HEALTHCARE SURFACES INSTITUTE
A Division of ISSA

FINAL DRAFT

March 2025

Request for Information: Materials and Assemblies Compatibility Testing Services

Introduction

The Healthcare Surfaces Institute (HSI), a division of ISSA, is requesting information from testing laboratories for compatibility and validation testing services of manufactured medical devices that are intended to be reprocessed using standard disinfectants and are found in the medical environment.

HSI is also interested in the facility's willingness to act as an advisor in the development of the Standard for validation of the testing methods and certification of the results.

Purpose

The purpose of this RFI is to gather information from each responding laboratory that may meet the goods, services and operational needs outlined below.

HSI is taking action to define how surfaces are designed, manufactured, installed, and maintained to significantly reduce the spread of Healthcare Associated Infections (HAIs). Compatibility with healthcare cleaning and disinfecting agents holds the key to preventing continued transmission of microorganisms and the causation of HAIs on one or more surfaces used in healthcare product design, fabrication, and market readiness

Goods, Services and Operational Needs

Contributing to the Development of Testing and Compatibility Standards

1. The responding Testing Laboratories must show evidence that they possess experience, knowledge and certification in the testing of non-textiles including but not limited to hard surface, rigid materials, plastics, elastomers, silicone for manufacturing of device assemblies that will be used and reprocessed in the healthcare environment per the following:
    a. ISO 17025 Certified
    b. Good Laboratory Practices -GLP

c. A2LA accredited testing laboratory by AOAC with:

    1. Independent assessment of your lab's data accuracy and reliability
    2. Comprehensive testing programs provide a wide array of analytes/matrices/ and specific elements of the required outcomes of Standards
    3. High quality, homogeneous, stable testing samples that arrive ready to test
    4. Confidential and secure website to enter data and access historical data and reports
    5. State of art detailed automated reporting
    6. Responsive technical support
    7. Access to international quality experts

d. ASTM, FDA or other regulatory standards and guidelines agencies

2. HSI desires to use the expertise of responding Testing Laboratories in creating and updating of the current standard draft titled: "Standard Testing for the Validation of Cleaning and Disinfection (C&D) of Reusable Medical and other Devices and Assemblies in the Medical Environment". This shall consist of:

    a. understanding the goals of the standard,

    b. what current testing exists or new testing modalities that will need to be developed to effectively achieve the required outcomes, and

    c. to develop actionable reports to provide to the manufacturer whose materials or assemblies were tested to these HSI standards.

Process for Submitting Products for Testing

3. The responding Testing Laboratories should provide a process for manufacturers to submit products to include:

    a. Required Packaging for product shipment to the labs

    b. Intake form information fields need to understand the design capabilities and requested testing.

    c. Specific questions about the submitted assemblies that will assist in the testing process and uphold the Standard. Example, power requirements.

    d. Policies that the Testing Laboratory may have pertained to requesting additional products/materials to complete testing, return of tested products, special circumstances regarding product/materials submitted, etc.

    e. Other pertinent information that the Testing Laboratory may be required to assure final test results

Reference accounts

4. The willingness of the Testing Laboratory to provide up to 3 references accounts that may have previously used their services for testing like those being requested in this RFI.

Please provide the following information when submitting your response:

Company Overview

- Provide a brief overview of your company. (Please include history, expertise, and relevant experience.)
- Is your company bonded or insured? (Please list type and what dollar amount.)
- Does your company function primarily as a testing laboratory for medical devices? If not, please list other testing modalities that you provide, and which industries solicit your services.
- What is your capacity to expand your testing services to onboard this new business need?
- Are the employees in your laboratory certified and authorized to perform the testing? If so, what type of certification and by which agencies.
- Do you have knowledge of the following certifications?

    1. ISO 17025 Certified
    2. Good Laboratory Practices -GLP
    3. A2LA accredited testing laboratory by AOAC
    4. ASTM, FDA or other regulatory standards and guidelines agencies

- Please list the current certifications your testing laboratory has.
- Provide your company's experience with handling microorganisms in the case that it becomes a requirement of testing.
- Please upload a copy of your NDA policies and requirements and intellectual property policies.
- Please detail your facility's experience with and examples of testing standards development.

1. Proposal and Implementation:

- Provide a description of how your testing laboratory proposes to provide the goods and services, including key elements that meet the operational needs outlined above.
- Outline an implementation process to include a timeline to accomplish the tasks including setting up the specific testing environment if needed, sample testing of the Standard Procedures from beginning to end and start of test offering to manufacturers to meet a Q1 2026 launch.

- Describe your company's support for manufacturers including issue resolution processes and response times.
- Provide any other relevant information and data to assist the HSI RFI Committee in fully understanding your facility's ability to satisfy the goods, services and operational needs described.

Address questions to:

Linda Lybert, Executive Director, lindal@issa.com

Please submit your response electronically via the submission form.

Thank you for your interest in this opportunity. Testing Laboratories will be notified if they will receive a formal RFP by April 1, 2025.

Healthcare Surfaces Institute, a Division of ISSA https://healthcaresurfacesinstitute.org/