ISO/TC 198 Revised Strategic Business Plan

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STRATEGIC BUSINESS PLAN

ISO/TC 198, Sterilization of health care products

EXECUTIVE SUMMARY

ISO/TC 198 is responsible for specifying requirements for cleaning, disinfecting, sterilizing and aseptic processing of health care products together with associated equipment and ancillary products used in ensuring effective application of these processes. ISO/TC 198 is also responsible for harmonizing terminology related to its scope of work.

Health care products encompass medical devices, including in vitro diagnostic medical devices, and medicinal products (pharmaceuticals including biopharmaceuticals).

Processes addressed by ISO/TC 198 comprise those used both in industrial facilities and by health care facilities. Industrial sterilization processes were initially addressed in the work of ISO/TC 198 because of the need for international standards to facilitate global trade of sterile medical devices. Regardless of whether sterilization is performed in an industrial facility or health care facility, the requirements for developing, validating and routinely controlling the sterilization process do not vary.

ISO/TC 198 also addresses

- sterile barrier systems used to ensure the maintenance of the sterility of sterilized health care products,
- indicators for process validation and process monitoring,
- microbiological methods used in development, validation and routine control of processes,
- instructions for processing of reusable heath care products.

Standardization in these areas achieves two important goals:

1. Promoting good cleaning, disinfection and sterilization practices in order to prevent infections and support patient health.
2. Providing global standards that can be used by manufacturers and regulatory agencies in order to minimize technical barriers to trade due to differences in regulation of sterile health care products, health care products intended to be reprocessed, associated equipment and ancillary products.

Inspecting or testing a health care product after processing cannot demonstrate cleanliness, disinfection or sterility. Consequently, in specifying requirements for sterilization processes, aseptic processing, sterilizing equipment, washer-disinfectors, associated equipment and ancillary products, ISO/TC 198 helps ensure that processes and equipment employed provide assurance that health care products that need to be provided sterile, or for which cleanliness is critical, are in an appropriate condition for their intended use.

1 INTRODUCTION

1.1 ISO technical committees and business planning

The extension of formal business planning to ISO Technical Committees (ISO/TCs) is an important measure, which forms part of a major review of business. The aim is to

- align the ISO work programme with expressed business environment needs and trends,
- allow ISO/TCs to prioritize among different projects,
- identify the benefits expected from the availability of International Standards, and
- ensure availability of adequate resources for projects throughout their development.

1.2 International standardization and the role of ISO

The foremost aim of international standardization is to facilitate the exchange of goods and services through the elimination of technical barriers to trade.

Three bodies are responsible for the planning, development and adoption of International Standards: ISO (International Organization for Standardization) is responsible for all sectors excluding Electrotechnical, which is the responsibility of IEC (International Electrotechnical Committee), and most of the Telecommunications Technologies, which are largely the responsibility of ITU (International Telecommunication Union).

ISO is a legal association, the members of which are the National Standards Bodies (NSBs) of some 140 countries (organizations representing social and economic interests at the international level), supported by a Central Secretariat based in Geneva, Switzerland.

The principal deliverable of ISO is the International Standard.

An International Standard embodies the essential principles of global openness and transparency, consensus and technical coherence. These are safeguarded through its development in an ISO Technical Committee (ISO/TC), representative of all interested parties, supported by a public comment phase (the ISO Technical Enquiry). ISO and its Technical Committees are also able to offer the ISO Technical Specification (ISO/TS), the ISO Public Available Specification (ISO/PAS) and the ISO Technical Report (ISO/TR) as solutions to market needs. These ISO products represent lower levels of consensus and have therefore not the same status as an International Standard.

ISO offers also the International Workshop Agreement (IWA) as a deliverable which aims to bridge the gap between the activities of consortia and the formal process of standardization represented by ISO and its national members. An important distinction is that the IWA is developed by ISO workshops and fora, comprising only participants with direct interest, and so it is not accorded the status of an International Standard.

2 BUSINESS ENVIRONMENT OF ISO/TC 198

2.1 Description of the Business Environment

A large portion of health care products are either single use and sold sterile or are reusable and sterilized by health care providers prior to use. Most countries or regions regulate the sale of such products and many utilize standards to support their regulatory regimes. For such countries, International Standards for cleaning, disinfection and sterilization processes, aseptic processing, associated equipment and ancillary products promote the microbiological safety of health care products, facilitate trade among countries and increase regulatory and market efficiency. Even in countries that may not have well-established regulatory schemes, International Standards can promote effective practices by health care providers and help assure that products sold as sterile are, in fact, sterile (see section 3) and that reusable products that need to be clean, disinfected and sterilized prior to use are in a suitable condition for their intended use.

Relevant stakeholders in the work of ISO/TC 198 are

- National or regional regulatory authorities (for example, Argentinian ANMAT, Australian TGA, Brazilian ABNT, Health Canada, European Union competent authorities and notified bodies, Japanese MHLW, South Korea MFDS, UK MHRA and approved bodies, and U.S. FDA),

- International and national healthcare organizations and associations,
- Pharmaceutical industries,
- Medical device industries,
- Manufacturers of sterilizing equipment, washer-disinfectors and ancillary products,
- Notified bodies and testing laboratories,
- Health care providers and health care facilities,
- Patients and other users of health care products.

2.2 Quantitative Indicators of the Business Environment

Cleaned, disinfected and sterile health care products are used by or on virtually all individuals living in developed countries and by large segments of the populations of emerging economies. These may be reusable products that are reprocessed in hospitals or other health care facilities, or they may be single-use products that are sterilized as part of the manufacturing process and are packaged and shipped in a sterile state.

The largest markets for sterile medical products are in developed economies around the world. Markets in emerging economies are growing rapidly as those countries industrialize and modernize.

Given the diversity of the market (both geographically and in terms of the products covered by the standards of ISO/TC 198) and the lack of reliable public sales data, it is not possible to provide summary statistics of the total global market for sterile health care products and sterilization services. International trade in medical devices alone, however, was estimated at $543 billion in 2023 and was expected to increase in the coming years.[1]

3 BENEFITS EXPECTED FROM THE WORK OF ISO/TC 198

The specific benefits provided by the results of the ISO/TC 198 work can be organized as follows:

- Patient safety: Providing manufacturers of health care products and providers of health care with clearly defined requirements for cleaning, disinfection and sterilization processes and aseptic processing, associated equipment and ancillary products will help to decrease the probability that patients using health care products will be exposed to potentially pathogenic microorganisms.
- Economy: By providing international standards for processing and requirements for associated products, ISO/TC 198 will promote free and open international trade of sterile health care products, health care products that are to be sterilized, associated equipment and ancillary products.
- Market access: By providing international standards for cleaning, disinfection and sterilization processes and associated equipment and ancillary processes that can be utilised as the basis for national standards and to support regulations, ISO/TC 198 is helping to ensure that such regulations or standards do not become technical barriers to trade. These standards will also assist regulatory authorities as they are based on state of the art and best practices for the processes and associated equipment and ancillary products.

ISO/TC 198 recognises the United Nations Sustainable Development Goals on Climate Action and ISO's London Declaration and will strive to incorporate these principles where appropriate in future work.

4 REPRESENTATION AND PARTICIPATION IN ISO/TC 198

4.1 *Countries/ISO member bodies that are P and O members of the ISO committee*

[1] Skyquest. (2024). Global Medical Devices Market (Report ID SQMIG35J2050). Retrieved from https://www.skyquestt.com/report/medical-devices-market.

4.2 Analysis of the participation

Active participation on ISO/TC 198 includes both developed countries and countries with economies in transition. In addition, because most of the work items are being developed as joint ISO and European projects under the Vienna Agreement, most of the countries of the European Union are also involved in the work of ISO/TC 198.

The countries participating in ISO/TC 198 comprise the majority of the world's producers and consumers of health care products.

5 OBJECTIVES OF ISO/TC 198 AND STRATEGIES FOR THEIR ACHIEVEMENT

5.1 Defined objectives of the ISO/TC

ISO/TC 198 will continue to work on standards for sterilization processes and aseptic processing, with the goal of providing standards that can be used to develop, validate and monitor processes to:

- help assure that processes employed by manufacturers or health care service providers deliver an appropriate assurance of cleaning, disinfection and sterility;
- assist those performing such processes by providing standards to develop, validate and monitor such processes; and
- provide a body of standards that can be adopted or adapted by regulatory authorities in order to ensure regulatory transparency and international harmonisation of technical requirements for the production of clean, disinfected and sterile health care products.

ISO/TC 198 will also develop standards for associated equipment and ancillary products to:

- help assure that equipment for cleaning, disinfection and sterilization, together with associated accessories, are capable of delivering or monitoring processes as described above; and
- reduce the possibility that divergent national technical requirements for such equipment will act as technical barriers to trade for cleaned, disinfected and sterilized health care products or for cleaning, disinfection and sterilization equipment and accessories used to create such.

ISO/TC 198 will develop its standards using common terminology that can be accurately translated by all nations interested in adopting its standards.

For the specific work plan and work items, please see the ISO/TC 198 work programme.

5.2 Identified strategies to achieve the ISO/TC's defined objectives

ISO will continue to develop its standards in a cooperative approach with regional or national standards developers that have adopted and employed ISO/TC 198 standards.

ISO/TC 198 will work with CEN/TC 102, *Sterilizers and associated equipment for processing of medical devices*, and CEN/TC 204, *Sterilization of medical devices*, under the Vienna Agreement to develop joint International and European Standards.

ISO/TC 198 encourages national adoption of its standards and many have been adopted in North America, South America, Australia and Asia, either as national standards or by regulatory reference.

ISO/TC 198 will continue to seek to expand its membership and encourage active involvement from member bodies not currently participating in its work.

6 FACTORS AFFECTING COMPLETION AND IMPLEMENTATION OF THE ISO/TC 198 WORK

PROGRAMME

ISO/TC 198 does not see any specific structural or political factors that will inhibit progress on its work programme.

7 STRUCTURE, CURRENT PROJECTS AND PUBLICATIONS OF ISO/TC 198

This section gives an overview of the ISO/TC's structure, scopes of the ISO/TCs and any existing subcommittees and information on existing and planned standardization projects, publication of the ISO/TC and its subcommittees.

7.1 *Structure of the ISO committee*

7.2 *Current projects of the ISO technical committee and its subcommittees*

7.3 *Publications of the ISO technical committee and its subcommittees*

Reference information

Glossary of terms and abbreviations used in ISO

General information on the principles of ISO's technical work