Title: Standard Operating Instruction: ISO 14698 Compliant Sampling	ATS-SOI-5815	**Page:** 1 of 5
	Revision: B	**Effective Date:** 18 JUN 2014

Approval Block		
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Historical Reference Section:

Section Name	***Section Number (i.e., 5.2.1)***	***Revision Affected***	***Explanation of Change***
Approval block	**N/A**	**A**	**Added Approval Block**
Responsibility	**6**	**A**	**Changed Certification Manager to President**
References	**3**	**A**	**Updated References**
References	**3**	**B**	**Updated References**

1. Purpose

This document provides instruction for air and contact viable sampling and incubation of samples for ISO 14698 compliant systems.

2. Scope

This procedure shall be followed by personnel performing viable sampling. Additional testing and or deviation from this SOI shall be agreed upon prior to the start of testing.

3. References

1. ATS-SOI-5950 Rev (B) Standard Operating Instruction: Operation of Viable Air Sampler
2. ISO 14698
3. ATS-SOI-5820 Rev (A) Standard Operating Instruction: Viable Sample Workflow

4. Equipment and Materials

Equipment:

1. VAI SMA-P-100 Viable Air Sampler or equivalent

5. Safety

1. Wear proper attire as specified by facility SOP or as instructed by facility point of contact.

2. Avoid lifting heavy equipment. Wait for help from another employee prior to lifting any heavy equipment.

3. Avoid reaching while working on a ladder. Move the ladder to ensure proper access to your concern. Do not step on the top two rungs of a step ladder.

4. Refer to manufacturer's safety precautions and Material Safety Data Sheet (MSDS) for appropriate protective equipment and safe handling procedures when using chemicals.

6. Responsibility

1. It is the responsibility of the President to maintain this document and oversee these activities.

2. It is the responsibility of the individual(s) performing this task to follow this procedure.

7. Preliminary Operations

1. Collect all materials and equipment necessary to conduct the project.

2. Ensure all equipment is within calibration prior to the start of use.

3. Wipe down all equipment in accordance with the facility SOP or use a 70% IPA, 30% water solution unless otherwise instructed by the facility point of contact.

8. SAMPLING PROCEDURES

A. Viable Air Sampling

1. Purpose

This purpose of viable airborne sampling is to determine whether airborne contaminants exist within the zone and if the zone meets the sterility requirements of ISO 14698.

2. Apparatus / Description

Portable SMA (SMA-P100). The SMA Atrium is used for the quantitative collection of microorganisms that may be present in air. The design and construction assures that a sterile test instrument is present to evaluate possible viable contaminants.

3. Procedure

3.1. Setup

a. Ensure that all equipment and connection devices are properly cleaned and sterilized as required prior to start of test setup. Refer to operating manual for proper cleaning and maintenance of equipment.

b. Put on gloves suitable for sterile sampling and spray gloves with 70% isopropyl alcohol or decontaminate gloves in accordance with facility SOP.

1. Ensure that two plates from each lot number are set aside and marked as positive and negative samples for growth verification for the entire lot. If there are not enough plates to spare, you must use a separate lot for sampling.

c. Place SMA-P100 sampler in an unobstructed location. Record the location.

d. Remove the top half of the atrium and disinfect the inside with 70% isopropyl alcohol, being careful not to touch the surfaces in which the sampling media will be located.

e. Aseptically place a 100 mm agar plate on the atrium using the technique described in the instructions provided with the sampling media. Always be sure never to touch the sampling media at any time during the sampling procedure.

f. Replace the top of the atrium.

3.2 Sampling

a. Turn on the SMA-P100 sampler.

b. Set the sample duration in accordance with the operating manual. For spaces which are defined as ISO Class 7 or ISO Class 8, 400L of air will be sampled. For spaces defined as ISO Class 5, 1000L of air will be sampled.

c. Aseptically place the media in an approved container for transport (See ATS-SOI-5820.) Label each container per instructions provided with the sample media.

B. Viable Contact Sampling

1. Purpose

This purpose of viable contact sampling is to determine whether the walls and floors of the zone meet the sterility requirements of ISO 14698.

2. Apparatus / Description

   Swabs or RODAC Plates. The Swabs or RODAC plates are used for the quantitative collection of surface microorganisms.

3. Procedure

   3.2. Setup

   a. Put on gloves suitable for sterile sampling and spray gloves with 70% isopropyl alcohol or decontaminate gloves in accordance with facility SOP.

      1. Ensure that two plates from each lot number are set aside and marked as positive and negative samples for growth verification for the entire lot. If there are not enough plates to spare, you must use a separate lot for sampling.

   3.3 Sampling

   a. Aseptically sample a 2" x 2" area with the swab or RODAC Plate using the technique described in the instructions provided with the sampling media. Always be sure never to touch the sampling media at any time during the sampling procedure. Record the location of the sample.

   b. Aseptically place the media in an approved container for transport (See ATS-SOI-5820.) Label each container per instructions provided with the sample media.

9. Field Chain of Custody for Samples

1. Field Chain of custody forms shall be filled out in their entirety prior to shipping samples. See ATS-SOI-5820 for details.