BUREAU OF INDIAN STANDARDS

MEDICAL EQUIPMENT AND HOSPITAL PLANNING DEPARTMENT

(MHD)

AGENDA

Working Panel	Meeting No:	Date, Day & Time
Sustainability of Steel Surgical Instruments, MHD 04/ P8	3	18 November 2024, Monday, 3:00 PM

Via Webex platform

Meeting Link:
https://bismanak.webex.com/bismanak/j.php?MTID=m61ac29b9f393b55d151c841115368d8f

Meeting Number: 2514 300 6119

Password: MHD04P8

Convenor	Dr. Vikas Gupta, Additional Professor, ENT – Head & Neck Surgery, AIIMS, Bhopal.
Member Secretary	Karthik Reddy Katipally, Scientist-B, Bureau of Indian Standards.

ITEM 0 GENERAL

0.1 WELCOME ADDRESS BY MEMBER SECRETARY

0.2 OPENING REMARKS BY CONVENOR

ITEM 1 IDENTIFYING THE SUSTAINABILITY ISSUES TO BE ADDRESSED IN THE DRAFT.

Members are requested to provide their inputs on how sustainability of steel surgical instruments can be addressed. Sustainability Questionnaire is placed at ***Annexure-A.***

ITEM 2 DISCUSSION ON THE DRAFT

In the last meeting it was recommended that members of working panel will review the draft and provide inputs. However, No inputs were received on the draft. Draft is paced at ***Annexure-B.***

ITEM 3 IDENTIFICATION EXPERTS

ITEM 4 ANY OTHER BUSINESS

Annexure-A

Sustainability Questionnaire

1) RAW MATERIALS

1. Usage of Safer Materials
2. Usage of secondary raw materials/waste materials
3. Usage of alternative and renewable materials

2) PROCESS

1. Process Efficiency
2. Waste Minimization, Prevention and Management
3. Establishment of in-process Controls for Pollution Prevention
4. Lesser/Free of Ozone depleting chemicals, lesser/no Greenhouse gas emissions, no production of toxic compounds and by-products.
5. Enhanced energy efficiency and use of renewable energy sources
6. Enhanced water efficiency
7. Biodiversity impact

3) SAFETY AND HEALTH

Process/Use safer conditions

4) PACKAGING

Use of safe/eco-friendly/biodegradable packaging materials

5) USE/OPERATION

Biodegradability/recyclability/reparability or reusability either in part or as a whole

6) END OF LIFE

1. Safe and sustainable disposal practices
2. Waste generation and management

7) LIFE CYCLE ANALYSIS

1. Life cycle analysis would generally comprise analysis of impact on environment as high/medium/low during following stages:
2. Raw material sourcing and extraction
3. Manufacturing processes
4. Distribution and transportation
5. Use phase impact
6. End-of-life disposal or recycling

Annexure-B

Draft

Sustainability of Steel Surgical Instruments

1. Scope

This standard provides guidance on implementing sustainable practices in the life cycle of steel surgical instruments. Various aspects for achieving sustainable goals i.e, design, manufacturing process, product usage, and end-of-life management of steel surgical instruments used in healthcare settings.

2. Normative References

IS/ISO 7153-1 Surgical instruments – Metallic materials.

IS/ISO 14971: Medical devices – Application of risk management to medical devices.

IS/ISO 13408-1 : 2008 Aseptic processing of health care products Part 1 General requirements

IS/ISO 11607 : 2019 Packaging for terminally sterilized medical devices Part 1: Requirements for materials sterile barrier systems and packaging systems First Revision

IS/ISO 11607 : 2019 Packing for Terminally Sterilized Medical Devices Part 2 Validation Requirements for Forming Sealing and Assembly Processes (First Revision)

ISO 14040:2006 Environmental management — Life cycle assessment — Principles and framework

ISO 14044:2006 Environmental management — Life cycle assessment — Requirements and guidelines

ISO 14045:2012 Environmental management — Eco-efficiency assessment of product systems — Principles, requirements and guidelines

ISO/TS 14072:2014 Environmental management — Life cycle assessment — Requirements and guidelines for organizational life cycle assessment

ISO 59014:2024 Environmental management and circular economy — Sustainability and traceability of the recovery of secondary materials — Principles, requirements and guidance

3. Terms and Definitions

(can be added at a later stage)

4 Material Sourcing

Raw Materials for the manufacturing of steel surgical instruments can be sourced from steel plants, can also be sourced from used surgical instruments. Surgical instruments in general are

manufactured out of SS300 and SS400 series given in IS/ ISO 7153-1. Both types of SS that are often used within the Operating Room are recyclable by means of melting and reprocessing. Stainless steel offers great prospects for recycling. Its long service life, recyclability, and valuable raw materials make it an excellent environmental performer. It's actively recycled on a large scale by remelting scrap to manufacture new steel without altering the material's properties, creating a closed loop.

When the raw materials are sourced from health care settings materials should be disinfected before proceeding for recycling. Established regulations shall be followed in procuring such materials. The disinfection protocols should be documented and validated.

5 Design Considerations

In the market, reusable and disposable instruments are available depending on the applications. The reusable products are commonly made from high-quality stainless steel which can be sterilised and reused for several years. The disposable products were originally intended for exceptional circumstances or conditions where proper disinfection is of utmost importance but cannot be guaranteed (e.g. disasters like earthquakes, areas with a high rate of HIV infection).

Instruments should be designed for durability, ease of disassembly, and maintenance. Design principles should comply with ISO 14971 to ensure risk management is integrated into the design process. Materials should be optimized to reduce waste.

Manufacturing should minimize energy consumption, waste, and emissions, adhering to the environmental management systems outlined in ISO 14044 series.

6) Manufacturing process

There are two primary methods for steelmaking, the basic oxygen furnace (BOF) process and the electric arc furnace (EAF) process. The BOF process involves blowing oxygen into the molten iron to remove impurities, such as carbon, silicon, and phosphorus. This is achieved by a chemical reaction that oxidizes these elements and forms gaseous byproducts. The addition of scrap steel further enhances the quality and desired composition of the steel. The BOF process is commonly used for large-scale production of steel, particularly in integrated steel plants. The EAF process utilizes an electric arc generated by graphite electrodes to melt the scrap steel. Unlike the BOF process, which relies on iron ore as the primary raw material, the EAF process mainly utilizes recycled steel. The electric arc provides the necessary heat to melt the scrap, and the composition of the steel can be adjusted by adding various alloys and fluxes.

The vast majority of steel recycling involves re-melting scrap to produce new steels with no change in the inherent properties of the basic steel material, and therefore, steel recycling can be regarded as closed loop. The EAF process is more flexible, efficient, and environmentally friendly, making it suitable for smaller-scale steel production or for specialized steel grades. After the steel has been produced using either the BOF or EAF process, it undergoes further refining to ensure the desired properties and quality. In comparison to blast furnaces, the carbon

footprint of EAFs is drastically diminished. CO2 emissions can be substantially reduced in comparison to conventional methods. Reduction in net energy consumption as a result of electric power. Significant Potential for further emission reductions via electricity generation from renewable energy sources.

The final stage of the steelmaking process involves various finishing treatments to enhance the steel's properties and meet specific customer requirements. These treatments include heat treatment, rolling, forging, coating, and surface finishing. Heat treatment processes, such as quenching and tempering, can improve the steel's hardness, strength, and ductility. Rolling, forging, and shaping operations convert the cast steel.

Any inputs on addressing Process Efficiency, Waste Minimization, Prevention and Management, Establishment of in-process Controls for Pollution Prevention, Lesser/Free of Ozone depleting chemicals, lesser/no Greenhouse gas emissions, no production of toxic compounds and by-products, Enhanced energy efficiency and use of renewable energy sources, Enhanced water efficiency .

7) Packaging

Sustainable choices must be made despite challenges in the medical sector, such as replacing traditional plastics with recyclable or biodegradable materials to reduce landfill waste. Non-biodegradable plastics, which contribute to microplastic pollution, should be replaced by eco-friendly alternatives like starch, cellulose, chitosan, or protein-based bioplastics. Advances in plastic-degrading enzymes and bioplastics should be explored, keeping in mind their scalability and cost-effectiveness.

Eco-friendly packaging materials and methods shall be used, with a preference for sustainable, bio-based, or biodegradable materials that minimize the use of single-use plastics and reduce environmental impact. Packaging shall provide strength, durability, and light weight, minimizing material usage while ensuring sterility and protection. Efforts must be made to reduce unnecessary packaging, and reusable containers or refillable versions of products should be developed. Materials used in packaging shall not leach harmful substances into the environment.

Sterile packaging, essential for patient safety, shall be produced with minimal plastic usage where feasible. Bioplastics, including starch-based and chitosan-based materials, must be considered as viable alternatives for sterile medical packaging.

Protective packing materials for delicate medical equipment shall be made from recycled or biodegradable materials, such as paper bubble wrap, shredded cardboard, and biodegradable foam peanuts. Closed-loop recycling of packaging materials should be implemented to minimize waste and create sustainable life cycles.

More detailes can be added by referring to IS/ISO 13408-1 : 2008 Aseptic processing of health care products Part 1 General requirements

IS/ISO 11607 : 2019 Packaging for terminally sterilized medical devices Part 1: Requirements for materials sterile barrier systems and packaging systems First Revision

IS/ISO 11607 : 2019 Packing for Terminally Sterilized Medical Devices Part 2 Validation Requirements for Forming Sealing and Assembly Processes (First Revision)

8) Maintenance

The information regarding cleaning, disinfection and sterilization should be provided by the manufacturer .

There are two types of instruments, single use and multi- use, single use instruments should be disinfected and Sterilization methods should minimize environmental impact, such as using steam sterilization (autoclaving) which is compliant with ISO 17665-1 or alternative methods that reduce chemical usage. Sterilization procedures must maintain the instrument's sterility as per ISO 17664.

Instrument Maintenance: Manufacturers must provide detailed maintenance guidelines to ensure the longevity of the instruments. Regular maintenance procedures should follow standards outlined in ISO 17664.

9) End-of-Life Management

Stainless steel objects should never be discarded as waste at the end of their useful life. Instead, they should be separated, recovered, and reintroduced into the production process through recycling. Stainless steel contains valuable materials like chromium and nickel, which make its recycling economically viable. Instruments that cannot be recycled should be disposed of in a manner that minimizes environmental impact, following the Biomedical Waste Management Rules, 2016.

10) Life cycle assessment (LCA)

LCA assists in identifying opportunities to improve the environmental performance of products at various points in their life cycle, informing decision-makers in industry, government or non-government organizations (e.g. for the purpose of strategic planning, priority setting, product or process design or redesign), the selection of relevant indicators of environmental performance, including measurement techniques, and marketing (e.g. implementing an ecolabelling scheme, making an environmental claim, or producing an environmental product declaration).

LCA addresses the environmental aspects and potential environmental impacts (e.g. use of resources and environmental consequences of releases) throughout a product's life cycle from raw material acquisition through production, use, end-of-life treatment, recycling and final

disposal. The Manufacturer/ Industry is recommended to conduct LCA according to ISO 14044.

11 . Documentation and Labelling

Implementing an ecolabelling scheme, making an environmental claim, or producing an environmental product declaration –

The manufacturer should provide the following documentation
Instructions to clean