Scientific Equipment & Furniture Association
SEFA Lab Grade Washers Committee
Web Meeting Minutes
Tuesday, March 12, 2024 - 11:00 AM EST

Present:	**Co-Chair** :	Kelly Williams	LABCONCO
	Attendees:	Abbie Gregg	AM Technical Solutions
		Punit Jain	Cannon Design
		Jeff Talka	JT Architectural Solutions
		Kurt Rindoks	Kewaunee Scientific
		Dave Edwards	The S/L/A/M Collaborative
	Guest :	Sterling Greni	LabBuild
	SEFA Staff:	Barbara Carr	
		David J. Sutton, Executive Director, Gen'l Counsel	
		Ross Sutton	

At 11:03 AM Kelly Williams welcomed everyone and called the Lab Grade Washers Meeting to order at 11:03 AM. David Sutton reminded everyone that this Committee was formed as a result of the Advisory Board's request that SEFA work on developing standards for all of the equipment in the lab environment.

The first item on the Agenda was a review and approval of the Purpose, Scope and Definitions. Kelly read the purpose as drafted. Jeff Talka asked about the use of the term "lab instruments" at the end of the Purpose. After discussion, the committee substituted "lab instruments" with "washable lab implements" ("Labware"). It was also suggested that the "Industry Standard Practices" should be changed to lower case type.

Kurt Rindoks said this was a good first step for the standard and also indicated that since this is a new standard for SEFA there will likely be terms will need to be added to SEFA 4 – Glossary of terms. He suggested that the term "Lab Grade Washer" should be added to Glossary.

Kelly then reviewed the draft of the Scope. Jeff Talka suggested adding the following language to the end of the second paragraph "and other relevant systems supporting the Lab Grade Washer." In addition the Committee discussed and agreed to the addition of the following points:

- The Laboratory Grade Washer Standard will address the required facilitization of the laboratory grade washer system.

- The Laboratory Grade Washer Standard does not address regulatory sterilization and reprocessing of glassware and other labware.

Kelly called for a motion to approve the Purpose and Scope as amended. The motion was made by Abbie Gregg, seconded by Kurt Rindoks and unanimously approved.

A question was raised concerning the different levels on clean for different lab applications. Jeff Talka said that there are standards that address clean as well as sterile and the Committee should look into this. Some possible references might be GMP standards; 21 CFR; and ISO. Abbie Gregg indicated that Sigma Aldrich (https://www.sigmaaldrich.com) has a lot of information on optizimation and cleaning glassware. Abbie shared some links in the Chat which are attached to these minutes.

At 12:03 PM Kelly thanked everyone for their participation and input. She indicated that she would share the information from this meeting with Co-Chair, Josh Camp and they would work on identifying the next steps to move forward.

The meeting was adjourned on motion by Kurt Rindoks seconded Punit Jain and unanimously approved.

ACTION ITEMS – SUGGESTIONS

- **Set up a separate running list of new terms relevant to this Standard for inclusion in the Glossary of Terms;**

Me to Kelly 11:37 AM facilitization
Punit Jain to Everyone 11:38 AM FACILITIZATION means placement and rough hook-up of electrical, gas, and vacuum utilities to the Equipment and Items.
Me to David Sutton 11:47 AM Can you see her screen now?
David Sutton to Everyone 11:59 AM yes. I signed in again
Abbie Gregg to Everyone 12:00 PM
https://www.sigmaaldrich.com/US/en/technical-documents/protocol/chemistry-and-synthesis/reaction-design-and-optimization/cleaning-glassware
Jeff Talka to Everyone 12:00 PM I need to sign off. Thanks to all.
Abbie Gregg to Everyone 12:02 PM
https://mycoscience.com/how-to-perform-cleaning-validations-for-glassware/
Abbie Gregg to Everyone 12:06 PM
Look for an analytical service…
Request a quote
France
Belgique
Suisse
SECTORS OF ACTIVITY
OUR SERVICES
TRAINING
OUR TECHNICAL RESOURCES
ABOUT US
CONTACT
Home • Our services • Expertise • Laboratory analysis of cleaning residue found on Medical Devices in accordance with the ISO 19227 standard • Method validation according to ISO 19227

Method validation according to ISO 19227
Manufacturers of Medical Devices, you want to validate a method according to the ISO 19227 standard?
What is a method validation according to ISO 19227?
Method validation consists of guaranteeing the performance of a method by examination and providing objective proof of its use.

Furthermore, the ISO 19227 standard is specific to the field of medical devices. Indeed, ISO 19227 describes the requirements for the cleanliness of orthopaedic implants and the validation of the cleaning processes used.

Why validate your method according to ISO 19227?
The objective of cleaning validation via ISO 19227 is to verify the effectiveness of the cleaning process in reducing physical, chemical and microbiological contaminants below a customer-defined level.

To achieve this, the evaluation and validation of cleaning methods requires a thorough knowledge of the orthopaedic implant manufacturing process in order to identify potential contaminants and potential interactions between the cleaning process, the implant materials and the environment.
Abbie Gregg to Everyone 12:07 PM Do not expect lab glassware to be included in the processing equipment cleaning validation program. Glassware must, of course, be clean and the CGMPs consider lab equipment to be included in the scope of 211.67.

The assurance of cleanliness is best assessed by inspecting laboratory procedures for the use of non-dedicated glassware and other equipment, method validation (ruggedness, e.g.), and the absence of extraneous or interfering data in the results of sample analyses. Lab cleaning procedures may include repetitive rinses with the solvent used to prepare the analyte and oven drying. The equipment need not be swabbed or otherwise tested to ensure removal of potentially contaminating residues. A firm may elect to sample its glassware for residual contamination to exclude or explore the possibility of interference in the case of particularly sensitive analyses or highly difficult to clean compounds. The possibility of carryover contamination affecting a method's performance or integrity of the results is generally considered to have a low risk to product or consumers. Contaminated lab equipment, however, should not be a frequent excuse for rejecting or discarding aberrant results. We expect that firms maintain lab equipment in a clean and sanitary manner so as to provide confidence in the results of analysis.