**Quality Assurance (QA) Summary Template for**

**A-9kdj Dataset**

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| --- |
| **Research Effort Title: Development and Application of Analytical Method for Decontamination Testing of Virucidal Chemicals on Porous and Heavily Soiled Surfaces** |
| **Date: September 11, 2018** |
| **QAPP Title/Version #/Approval Date**  **Decontamination of Heavily Soiled Surfaces Phase 2: Decontamination Study**  **Revision 0 and Amendments**  **November, 2014** |
| **Research Effort Lead:**  **Michael Worth Calfee** |
| **Supervisor:**  **Paul Lemieux** |
| **SDM Manager:**  **Eletha Roberts** |
| **QA Manager:**  **Eletha Roberts** |

1. Did the Research Effort Lead (or designee) verify the dataset?

|  |  |
| --- | --- |
| Yes | X |
| No |  |

1. Were there deviations from the approved QAPP, or other planning documents, that impacted the dataset?

|  |  |
| --- | --- |
| Yes |  |
| No | X |

If yes, describe:

1. Were all QA/QC verification checks performed as specified in the QAPP or SOP?

|  |  |
| --- | --- |
| Yes | X |
| No |  |

Discuss the impact to the reported dataset due to any unacceptable QA/QC results or deviations from the approved QAPP or other planning documents:

1. Were any QA oversight activities performed (e.g., audit or technical review)?

|  |  |
| --- | --- |
| Yes | X |
| No |  |

If yes, indicate the type of activity and date performed:

Data quality audits

# Quality Assurance and Quality Control

All test activities were documented via narratives in laboratory notebooks and the use of digital photography. The documentation included, but was not limited to, a record for each decontamination procedure, any deviations from the QAPP, and physical impacts on materials. All tests were conducted in accordance with established EPA Decontamination Technologies Research Laboratory (DTRL) and NHSRC RTP Microbiology Laboratory procedures to ensure repeatability and adherence to the data quality validation criteria set for this project



## Criteria for Critical Measurements/Parameters

The data quality objectives (DQOs) are used to determine the critical measurements needed to address the stated objectives and specify tolerable levels of potential errors associated with simulating the prescribed decontamination environments. The following measurements were deemed critical to accomplish part or all of the project objectives:

* pH and temperature of the pAB solution
* Sodium hypochlorite concentration (FAC) of the pAB decontamination solution
* Citric acid concentration of the 2% citric acid decontamination solution
* Temperature of incubation
* CFU or PFU abundance per plate
* Neutralizer volume
* Mass of grime applied onto test coupons
* Backpack sprayer spray diameter at one foot
* Chemical sprayer spray diameter at three feet
* Flow rate of backpack sprayer, chemical sprayer, and water hose
* Pressure of backpack sprayer and garden hose.

The following measurements were non-critical, but were monitored and recorded throughout the entire testing schedule:

* Temperature and pH of the Spor-Klenz® RTU and citric acid liquid sporicide solutions and of the rinse water
* Head pressure for the rinse water.

## Data Quality Indicators

The data quality indicators (DQIs) for the critical measurements listed in Table 9.2-1 were used to determine if the collected data met the quality assurance objectives. If a measurement method or device resulted in data that did not meet these goals, the data derived from the critical measurement were rejected. Decisions to accept or reject test results were based on engineering judgment used to assess the likely impact of the failed criterion on the conclusions drawn from the data. The acceptance criteria were set at the most stringent levels that can routinely be achieved. All the DQIs were within the target acceptance criteria set for this project as shown in Table - 9.2-1.

Table 9.2-1. DQIs for Critical Measurements

| **Measurement Parameter** | **Analysis Method** | **Accuracy** | **Acceptance Criteria** | **Mean Value / Pass or Fail Test** |
| --- | --- | --- | --- | --- |
| Mass of grime | Gravimetric | 0.1 g | ± 10% of target value  30% RSD between test set | 56.5 g  (Pass) |
| FAC and pH in pAB solution | Na2S2O3/KI titration pH meter/NIST-traceable buffer solutions | ±0.06 g/L  ±0.01 pH units | 6,000 to 6,700 mg/mL  6.5<pH<7 | 6,169 mg/mL 6.74 pH  (Pass) |
| Citric acid concentration and pH\*\* in citric acid decontamination solution\*\*\* | NaOH titration  pH meter/NIST-traceable buffer solutions | ± 0.03 g/L  ± 0.01 pH units | ± 10% of target value | 2.04 % Citric Acid 2.14 pH  (Pass) |
| Time | NIST-calibrated stopwatch | ± 1 minute per hour | ± 2 min (2 x ± 1 min) | Pass |
| Volumes | Serological pipette tips | 0.1 mL | ± 10% of target value | Pass |
| Pressure of backpack and chemical sprayer | Class B pressure gauge | ± 2 psi | ± 20% of target value | Pass |
| Flow rate of backpack and chemical sprayer and water hose | Volume collected in a graduated cylinder per time | ± 50 mL | ± 20% of target value | Pass |
| Chemical sprayer spray diameter at three feet | Tape measure | 1/8 in | ± 20% of target value | Pass |
| Backpack sprayer spray diameter at one foot | Tape measure | 1/8 in | ± 20% of target value | Pass |
| Counts of CFU or PFU per plate | Manual counting | ± 10% CFU/ plate between 1st and 2nd count | 100% RSD between triplicates | Pass |
| Plated volume | Pipette | 2% | ± 1% | Pass |
| Temperature of incubation chamber | NIST-traceable thermometer (daily) | + 2 oC | Not applicable | Pass |
| Mg/mL = milligrams/milliliter  NIST = National Institute of Standards and Technology  g/L = grams per liter  \* Performed only for neutralization testing (see Section 5 for details).  \*\* pH of Spor-Klenz® RTU and citric acid decontamination solutions were established experimentally before testing in a series of preliminary experiments through triplicate measurements of this parameter performed for each liquid decontaminant. The averages from these measurements were then established as baseline or threshold pH for Spor-Klenz® RTU and citric acid decontamination formulations. | | | | |

* 1. **Quality Control Checks**

Many QA/QC checks were used in this project to ensure that the data collected met all the critical measurements listed in Table 9.2-1. The measurement/parameter criteria were set at the most stringent level that can routinely be achieved. The integrity of the sample during collection and analysis was evaluated. Control samples and procedural blanks were included along with the test samples so that well-controlled quantitative values were obtained. Background checks for the presence of bacterial spores were included as part of the standard protocol. Replicate coupons were included for each set of test conditions. Specific quality control checks that were performed in this project are described in the following sections.

* + 1. ***Integrity of Samples and Supplies***

Samples were carefully maintained and preserved to ensure their integrity. Samples were stored away from standards or other samples that could possibly cross-contaminate them.

Project personnel carefully checked supplies and consumables prior to use to verify that they met specified project quality objectives. All pipettes were calibrated yearly by an outside contractor (Calibrate, Inc.), incubation temperature was monitored using NIST-traceable thermometers, and balances were calibrated yearly by the EPA Metrology Laboratory.

* + 1. ***NHRSC Biolab Control Checks***

Quantitative standards do not exist for biological agents. Quantitative determinations of organisms in this investigation did not involve the use of analytical measurement devices. Rather, the CFU were enumerated manually and recorded. If the CFU count for bacterial growth did not fall within the target range, the sample was either filtered or re-plated. For each set of results (per test), a second count was performed on 25 percent of the plates within the quantification range (plates with 30 - 300 CFU). All second counts were found to be within 10 percent of the original count.

* 1. **QA/QC Sample Acceptance Criteria**

The acceptance criteria for the critical CFU measurements were set at the most stringent level that could be achieved routinely. Positive controls and procedural blanks were included along with the test samples in the experiments so that well-controlled quantitative values were obtained. Background checks were also included as part of the standard protocol. Replicate coupons were included for each set of test conditions. Further QC samples were collected and analyzed to check the ability of the NHSRC Biolab to culture the test organism, as well as to demonstrate that materials used in this effort did not themselves contain spores. The checks included the following:

* Negative control coupons: sterile coupons that underwent the same sampling process without spore deposition.
* Field blank coupons: sterile coupons carried to the decontamination location but not decontaminated.
* Laboratory blank coupons: sterile coupons not removed from NHSRC Biolab.
* Laboratory material coupons: includes all materials, individually, used by the NHSRC Biolab in sample analysis.
* Stainless steel positive control coupons: coupons inoculated but not decontaminated.

QA/QC acceptance criteria are shown in Table 9.4-1. These criteria provide assurances against cross-contamination and other biases of microbiological samples.

**Table 9.4-1. Additional DQIs Specific to Microbiological Data**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Coupon or Sample Type** | **Acceptance Criteria** | **Information Provided** | **Corrective Action** | **Pass/Fail** |
| Positive control coupons  sample from material coupon contaminated with biological agent and sampled using the wipe method | 1 x 107 for *B. atrophaeus*  1 x 108 for MS2  30% RSD between coupons in each test set | Shows viability of wipe sampling technique and plate’s ability to support growth of *B. atrophaeus* and MS2 | Identify and remove source of variability if possible | Pass |
| Procedural blank  coupon without biological agent that underwent the sampling procedure | Non-detect | Controls for sterility of materials and methods used in the procedure | Analyze data with procedural blank results as test minimum; identify and remove source of contamination if possible | Pass |
| Material blank  grime, roller, and sterilized coupon of each material | Non-detect | Controls for sterility of materials and methods used in the procedure | Analyze data with procedural blank results as test minimum; identify and remove source of contamination if possible | Pass |
| Blank plating of microbiological supplies | No observed growth after incubation | Controls for sterility of supplies used in dilution plating | Sterilize or dispose of source of contamination; replate samples. | Pass |
| Blank tryptic soy agar sterility control Plate incubated but not inoculated | No observed growth after incubation | Controls for sterility of plates | All plates incubated before use, so contaminated plates discarded before use | Pass |
| Exposed field blank samples; a wipe kit will be handled | Non-detect | Level of contamination present during sampling | Clean up environment; sterilize sampling materials before use | Pass |
| Unexposed field blank samples; a wipe kit will be transferred without handling | Non-detect | Level of contamination present during sampling | Clean up environment; sterilize sampling materials before use | Pass |