NEW WORK ITEM PROPOSAL	
Date of presentation	Reference number (to be given by the Secretariat)
Proposer AFNOR	ISO/TC 217 / SC **N**
Secretariat ISIRI	

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: Cosmetics - Analytical Methods - Validation Criteria for analytical results using non chromatographic techniques

French title (if available): **Cosmétiques- Méthodes Analytiques** - Critères de validation des résultats analytiques obtenus avec des méthodes non chromatographiques

Scope of proposed project

To determine the validation criteria to be applied to non chromatographic analytical methods for cosmetics in order to check and assess the liability of the results obtained.

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)

Cosmetic products are diverse and complex. Their diversity and complexity is due to the large extent of their presentations, formulation matrices and nature of their components. General analytical methods exist or are to be developed to assess the quality of cosmetics. Such general methods are given to be pertinent for their intended use, widely usable, comprehensible and transferable. Nevertheless, their application to specific cosmetic matrices and to specific ingredient or traces, requires the use of specific validation criteria in order to assess the accuracy and liability of the results obtained.

A previous New Work Item has taken into account at the ISO level the validation criteria for results obtained using chromatographic methods (ISO DIS 12787)

In this context, this New Work Item Proposal aims to propose a dedicated approach for ingredients or traces in cosmetic products which will not use chromatographic methods. To illustrate this new work item the research of heavy metals or asbestos fiber in cosmetic products and potentially the research of nano-particules can be proposed.

Target date for availability (date by which publication is considered to be necessary) 2012

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

Relevant documents to be considered

- Validation of Analytical Procedures: Text and Methodology Q2 (R1), ICH Harmonised tripartite guideline, Oct. 1994 and Nov. 1996 (1st revision Nov. 2005)
- Validation of compendial methods, USP 25
- Guidance for industry. Analytical procedures and methods validation, US Departments of health and human services, FDA, Aug. 2000
- ISO 5725-1 to ISO 5725-4, ISO 5725-6, Dec. 1994
- European Pharmacopoeia, USP (To be discussed)
- Pharmacopeial Forum (USP) Vol 36(1) Jan-Feb 2010- Elemental impurities-Procedures (Chapter 23)

Relationship of project to activities of other international bodies

Liaison organizations	**Need for coordination with:** ☐ 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

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)
Mr. Marc André Lefebvre L'Oreal Research Center River Plaza. 25-29 Quai Aulagnier- 92665 ASNIERES-sur-SEINE cedex-France	Mrs Valerie BERNAT Association Française de Normalisation 11, Rue Francis de Pressensé 93571 La Plaine Saint-Denis Cedex France

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.

Proposals for correction (i.e. proposals for a Technical Corrigendum) should be submitted in writing directly to the secretariat concerned.

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.