

# Standard Operating Procedure

## Title: Microbiological Monitoring of Plant Water Systems

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### 7. Bioburden Waste Tank Water Sampling

#### 7.1. Sampling

Waste tanks are usually in the non sterile area. Trained Microbiology staff are responsible for sampling from these machines. Sampling is to be carried out using a sterile 10mL pipette into a pre-sterilised 20mL bottle. Sampling of machine waste water tanks may be conducted as part of a larger investigation. Sampling of waste water tanks is not routinely required.

#### 7.2. Test Method

Filter appropriate volume in order to determine count from wast water. Follow procedures outlines for routine bioburden testing of water samples (Section 3.0)

#### 7.3. Results

After incubation, the total count for each machine is recorded in appropriate log book.

Alert level 2cfu/0.1mL

Action level: 5cfu/0.1mL

Further identification of isolates should be assessed on case by case basis, depending on the reason for conducting sampling in the first instance.

### 8. Clean Steam Sampling & Testing

#### 8.1. Sampling

8.1.1. The microbiological quality of clean steam is to be tested on an annual basis as per validation protocols.

8.1.2. Samples are to be collected by a trained and competent operator as listed below.

- 1 x 500mL condensed steam bioburden sample, in sterile Schott bottle.
- 1 x 3ml condensed steam pyrogen sample, in de-pyrogenated sample container.

#### 8.2. Test Method and Results

8.2.1. Clean steam is to be treated as WFI for the purpose of testing and should be tested for Bioburden and Endotoxin as outlined in Section 3.0 and 4.0 above.

8.2.2. Record results directly into Validation protocol. Any colonies if present are to be Gram stained and identified to at least Genus level. WFI Alert and Action levels apply to clean steam.

8.3.3 If spore forming organisms are isolated, their heat resistance must be evaluated according to MICLAB 065

Alert level: D-value of 1.5min.

### 9. OOL/OOS Result Actions

9.1. Initiate a Laboratory Investigation as per MICLAB 110. Microbiology Laboratory Investigation and Retest Procedure for Atypical Results and Out-of-Specification Results. Initiate a phase 1 investigation and record details in the investigation form.

9.2. In the initial instance of recording an OOL/OOS result, Allocate the plate and colony types a colony identification number as per procedure MICLAB 070. and record the Identification number in the comments. Record the identification numbers on the isolate identification form Form 675 and complete the initial required sections of the form.

9.3. Colony types are to be gram stained and colony and gram morphologies recorded in form Form 675. Gram Negative rods isolated from Chiller, purified and WFI water are to be identified to species level.