



## FORM 1: PROPOSAL FOR A NEW FIELD OF TECHNICAL ACTIVITY

<b>Circulation date</b> 2019-09-28	<b>Reference number:</b> TS/P 283 (to be given by ISO Central Secretariat)
<b>Closing date for voting</b> 2019-12-21	
<b>Proposer</b> AFNOR	<b>ISO/TS/P 283</b>

A proposal for a new field of technical activity shall be submitted to the ISO Central Secretariat, which will assign it a reference number and process the proposal in accordance with the [ISO/IEC Directives Part 1, Clause 1.5](#). The proposer may be a member body of ISO, a technical committee, subcommittee or project committee, the Technical Management Board or a General Assembly committee, the Secretary-General, a body responsible for managing a certification system operating under the auspices of ISO, or another international organization with national body membership. Guidelines for proposing and justifying a new field of technical activity are given in the [ISO/IEC Directives Part 1, Annex C](#).

### **Proposal** (to be completed by the proposer)

<p><b>Title of the proposed new committee (The title shall indicate clearly yet concisely the new field of technical activity which the proposal is intended to cover).</b></p> <p>Surfaces with biocidal and antimicrobial properties</p>
<p><b>Scope statement of the proposed new committee (The scope shall precisely define the limits of the field of activity. Scopes shall not repeat general aims and principles governing the work of the organization but shall indicate the specific area concerned).</b></p> <p>Standardization of test methods used to assess the biocidal performance and efficacy of any surfaces with antimicrobial activities, including their compatibility with different families of disinfectants and cleaning agents. Such methods aim at evaluating the biocidal activity (i.e. that which irreversibly inactivates microorganism) and at differentiating it from the biostatic activity (i.e. the inhibition of the growth of microorganisms).</p> <p>The field of covers the assessment of surfaces displaying intrinsic biocidal properties and of surfaces processed by any means so as to deliver biocidal properties.</p> <p>Areas of interest include medical and veterinary applications, aerospace, agriculture, food hygiene and other industrial fields, institutional and domestic applications.</p> <p>Excluded: Toxicological and ecotoxicological surface testing methods, antimicrobial activities of textile products.</p>

- The proposer has checked whether the proposed scope of the new committee overlaps with the scope of any existing ISO committee**
- If an overlap or the potential for overlap is identified, the affected committee has been informed and consultation has taken place between proposer and committee on**
  - i. modification/restriction of the scope of the proposal to eliminate the overlap,**
  - ii. potential modification/restriction of the scope of the existing committee to eliminate the overlap.**
- If agreement with the existing committee has not been reached, arguments are presented in this proposal (under question 7) as to why it should be approved.**

**Proposed initial programme of work. (The proposed programme of work shall correspond to and clearly reflect the aims of the standardization activities and shall, therefore, show the relationship between the subject proposed. Each item on the programme of work shall be defined by both the subject aspect(s) to be standardized (for products, for example, the items would be the types of products, characteristics, other requirements, data to be supplied, test methods, etc.). Supplementary justification may be combined with particular items in the programme of work. The proposed programme of work shall also suggest priorities and target dates.)**

The proposed work programme is the following:

1) Standards to evaluate the basic biocidal activity of surfaces

Such standards will help evaluating the biocidal efficacy of surfaces, close to general ambient conditions, but without developing variations taking into account each specific set of use conditions. They will also provide tools to demonstrate the biocidal activity (i.e. that which irreversibly inactivates microorganisms) of surfaces, while providing disambiguation regarding biostatic activity (i.e. inhibition of the growth of microorganisms).

2) Standards to evaluate the biocidal activity of surfaces in various areas of application, integrating the effect of interfering substances, of specific microorganisms, of log reduction in correlation with field's and user's needs, including the ability to sustain the level of performance over time;

3) Any guidance documents that the TC would deem needed in support to the use of the standards envisaged here above. This may include guidance for performing hygiene with biocidal surfaces or publish round-robin tests results conducted in support of the standards.

**Indication(s) of the preferred type or types of deliverable(s) to be produced under the proposal (This may be combined with the "Proposed initial programme of work" if more convenient).**

Test method standards  
Technical specifications  
Guidance documents  
Technical reports

**A listing of relevant existing documents at the international, regional and national levels. (Any known relevant document (such as standards and regulations) shall be listed, regardless of their source and should be accompanied by an indication of their significance.)**

- ISO 22196 *“Measurement of antibacterial activity on plastics and other non-porous surfaces”*

National standards identified:

- NF S90-700 *“Surfaces with biocidal properties - Method for the evaluation of basic bactericidal activity of a non-porous surface”*
- ABNT NBR 16316 (2014-11) *“Antimicrobial copper surfaces - Requirements and test methods”*
- SANS 5730:2009\*SABS SM 730:2009 *“Antibacterial efficacy of solid and semi-solid antiseptics”*

Other reference documents:

- ASTM E 2180 *“Standard Test Method for Determining the Activity of Incorporated Antimicrobial Agent(s) In Polymeric or Hydrophobic Materials”*
- OECD Guidance Document on Quantitative Methods for Evaluating the Activity of Microbicides used on Hard Non-Porous Surfaces. ENV.JM.MONO(2014)18

**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. If seemingly similar or related work is already in the scope of other committees of the organization or in other organizations, the proposed scope shall distinguish between the proposed work and the other work. The proposer shall indicate whether his or her proposal could be dealt with by widening the scope of an existing committee or by establishing a new committee.)**

The proposed work programme is the following

- Standards to evaluate the basic activity of the surfaces and to differentiate the biocidal from the biostatic activity
- Standards or technical specifications to evaluate the activity of the surfaces in different areas, their related conditions of use and performance retention ability
- Guidance documents for performing day-to-day hygiene with biocidal surfaces

None of these items are covered by an existing ISO TC or SC. No transversal methods has been set in order to support and clarify end user choices for identifying surfaces with efficacy criteria in correlation with areas risks. Such lack of transversal standards leads to the impossibility to compare efficacy of different type of surfaces with antimicrobial and biocidal properties making those surfaces less used than their potentials for reducing contamination could ensure. There is no intend to developed materials specific standards.

It should be noted that ISO subcommittee 6 *Ageing, chemical and environmental on plastics and other non-porous surfaces*, which is related to the scope of the propose *resistance* of ISO/TC 61 *Plastics* has developed ISO 22196 *Measurement of antibacterial activity* d TC. However this standard is a test method mostly designed for a specific type of product, without possible distinction between biocidal and biostatic activities. Furthermore, the laboratory test conditions of the method are very far from generic ambient use conditions.

This standard so as other material specific's methods (eg: pr ISO 17721-1 and -2...) will be taken into account in the work.

International market already propose a wide range of products claiming to have antimicrobial properties (copper, ceramic, chemical treated surfaces, nanomaterials, silver...). The real added value of this new ISO TC will be to develop a holistic and global approach for evaluating the effectiveness of any type of biocidal surfaces (porous and non-porous) independently of the product compounds and for also taking into account the needs of different sectors.

In order to ensure consistency of ISO standards collection and to take into account needs from various sector and cooperation with technical committees wishing to apply standards for materials or product within their scopes, several liaisons are expected to be needed.

**A listing of relevant countries where the subject of the proposal is important to their national commercial interests.**

This standardization endeavor is intended to involve all countries, considering the numerous sectors concerned by this topic

**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). (In order to avoid conflict with, or duplication of efforts of, other bodies, it is important to indicate all points of possible conflict or overlap. The result of any communication with other interested bodies shall also be included.)**

To have feedbacks and cooperation with hygiene experts from various area:

ISO/TC 84 Devices for administration of medicinal products and catheters

ISO/TC 194 Biological and clinical evaluation of medical devices

ISO/TC 198 Sterilization of health care products

ISO/TC 209 Cleanrooms and associated controlled environments

ISO/TC 212 Clinical laboratory testing and in vitro diagnostic test systems

ISO/TC 217 Cosmetics

CEN/TC 205 Non-active medical devices

CEN/TC 216 Chemical antiseptics and disinfectants

To avoid conflict with sector-specific methods and to ensure cooperation with product specific bodies:

ISO/TC 26 Copper and copper alloys

ISO/TC 34 Food products

ISO/TC 35 Paints and varnishes

ISO/TC 38 Textiles

ISO/TC 45 Rubber and rubber products

ISO/TC 61 Plastics

ISO/TC 91 Surface active agents

ISO/TC 102 Iron ore and direct reduced iron

ISO/TC 107 Metallic and other inorganic coatings

ISO/TC 153 Valves

ISO/TC 189 Ceramic tile

ISO/TC 201 Surface chemical analysis

ISO/TC 206 Fine Ceramics

ISO/TC 229 Nanotechnologies

ISO/TC 261 Additive manufacturing

**A simple and concise statement identifying and describing relevant affected stakeholder categories (including small and medium sized enterprises) and how they will each benefit from or be impacted by the proposed deliverable(s).**

Prior proposing this committee to ISO members, AFNOR get confirmation from a wide range of stakeholders that such work would be of interest:

- SMEs, and more generally all manufacturers will benefit from ISO standards supporting and guiding their R&D and market assertions.
- Laboratories and testing houses will have clear testing methods to apply to assess the biocidal efficacy of surfaces.
- Product users will have a clear tools to recognize, compare and identify products that meet their expectations and needs
- Hygienists (governments, healthcare professionals, cleanrooms owners and users...) from a number of areas and sectors, for instance ..., ...and ..., will benefit from these new standards that will clarify and increase their trust in the marketing claims and facilitate product's benchmarks.
- Regulatory authorities can also use the standard to control product claims.

**An expression of commitment from the proposer to provide the committee secretariat if the proposal succeeds.**

If the proposal is accepted, AFNOR is willing to undertake the work of secretariat of the new TC, and is committed to providing all resources to successfully run the secretariat.

**Purpose and justification for the proposal. (The purpose and justification for the creation of a new technical committee shall be made clear and the need for standardization in this field shall be justified. Clause C.4.13.3 of [Annex C](#) of the ISO/IEC Directives, Part 1 contains a menu of suggestions or ideas for possible documentation to support and purpose and justification of proposals. Proposers should consider these suggestions, but they are not limited to them, nor are they required to comply strictly with them. What is most important is that proposers develop and provide purpose and justification information that is most relevant to their proposals and that makes a substantial business case for the market relevance and the need for their proposals. Thorough, well-developed and robust purpose and justification documentation will lead to more informed consideration of proposals and ultimately their possible success in the ISO IEC system.)**

The worldwide community agrees that infection or biological contamination prevention is still one of its biggest challenges of the next century. Based on the various existing products on the market and scientific researches since at least 20 years, biocidal surfaces have clearly a key role to play to reinforce current programs for fighting infections and the spread of pathogens. To achieve this objective, standardization of transversal testing methods to assess biocidal activity of any surfaces is necessary to ensure that we have reliable and performant surfaces.

Addressing antimicrobial and biocidal efficacies of surfaces independently of the product compounds is innovative and addresses a worldwide need of the market that is to evaluate biocidal efficacy of surfaces in order to reinforce available tools against pathogen microorganisms and reliability on the surfaces efficacy in use conditions.

Various sectors have to ensure contamination control such as:

- The medical sector:

Indeed, according to the World Health Organization (WHO):

- 1 in 10 patients catch an infection while receiving care,
- Effective infection prevention and control reduces healthcare associated infections by at least 30%.

Moreover, the colonization of undesired microorganisms on surfaces and on devices used in biomedical and clinical applications has become a persistent problem<sup>1</sup>:

- Donskey CJ *et al.* Beyond high-touch surfaces: Portable equipment and floors as potential sources of transmission of health care-associated pathogens, *Am J Infect Control.* 2019
- Kramer A. How long do nosocomial pathogens persist on inanimate surfaces? A systematic review *BMC Infect Dis.* 2006
- Boyle MA *et al.* Off the rails': hospital bed rail design, contamination, and the evaluation of their microbial ecology. *J Hosp Infect.* 2019
- Russotto V *et al.* Bacterial contamination of inanimate surfaces and equipment in the intensive care unit. *J Intensive Care.* 2015

- The food sector: food safety management, reduction of chemical preservative agent, heat method vs nutrition...

- The farming sector: reduction of pathogens microorganism, antibiotic resistance

- and also the pharmaceutical, cosmetics or transportation sectors

International standardized test methods are necessary not only for safety reasons but also for economic ones to facilitate the best choice for each use.

Several studies have underlined (non-exhaustive list) how surface cleaning could varied and the role of biocidal surfaces for reducing microorganism.

- Muller MP *et al.* Antimicrobial surfaces to prevent healthcare-associated infections: a systematic review. *J Hosp Infect.* 2016

- B.C Eckstein *et al*, Reduction of Clostridium Difficile and vancomycin-resistant Enterococcus contamination of environmental surfaces after an intervention to improve cleaning methods 2007
- Weber DJ *et al*. The role of the surface environment in healthcare-associated infections. Curr Opin Infect Dis. 2013
- Vincent M *et al*. Contact killing and antimicrobial properties of copper. J Appl Microbiol. 2018
- Francolini I *et al*. Antifouling and antimicrobial biomaterials: an overview APMIS. 2017

Effect of biocidal surfaces in a contamination control context, is alone, not sufficient to ensure safety but in combination with other safety devices/practices (Training, hand hygiene, surfaces disinfection and cleaning, air contamination control, water... ), it is part of a global system that highly reduces risks of infections. Creating such ISO committee and placing hygiene as the starting point of the creation of horizontal standards to evaluate antimicrobial and biocidal efficacy will support this objective.

**Signature of the proposer**

Alain COSTES,  
AFNOR Standardisation Director

*Further information to assist with understanding the requirements for the items above can be found in the [Directives, Part 1, Annex C](#).*