6.0 Quality System, Document Control, Internal Audits and Management Reviews

6.1 The type evaluation laboratory has established and maintains a quality system that supports the tests conducted by the laboratory. The quality system is described in this quality manual, the appendices, and applicable sections of the references named herein. These documents are readily available to all laboratory staff and serve as the basis for evaluating the integrity of the measurements and associated reports. The laboratory conducts internal audits of the laboratory quality system on behalf of management to ensure that the laboratory's policies and procedures as set forth in this quality manual are being followed. Management periodically reviews the quality system, including review of internal audit results (see Appendix H, AP No. 7, Procedures for Internal Audits and Management Review).

6.2 Quality System

6.2.1 The basic elements of the quality system include:

6.2.1.1 the quality manual;

6.2.1.2 NCWM Publication 14 test procedures (see Appendix H and also Section 11);

6.2.1.3 work instructions (maintained in the laboratory);

6.2.1.4 records, forms, reports (see section 13, Appendix O and Section 14); and

6.2.1.5 equipment instruction manuals (maintained in the laboratory)

6.2.2 To ensure proper operation of the quality system, there are:

6.2.2.1 Qualified personnel for each measurement (see Section 7, Personnel, Appendices L, Personnel Training & Competency and M, Job Descriptions and Duty Statements);

6.2.2.2 Management and senior personnel reviews and supervision (see

Section 5, Organization and Management, and Appendix B, Organization Chart);

6.2.2.3 Appropriately maintained and calibrated working standards, equipment, and associated apparatus (see Section 9, Standards, Equipment and Associated Apparatus, Appendices G, Standards and Reference Materials and F, Equipment and Materials);

6.2.2.4 Environmentally-controlled facilities, where appropriate, and/or proper accounting of relevant environmental factors (see Section 8, "Laboratory Facilities and Environment;" Appendices D, "Diagram of Facilities" and E, "Environmental Conditions"); and

6.2.2.5 Appropriate sampling procedures, where necessary (see Section 20).

6.2.3 All elements of the quality system are considered when developing test methods and procedures, training and qualification of personnel and in the selection and calibration of equipment.

6.3 Quality System Documentation

6.3.1 An outline of the laboratory quality system documentation is in Appendix Q, Documentation Outline.

6.3.2 Internal Document Control

6.3.2.1 General

6.3.2.1.1 Appendix N provides a detailed list of controlled documents with revision dates, retention periods, and locations. The procedures for document control include:

a. information on document control numbers,
b. designation of responsibility,
c. assurance that authorized editions of appropriate documents are available at all locations that are essential to the proper functioning of the laboratory,
d. periodic review and, as necessary, revision of the documents to ensure suitability and compliance with

e. applicable requirements,
f. removal of invalid or obsolete documents,
g. access and changes to hard and electronic document, and
h. marking obsolete documents used for legal purposes. (See procedures list in Appendix H, AP No. 3, Document Control.) Section 13 Records lists the records maintained by the laboratory, the location of the records, and the retention time. Handwritten documents are clearly marked, initialed, and dated.

6.3.2.1.2 All documents are reviewed and approved for use by authorized personnel prior to issuing the document to personnel in the laboratory. A control document distribution list is maintained in the laboratory, including the current revision status and distribution of the document. (See Appendix H, AP No. 3)

6.3.2.1.3 Document changes are reviewed and approved following the same procedures for the original review process (see Appendix H, AP No. 3). The altered and/or new text is identified in the document. Handwritten changes to hard copy documents are clearly marked, initialed and dated by laboratory staff authorized to make changes to the documents. Some laboratory documents are maintained on the computer and changes are made electronically. These documents require a password to access the file or are read-only files and must be saved with a different file name when changes are made. Changes in electronic documents are tracked by the word processing system and are accepted by authorized laboratory staff. Procedures and authorities are defined in Appendix H, AP No. 3, for handwritten and electronic changes.

6.3.3 Authority

6.3.3.1 Persons authorized to modify or update laboratory documents are included on the control document distribution list that is maintained

in the laboratory. The quality manager has the designated authority to modify or update the quality manual. The quality manual is annually reviewed and updated as needed by the end of September. The laboratory director is responsible for final approval of all changes made to the quality manual, and the revised document takes effect when signed and dated by the laboratory director.

6.3.3.2 This quality manual (along with associated appendices and references) is available to all laboratory staff and management. Management is responsible for providing the documented quality system to staff and ensuring that all staff familiarize themselves and comply with the policies and procedures established in the manual and associated documentation. The quality manager notifies staff of the most current and approved version of the quality manual through memorandums or e-mails.

6.3.4 Controlled Copies of the Quality Manual

6.3.4.1 Controlled copies of this quality manual are issued to the director, program manager, type evaluation manager, and authorization or accreditation bodies, and are made available to all laboratory personnel. All controlled copies are marked as controlled and are numbered and updated by the quality manager whenever changes are made. Recipients of controlled copies are issued the revised quality manual. It is the responsibility of the quality manager to ensure that the most current quality manual is issued and followed by all laboratory and administrative staff. A list of the names, control numbers, and
location of all controlled copies is maintained in the laboratory files.

6.3.5 Uncontrolled Copies of the Quality Manual

6.3.5.1 Uncontrolled copies of the quality manual are marked "uncontrolled", issued upon request, and are not updated.

6.4 Internal Audits and Management Reviews

6.4.1 Internal Audits

6.4.1.1 The internal audit program addresses all elements of the quality system, including testing. A review of the quality system in accordance with ISO/IEC 17025 is conducted and a checklist is completed. Internal audit reports are maintained in the laboratory. The internal audits include an audit of the laboratory:

a. Equipment
b. Standards
c. Staff (training needs)
d. Facilities
e. Quality documentation
f. Management action items
g. Test results
h. Statistical control data

The laboratory quality manager annually plans the internal audit to review the laboratory's quality system and testing activities to ensure its continuing suitability and effectiveness and to introduce necessary changes or improvements. Internal audits are conducted in August to verify that operations continue to comply with the quality system. Auditors are trained in auditing techniques, have technical insight concerning the laboratory's functions, and (wherever possible) are independent of the activity to be audited. The laboratory manager investigates any deficiencies found during the internal audit to determine appropriate actions. If necessary, the laboratory manager will notify any clients whose tests were affected by the deficiency. (See Section 13 Records and Appendix H, AP No. 7, “Internal Audits and Management Reviews”).

6.4.2 Management Reviews

6.4.2.1 The laboratory director and manager conduct annual management reviews of the quality system (see Appendix H, AP No. 7, “Internal Audits and Management Reviews”.

6.4.2.2 Laboratory staff participate in the review meetings. The management review includes:

6.4.2.2.1 Identification of problems that arise as a result of any client-discovered errors and/or discrepant results from the analysis of the laboratory test data (see Section 17).

6.4.2.2.2 Evidence from internal audits and statistical control data and/or charts, where appropriate. (See Section 13, and Appendices J and N.);

6.4.2.2.3 Evidence from proficiency tests, round robins, and/or interlaboratory collaborative experiments. (See Section 13, and Appendices J and K.);

6.4.2.2.4 Review of policies and procedures;

6.4.2.2.5 Reports of managerial and supervisory personnel;

6.4.2.2.6 Preventive and corrective actions;

6.4.2.2.7 Assessments by external bodies; and

6.4.2.2.8 Changes in volume and type of work, staff needs, facility and equipment needs.

6.4.3 Authorization Review

6.4.3.1 The laboratory submits updated authorization material annually to _____ [NOTE: Insert authorization body, as appropriate.] for review. The material that is submitted for review depends upon the request from the authorization body and may consist of:

a. General laboratory information;
b. Equipment and standard information;
c. Internal audit information;
d. Management reviews
e. Scope or laboratory activities;

f. Staff assignments and training records; and
g. Updated quality manual

6.4.4. All internal audit and authorization review findings, and any corrective actions that arise from them, are promptly settled within the agreed time, documented by the quality manager, and maintained in the laboratory files.