literature
Compendia of international congresses

Please fill out the relevant parts of the table below to identify relevant affected stakeholder categories and how they will each benefit from or be impacted by the proposed deliverable(s).

	Benefits/impacts	Examples of organizations / companies to be contacted
Industry and commerce large industry	Methods for ensuring safe and qualitatively harmless products for international trade. Global comparability of quality.	important, export and trading companies
Industry and commerce SMEs	Legal protection for companies. Methods suitable and applicable for all company sizes. Hardly any additional investments necessary.	important, export and trading companies
Government	Safer products	regulation authorities
Consumers	Safer, healthier products with more uniform quality standards	patients
Labour	easier work	testing laboratories
Academic and research bodies	Large-area capabilities to capture global statistical data through unified methods and procedures	universities, private research organizations
Standards application businesses	All participants need the respective standards	certification bodies
Non-governmental organizations	Uniform products with high safety and global comparability	associations
Other (please specify)	n.a.	

Liaisons: A listing of relevant external international organizations or internal parties (other ISO and/or IEC committees) to be engaged as liaisons in the development of the deliverable(s).	Joint/parallel work: Possible joint/parallel work with: ☐ IEC (please specify committee ID) ☐ CEN (please specify committee ID) ☐ Other (please specify)
A listing of relevant countries which are not already P-members of the committee. Note: The committee secretary shall distribute this NWIP to the countries listed above to see if they wish to participate in this work	
Proposed Project Leader (name and e-mail address) Hans Rausch Phytochem@t-online.de	**Name of the Proposer** (include contact information) Matthias Kritzler-Picht matthias.kritzler-picht@din.de
This proposal will be developed by: ☒ An existing Working Group: ISO/TC 249/WG 2 ☐ A new Working Group: (Note: establishment of a new WG must be approved by committee resolution) ☐ The TC/SC directly ☐ To be determined:	

Supplementary information relating to the proposal

☒ This proposal relates to a new 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:

Maintenance agencies and registration authorities

☐ This proposal requires the service of a maintenance agency. If yes, please identify the potential candidate:

☐ This proposal requires the service of a registration authority. If yes, please identify the potential candidate:

NOTE: Selection and appointment of the MA or RA is subject to the procedure outlined in the ISO/IEC Directives, Annex G and Annex H, and the RA policy in the ISO Supplement, Annex SN.

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

WD-Traditional Chinese Medicine -- Quality and Safety of natural materials and manufacturing products made with natural materials – Part 3: Testing of the absence of contaminants

Additional information/question(s)