14.0 Type Evaluation Test Reports (Certificates of Conformance)

14.1 Type evaluation tests reports (Certificates of Conformance) are reviewed by the laboratory staff to correct any inconsistencies in the report, supporting data, and calculations (see Section 13 Records for the location of calibration and test reports). Upon successful completion of testing, the laboratory drafts a Certificate of Conformance (CC) based on the test results. The CC is reviewed by the device manufacturer, the laboratory technical manager, and the type evaluation manager before issuance (see Appendix P, page 5 of 10). The CC contains the results from the test report.

14.2 *If accredited by NVLAP,* the laboratory follows the NVLAP policy (NIST HB 150 Annex A) regarding the use of the NVLAP logo, (see Appendix H, AP No. 25).

14.3 Test results and data are reported accurately, clearly, unambiguously and objectively in accordance with any specific instructions in the test methods.

The test results are initially provided in a test report, and information from the test report is included in a CC. The test report includes all information requested by the client as appropriate in accordance with the test procedures and necessary for the interpretation of the test results and required by the method. If tests are performed for internal clients, or as requested in a written agreement with the client, the test results are reported in a simplified way, but all information that is usually included in the test report is available in the laboratory.

14.4 Any opinions and interpretations included in test reports are clearly marked as such and indicate the basis upon which the opinions and interpretations were made. Any opinions and interpretations that are communicated through conversation with the client are documented on the test report.

14.5 Test reports (Certificate of Conformance) include the following information:
[NOTE: Laboratories should edit this section following the guidelines in ISO/IEC 17025 Section 5.10.2 and 5.10.3.]

14.5.1 A report title;

14.5.2 Name and address of the laboratory and location where the test was conducted if different from the laboratory;

14.5.3 Unique identification of the test (CC Number) on every page of the CC, identification which shows the end of the page, and page number and total number of pages;

14.5.4 Name and address of client;

14.5.5 Item identification including: description, manufacturer, model, and serial number (where available);

14.5.6 Test date;

14.5.7 Condition and characterization of the item (where relevant);

14.5.8 Identification of the test method used;

14.5.9 Additions, exclusions or deviations from the test method and other relevant information including environmental conditions existing during test (when applicable);

14.5.10 Tables, graphs, and other supporting information when necessary for the interpretation of the report;

14.5.11 Test results with units of measure and accuracy and tolerance conformity as appropriate.

14.5.12 Date of issue and signature of the technical manager, laboratory staff, or other official who accepts responsibility for the validity of the results and the content of the report;

14.5.13 Where relevant, a statement that the report relates only to the items listed in the report “at the time of test;”

14.5.14 The estimated uncertainty if the uncertainty affects compliance to specification limits;

14.5.15 Clear identification of reported results or test if performed by subcontractors;

14.5.16 Where relevant, reference to sampling procedures, date of sampling, identification of samples, sampling location, environmental conditions, during sampling, that can affect the test results, and standards or specifications for sampling.

14.5.17 A statement that the CC shall not be reproduced, except in full, without the written approval of the laboratory;

14.5.18 Statement that the client shall not use the report to claim product endorsement by the laboratory accrediting body, as appropriate;

14.5.19 Signature of an approved signatory for all test and calibration reports endorsed with the accreditation status or NVLAP logo (see Section 13 Records, List of Approved Signatories);

14.5.20 Special limitations of use;

14.5.21 Traceability statement, as appropriate;

14.5.22 Date test item received, test complete and draft CC complete (this information is kept on file; not placed on the CC); and

14.5.23 Opinions and interpretations, and any additional information required by the test method, where appropriate.

14.6 The laboratory follows a failure process and procedures to address tests or test results that do not conform to the test requirements (see Appendix P). The procedures ensure that:

14.6.1 Management responsibilities and authorities for addressing nonconforming work and the actions to be taken are identified;

14.6.2 The significance of the nonconformance is evaluated;

14.6.3 Remedial actions are addressed and decision are made quickly;

14.6.4 The client is notified and the work is recalled;

14.6.5 Persons responsible for authorizing the work to continue are identified; and

14.6.6 When there is indication that non-conforming work could recur, the laboratory follows the corrective action procedure (see Appendix H, AP No. 18).

14.7 The laboratory notifies its customers in writing of any events that cast doubt on the validity of the results given in any test report or amendment to a report.

14.8 Amendments are made in the form of an additional document or data transfer and the Certificate is labeled with an amendment number for each amendment (e.g., A1, A2, A3. . .). If a new document is issued, it contains a reference to the original that it replaces. Records of these documents are maintained by the laboratory staff and located in the laboratory files (see Section 13 Records, Test Reports (Certificates)/Supplements to Test Reports (Certificates).

14.9 Tests performed by subcontractors are clearly identified on the test report by including a note that states the data and results were received from a subcontractor (see QM Section 15). [NOTE: Edit QM section 14.9 to describe how your laboratory would identify subcontracted work on a test report; delete this section if you do not subcontract.]

14.10 Opinions and interpretations are clearly identified on the test report by writing notes on the test report adjacent to the test results for each test of the device, which includes the basis upon which the opinions and interpretations are made.

14.11 When test results are transmitted by telephone or electronically the procedures for the control of data are followed (see QM Section 11.5 and Appendix H, AP No. 8).

14.12 The test reports (certificates) are clear and understandable. The test report formats are included in NCWM Publication 14 (see QM Section 2, References and Definitions).