一、国际标准新工作项目提案审核表填写要求

总体要求：只需要填写以下部分：“提案单位”、 “提案中、英文名称”、“提案类型”、“提案来源”、“提案科研情况”、“提案内容概要”、“提案立项可行性说明”。本表格现有内容不可修改，不可变更格式。

1. 提案单位：填写提案负责人所在单位全称，单位法人代表签名，加盖单位公章，并填写时间。如与港澳地区专家合作，与大陆地区单位要求相同。如与外籍专家联合提案，不必填写外籍联合提案人信息。注意：打印的单位名称必须与Form4中英文版填写的单位名称以及单位公章完全一致；如果公章较大，可以压上下线。
2. 提案名称、提案类型、提案来源、提案科研情况、提案内容概要：根据项目具体情况填写。“提案类型”在所选类型处划勾“√”，其中“技术报告”不可选。
3. 提案立项可行性说明：填写提案立项的背景、前期开展的工作以及立项主要困难等，如果已经参加过国际交流，请简要说明交流情况。

二、新工作项目提案表（Form 04）及附件填写要求

新工作项目提案表及附件

填写说明

注：请用中、英文填写此表格及附件各一份，中英文应一致。

1. 不必填写下表，也请不要修改：

|  |  |
| --- | --- |
| **Circulation date**  Click here to enter a date.  **Closing date for voting**  Click here to enter a date. | **Reference number:** Enter Number  (to be given by ISO Central Secretariat)  **ISO/TC** Enter Number **/SC** Enter Number  Proposal for a new PC  **N** Click here to enter text. |
| **Proposer**  ISO member body:  SAC  Committee, liaison or other¹:  Click here to enter text. |
| **Secretariat**  SAC |

1. IMPORTANT NOTE：请认真阅读该提示，根据最新版《ISO/IEC导则：第一部分》Annex C（内容点击链接即可）的要求填写本表格。
2. The proposer has considered the guidance given in the Annex C during the preparation of the NWIP.：请勾选。
3. Resource availability: There are resources available to allow the development of the project to start immediately after project approval\* (i.e. project leader, related WG or committee work programme)：请勾选。
4. English title：请不要含有"standard/specification/guide"词语,此表格和附件如果涉及“中医药”，请用"Traditional Chinese Medicine "，如需缩写，请用"TCM "。第一个单词、专有名词首字母大写，其余单词全部小写。
5. French title：如果不能提供请填写"N.A. "。
6. Scope of the proposed deliverable：请填写提案范围。
7. Purpose and justification of the proposal：请填写提案目的和依据，此为投票主要依据，如果地方不够，可以建附件。
8. Please select any UN Sustainable Development Goals (SDGs) that this document will support. For more information on SDGs, please visit our website at [www.iso.org/SDGs](http://www.iso.org/SDGs)."：请按照提案范围勾选。
9. Preparatory work ( An outline should be included with the proposal) ：按照ISO/TC249规定需要附草案，故勾选“A draft is attached”。如果特殊情况未附草案，应按实际情况选择。

The proposer or the proposer’s organization is prepared to undertake the preparatory work required：如无特殊情况，请选择“Yes”，即提案人将负责本项目的相关准备工作。

1. 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):

如无特殊情况，请选择第一项：即作为新工作项目注册。

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 clause 2.13 of the ISO/IEC Directives, Part 1 (see also the Declaration on copyright).

如果附现有文件作为草案模板，应按照最新版《ISO/IEC导则：第一部分》2.13条解决版权问题。

1. Is this a Management Systems Standard (MSS)?

如无特殊情况请选择"NO"：即此提案非管理系统标准。

1. Indication(s) of the preferred type or types of deliverable to be developed.

请根据提案实际情况进行选择。

1. Proposed development track (SDT).

如无特殊情况，请选择第二项：即标准制定周期为36个月。

1. Draft project plan (as discussed with committee leadership)：请列出关键节点的时间。
2. Known patented items (see ISO/IEC Directives, Part 1 clause 2.14 for important guidance) .

应按照最新版《ISO/IEC导则：第一部分》2.14条了解ISO的专利政策，如果有相关专利资料，请作为附件附上，并在“Annex(es) are included with this proposal (give details)”中填写名称。

1. Co-ordination of work

是否有类似的标准提案提交到其他标准制定机构？如无，请选择“No”，如有，请在下方写明详细信息。

1. 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.

如果没有相关标准，请声明；如果有，请按照要求详细说明。

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

如果有，请按照ISO/IEC、其他国际组织、国家文件顺序；如果没有，请填写"N.A. "。

1. 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).

请从相关利益方获益角度，说明具体益处，并列举。

1. Liaisons: 如无请填写"N.A."。
2. Joint/parallel work：如无可不必填写。
3. A listing of relevant countries which are not already P-members of the committee.

如无请填写“N.A.”。

1. Proposed Project Leader (name and e-mail address) .

此处填写提案人信息，请按以下格式填写：

称呼, 姓名;如Prof. XXX

单位全称（务必与单位公章一致）;

地址Add;

电话Tel;（请填写手机号）

传真Fax;

邮箱E-mail.

上述所有项目需填写完整，每一项占一行。

1. Name of the proposer (include contact information).

请不要修改。

1. This proposal will be developed by:

如无特殊情况，请选择第一项，即本提案将由现有WG制定，并填写WG编号。

1. Supplementary information relating to the proposal

如无特殊情况，请选择第一项，即本提案为新的ISO文件。

1. Maintenance agencies (MA) and registration authorities (RA)

如无特殊情况，可不必填写。

1. Annex(es) are included with this proposal (give details)：

请按以下格式填写：“Annex A(/B..)材料名称+of +提案名称”，如“Annex A Draft of +提案名称”。

1. Additional information/questions：

如无特殊情况，可不必填写。

**附录1：ISO/TC249工作范围**

ISO Technical Committee 249 Traditional Chinese Medicine (ISO/TC 249) focuses on the field of medical systems derived from ancient Chinese medicine which are able to share one common set of standards. Both traditional and modern aspects of these systems are included.

Standardization in the field of medical systems derived from ancient Chinese medicine which shall be able to share one common set of standards. Both traditional and modern aspects of these systems are covered. The committee focuses on quality and safety of raw materials, manufactured products and medical devices and of informatics, including service standards limited to involving the safe use and delivery of devices & medicine, but not into the clinical practice or application of those products.

**附录2：ISO/TC249 WG工作范围**

***1 Working Group 1***

**Title:** Quality and safety of raw materials and traditional processing

**Scope:** The scope of WG1 is to create standards related to raw materials at any stage up to and including harvest of a plant ingredient and collection of an animal or mineral ingredient, and the traditional processing of raw materials.

***2 Working Group 2***

**Title:** Quality and safety of TCM manufactured products.

**Scope:** The scope of WG2 is to create standards for testing, processing (other than traditional processing) and manufacturing of TCM and related products, from starting materials to finished products, in a framework of quality and safety.

***3 Working Group 3***

**Title:** Quality of acupuncture needles and safe use of acupuncture.

**Scope:** The scope of WG3 is standardization in the field of quality of acupuncture needles and safe use of acupuncture, not including the clinical treatment or efficacy of acupuncture.

***4 Working Group 4***

**Title:** Quality and safety of medical devices other than acupuncture needles

**Scope:** The scope of WG 4 is to develop standards for quality, safety and safe use of medical devices other than acupuncture needles, not including clinical treatment and efficacy of medical devices. Exclusion: the safety and/or performance of electromedical equipment (see ISO/TC249/JWG6).

***5 Working Group 5***

**Title:** Terminology and informatics

**Scope:** The scope of WG5 is standardization of TCM nomenclatures, terminology, classification and ontology. Health informatics technology, as it relates to TCM, shall be addressed within the scope of JWG1.

***6 Joint Working Group 1 with ISO/TC 215***

**Title:** Informatics

**Scope:** Health informatics technology related to TCM.

***7 Joint Working Group 6 with IEC subcommittee 62D***

**Title:** Electromedical equipment

**Scope:** The scope of JWG6 is standardization of the safety and/or performance of electrical equipment used in medical practice.

三、新工作项目提案检查核对表（Confirmation Check sheet for a New Work Item Proposal by Proposer）填写要求

**（一）提交要求**

1. Confirmation Check sheet for a New Work Item Proposal by Proposer英文版word文档。
2. 支撑材料中、英文版各一份word文档。

**（二）表格填写**

1. 请根据提案内容填写抬头及1.3即可，其他部分不必填写。
2. Proposer：在此处是指提案人。Contact details：请填写邮箱。
3. 已填写的部分不必修改。

**（三）支撑材料（Supporting document）**

1. 支撑材料请用中、英文各填写一份，中英文应完全一致。
2. 按照以下说明附支撑材料，并按序号标识清楚。
3. 1.3 Performance based or design prescriptive ISO deliverable：根据标准内容（基于性能、设计规定或二者兼有）进行选择，必要时建议附支撑材料。
4. 1.4 Necessary resources are available：即“项目团队已经具备的基础条件”，请提供支撑材料重点说明是否能够提供必要的人力、物力等支持。
5. 2-1 Effectively responds to market needs in the global marketplace：即“是否符合全球市场的需求”，请提供支撑材料具体说明。
6. 2-2 Responds to scientific and technical developments in various countries：即“是否符合全球科技发展”，请提供支撑材料具体说明。
7. 2-3 Distorts the market：即“扭曲市场”，请提供支撑材料。
8. 2-4 Has adverse effects on fair competition：即“妨碍公平竞争”，请提供支撑材料。
9. 2-5 Stifles innovation and technological development：即“遏制创新和技术发展”，请提供支撑材料。
10. 2-6 Gives preference to characteristics or requirement of specific countries or regions when different needs or interests exist in other countries or regions：即“标准所规定特征或要求仅限于特定国家或地区，而其他国家或地区有不同的需求或利益”，请提供支撑材料说明。
11. 3-4 Relevant affected stakeholder categories are clearly identified：即“受影响的利益相关方已经清楚确认”，请附支撑材料说明利益相关方。
12. 3-6 Benefits to be gained：需说明标准制定将为国际社会带来的益处，请附支撑材料。
13. 3-7 Product or service used in 5 and more countries：需说明产品或服务在5个及以上国家（地区）应用，请附支撑材料。

四、承诺书

承诺书仅供申报单位为港澳地区单位的申报人填写，由申报单位加盖公章。非港澳地区单位的申报人不必填写。

五、聘用证明

申报单位为港澳地区单位的申报人须提交受聘单位的出具全职聘用证明。非港澳地区单位的申报人不必填写。