COLUMBIA/
BIO MEDICAL LABORATORIES
QUALITY ASSURANCE MANUAL (PLAN)
FOR COLIFORM ANALYSIS

1200 NORTH 14TH AVENUE
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COLUMBIA/BIO MEDICAL LABORATORIES
QUALITY ASSURANCE MANUAL (PLAN)
ASSIGNMENT PAGE

Document Control No.: 001

Assigned To: Marden R. Kohler

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QUALITY ASSURANCE MANUAL (PLAN)
FOR COLIFORM ANALYSIS
REVISION CONTROL LOG

Revision No.	Revision Date	Affected Pages	Document Control No.	Description of Change

TABLE OF CONTENTS

Section/Page

1.0 QUALITY ASSURANCE MANUAL (PLAN) IDENTIFICATION FORM AND POLICY

Document Title:	Columbia/Bio Medical Laboratories Quality Assurance Manual (Plan) for Coliform Analysis
Laboratory Title:	Columbia/Bio Medical Laboratories (CBML)
Laboratory Address:	1200 North 14th Avenue Pasco, WA 99301
Director:	Marden R. Kohler, Ph.D. Phone Number 509-547-3336
Operations Manager:	Carol Kerkow, M.T., (ASCP), CLS Phone Number 509-547-3336

This program outlines Columbia/Bio Medical Laboratories' (CBML) Quality Assurance Plan; it addresses the activities of the laboratory regarding coliform assays. Items of concern include: sample receipt; data generation; and the release of results to appropriate entities. This plan is directly applicable to the analysis of water for coliforms.

QUALITY ASSURANCE POLICY

It is the purpose and policy of Columbia/Bio Medical Laboratories (CBML) that the analytical data generated and formulated in this laboratory subject to State of Washington Department of Health, State of Washington Department of Ecology, U.S. Department of Energy, and the U.S. Environmental Protection Agency or other specific entity be of known and acceptable quality. This program is intended to establish and assure an effective quality assurance system. The objective is the production and reporting of data of acceptable quality.

This plan is designed to satisfy the minimum requirements of various agencies surveying CBML laboratory operations.

The quality assurance policy and plan described in this manual has the commitment of Columbia/Bio Medical Laboratories (CBML) employees and management.

APPROVED:

By: Marden R. Kohler
Marden R. Kohler, Ph.D.
Director

Date: 10-14-91

By: Carol Kerkow
Carol Kerkow, M.T. (ASCP)
Operations Manager

Date: 10-14-91

2.0 INTRODUCTION

2.1 Purpose

It is the purpose of this plan to describe the specific aspects of quality assurance as it pertains to coliform analyses. In addition, this plan has been written to meet the general requirements of the United States Department of Energy and the United States Environmental Protection Agency.

2.2 Applicability and Scope

The quality assurance plan presented in this document is applicable to environmental data generated and processed at Columbia/Bio Medical Laboratories (CBML) and serves to assure that such data meets users' requirements in terms of accuracy, precision, completeness, and comparability.

This plan is designed to meet analytical and documentation requirements, sample control procedures, document control procedures and activities related to noncompliance situations. The program outlines the purpose, organization, objectives, and operations established to support coliform analyses conducted at CBML.

This plan is intended to provide general direction for the coliform analyses and is not intended to provide in-depth technical discussions. Standard Operating Procedures (SOPs) are designed to provide in-depth technical discussions in support of analytical activities necessary to provide data of consistent quality.

2.3 Approval, Revision, Distribution and Control

The approval of the plan, manuals, and test procedures will be indicated by approval signatures and dates. Responsibility for control, revision and distribution of the QA Manual and the test procedures resides with the managers listed below.

Columbia/Bio Medical Quality Assurance Plan

Laboratory Director
Quality Assurance/Operations Manager

Columbia/Bio Medical Test Procedures

Laboratory Director
Quality Assurance/Operations Manager
Departmental Supervisor

3.0 QUALITY ASSURANCE MANAGEMENT

3.1 Introduction

Ultimate responsibility for testing performance and the implementation of all programs at Columbia/Bio Medical Laboratories (CBML) resides with the Laboratory Director. The laboratory quality assurance program is administered by the Quality Assurance/Operations Manager who reports directly to the Laboratory Director. Functional performance of the test analysis and analytical work is delegated to Departmental Supervisors.

The following illustrates the relation of the QA to all the sections of the laboratory.

3.2 Assignment of Responsibilities

3.2.1 Laboratory Director

The Laboratory Director manages the entire laboratory operation and public relations with the community and those groups that utilize laboratory services. This person oversees and supports the Quality Assurance/Operations Manager.

3.2.2 Quality Assurance/Operations Manager

The Quality Assurance/Operations Manager is the manager of the operations of all the laboratories and assures that laboratory work is performed accurately. This person also supervises quality assurance, oversees quality control, and addresses safety regulations. This individual reports directly to the Laboratory Director.

3.2.3 Departmental Supervisors

Each Departmental Supervisor (DS) manages the operations of the assigned department. The DS assures that tests are performed accurately and that QC is appropriately applied and constantly monitored. Each DS reports directly to the Quality Assurance/Operations Manager.

3.2.4 Technologists

Each Technologist performs assigned analytical test protocols accurately, applies QC procedures, maintains records of QC and test results, and reports test results. Each Technologist reports to the appropriate Supervisor.

3.2.5 Technicians

Assigned Technicians receive coliform samples, complete and initiate documentation, perform approved test procedures accurately, apply QC procedures, maintain records of QC and test results, and report test results. This position reports to the Supervisor.

3.3 Communication

An adequate QA plan requires effective communication. An effective communication system includes various activities and meetings as detailed in for following:

3.3.1 Daily

Coliform samples received on a daily basis are evaluated to assess QA requirements. Any problems or current needs are brought to the attention of the Quality Assurance/Operations Manager. If necessary, certain changes or additions to the QA Plan will be made.

3.3.2 Monthly

A monthly meeting attended by the Laboratory Director, Quality Assurance/Operations Manager and the Department Supervisors is convened. The topics discussed include specific QA problems or activities of the laboratory. Any corrective changes which may have become necessary during previous work activities are implemented here. Short range projections of activities or projects and requirements are discussed.

3.3.3 Semi-Annual

Semi-annually the Quality Assurance/Operations Manager will review all QA Plan and test procedure manuals. The manuals will be checked to verify that they are current. Upon approval, the Quality Assurance/Operations Manager will sign the appropriate Control Log.

3.3.4 Annual

The QA Manual and all test procedures will be reviewed annually by the Laboratory Director for appropriateness, accuracy, and completeness. Survey completion, corrections effected and/or approval of procedures will be documented in the appropriate control log.

3.4 Sample Control

Methods and procedures to be used for sample custody and processing are described here.

3.4.1 Sample Receiving and Logging

CBML utilizes well established and controlled procedures for sample handling including receiving, logging and tracking. Samples are examined upon receipt by the authorized CBML Sample Receipt Technician (SRT) to assure that the Analytical Request Form and Chain-of-Custody Documents are present, correct and complete. Any problems are resolved by consultation with appropriate personnel and the samples are cleared for logging. The SRT assigns each individual sample a specific laboratory number for logging, tracking and accounting purposes.

3.4.2 Sample Security, Storage, and Disposal

The laboratory is locked except during the regular business day between the hours of 8:00 a.m. and 5:00 p.m. Admittance of visitors to the building during business hours is available only through an assigned escort. Coliform samples not under the direct observation of an analyst will be secured in a locked refrigerator.

Samples are disposed of after appropriate designated holding periods.

3.4.3 Sample Tracking

Samples are received at the laboratory by the designated Sample Receipt Technician or (designee). At the time of sample receipt at the laboratory, the individual accepting the samples signs the field Chain-of-Custody Record. Any subsequent sample custody transfer will be entered by signature, time and date on the Chain-of-Custody Record in the presence of the relinquishing and receiving individuals through laboratory analysis to final sample storage.

After sample receipt and the accompanying required documentation of the Chain-of-Custody Record is completed, CBML reference numbers are assigned and a CBML Work Order is generated. The sample information is then entered into the computer based logbook. Samples are assigned by the Departmental Supervisor to appropriate analytical personnel.

3.5 Document Control

Document control addresses the accumulation, organization, reporting and filing of all documents pertinent to the analysis of coliform samples. The goal of document control is to assure that the required documents are appropriately completed, reports distributed, and residual calculation data and QC data are filed. Document control is not limited to but includes requisition forms, information in analysis logs and instrument recording logs, tapes, computer printouts, and proficiency test results. The Quality Control/Operations Manager reviews the collection, accumulation and organization of documents and files them into permanent storage. All computer stored data is processed onto micro fische film which is stored in a fireproof safe at the commercial processing laboratory facilities. A second copy is available for resource at the main laboratory facility. All quality control related records will be entered into bound laboratory notebooks which are controlled by the Quality Assurance Officer.

3.6 Performance Audits and Proficiency Tests and Frequency

Outside performance evaluation (PE) samples will be tested on a semi-annual basis exactly as the usual coliform samples are tested. The data from the PE tests are monitored by the Quality Assurance Manager (QAM). Any required corrective measures are initiated by the QAM.

4.0 STANDARD OPERATING PROCEDURES (SOPs)

4.1 Introduction

All environmental analytical work will be performed in accordance with tested, written and approved procedures (SOPs). This section contains an outline of the functions and activities that relate to the quality requirements associated with the procedures employed at CBML.

4.2 Standard Operating Procedure Format

The QAM shall have the primary responsibility for approving, issuing, revising and controlling the SOPs. These SOPs will include analytical methods and any ancillary activities required for the completion and reporting of analytical data.

All Standard Operating Procedures shall have a unique format with all necessary approval signatures, revision control identification, date and title description (Exhibit 4.1).

CBML SOPs are written to conform with the following format:

1.0 Purpose of the Document

2.0 Scope and Area of Application

3.0 Responsibilities of Specified Personnel

4.0 Referenced Documents; e.g., Analytical Methods, Instrument Operational Instruction Manual

5.0 Procedural Requirements; e.g. equipment, reagents, materials

6.0 Procedural Details

7.0 Precision and Accuracy Statements

8.0 QA/QC Requirements

9.0 Definitions or Calculations Applicable to SOP

10.0 Appendices

4.3 Responsibility and Approval

All new or revised SOPs must be approved in writing by authorized personnel in accordance with the following:

CBML Director - Ultimate responsibility for approving all general and Quality Assurance SOPs relating to the operation performed in CBML.

Quality Assurance Manager - Responsible for approval and designation of all SOPs.

4.4 Distribution and Control

All documents associated with the quality assurance program are regulated with regard to their traceability, distribution, and revision. Document control extends to all CBML Standard Operating Procedures and analytical methods written by CBML. Document control does not extend to analytical methods or procedures produced or published outside of CBML. The standard indexing format which is included at the top right-hand corner of each page of the document will include the following information:

- Document Identification
- Section
- Revision Number
- Date
- Page

The QAM maintains a master file of all SOPs, analytical methods, revisions, and history of distribution. Authorized copies of SOPs, revisions and analytical methods are exclusively made through the QAM.

The QAM is responsible for distribution and control of all CBML authorized SOPs, revisions and analytical methods. Departmental Supervisors will maintain a controlled SOP file in each laboratory for which the Supervisor is responsible. As new documents are approved, authorized copies are distributed by the QAM to the applicable controlled SOP file. A record of the distribution of controlled SOP files, including revisions, is maintained by

the QAM. Exhibits 4.2 and 4.3 are examples of the Revision Control Log and Assignment Page used to document the distribution and control of CBML Program Plans, manuals or SOPs. Exhibit 4.4 is an example of a controlled SOP Distribution Record used for internal tracking of documents.

TABLE 4.1
OPERATIONAL FUNCTIONS

FUNCTION	DESCRIPTION	DOCUMENTS USED	PERFORMED BY
Sample Receiving	Containers are unpacked, inspected and secured. Transfer and chain-of-custody documents are reviewed and signed. The QAM and Departmental Supervisors are notified. Sample information is entered into the sample log. Sample numbering and labeling is performed. Samples are stored in a designated storage area.	Chain-of-Custody Standard Operating Procedures Analytical Request Form Sample Labels	Sample Receipt Technician
Initiation of Analysis	Completed work order initiated for analytical request.	Analytical Request Form Sample Work Order	Sample Receipt Technician
Analysis	Samples acquired from storage and procedural preparation is performed.	Laboratory Notebooks/ Worksheets SOPs	Analyst
	Analytical test performed on prepared sample.	SOPs	Analyst
	Samples are analyzed on appropriate instrument(s).	Laboratory Notebooks/ Worksheets Instrument Calibration Logs Instrument printouts SOPs	Analyst
Data Processing and Validation	Analytical data and print-outs reviewed, calibrations verified.	Laboratory Notebooks/ Worksheets Instrument Calibration Logs QC Data	Peer Analyst
	Data reviewed for completeness and DQO verification; approval or rejection of results.	Laboratory Notebooks/ Worksheets QC Data Client/Project Requirements	Departmental Supervisor
Reporting	Data entered into computer network is generated and verified.	Laboratory Worksheets Client Data Report	Analyst/Data Entry Technicians
	Client report is verified, approved and signed.	Client Data Report	Departmental Supervisor
File Records	Client/project files are updated	Client forms; notebooks copies; worksheets; instrument print-outs; data reports; QC data	Record Custodian

EXHIBIT 4.1
STANDARD OPERATING PROCEDURE APPROVAL SHEET

SOP TITLE:

DOCUMENT CONTROL NUMBER:

EFFECTIVE DATE:

APPROVALS:

LABORATORY DIRECTOR _____ Date _____

QUALITY ASSURANCE MANAGER _____ Date _____

RECORD OF MINOR REVISIONS:

DATE	LOCATION OF REVISION	QAM APPROVAL

RECORD OF MAJOR REVISIONS:

NEW	1	2	3	4	5	6
_____	_____	_____	_____	_____	_____	_____

EXHIBIT 4.2

REVISION CONTROL LOG				
Revision No.	Revision Date	Affected Pages	Document Control No.	Description of Change

EXHIBIT 4.3
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EXHIBIT 4.4
COLUMBIA/BIO MEDICAL LABORATORIES
SOP DISTRIBUTION RECORD

SOP- - :			REVISION #		REVISION #		REVISION #	
BOOK #	SIGNED TO	LOCATION	DATE	INITIALS	DATE	INITIALS	DATE	INITIALS

5.0 PERSONNEL QUALIFICATIONS AND TRAINING

5.1 Introduction

Laboratory policy mandates each person demonstrates a high level of proficiency before performing specific analytical procedures. All analytical personnel will be tested and approved by the Quality Assurance/Operations Manager before being allowed to perform each assigned analytical procedure. A written notation of the approved procedures will be maintained in the employee's file. As educational opportunities arise whereby an employee may increase the number of approved tests, the employee will be encouraged to participate in continuing education. Personnel policies contain an outline of assistance that will be made available by the laboratory and the conditions which apply.

5.2 Quality Assurance Training

The Quality Assurance/Operations Manager is responsible for conducting the orientation of personnel to the CBML Quality Assurance Plan (Exhibit 5.1). All training will be documented using the employee training form and will be retained in the permanent file of the employee.

5.3 Analytical Training and Proficiency

All CBML personnel shall receive the necessary technical training to assure that procedures are followed and that data of known and expected quality are generated. The Quality Assurance/Operations Manager initiates and maintains records of approved procedures for all CBML employees. Education and training experience obtained prior to employment at CBML will be verified and performance evaluated by the Departmental Supervisor. Each individual technician or technologist will maintain records of any continuing educational courses which the employee has completed.

Technicians without prior training or experience concerning a specific analytical procedure are required to demonstrate satisfactory test performance under the supervision of the Quality Assurance/Operations

Manager. Upon satisfactory performance for a procedure or analytical method, the personnel training record will be updated (Exhibit 5.2).

5.4 Safety Training

The Quality Assurance/Operations Manager has the responsibility to conduct safety training for all new employees and provide additional training as necessary or required.

Exhibit 5.1

COLUMBIA/BIO MEDICAL LABORATORIES
QUALITY ASSURANCE PLAN TRAINING

ANALYST: _____

SECTION: _____

*SYSTEM	DESCRIPTION/COMMENTS	QA APPROVAL	DATE

* Indicate the section and/or procedure addressed

Exhibit 5.2

ANALYST RECORD OF TRAINING AND PROFICIENCY

ANALYST: _____

SECTION: _____

*SYSTEM	DESCRIPTION/ SUPERVISOR COMMENTS	SUPERVISOR APPROVAL	DATE APPROVED

* Indicate the system by listing an analytical procedure, applicable instrumentation, or preparation procedure.

6.0 FACILITIES, EQUIPMENT AND SERVICES

CBML ensures that the following are maintained in the laboratories:

- Adequate and acceptable facilities with suitable lighting, ventilation, temperature and humidity.
- Adequate and acceptable utility services, such as voltage control, air, water and vacuum.
- Adequate and acceptable general laboratory facilities and equipment, such as refrigerators, fume hoods, ovens, sinks, and bench area.

Each major analytical instrument is maintained under a program of regularly scheduled preventive maintenance performed by a factory trained service engineer. For less complicated equipment and instrumentation, service checks, some preventive maintenance checks, and QC are regularly performed by an assigned technologist. Documentation of equipment maintenance and standard checks is maintained in appropriate records.

7.0 DATA GENERATION

7.1 Introduction

QA Project Plans are developed and implemented for environmentally related measurement activities addressed by CBML so that all data generated and processed by CBML are scientifically valid, defensible, of known accuracy and precision, and of acceptable completeness, representativeness, and comparability.

7.2 Quality Assurance Project Plans

As required, QA Project Plans are prepared for specific projects or continuing operations to ensure that data generated and processed are of known quality and integrity. QA Project Plans contain the following, as applicable:

1. Title Page, with provision for approval signatures;
2. Table of Contents;
3. Project Description, including objectives, goals, and data usage;
4. Project Organization and Responsibilities;
5. QA Objectives for Measurement Data, in terms of precision, accuracy, completeness, comparability, and representativeness;
6. Sampling Procedures;
7. Calibration Procedures and References;
8. Analytical Procedures;
9. Data Reduction, Validation, and Reporting;
10. Internal Quality Control Checks;
11. Performance and Systems Audits;
12. Preventive Maintenance Procedures and Schedules;
13. Specific procedures to be used routinely to assess data precision, accuracy, and completeness of the specific measurement parameters involved;

14. Corrective Action;

15. Quality Assurance Reports to Management.

QA Project Plans also address the following activities, as applicable:

1. General network design, objectives, and limitations;

2. Specific sampling site selection criteria;

3. Sampling and analytical methodology;

4. Probes, collection devices, storage containers, sample additives and preservatives, temperature, and pH;

5. Federal reference, equivalent, and alternate test procedures;

6. Instrumentation selection and use;

7. Calibration and standardization;

8. Preventive and remedial maintenance and service contracts;

9. Replicate sampling and analysis;

10. Blind and spiked samples;

11. Quality control procedures such as inter- and intra-field and laboratory activities;

12. Sample custody and handling procedures, including special precautions such as holding times, protection from heat and light, reactivity, combustibility, and packaging;

13. Sample labeling, package marking and placarding in accordance with Department of Transportation Regulations prior to shipment or transportation;

14. Safety;

15. Data handling evaluation procedures;

16. Precision, accuracy, completeness, representativeness and comparability;

17. Document control.

7.1.1 Standard Operating Procedures

Unique Standard Operating Procedures (SOPs) may be developed for specific projects. Standard Operating Procedures, detailed documents describing who does what, when, where, how, and why in a stepwise manner, are prepared for routine tasks. They are sufficiently complete and detailed to ensure:

1. That data of known quality and integrity are collected to meet the project objectives;

2. A minimum loss of data due to out-of-control conditions.

7.1.2 Analytical Procedures

Coliform samples will be analyzed in accordance with methods 9131 and 9132 described in USEPA Test Methods for Evaluating Solid Waste, SW-846, Third Edition, November 1986, Revision 1, December 1987. (See Reference 2 of the Appendix) Each client is required to specify the method of analysis to be applied for each sample.

8.0 DATA PROCESSING

8.1 Introduction

As applicable, CBML employs automated data processing procedures. These include:

- The generation of standard calibration curves
- Mathematical modeling of standard curves
- Statistical analysis
- Calculations
- Data storage and retrieval
- The generation of hard copy output

Data processing includes the collection system consisting of the following instrumentation:

1. Mainframe Data Collection Systems
   a. Digital Equipment Corp.
      11/73 CUP with a DSM-11 Operating system equipped with 1 MB DOS memory.
   b. Fujitsu Disc Drive
      336 MB Disc Drive
   c. Emulex
      Multiplexers 16 line (2)
2. Satellite Laboratory Communications
   a. Multi Tech
      Four Channel Stat Mux (4)
      Eight Channel Stat Mux (1)
      Error correcting Modem (1)
3. Peripherals
   a. Wyse Video CRT Terminals (14)
   b. C. ITOH Printer 310 (9)
   c. C. ITOH High Speed printer 4000 (2)

8.2 Validation

At the completion of the analysis of each coliform sample, the assigned technologist either calculates pertinent data and manually enters these data into the computer, or transfers data directly to the mainframe memory using the analyzing instrument. All transferred data are validated by the technologist. Samples which require repeat analysis, rechecking, or alteration of the report to effect completeness are noted and remedial action taken. Corrective action is recorded in the daily log. Coliform analysis requires the additional validation of data by a peer technologist, Departmental Supervisor, Operations Manager or the Director (as assigned) thereby assuring that results are validated by two additional scientists, one of which is at supervisor level or above.

8.3 Data Storage

The paperwork documenting the raw data for coliform samples (e.g., records, paper tapes, charts, calibration curves) is collected into a box labeled with department, date and other pertinent information. The computer stored data is transferred onto micro fische film for long term storage. These data are stored in a secured fireproof safe.

8.4 Transfer

After data are transferred to the mainframe computer, results derived from the analysis of the coliform samples are printed and transported to the appropriate ordering entity. The mainframe computer likewise prints data directly to specific offices as required.

Specific QA Plans for each project for which data are not transferred to the computer will describe the exact procedures to be employed to transfer the data to the user in an error free manner.

8.5 Reporting

Reports are generated immediately following completion of the analyses and associated data validation. For each sample, MPN/100 mL values are reported for EPA Method 9131 and total coliform colony count/100 mL values are reported for EPA Method 9132.

9.0 RECORDS MANAGEMENT

9.1 Introduction

All records generated in the process of analysis, temperature monitoring, and quality control must be stored in an orderly manner at CBML. All logbooks and data records must be in a bound laboratory notebook and contain identification of the specific information involved. Records will be archived in the basement of the main laboratory on shelves in an orderly manner so that timely retrieval can occur and deterioration will be minimized.

All records shall be maintained under document control and be archived under the following index format that includes:

1. Specific type of record preserved.
2. Appropriate client or project name.
3. Appropriate dates.
4. Location of off-site micro fische records.

An active log or record will be maintained for all records that are temporarily removed from the archives. An archive inventory shall be maintained by CBML to document records, facilitate traceability and timely retrieval.

9.2 Classification

All records that are archived at CBML shall be classified into two general categories:

- Records generated in analytical activities of a specific project for a specific client (Project Records).
- Records generated in the normal course of analytical activities at CBML (Operational Records).

9.3 Project Records

When CBML becomes involved in a specific contract, all records related to specific work on that project will be collected and maintained in a single file. Specific project records will be maintained by CBML in a designated area or cabinet. Project records shall contain all necessary information and

documentation to verify complete compliance with the requirements of the project.

9.4 Operational Records

CBML operational records pertain to the routine functions and operation of the laboratory. A controlled file of operational records shall be maintained. The general operational records shall contain:

9.4.1 Audit and Proficiency Reports

Files will be maintained for all audit and proficiency testing reports. This will include all evaluation reports.

9.4.2 Equipment Inventory

A current listing of all CBML equipment shall be compiled in this file. This file shall include date of purchase, CBML control numbers, and purchase cost.

9.4.3 Qualification and Training Records

This file contains job descriptions for each position at the CBML, current employee curricula vitae and resumes, position qualification documentation, statements of training, and approved analytical procedures.

9.5 Records Retention

All records archived at CBML shall be classified as to client project category.

The following is a list of the QA records which must be maintained for the life of the project:

- CBML SOPs and revisions
- CBML notebooks and worksheets
- Proficiency evaluations and audit records
- Computer documentation
- Instrument calibration and maintenance
- Quality control charts and analyses

- Sample receipt and log verifications
- Noncompliance corrective action reports

9.6 Reference Documents

CBML shall maintain a current assortment of reference documents such as journals, procedure manuals, instrument instruction manuals and reference books. These documents will be reviewed routinely to maintain correct information.

10.0 QUALITY CONTROL PROCEDURES FOR COLIFORM ANALYSIS

Quality control procedures to be followed for analysis of coliforms by the following methods are presented here.

10.1 EPA Method 9131

Total Coliform by Fermentation Technique: EPA Method 9131 (SW-846, 3rd Edition). (See Reference 2--Appendix)

10.1.1 Sample Preservation and Analytical Hold Time

Samples must be refrigerated at a temperature of 1°C - 4°C and analyzed within two hours from time of receipt at the receiving laboratory.

10.1.2 Quality Control of Sample Media

10.1.2.1 Media will be ordered to last for only one year; oldest stock will be used first. An inventory of all media ordered will be maintained, including a visual inspection record.

10.1.2.2 Unopened media will be held for no longer than two years. Opened media containers will be discarded after six months.

10.1.2.3 When preparing media, keep containers open as briefly as possible. Prepare media in deionized or distilled (Type II) water of proven quality. Check the pH of the media after solution and sterilization; it will be within 0.2 pH units of the stated value. Discard and remake if it is not.

10.1.2.4 Autoclave media for the minimal time specified by the manufacturer because the potential for damage increases with increased exposure to heat. Remove sterile media from the autoclave as soon as pressure is zero. Effectiveness of the sterilization will be checked weekly, using strips or ampuls of Bacillus stearothemophelus.

10.1.2.5 Agar plates will be kept slightly open for 15 minutes after pouring or removal from refrigeration to evaporate free moisture. Plates must be free of lumps, uneven surfaces, pock marks, or bubbles which can prevent good contact between the agar and medium.

10.1.2.6 Avoid shaking fermentation tubes as this can entrap air in the inner vial and produce a false positive result.

10.1.2.7 Store fermentation tube media in the dark at room temperature of 4°C. If refrigerated, incubate overnight at room temperature to detect false positive gas bubbles.

10.1.2.8 Quality control checks of prepared media will include the incubation of 5% of each batch of medium for two days at 35°C to inspect for growth and positive/negative checks with pure culture.

10.1.3 Analytical Quality Control Procedures

10.1.3.1 Duplicate analytical runs will be made on at least 10% of all known positive samples analyzed.

10.1.3.2 At least one positive control sample will be run each month for each parameter tested.

10.1.3.3 At least one negative (sterile) control will be run with each series of samples using buffered water and the medium batch used at the beginning of the test series and following every tenth sample. When sterile controls indicate contamination, new samples will be obtained and analyzed.

10.1.3.4 The Type II water used will be periodically checked for contamination.

10.1.3.5 For routine MPN tests, at least 5% of the positive confirmed samples will be tested by the complete test.

10.1.4

Results of all quality control testing will be maintained in a central file.

10.2 EPA Method 9132

Total Coliform by Membrane-Filter Technique: EPA Method 9132 (SW-846, 3rd Edition). (See Reference 2--Appendix).

10.2.1

Samples must be refrigerated at a temperature of 1°C - 4°C and analyzed within two hours from time of sample receipt at the receiving laboratory.

10.2.2 Quality Control of Sample Media

10.2.2.1 Media will be ordered to last for only one year; oldest stock will be used first. An inventory of all media ordered will be maintained including a visual inspection record.

10.2.2.2 Hold unopened media for no longer than two years. Opened media containers will be discarded after six months.

10.2.2.3 When preparing media, keep containers open as briefly as possible. Prepare media in deionized or distilled (Type II) water of proven quality. Check the pH of the media after solution and sterilization; it should be within 0.2 pH units of the stated value. Discard and remake if it is not.

10.2.2.4 Autoclave media for the minimal time specified by the manufacturer, because the potential for damage increases with increased exposure to heat. Remove sterile media from the autoclave as soon as pressure is zero. Effectiveness of the sterilization will be checked weekly, using strips or ampuls of Bacillus stearothemophelus.

10.2.2.5 Agar plates will be kept slightly open for 15 minutes after pouring or removal from refrigeration to evaporate free moisture. Plates must be free of lumps, uneven surfaces, pock marks, or bubbles which can prevent good contact between the agar medium

10.2.2.6 Quality control checks of prepared media will include the incubation of 5% of each batch of medium for two days at 35°C to inspect for growth and positive/negative checks with pure culture.

10.2.3 Analytical Quality Control Procedures

10.2.3.1 Duplicate analytical runs will be made on at least 10% of all known positive samples analyzed.

10.2.3.2 At least one positive control sample will be run each month for each parameter tested.

10.2.3.3 At least one negative (sterile) control will be run with each series of samples using buffered water and the medium batch used at the beginning of the test series and following every tenth sample. When sterile controls indicate contamination, new samples will be obtained and analyzed.

10.2.3.4 The Type II water used will be periodically checked for contamination.

10.2.4 Quality Control Specifications for Membrane Filters

10.2.4.1 Membrane filters can be purchased sterile or packaged for sterilization. They can be sterilized by autoclaving, ethylene oxide, or irradiation. Membrane manufacturers will certify that their membranes meet stated specifications on sterility, retention, recovery, pore size, flow rate, pH, total acidity, phosphate, and other extractables.

10.2.4.2 Membrane performance should be tested to ensure proper results. Each lot ordered will be inspected for proper shape, grid lines, diffusability, and correct colony development. Membranes containing sizable areas with no colony development are questionable.

10.2.5

Results of all Quality Control will be maintained in a central file.

11.0 DATA QUALITY ASSESSMENT

11.1 Introduction

The quality of all data generated and reported by CBML is assessed before it is reported to ensure that it satisfies the needs of the user and conforms to QA Project Plan requirements. The data are evaluated for accuracy, precision, completeness and comparability.

11.2 Data Sources

There are two primary means by which CBML assesses accuracy and precision. Samples assayed by peer laboratories (or of known content) are used by CBML to compare test values to assayed (true) values to determine accuracy. In addition, unassayed field samples are tested in duplicate or replicate to generate statistical data which may be used to assess precision.

11.3 Accuracy

A quality control plot with performance limits at mean $\pm$ two standard deviations is generated for each applicable analyte. During daily analytical runs, the values obtained from control samples are plotted and if values fall outside the acceptable two standard deviations from the mean, the analysis stops and corrective measures are taken. Also, observation of five consecutive data values on either side of the mean is not acceptable since this would be considered trending. This situation also requires corrective action.

11.4 Precision

The same samples, tested repeatedly, can be used to assess precision. This assessment is carried out on a daily, weekly and monthly basis, as appropriate. Precision is usually evaluated by analyte where the range of replicate values is divided by the average of the values, resulting is a measure of the precision. The precision value is compared to control limits previously determined either by the procedure manufacturer or by CBML.

11.5 Representativeness

Representativeness is the degree to which a QC sample accurately and precisely represents the conditions of the routine field sample. All assayed and unassayed QC materials will be tested in like manner as field samples and without consideration of source.

12.0 CORRECTIVE ACTION/NONCONFORMANCE

12.1 Introduction

The purpose of this document is to list procedures for the identification, documentation, and correction of deficiencies in the operation of the laboratory.

12.2 Scope

12.2.1 This SOP lists the specific steps required for the documentation of deficiencies, the correction of deficiencies, the assignment of specific corrective action as required, and implementation of follow-up action to verify that corrective action was effective.

12.2.2 This SOP also addresses instances of nonconformance. For the purposes of this SOP, a nonconformance event is defined as a specific deficiency for which no corrective action is required or assigned. Repeated instances of the same type of nonconformance event require the assignment of appropriate corrective action measures.

12.2.3 Documentation of all deficiencies including nonconformance events is required.

12.3 Responsibilities

12.3.1 It is the responsibility of each individual who detects a deficiency to initiate documentation of required corrective action or of nonconformance.

12.3.2 Documentation of each deficiency is submitted to the Quality Assurance Manager (QAM). The QAM is responsible for follow-up and close-out efforts required for corrective action. The QAM is also responsible for the review of all nonconformance documents. As a result of continuing review, the QAM will initiate corrective action as demanded by repeated nonconformance events of the same type.

12.3.3 It is the responsibility of the departmental supervisor or immediate supervisor of the individual who detects and documents the need for corrective action to assign the measures required for correction.

12.4 Documentation of Required Corrective Action

12.4.1 Each identified deficiency requiring corrective action will be documented using CBML's Quality Assurance/Quality Control Corrective Action Record (CAR) (Exhibit 12.1). Documentation will include a short narrative of the deficiency, signature of the individual initiating the action, and the date.

12.4.2 One and only one CAR form will be completed for each deficiency identified.

12.4.3 The departmental supervisor or immediate supervisor must write a brief narrative recommending measures to be implemented to correct the deficiency. This recommendation is written on the CAR.

12.4.4 The laboratory director (if applicable) approves the recommended corrective action by signing the CAR.

12.4.5 The QAM reviews and signs each CAR. The QAM assigns a document number to each CAR and files the document.

12.4.6 Data generated under each corrective action situation are reviewed by the QAM and appropriate departmental supervisor. The data are either accepted or rejected by the QAM based on this review and accompanying investigations. Aspects of the investigations related to acceptance or rejection of data shall be documented in the CAR. The laboratory director will be notified of any rejected data by memorandum from the QAM. A copy of the CAR will be included in the data package.

12.5 Corrective Action Follow-up

12.5.1 The QAM is responsible for follow-up and close-out of all documented deficiencies requiring corrective action. This is accomplished by either an internal audit or a written statement by the departmental supervisor or immediate supervisor that corrective action has resolved the problem.

12.5.2 Resolution of the problem is documented by the signature of the QAM or designee on the CAR.

12.6 Nonconformance Events

12.6.1 All nonconformance events must be documented.

12.6.2 Each nonconformance event is documented by the individual who identifies the event. Documentation is effected using CBML's Nonconformance Report form (Exhibit 12.2).

12.6.3 All reports are submitted to the QAM or designee.

12.6.4 The QAM is responsible for the review, monitoring, and filing of all Nonconformance Report forms.

12.6.5 The QAM will initiate appropriate corrective action using a CAR if undesirable trends or repeated deficiencies (nonconformance events) of the same type are identified.

12.6.6 Data generated under each nonconformance event are reviewed by the QAM and appropriate departmental supervisor. The data are either accepted or rejected by the QAM according to the documented circumstances of the nonconformance. The acceptance or rejection of data as well as aspects pertinent to the nonconformance event are documented by the QAM in the nonconformance report. The laboratory director will be notified of any rejected data by memorandum from the QAM. A copy of the nonconformance form will be included in the data package.

Exhibit 12.1

COLUMBIA/BIO MEDICAL LABORATORIES
QUALITY ASSURANCE/QUALITY CONTROL
CORRECTIVE ACTION RECORD

Document #: _____

Problem Analyte(s) _____ Sample or Project ID No(s) _____

Reporting Period _____

QUALITY ASSURANCE COMMENTS:

Signature: _____ Date: _____

ANALYST COMMENTS:

Signature: _____ Date: _____

DEPARTMENTAL SUPERVISOR COMMENTS:

Signature: _____ Date: _____

LABORATORY DIRECTOR COMMENTS:

Signature: _____ Date: _____

VERIFICATION OF COMPLETION OF CORRECTIVE ACTION AND RESOLUTION OF PROBLEM:

Signature: _____ Date: _____

EXHIBIT 12.2

COLUMBIA/BIO MEDICAL LABORATORIES
NONCONFORMANCE REPORT

LOT/CBML # _____ SUBMITTED BY: _____
(please print name)

ANALYSIS: _____ SIGNATURE: _____

CONTRACT/PROJECT ID: _____ DATE OF OCCURRENCE: _____

NO. OF SAMPLES AFFECTED: _____

Briefly describe nonconformance: _____

_____

_____

_____

THIS REPORT MUST BE SUBMITTED TO QA WITHIN 3 DAYS AFTER NONCONFORMANCE OCCURS.

_____

QUALITY ASSURANCE use only

IR NO. _____ CAR REQUIRED _____ YES _____ NO

If yes, CAR # _____

QA Comments: _____

_____

_____

Production Comments: _____

_____

_____

13.0 PROCUREMENT CONTROLS

13.1 Introduction

13.1.1 The purpose of this Standard Operating Procedure (SOP) is to establish sufficient quality control of purchased material and services (e.g., balance calibration services) and to insure that purchased materials and services meet quality specifications of Columbia/Bio Medical Laboratories (CBML).

13.2 Scope

13.2.1 This SOP describes the procurement of material, components, supplies, reagents, equipment, and services used in analytical testing.

13.2.2 Purchase order procedures, maintenance of records, certificate of conformance, and vendor requirements are detailed in this SOP.

13.3 Responsibility

13.3.1 The purchasing department is responsible for maintaining all records of material received from vendors. This includes the documentation of any rejected material for nonconformance.

13.3.2 The Quality Assurance Manager (QAM) or designee is responsible for the approval of designated analytical materials received from outside vendors.

13.3.3 The laboratory store clerk or designee is responsible for checking lots of material received for quantities, for certifications, and to check the packing slip against the purchase order.

13.4 Quality Assurance Review of Purchase Orders

13.4.1 Requisitions addressing quality related items, such as reference materials, must be approved by the QAM or designee. Reagent grade chemicals are excluded from this approval requirement.

13.4.2 Approval by the QAM or designee must be documented by recording of the applicable signature(s) on the requisition. No pertinent materials may be purchased or brought into the laboratory without this approval.

13.5 Receipt of Purchase Orders

13.5.1 All items requiring certification and/or certificates of conformance are identified and are filed and/or archived by the QA section.

13.5.2 Purchase orders are reviewed by the laboratory store clerk for completeness.

13.5.3 Upon receipt, items must be logged into an appropriate record noting identification of the material, vendor, date of receipt, P.O. number, CBML part number, quantity received, and per unit quantity received.

13.5.4 QAM or designee may require a check validation of a certification of a purchased item. This can be accomplished using CBML's own expertise or that of an outside laboratory.

13.5.5 If the material does not conform to the specifications of CBML, the vendor is notified by the Purchasing Department, the material is returned or discarded, and the conditions are noted on the requisition and in QA files.

13.5.6 Pertinent glassware shall meet ASTM specifications D-86 and D-216, as applicable. Documentation of the meeting of these ASTM specifications shall be maintained, as applicable, by the QAM.

13.6 Subcontracts

13.6.1 CBML shall require subcontract laboratories to follow the same quality assurance procedures as stated in CBML's applicable QA Plan. The QAM is responsible for evaluation and acceptance of the contractor's or subcontractor's Quality Assurance Program.

13.6.2 With respect to QA requirements, initial qualifying audits and subsequent periodic audits will be conducted by the QAM or designee of subcontractors.

13.7 Vendors

13.7.1 The QAM and the appropriate departmental supervisor (DS) are responsible for the evaluation and approval of all vendors. Internal audits, inspection, and examination of products or services shall be used for evaluation.

13.7.2 Contractors and subcontractors will be assessed at intervals consistent with importance for effectiveness of the quality control.

14.0 QUALITY ASSURANCE AUDITS AND REPORTS TO MANAGEMENT

14.1 Introduction

The QAM is required to submit reports to management regarding the evaluation and verification of the implementation and effectiveness of the Quality Assurance Plan.

14.2 Performance Audit Reports

CBML participates in various coliform analysis performance audits. The QAM is responsible for coordinating and reporting the performance audit results to the regulatory agency or other interested parties in a timely manner. A performance audit file will be maintained by the QAM for all coliform assay performance audits in which CBML is involved.

The QAM will submit a report to the CBML Laboratory Director, Departmental Supervisors and other involved management personnel on the performance evaluation results obtained from audit. Indicated deficiencies, biases and unacceptable performance results will initiate a corrective action investigation and compliance report by the QAM.

The performance audit file will contain the initial report, raw data, performance, QAM performance audit report and associated corrective action and compliance reports.

14.3 Procedure/System Audit Reports

Internal audits and inspections are conducted by the CBML Quality Assurance Manager (QAM) to verify that CBML procedures and practices are in compliance with written and approved policy.

Routine procedure and systems audits will be conducted at least quarterly by the QAM. An audit of a specific procedure or system may be requested by an analyst, or CBML manager at any time. Audits shall be coordinated and scheduled through the QAM.

Systems and procedures subject to QAM audit include, but are not limited to:

- Analytical standards and source material procurement, preparation, use, storage and disposal;
- Analytical procedures and methods, including sample screening and preparation, instrumental calibration, analysis, data collection, sample storage and inventory control;
- Analytical data reduction, validation, and reporting procedures;
- Complete analytical data sets, analyst's notebooks, maintenance and instrument logs, and other laboratory record books;
- Quality control sample preparation and documentation;

An internal audit checklist will be completed and a copy will be attached to the evaluation report. This evaluation report will be completed by the QAM and submitted to the CBML Laboratory Director, Departmental Supervisors and other involved management personnel.

Any deficiencies or noncompliance that are revealed by the audit will constitute the initiation of corrective action measures by the QAM. A Corrective Action Report (CAR) will be completed by the QAM following the initiation of corrective action measures. This CAR will document the effectiveness of the action taken and a copy will be included with the audit report in the procedure/system audit file.

14.4 Operational Audit Reports

The operations of the CBML shall be audited by the QAM at least quarterly for compliance with SOPs, analytical methods, contractual project and program requirements. The audit shall consist of observations by the QAM auditor of routine operational procedures at CBML for comparison against, and compliance with, established program and project criteria and requirements.

Operational aspects selected for routine audit by the QAM shall be independent of the CBML management.

All compliance and noncompliance with established program and project criteria shall be documented during the audit. Audit personnel shall submit findings to the QAM. The QAM shall prepare and submit an operational audit report to the CBML Laboratory Director, Departmental Supervisors and other involved management personnel. All noncompliance shall constitute corrective action measures. Documentation and verification of these measures will be maintained with the audit report in the operational audit file.

15. CALIBRATION OF REFRIGERATION UNITS, OVEN UNITS, AND BALANCES

15.1 Introduction

15.1.1 The purpose of this Standard Operating Procedure is to describe the procedures for documentation of the verification of performance of refrigeration unit thermometer equipment, oven thermometer equipment, and balances. This will allow the refrigeration and oven units and balances to provide the highest quality performance and to maintain the integrity of the data.

15.2 Responsibility

15.2.1 The Quality Assurance Manager (QAM) is responsible for the verification and documentation of all refrigeration unit temperatures, oven temperatures, and all analytical balances at Columbia/Bio Medical Laboratories (CBML). It is also the responsibility of the QAM to notify the appropriate departmental supervisor of any malfunctioning or necessary adjusting of the equipment.

15.2.2 It is the responsibility of the appropriate departmental supervisor to adjust and maintain the refrigeration equipment, oven equipment, and balances within the section with the assistance of the Operations Manager or outside source.

15.2.3 The Quality Assurance Manager (QAM) is responsible for contacting the balance manufacturer for service when out-of-control or noncompliance situations are found, or when annual calibrations are required.

15.2.4 Each analyst is responsible for notifying the appropriate departmental supervisor or the QAM of any noncompliant equipment.

15.3 Refrigeration and Oven Equipment

15.3.1 Temperature validation of refrigeration and oven units is documented each working day by the assigned technician or technologist. The assignee will be appointed by the Quality Assurance Manager (QAM).

15.3.2 Each uniquely numbered refrigeration unit and oven unit has an attached thermometer. The thermometer is read at eye level by the assigned individual.

15.3.2.1 Thermometers are validated once per year using a National Institute of Standards and Technology (NIST) traceable thermometer.

15.3.2.2 To validate the refrigeration and oven unit thermometers, place a partial immersion NIST thermometer into a beaker and fill the beaker with deionized water up to the specified immersion line. Place the beaker and thermometer into the refrigeration or oven unit. The deionized water will equilibrate to the temperature of the refrigeration unit within four (4) hours (+/- 15 minutes). After the elapsed time period, read the NIST thermometer and validate against the refrigeration or oven unit thermometer. The refrigeration unit thermometer must be within +/– 1/2°C to be validated. The oven thermometer must be within +/– 1°C to be validated.

15.3.2.3 Total immersion thermometers can also be used to validate the refrigeration and oven unit thermometers. Total immersion thermometers must previously be validated against a NIST thermometer. To validate against a NIST thermometer, place the total immersion thermometer into a 500-mL graduated cylinder and fill the cylinder with deionized water until the thermometer is totally immersed. Place the NIST thermometer into the deionized water so that the water is level with the NIST thermometer immersion line using a stopper or clip to hold in place. Put the cylinder, with thermometers, into a refrigeration or oven unit, or store at an applicable temperature for four hours +/– 30 minutes. If the temperatures are equivalent, the thermometer is validated. If the temperatures are not equivalent, a correction factor can be used to correct for the temperature of the total immersion thermometer. Each total immersion thermometer must be tagged with a correction factor, if necessary, and the date of validation. Validation of each total immersion thermometer must be made on a yearly basis. Refrigeration and oven unit thermometers are validated against a total immersion thermometer by placing the total immersion thermometer into the refrigeration unit for 30 minutes (+/– 5 minutes). Readings of the two thermometers must be within +/– 1/2°C to be validated.

15.3.2.4 Thermometers that are not within validation criteria can be corrected with a correction factor. Thermometers are tagged with the correction factor and the date of

validation, or are removed, discarded, and replaced with validated thermometers.

15.3.2.5 Thermometers are uniquely numbered by the Quality Assurance Manager.

15.3.2.6 Documentation of yearly validation shall be recorded in a thermometer logbook by the individual assigned to make the measurements. Daily temperature readings are recorded on a temperature log form. An example is included as Exhibit 15.1.

15.3.3 Refrigeration and oven units are assigned a unique unit number by an individual assigned by the QAM.

15.3.4 Documentation of each refrigeration and oven unit temperature is recorded in degrees Celsius on a form similar to Exhibit 15.1. The form is attached to each refrigeration unit. The form contains the following information:

- unit number;
- acceptable temperature range;
- the month for which temperatures were recorded;
- day when temperature was taken;
- temperatures (in°C);
- initials of the person verifying temperatures.

15.3.5 The assigned individual must verify the temperature reading, record the temperature, and write initials in the appropriate space according to the day of the reading.

15.3.6 The criteria for refrigerators are in the range of 2–6°C (36–43°F).

15.3.7 Any variances outside of the criteria or maintenance performed on the unit must be documented on the form (Exhibit 15.1) in the maintenance schedule section and must also be documented as nonconforming to criteria listed in section 3.6 of this SOP on the form (Exhibit 15.3).

15.3.7.1 The impact on the samples or data must be documented on the nonconformance form (Exhibit 15.3) in the manager's "Actions Taken" section.

15.3.8 After refrigeration and oven unit temperatures for each calendar month have been recorded, all pertinent forms are bound into binders. Binders are stored in QA area for three months, after which they are archived according to contractual requirements.

15.3.9 If the equipment is noncompliant with Quality Assurance standards, it is tagged with a tag similar to Exhibit 15.2 and the laboratory director and departmental supervisors are notified of the variance. The tag can be removed only by Quality Assurance. (See notification section 5.0 for notification procedure.)

15.4 Balances

15.4.1 All balances (analytical and top-loaders) are verified on a weekly basis by an appointed individual. An exception of this verification is the filter balances. They are serviced yearly by contract and are only adjusted by authorized personnel assigned by the QAM.

15.4.2 Balances are identified by the model number located on the instrument at the time of purchase.

15.4.3 The balances are verified against three National Institute of Standards and Technology (NIST) traceable weights in the approximate range of samples usually weighed for that particular balance. The operations manager will notify QA personnel of the expected weight range. The NIST weights verify the accuracy between the lowest and highest weights used during the verification of each balance.

15.4.4 Technicians and technologists are responsible to notify the appropriate manager or QA personnel of any noncompliant equipment. The technician/technologist may also verify the balance before each use or daily with the NIST weights. Any verification must be recorded in the balance logbook.

15.4.5 Documentation of all weights is recorded in a balance logbook specific for each balance by the technician/technologist. The balance logbook contains the following information:

- date of weight verification;
- three actual readings of weights (using NIST weights);
- initials of the assigned individual verifying the readings;
- brand name of balance;
- model number (also identification number);
- serial number;
- CBML property number;
- unit number.

15.4.6 Balance Criteria

15.4.6.1 Acceptable performance for top-loader balances is: within +/– 0.5 grams of the NIST weights.

15.4.6.2 Analytical balances are considered acceptable if data are within the range of +/– 0.001 grams of the NIST weights.

15.4.7 Balance calibration is performed by Quality Assurance or authorized personnel only. The analytical balances are contracted to be calibrated yearly. Top-loaders need not be calibrated yearly, as the weekly verification indicates any possible variances. Also, most materials weighed on the top-loader balances need not be exactly measured. If any balance is found to be noncompliant with the criteria specified in Section 4.6 and QA personnel cannot calibrate, an outside service must be notified.

15.4.8 Equipment not readily repaired is marked with a tag similar to Exhibit 15.2. Operation managers are notified of the variance or noncompliance. The tag can only be removed by Quality Assurance. (See notification Section 5.0 for procedure of notification.)

15.5 Notification of Variances

15.5.1 The laboratory director and appropriate departmental supervisor are to be notified of any variances or noncompliance by Quality Assurance personnel with a memorandum or a form similar to Exhibit 15.3.

15.5.2 The form must include the date of notification, inspector's name, equipment, unit number, department, appropriate departmental supervisor, and an explanation of the noncompliance. The QAM may also document any recommendations or actions taken.

15.5.3 The form must be sent to the laboratory director and the appropriate departmental supervisor. Copies will also be sent to the QAM. The departmental supervisor must return the form to the QAM within two working days, with a statement of action taken on the noncompliant equipment and a statement regarding the impact the variance had on the samples/ data. The QAM will approve/disapprove the equipment for use when provided with the proper validation check of the equipment. QAM will sign a form (Exhibit 15.3) and remove the noncompliance tag (if necessary). The equipment may then be used for analysis. A copy of this action will be kept on file by the QAM.

15.5.4 The technician/technologist must also record the variance on the temperature record form (Exhibit 15.1) in the maintenance schedule section or in the balance logbook.

Exhibit 15.1

CBML RECORD OF TEMPERATURE

Unit Number: _____

Acceptable Temperature Range: _____

Record for Month of: _____

Day	Temp (°C)	Name	Day	Temp(°C)	Name
1			17		
2			18		
3			19		
4			20		
5			21		
6			22		
7			23		
8			24		
9			25		
10			26		
11			27		
12			28		
13			29		
14			30		
15			31		
16					

MAINTENANCE SCHEDULE

Day	Comments/Action

EXHIBIT 15.2

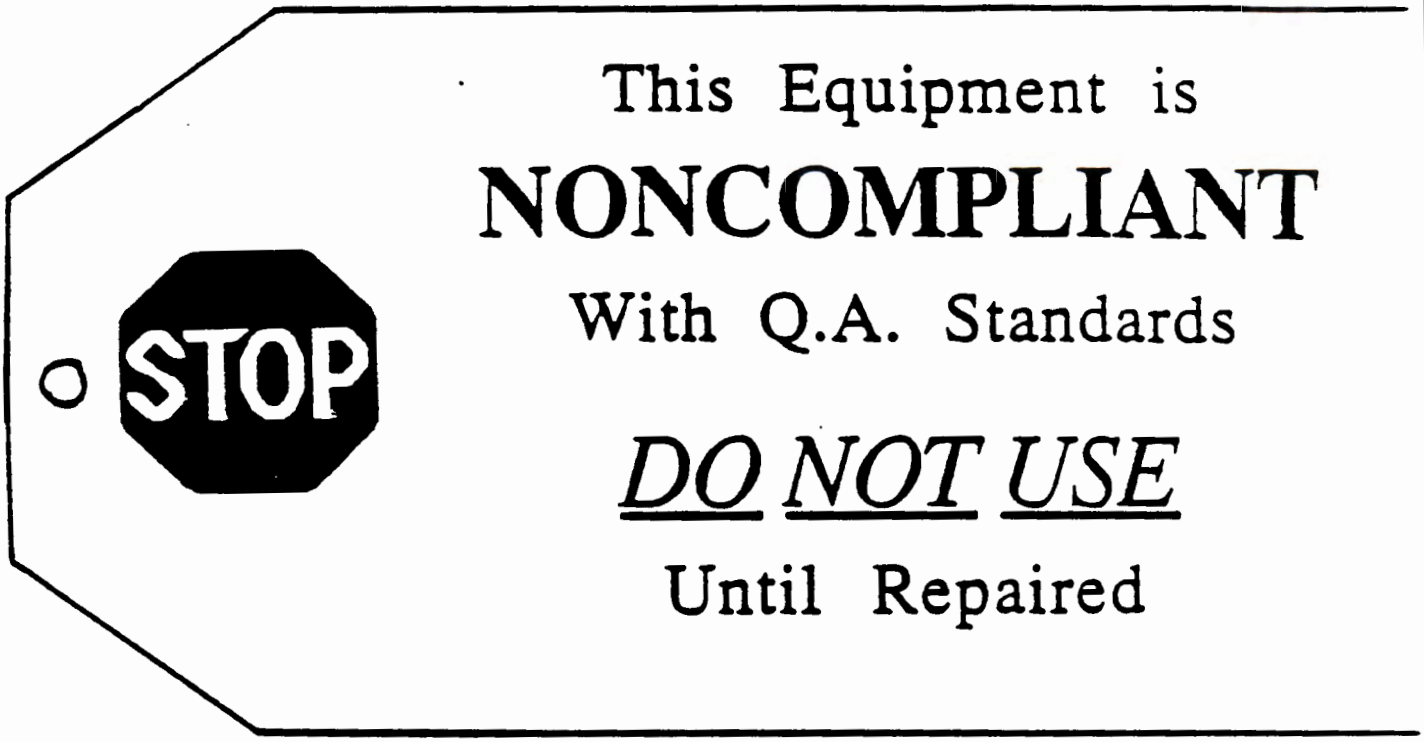
STOP
This Equipment is
NONCOMPLIANT
With Q.A. Standards
DO NOT USE
Until Repaired

EXHIBIT 15.3

QC NOTIFICATION OF EQUIPMENT NONCOMPLIANCE

Date of Notification: _____
QC Inspector: _____
Equipment: _____
Unit Number: _____
Departmental Supervisor: _____
Laboratory Director: _____

THE ABOVE EQUIPMENT HAS BEEN INSPECTED BY QC AND IS NONCOMPLIANT WITH QA STANDARDS.

THE FOLLOWING NONCOMPLIANCE HAS BEEN NOTED:

_____

_____

_____

QC RECOMMENDATIONS OR ACTIONS TAKEN:

_____

_____

_____

DEPARTMENTAL SUPERVISOR ACTIONS TAKEN:

_____

_____

_____

QA Manager approval to use equipment _____ Date _____

* Departmental Supervisor must return form to Quality Assurance Manager within two working days.

APPENDIX

Analytical Procedures

Two major references from which water coliform analytical methods are derived are:

1. American Public Health Association (APHA), Standard Methods for Examination of Water and Wastewater, 17th Edition, 1989.

2. USEPA, Test Methods for Evaluating Solid Waste, Volume One, Section C, USEPA publication SW-846, Third Edition, November 1986, Revision 1, December 1987.