CHANGES TO MODULE V FOR MICROBIOLOGY LABORATORIES

2019 TNI/NEMC CONFERENCE

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GENERAL

- MANY ACCREDITING BODIES ARE GOING WITH A JANUARY 2020 IMPLEMENTATION
- NEWEST V1M5 STANDARDS ARE WRITTEN BY WORKING MICROBIOLOGISTS
- ALL PRIOR STANDARD INTERPRETATIONS WERE CONSIDERED IN THE REVISION
- STANDARDS FOR NELAP COMPLIANCE, LABS ARE STILL REQUIRED TO MEET ANY APPLICABLE PROGRAM REQUIREMENT (**V1M5 1.2**) WHICH WILL PREVAIL

METHOD VALIDATION AND DOC

- CLARIFIED THE REQUIREMENTS FOR THE VALIDATION OF NON-REFERENCE METHODS **(V1M5 1.5)** REQUIRES THAT THE NON-REFERENCE METHOD IS STATISTICALLY EQUIVALENT OR BETTER THAN REFERENCE METHOD
- CLARIFIED THE DEMONSTRATION OF CAPABILITY (DOC) REQUIREMENTS **(V1M5 1.6)**
- INITIAL DOC **(V1M5 1.6.2)** ADDED RELATIVE STANDARD DEVIATION (RSD) AS AN EXAMPLE OF ACCEPTANCE CRITERIA FOR AN IDOC
- ONGOING DOC **(V1M5 1.6.3)** ADDED "OR SAMPLE SET" TO THE REQUIREMENTS FOR AN ACCEPTABLE PT FOR ONGOING DOC DEMONSTRATIONS AND CLARIFIED THE USE OF REAL WORLD SAMPLE IN SOME CASES WITH PRE-DEFINED ACCEPTANCE CRITERIA

QUALITY CONTROL- BEFORE AND DURING

- MANY UPDATES TO **V1M5 1.7** THAT DETAILS THE TECHNICAL/QUALITY CONTROL REQUIREMENTS FOR LABORATORIES
- DIFFERENTIATED BETWEEN QC THAT IS DONE **BEFORE** ANY SAMPLE TESTING CAN BEGIN (BEFORE) AND WHAT CAN BE DONE **DURING** SAMPLE TESTING
  - STERILITY AND PERFORMANCE CHECKS ARE FOR STANDARDS, REAGENTS, MATERIALS AND MEDIA USED FOR TESTING (**BEFORE**) **(V1M5 1.7.3.1)**
  - METHOD BLANKS ARE USED FOR METHOD AND TECHNIQUE (**DURING**) **(V1M5 1.7.3.2)**

QC-DILUTION WATER VS REAGENT WATER

- PROVIDED A CLARIFICATION FOR **DILUTION WATER** VS. **REAGENT WATER**
  - **REAGENT WATER** (OR LABORATORY PURE WATER AS DEFINED BY STATE PROGRAMS) IS THE WATER USED TO MAKE BUFFER WATER OR MEDIA OR MICROBIOLOGICAL REAGENTS **(V1M5 1.7.3.1.d)**
  - **DILUTION WATER** IS THE METHOD DEFINED WATER USED TO DILUTE SAMPLES, USED AS A RINSE FOR MEMBRANE FILTER TESTING THAT IS NOT SIMPLY REAGENT WATER
  - **DILUTION WATER** INCLUDES PHOSPHATE SALINE, PHOSPHATE BUFFER, PEPTONE WATER, ETC. **(V1M5 1.7.3.1.e)**

QC-TEST VARIABILITY/REPRODUCIBILITY & SELECTIVITY

- CLARIFIED THE REQUIREMENTS FOR TEST VARIABILITY/REPRODUCIBILITY (PARALLEL COUNTS)
  - FOR METHODS THAT SPECIFY COUNTS (I.E. CFU/100ML OR MPN/100ML) SUCH AS MEMBRANE FILTER, PLATED MEDIA OR OTHER METHODS WHICH SPECIFY A QUANTITATIVE RESULT **(V1M5 1.7.3.3)**
- CLARIFIED THE REQUIREMENTS FOR SELECTIVITY (CONTROL CULTURE TESTING, VERIFICATIONS)
  - ADDED ONCE PER LOT (PURCHASED) OR BATCH (LABORATORY MADE) **(V1M5 1.7.3.6.a)**

QC-VERIFICATIONS & + CULTURE CONTROL TESTS

- ADDED SELECTIVE MEDIA USE AND EC + MUG BROTH TO THE EXAMPLE IF HOW COLONIES SHALL BE VERIFIED **(V1M5 1.7.3.6.b)**
- CLARIFIED THAT FOR POSITIVE CONTROL CULTURE TESTING THAT ONE OR MORE KNOWN PURE POSITIVE CULTURE CONTROLS (I.E. TARGET ORGANISM) AS APPROPRIATE TO THE METHOD (I.E. QUANTITATIVE RESULTS FOR QUANTITATIVE METHOD) SHALL BE USED. **(V1M5 1.7.3.6.d.ii.b)**
- THIS CHANGE REQUIRES THAT LABS OBTAIN A NUMERICAL RESULT FOR THE CONTROL CULTURE **TESTING OF A QUANTITATIVE METHOD,** INSTEAD OF A QUALITATIVE RESPONSE LIKE “PRESENCE” OR “ABSENCE”.

QC- TEMPERATURE MONITORING DEVICES

- UPDATES TO THE SECTION FOR TEMPERATURE MEASURING DEVICES **(V1M5 1.7.3.7.b.i)** CLARIFIED THAT **THE LABORATORY SHALL** USE DEVICES TO **ASSESS AND DOCUMENT EQUIPMENT TEMPERATURES**
- BOTH GRADUATION AND RANGE OF THE THERMOMETERS SHALL MEET THE ACCURACY OF THE MEASUREMENT
- CLARIFIED THAT THE ANNUAL REQUIREMENT IS SPECIFIC TO TEMPERATURE MONITORING DEVICES IN THIS SECTION

QC- ADDITIONAL TEMPERATURE AND BREAKDOWN OF STERILIZATION REQUIREMENTS

- ADDED THAT LABS CAN USE A SINGLE POINT PROVIDED THAT IT REPRESENTS THE METHOD MANDATED TEMPERATURE AND USE CONDITIONS (I.E. CANT JUST USE ICE POINT VERIFICATION) AND STILL CONTAINS THE REFERENCE TO SUPPORT EQUIPMENT REQUIREMENTS AT **V1M2 5.5.13.1**
- REVISED THE OVEN AND AUTOCLAVE REQUIREMENTS TO MOVE THEM INTO ONE SECTION FOR "STERILIZATION EQUIPMENT" **(V1M5 1.7.3.7.b.ii)**

QC- AUTOCLAVE AND VOLUMETRIC EQUIPMENT

- REMOVED THE NOTE FROM THE FORMER SECTION FOR AUTOCLAVES "THAT IF THE LAB CAN DEMONSTRATE THAT THE AUTOCLAVE HAS NO LEAKS USING THE FORMULA PV = nRT": **NOW IT IS PART OF THE ACTUAL STANDARD LANGUAGE V1M5 1.7.3.7.b.ii.a.4**

ASSESSOR'S TIP: IF YOU ARE USING A SERVICE REPRESENTATIVE/SERVICE CONTRACT: MAKE SURE THE REPORT ACTUALLY GIVES YOU USEABLE INFORMATION FOR THE ANNUAL MAINTENANCE INSTEAD OF SIMPLY NOTING A "PASS" OR "FAIL" IN THE REPORT FOR PRESSURE AND TEMPERATURE.

- CHANGES WERE MADE TO THE SECTION FOR VOLUMETRIC EQUIPMENT ESPECIALLY FOR EQUIPMENT USED TO MEASURE SAMPLE VOLUME

QC- SAMPLE MEASUREMENT

- EQUIPMENT USED FOR MEASURING VOLUME INCLUDES A REFERENCE TO THE ACCURACY BEING WITHIN 2.5% OF EXPECTED VOLUME **(V1M5 1.7.3.7.b.iii.d)**

ASSESSOR'S NOTE: THE US EPA REQUIRES AT LEAST 100 ML OF SAMPLE FOR MOST DRINKING WATER TESTING BY FEDERAL REGISTER REQUIREMENTS AND THE WIDELY USED DEFINITION OF A GRAB SAMPLE IS THAT IT IS AT LEAST 100 ML IN VOLUME. SO ANTHING LESS THAN 100 ML DOES NOT MEET THE REQUIREMENTS OF THE FEDERAL REGISTER FOR DRINKING WATER TESTING.

FOR EXAMPLE, IF THE MEASUREMENT CHECK SHOWS A VALUE OF 97.5-99.4 ML, THIS VOLUME DOES NOT MEET THE REQUIREMENT FOR MANY STATE ABs. IN FACT FOR NJ, THE SAMPLE VOLUME CANNOT BE LESS THAN 99.5 ML (99.5 ROUNDED TO THE NEAREST EVEN WHOLE NUMBER OF 100) IN ORDER TO MEET THE FEDERAL REQUIREMENTS.

QC-INCUBATORS AND WATER BATHS

- FOR INCUBATORS AND WATER BATHS **(V1M5 1.7.3.7.b.v)** THE STANDARD WAS CLARIFIED TO ADDRESS EQUILIBRIUM CONDITIONS, NOT JUST TEMPERATURE DISTRIBUTION IN THE DEVICES USED
- REQUIRED PRIOR TO FIRST USE AFTER INSTALLATION OR SERVICE
- EQUILIBRIUM CHECK MUST INCLUDE THE TIME THAT THE DEVICES REQUIRE TO COME BACK TO TEST TEMPERATURE AFTER SAMPLE ADDITION
- THIS MUST BE DONE UNDER FULL CAPACITY LOAD CONDITIONS

QC- INCUBATORS AND WATER BATHS AND IRT TESTING

- WITH NEVER ANY INTENT TO MAKE LABS MONITOR TEMPERATURE OF INCUBATION UNITS IF NO SAMPLES ARE UNDER TEST, THIS POINT WAS OFFICIALLY CLARIFIED IN THE STANDARD.
- **V1M5 1.7.3.7.b.vi** WAS REVISED FOR THE INHIBITORY RESIDUE TESTING TO ADD THE REQUIREMENT TO PERFORM THE TESTING **INITIALLY** INSTEAD OF ANNUALLY (AND EACH TIME THE LAB CHANGES THE **FORMULATION** OF THE DETERGENT USED OR THE WASHING PROCEDURES USED AT THE LABORATORY).
- **ASSESSOR'S NOTE: SM 9020B, 22ND EDITION STILL CONTAINS THE REQUIREMENT FOR AN ANNUAL CHECK. 23RD EDITION CHANGED THE SECTION.**

SAMPLE HANDLING

- **V1M5 1.7.5** FOR SAMPLE HANDLING WAS REVISED TO ADD THAT THE RECEIPT OF SAMPLES MUST COMPLY WITH THE REQUIREMENTS FOUND **V1M2 5.8** IN ADDITION TO THE REQUIREMENTS OF MODULE V.
- **V1M5 1.7.5.1** WAS REVISED TO CLARIFY THAT SAMPLES THAT ARE DELIVERED TO THE LAB ON THE SAME DAY AS THE COLLECTION DAY MAY NOT MEET THE REQUIREMENTS **OF THE SECTION OR THE METHOD OR REGULATORY REQUIREMENTS**.
- **V1M5 1.7.5.1** NOW ALSO INCLUDES THE REVISED LANGUAGE RELATED TO THE FACT THAT THE SAMPLES **RECEIVED ON ICE MAY ONLY BE ACCEPTABLE IF THERE IS EVIDENCE THAT THE COOLING PROCESS BEGAN** ONCE THE SAMPLES WERE PLACED IN THE COOLER OR OTHER REPRESENTATIVE SAMPLE TRANSPORT CONTAINER.

SAMPLE HANDLING AND DISINFECTANT RESIDUAL

- **BOTTOMLINE: THE INTENT IS FOR THE SAMPLES TO BE PRESERVED IMMEDIATELY AND ANALYZED AS SOON AS POSSIBLE (OR AT LEAST WITHIN THE SPECIFIED HOLDING TIME FROM SAMPLE COLLECTION TO ANALYSIS) TO PROTECT THE BACTERIAL INTEGRITY OF THE SAMPLES.**
- **THE MONTHLY CHLORINE CHECK OF MICROBIOLOGICAL SAMPLES WAS REMOVED. (V1M5 1.7.5.2)**
- **INSTEAD LABS MUST FOLLOW THE NEW STANDARD AND MEET ALL OF THE FOUR EXEMPTIONS OR TEST EVERY SAMPLE THAT IT RECEIVES:**
  - **THAT THE SAMPLE CONTAINERS MEET ALL QC WITH DOCUMENTATION**
  - **THAT SUFFICIENT (AND NOT AN OVERDOSE OF) SODIUM THIOSULFATE IS IN THE CONTAINE**
  - **THAT A DISINFECTANT RESIDUAL IS CHECKED IN THE FIELD AT THE TIME OF COLLECTION (EPA PREFERENCE FROM LAB CERT MANUAL FOR DRINKING WATER SAMPLES)**

SUMMARY

- LABORATORIES MUST BE PREPARED TO MEET THE NEW STANDARD REQUIREMENTS
- NOW IS THE TIME TO REVIEW THE NEW REQUIREMENTS
- PERFORM AN INTERNAL AUDIT OF THE MICROBIOLOGY LAB TO CHECK PREPAREDNESS
- CHECK WITH YOUR AB WITH ANY QUESTIONS ABOUT ITS PREVAILING REQUIREMENTS SO THAT THEY CAN ALSO BE MET
- BEGIN TO START THE PROCESS OF REVISING THE SOPS AND QUALITY MANUAL
- BEGIN TO IMPLEMENT ANY ADDITIONAL (NEW LANGUAGE) REQUIREMENTS AND BE READY TO MAKE ANY CHANGES WHERE THE STANDARD REQUIREMENT WAS RELAXED **AFTER** IMPLEMENTATION OF THE NEW STANDARD BY THE ABs