Form 4: New Work Item Proposal

Circulation date: 2022-04-05 Closing date for voting: 2022-06-28	Reference number: ISO/NP 17481 (to be given by Central Secretariat) ISO/TC 304 **N 302**
Proposer (e.g. ISO member body or A liaison organization) ISO/TC 304	
Secretariat ANSI	

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 NP.

Resource availability

☒ There are resources available to allow the development of the project to start immediately after project approval (e.g. project leader, related WG or committee work programme)

Note: If resources are not available, it is recommended that the project be first registered as a preliminary work item (a Form 4 is not required for this) and when the development can start, Form 4 should be completed to initiate the NP ballot.

Proposal (to be completed by the proposer)

Title of the proposed deliverable.

English title:

Conformity assessment requirements for bodies providing audit and certification of management systems. Part XX Requirements for healthcare quality management systems

French title:

(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 document specifies additional competence requirements for personnel involved in the audit and certification process for healthcare quality management systems and complements the existing requirements of ISO/IEC 17021 -1 and ISO/IEC 17021 -3

Purpose and justification of the proposal*

ISO 7101 is a management system standard intended to be used for accreditation of healthcare facilities. This new document will specify the requirements for personnel involved in the audit and certification process for healthcare facilities implementing ISO7101.

This new document will be supplementary to ISO 17021 Parts 1 and 3

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 1: No Poverty
Goal 3: Good Health and Well-Being for People
Goal 8: Decent Work and Economic Growth
Goal 10: Reducing Inequalities
Goal 12: Responsible Consumption and Production

Preparatory work (An outline should be included with the proposal)

☐ A draft is attached ☒ An outline is attached ☐ An existing document will serve as the 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 can be registered at Working Draft stage (WD - stage 20.00)
☐ Draft document can be registered at Committee Draft stage (CD - stage 30.00)
☐ Draft document can be registered at Draft International Standard stage (DIS - stage 40.00)

If the attached document is copyrighted or includes copyrighted content:

☐ The proposer confirms that copyright permission has been granted for ISO to use this content in compliance with the ISO/IEC Directives, Part 1 (see also the Declaration on copyright).

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 of the preferred type to be developed

☒ International Standard ☐ Technical Specification

☐ Publicly Available Specification

Proposed Standard Development Track (SDT)

☐ 18 months* ☐ 24 months ☒ 36 months

*Projects using SDT 18 are eligible for the 'Direct publication process' offered by ISO /CS which reduces publication processing time by approximately 1 month.

Draft project plan (as discussed with committee leadership)

Proposed date for first meeting: 2022-07-04

Dates for key milestones: Circulation of 1st Working Draft (if any) to experts: 2022-10-04

Committee Draft ballot (if any): 2023-06-28

DIS submission*: 2024-06-28

Publication*: 2025-06-28

*Target Dates for DIS submission and Publication should preferably be set a few weeks ahead of the limit dates (automatically given by the selected SDT).

For guidance and support on project management, descriptions of the key milestones, and to help you define your project plan and select the appropriate development track, see: go.iso.org/projectmanagement

NOTE: ISO/Meetings and ISO/Projects allow you to register and continuously update the meeting dates

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.

The proposed document will be developed with the cooperation and assistance of ISO/CASCO to ensure alignment with ISO 17021 parts 1 and 3

A listing of relevant existing documents at the international, regional and national levels ISO 17021 – 1 and ISO 17021 - 3		
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.		
	Benefits/impacts	**Examples of organizations / companies to be contacted**
Industry and commerce large industry	Certification can serve as a factor in making funding decisions (allocating loans, grants, etc) If costs are decreased due to heightened quality standards, the organization (health department, ministry of health) will have more capital to purchase equipment and hire staf	
Industry and commerce SMEs	Personnel conducting audits will benefit from having guidance on the application of ISO 7101. This in turn will assure healthcare workers that their facilities are being audited by competent people	
Government	Governments will have assurance that accreditation/certification of healthcare facilities is standardized. Implementation of a quality management system, auditing and certification can lead to decreased government spending. Improved health system quality results in lower mortality and morbidity, thus decreasing government burden, and increasing ability of citizens to be healthy and work. Improved health system quality means less people needing government assistance/disability. Governments will be able to show accountability and commitment to its citizens	Ministries of Health and ministries governing health and human services, such as long-term care and seniors
Consumers	Consumers will have an assurance of quality care being delivered by accredited healthcare facilities. Consumers will have a documented way to voice their concerns about the quality of care being received, as part of the accreditation process. Access to quality and affordable care will increase. Population health will increase, thereby decreasing poverty and improving quality of life.	Patient advocacy groups and patients

Labour	Healthcare personnel will benefit from working in an organization that has been accredited. Accreditation is an assurance of quality and competence on the part of both personnel and the way business is conducted and services delivered.	Labour unions whose members are engaged in healthcare delivery. Healthcare professions regulatory agencies
Academic and research bodies	When academic and research facilities are choosing health care organizations as partners for specific projects, such as clinical trials, they can be assured of the competence of a chosen healthcare facility if it carries a certificate of accreditation to ISO 7101.	Collective academic research organizations, national research facilities
Standards application businesses	Accreditation and certification agencies will benefit from the guidance provided by this new document. It will aid them in interpreting the requirements of ISO 7101 and assure standardization across the range of healthcare facilities that they serve. When this new document is used in combination with ISO17021-1 and ISO 17021-3, it will facilitate provision of competent services to clients and enhance the reputation of the accrediting organization	ILAC, ISQua, national/regional accreditation agencies
Non-governmental organizations	Accreditation/certification may help NGOs make decisions about the best use of their resources.	WHO, Health related Foundations and other similar philanthropic organizations.
Other (please specify)	ISO 7101 is expected to be adopted globally as the standard for assuring the competence and quality of services delivered by healthcare facilities. Most developed countries already have some form of certification/accreditation for healthcare facilities. This new document will serve to harmonize the processes across existing agencies, as well as new accreditation /certification agencies globally.	

Liaisons:	**Joint/parallel work:**
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.	**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.

All O members of ISO TC304 should receive this proposal

Note: The Committee Manager shall distribute this NP to the ISO members of the countries listed above to ask if they wish to participate in this work

Proposed Project Leader (name and e-mail address)	**Name of the Proposer** (include contact information)
Jan Mackereth-Hill jan.mackerethhill@gmail.com	Sheila Woodcock swoodcock@qseconsulting.com

This proposal will be developed by:

☒ An existing Working Group: ISO/TC 304/WG 5

☐ 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 (MA) and registration authorities (RA)

☐ 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 (provide details)

Draft Outline for 17021-1

Additional information/question(s)