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DEPT. OF HEALTH AND HUMAN SERVICES

Nebraska Department of Health and Human Services

Quality Assurance Manual Checklist

Please indicate, by section number and/or page number, where the following elements are found in the submitted Laboratory Quality Assurance Manual. See the Manual for the Certification of Laboratories Analyzing Drinking Water, section labeled Laboratory Quality Assurance Plan starting on page III - 4 for more information. If a particular item is not relevant, the QC plan should state this and provide a brief explanation.

Mandatory Elements	Quality Manual Reference
Title page signed and dated	
1a. Chart or table showing laboratory organization and responsibility and relationship between management and the quality system	
1b. List of key individuals responsible for production of valid results and routine assessment of the quality systems	
1c. Reference to job descriptions of staff, training provided, and documentation of staff proficiency	
2. Process used to identify clients Data Quality Objectives	
3a. List of SOP's with dates of last revisions	
3b. Where current copies of SOP's are stored	
3c. SOP's are reviewed annually and revised as changes are made	
3d. SOP's have signature pages and revisions dated	
4a. Sampling, preserving, shipping, receiving, and storage procedures	
4b. How forms are filled out and availability of hard copies of electronic data	
4c. How samples are checked on arrival	
4d. Sample instructions are available	
5. Laboratory sample handling procedures	
5a. Sample login procedure	
5b. Storage of samples	
5c. Sample tracking process	
5d. Sample chain of custody	
5e. Sample rejection	
6. Calibration procedures for chemistry	
6a. Specify type of calibration used for each method and frequency of use	
6b. Standards source, age, storage, labeling	
6c. Perform data comparability checks	
6d. Use of control charts	
7. Analytical procedures (may reference SOP)	
7a. Cite complete method manual	
7b. Quality control procedures required by the methods that must be followed	

8. Data reduction, validation, reporting, and verification	
8a. Data reduction process	
8b. Data validation process	
8c. Reporting, including procedures and format	
8d. Data verification process	
8e. Procedure for data corrections	
9. Type of quality control checks and the frequency of use	
9a. Instrument performance check standards	
9b. Frequency and acceptability of method detection limit calculations	
9c. Calibration, internal, and surrogate standards	
9d. Laboratory reagent blank, field reagent blank, and trip blank	
9e. Field and laboratory matrix replicates	
9f. Quality control and performance evaluation samples	
9g. Laboratory fortified blank and laboratory fortified sample matrix replicates	
9h. Initial demonstration of method capability and use of control charts	
9i. Qualitative identification/confirmation of contaminants	
9j. Parameters for microbiology should include or reference:	
aa: Positive and negative controls used	
bb: Confirmation, verification of presumptive total coliform positive samples	
cc: Sterility controls	
dd: Performance evaluation and quality control samples	
10. Lit schedules of internal and external system and data quality audits and inter-laboratory comparisons (may reference SOP)	
11. Preventative maintenance procedures and schedules	
11a. Location of instrument manuals and schedules and documentation of routine equipment maintenance	
11b. Availability of instrument spare parts in the laboratory	
11c. List any maintenance contracts in place	
12. Corrective action contingencies	
12a. Response to obtaining unacceptable results from analysis of PT samples and from internal QC checks	
12b. Name of person(s) responsible for various corrective actions	
12c. How corrective actions taken are documented	
13. Record keeping procedures	
13a. Procedures and documentation of those procedures	
13b. Length of storage, media type (electronic or hard copy)	
13c. Security policy of electronic databases	