5.0 Organization and Management

5.1 Legal Status

5.1.1 The type evaluation laboratory is maintained under State statute XYZ [NOTE: enter State statute title, number, and/or article number].

OR

5.1.1 The type evaluation laboratory is maintained under NIST HB 130, Uniform Laws and Regulations, Uniform Regulation for National Type Evaluation, which is adopted by State statute XYZ.

5.2 Organization

5.2.1 The type evaluation laboratory is part of the State or Federal Government [NOTE: enter State or Federal agency and department of the State or Federal agency that the laboratory is a part of]. Authority, interrelation, and responsibilities of all laboratory personnel are on file in the form of job descriptions contained in Appendix M and organizational charts provided in Appendix B. The laboratory manager designates staff responsibilities of quality and technical managers and deputies. The quality and technical managers are designated based on knowledge of the quality system and technical activities of the laboratory. (See laboratory organization chart, Appendix B.) In the event that either the quality or technical manager is absent for an extended period, his/her duties are assigned to deputies.

5.2.2 Testing activities are conducted such that they meet the requirements of ISO/IEC 17025 and this quality manual, and satisfy the needs of the client and the regulatory authorities and/or organizations providing authorization and/or accreditation.

5.2.3 The laboratory performs some evaluations of weighing and measuring devices at sites that are outside the permanent laboratory facilities. These sites may be located at a device owner's facility or other site, either within a building or outdoors. Site evaluations are conducted in accordance with the laboratory management system.

5.2.4 The responsibilities of key personnel in the organization who perform other

activities and who have an involvement or influence on the testing activities of the laboratory are defined in order to identify potential conflicts of interest. A list of key personnel performing other activities is maintained in the laboratory. The list includes their current position, in the type evaluation laboratory, other activities conducted, and a statement as to whether or not any conflict exists. (See Quality Manual Section 13 Records, "List of Key Personnel Performing other Activities.") Laboratory personnel do not participate in activities that might adversely affect confidence in the type evaluation (see Appendix H, AP No. 24).

5.3 Responsibility

The managerial and technical personnel of the laboratory are equipped with the authority and resources to perform their duties. The laboratory personnel responsibilities are defined below.

[NOTE: The following is an example of laboratory personnel responsibilities. The type evaluation laboratories must edit this section so that the titles and responsibilities of your laboratory personnel are reflected in this section.]

5.3.1 Director

5.3.1.1 The Director is responsible for the overall compliance of the laboratory to this quality manual and has direct responsibility for the type evaluation laboratory, which includes final approval of all changes made to the quality manual. The Director participates in management reviews of the quality system

5.3.2 Management (Laboratory Manager, however named)

5.3.2.1 The management of the laboratory:

a. implements and enforces the applicable good laboratory practices described in reference documents;
b. provides resources, adjusts workloads, and provides training opportunities for laboratory staff to facilitate completion of assigned tasks in a safe work environment consistent with test requirements and personnel capabilities;
c. assigns deputies for both the technical and quality managers in

the case of an absence;
d. participates in management reviews of the quality system; and
e. supervises the activities of the laboratory

5.3.3 Technical Manager or Deputy [NOTE: The deputy may or may not have the same duties as the technical manager.]

5.3.3.1 The technical manager:
a. is a type evaluation laboratory person who has completed the appropriate level of type evaluation training as specified in the laboratory training procedures in the areas for which the laboratory is authorized;
b. is responsible for the overall administrative and technical operations of the laboratory;
c. specifies and/or approves all methodologies used;
d. implements good laboratory practices by providing instruction and training as needed, develops work plans and procedures, and requires that these be followed in all day-to-day operations;
e. verifies personnel training;
f. assigns only competent personnel to complete tests;
g. attests, by signature, to the validity of all laboratory tests performed and reports (a list of approved signatories is maintained in the laboratory (see Quality Manual Section 13 Records);
h. ensures continued authorization of the laboratory;
i. where necessary, identifies, develops, and implements improvement of the laboratory measurement capability to meet the requirements of ISO/IEC17025, department programs, and laboratory clients; and
j. participates in management reviews of the quality system.

5.3.4 Quality Manager or Deputy [NOTE: The deputy may or may not have the same duties as the quality manager.]

5.3.4.1 The quality manager:
a. is a type evaluation laboratory person who has completed the required level of training as specified in the laboratory training

procedures in the areas for which the laboratory is authorized;
b. coordinates internal audits of the laboratory in accordance with Section 6 of this quality manual;
c. participates in available and relevant proficiency tests, round robins, and/or interlaboratory collaborative studies;
d. maintains the quality manual;
e. has direct access to management and to the technical manager;
f. identifies departures from the quality system or from procedures, and initiate actions to prevent or minimize such departures,
g. coordinates and participates in management reviews of the quality system; and
h. supervises the quality activities of the laboratory.

[NOTE: Type evaluation laboratories may be limited in staff. One person or a part-time person may operate these laboratories. In these cases, one person has the responsibilities of both technical and quality manager. Special care and precaution must be taken and documented to ensure that limited laboratory staff does not adversely affect the quality system and type evaluations.]

5.4 Independence

5.4.1 Management ensures that the laboratory is independent from any pressures – commercial, financial, or others, which adversely affect the quality of test and resulting reports. State policy provides guidelines to ensure laboratory independence. [NOTE: As appropriate the laboratory should reference the State policy.]

5.5 Confidentiality

5.5.1 The laboratory maintains the confidentiality and proprietary rights of all information, including the type of work performed and the results of tests to the extent allowable by State law and in accordance with the administrative procedures. [NOTE: The laboratory should include the specific State law in this statement and document the law in Section 2 of the quality manual.] All laboratory personnel and staff are informed of this policy. (See Appendix H, AP No. 1, Procedures for Client Confidentiality and Proprietary Rights.)