11.0 Type Evaluation Test Methods and Procedures

11.1 The administrative and test procedures are maintained in the laboratory files. The procedures are available to the laboratory staff and are followed to ensure the integrity of the test results, and that the administrative and test procedures are conducted uniformly in the laboratory (see Appendix H, Procedures List). Equipment manuals, operating instructions, reference data, specifications, and tolerance tables relevant to the laboratory are maintained in an up-to-date file in the laboratory and are readily available.

11.2 The selected test procedures are appropriate for the device under test, and the latest edition of the procedure is used to test the device. When documented or published procedures are unavailable, or when deviations from documented procedures occur, procedures for a specific test are developed, validated, and agreed to by the laboratory and the type evaluation body. The extent of the validation meets the needs of the application. The results of the validation are maintained in the laboratory and include the validation procedures used and a statement that the method is fit for its intended use (see Appendix H, AP No. 19 and Section 13, Records). Before a new test is conducted, the laboratory reviews the test procedure to ensure that the test can be performed adequately. If the test procedure is revised, the review is repeated. The test report states the procedure used to perform the test. Records regarding departures from documented policies and procedures or from standard specifications are initiated by laboratory management and are maintained in the laboratory files (see Section 13, Records and Appendix O, Forms). Procedures for departure from documented policies and procedures are maintained in the laboratory (see Appendix H, AP No. 15 and AP No. 19).

11.3 Type Evaluation Testing Procedures

11.3.1 The laboratory follows the procedures and checklist in NCWM Publication 14 (see Appendix H, Measurement Procedures List).

11.3.2 The type evaluation procedures of NCWM Publication 14 include specific technical policy and specific references to NIST HB 44.

11.3.3 The laboratory identifies all the components of the uncertainty that might affect the integrity of the test results in accordance with the NIST TN 1297 and the ISO Guide to the Uncertainty in Measurement. The device under test must meet

the tolerances and specifications of NIST HB 44 according to the test methods of NCWM Publication 14 (and/or must meet the tolerances and specification of OIML recommendations). Type evaluations of weighing and measuring devices are conducted by using standards to verify the accuracy of the device and other tests are performed to ensure that the device meets the required specifications. Laboratory staff are trained before they may conduct the test. Test methods and reporting instructions are followed when conducting the test (see Appendix H, measurement procedures list).

11.4 Administrative Procedures

11.4.1 The administrative procedures required by ISO/IEC 17025 are developed by the laboratory and listed in Appendix H. Additional administrative procedures are located in NCWM Publication 14 and are maintained in the laboratory. The administrative procedures ensure that the overall operations of the laboratory promote the quality and integrity of the test results and test items.

11.4.2 The technical manager maintains the procedures for the purchase, receipt and storage of consumable materials used for the technical operations of the laboratory (see Appendix H, AP No. 9).

11.5 Control of Data

11.5.1 As a minimum, laboratory staff review data, calculations, and test results to ensure the integrity of the type evaluation. Checks or quality control procedures include interlaboratory or proficiency testing and replicate tests or retesting, as appropriate for the device under test. Records are maintained regarding feedback and corrective action whenever testing discrepancies are detected. (See Section 13 Records, Appendix O, Forms, Appendix H, AP No. 6, Feedback, Corrective and Preventive Actions, Appendix H, AP No. 20, Monitoring the Validity of Test Results and Appendix H, AP No. 8 Control of data and Software Data Integrity.) Where computers are involved in data recording, retrieval, processing, calculation, analysis, or reporting, the laboratory ensures that:

11.5.1.1 The requirements of this manual are maintained;

11.5.1.2 Computer software developed by the laboratory has been documented and verified by using data sets. (See Section 13 Records and Appendix O, Forms); and

11.5.1.3 Computer equipment is maintained in accordance with the procedures for maintenance of equipment (see Appendix H AP 14) and is used in suitable environmental and operating conditions.

11.5.2 The laboratory procedure for software data integrity, Appendix H, AP No. 8, includes guidance on how to:

11.5.2.1 Protect the integrity and confidentiality of stored test data, test data entry or collection;

11.5.2.2 Limit access to maintain security of the programs in use;

11.5.2.3 Backup programs and test records;

11.5.2.4 Revise the software if updates occur;

11.5.2.5 Protect test data transmission and processing.

11.5.3 The technical manager maintains the procedures for software documentation and verification, which are located in the laboratory files (see Appendix H, AP No. 8).