



FIELD SAMPLING AND MEASUREMENT ORGANIZATION SECTOR

VOLUME 1

GENERAL REQUIREMENTS FOR FIELD SAMPLING AND MEASUREMENT ORGANIZATIONS

~~TNI Standard~~

Voting Draft Standard

~~November 15th, 2012~~ November 28, 2012

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PREFACE

This Standard is the result of many hours of effort by those volunteers on The NELAC Institute (TNI) Field Activities Committee. The TNI Board of Directors wishes to thank these committee members for their efforts in preparing this Standard as well as those TNI members who offered comments during the voting process.

It is conformant with the requirements of ISO/IEC 17025:2005(E). This publicly available TNI document does not contain the ISO/IEC copyright protected language, but does reference applicable ISO clauses. In these situations, it is useful to read the TNI Standard along with the ISO/IEC standard. Wherever an ISO clause is referenced (*in italics*), the language from that clause is applicable. Any additional TNI language then follows, in plain text, as a NOTE or as an additional numbered standard item.

TNI has an agreement with ASTM International and the American National Standards Institute (ANSI) to provide, to TNI members at a discounted rate, a version of this Standard with the ISO/IEC language included; contact Jerry Parr at TNI for more information.

This Standard may be used by any organization that wishes to implement a program for the accreditation of organizations performing sampling or field measurements.

Standard Revision History

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VOLUME 1

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VOLUME 1

GENERAL REQUIREMENTS FOR FIELD SAMPLING AND MEASUREMENT ORGANIZATIONS

1.0 INTRODUCTION, SCOPE, AND APPLICABILITY

This Standard includes requirements applicable to those organizations engaged in environmental sampling and field measurement activities. Such organizations are referred to as Field Sampling and Measurement Organizations (FSMO or FSMOs).

This TNI Standard is intended as an application of *ISO/IEC 17025:2005(E)*, General Requirements for the Competence of Testing and Calibration Laboratories. The ISO/IEC clauses are provided in *italics*, with the additional TNI clauses in normal font.

Users of this Standard should make the following substitutions and recognize that the context may require minor variations to these terms:

For this term:	Substitute this term:
Laboratory('s) or Laboratories	<i>Field Sampling and Measurement Organization('s), FSMO(s)</i>
Test and/or calibration	<i>Environmental Sampling and Field Measurement</i>
Tests and/or calibrations	<i>Environmental Sampling and Field Measurement Activities</i>

Unless the contrary is clearly indicated, all references to singular nouns include the plural noun, and all references to plural nouns include the singular.

Some clauses in this Standard contain notes. The notes are used to explain a particular requirement or to provide clarifying examples. The notes do not supersede or modify requirements of the Standard and do not convey any additional requirements.

1.1 Scope (*ISO/IEC 17025:2005(E) Clause 1*)

2.0 NORMATIVE REFERENCES (*ISO/IEC 17025:2005(E) Clause 2*)

53.0 TERMS AND DEFINITIONS (*ISO/IEC 17025:2005(E), Clause 3*)

NOTE 2: The relevant definitions listed in the referenced ISO documents apply when using this document. Definitions related to this document, which are used differently or do not exist in the ISO references, are defined below.

4.153.1 **Environmental Sampling:** Equivalent to "Field Sampling." See Clause 3.35.

4.163.2 **Field:** Any location where work is performed outside of the legal entity's facility (e.g. laboratory location).

4.173.3 **Field Sampling:** The process of obtaining a representative portion of an environmental matrix suitable for laboratory or field measurement or analysis.

4.183.4 **FSMO:** Field Sampling and Measurement Organization. See Clause 1.

4.193.5 **Matrix:** The substance upon which a measurement is made or from which a sample is collected. The matrix includes the physical, chemical, biological, and radiological characteristics of the substance.

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4.203.6 Preservation: The physical, chemical, and/or radiological treatment of a sample to prevent the gain or loss of target analytes before analysis; filtration, refrigeration, and addition of chemical reagents are examples of preservation techniques.

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3.7 Management System: See *ISO/IEC 17025:2005(E) Clause 1.4, Note 1 and Clause 4.2.*

4.213.8 Sampling: See *ISO/IEC 17025:2005(E) Clause 5.7.1, Note 1.*

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4.223.9 Measurement: The process or result of determining, by comparison to a standard unit, the dimensions, quantity, capacity, or other characteristic of a thing or event.

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4.233.10 Validation: See *ISO/IEC 17025:2005(E) Clause 5.4.5.1.*

3.11 Proficiency Testing (PT): A means to evaluate a laboratory's performance under controlled conditions relative to a given set of criteria, through analysis of unknown samples provided by an external source.

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4.243.12 Chain of Custody Form: Record that documents the possession of the samples from the time of collection to receipt in the laboratory. This record generally includes: the number and types of containers, the mode of collection, the collector, time of collection, preservation, and requested analyses.

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4.0 MANAGEMENT REQUIREMENTS

4.1 Organization

4.1.1 *ISO/IEC 17025:2005(E), Clause 4.1.1*

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~~4.1.2~~ *ISO/IEC 17025:2005(E), Clause 4.1.2*

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4.1.3 *ISO/IEC 17025:2005(E), Clause 4.1.3*

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4.1.4 *ISO/IEC 17025:2005(E), Clause 4.1.4*

4.1.5 *ISO/IEC 17025:2005(E), Clause 4.1.5*

f) documentation required shall include a clear description of the lines of responsibility in the FSMO and shall be proportioned in such a way that adequate supervision is ensured;

g) supervisors shall be qualified for that duty by their knowledge of the field measurement methods, environmental sampling procedures, the purpose of those activities, and their competence to assess the work;

4.1.6 *ISO/IEC 17025:2005(E), Clause 4.1.6*

4.2 Management System (*ISO/IEC 17025:2005(E) Clause 4.2*)

4.2.8 The FSMO shall establish and maintain data integrity procedures, which shall be defined or referenced in the quality manual. The term "data" used in this clause refers to samples and results of field measurements, data and all other ~~record keeping records relating to the quality of those samples and results.~~ The data integrity ~~procedures that documents field sampling and measurement activities~~ shall provide assurance that a highly ethical approach to field sampling and measurement

is a key component of all FSMO planning, training and method implementation. The data integrity procedures shall include provisions for the following:

- a) data integrity training provided as an element of new-hire employee training and during refresher training at least annually;
- b) formal commitment to data integrity procedures signed by all FSMO employees;
- c) confidential reporting of data integrity issues to senior management; ~~and~~
- d) in-depth periodic review of data to verify its integrity and compliance with data integrity procedures;
- e) the data integrity procedures shall be signed and dated by senior management;
- f) the data integrity procedures and the associated implementation records shall be properly maintained; and
- g) the data integrity procedures shall be annually reviewed and updated by management.

4.3 Document Control (ISO/IEC 17025:2005(E) Clause 4.3)

4.4 Review of Requests, Tenders and Contracts (ISO/IEC 17025:2005(E) Clause 4.4)

4.5 Subcontracting of Environmental Sampling and Field Measurement Activities (ISO/IEC 17025:2005(E) Clause 4.5)

4.6 Purchasing Services and Supplies (ISO/IEC 17025:2005(E) Clause 4.6)

4.7 Service to the Customer (ISO/IEC 17025:2005(E) Clause 4.7)

4.8 Complaints (ISO/IEC 17025:2005(E) Clause 4.8)

4.9 Control of Nonconforming Work (ISO/IEC 17025:2005(E) Clause 4.9)

4.10 Improvement (ISO/IEC 17025:2005(E) Clause 4.10)

4.11 Corrective Action (ISO/IEC 17025:2005(E) Clause 4.11)

4.12 Preventive Action (ISO/IEC 17025:2005(E) Clause 4.12)

4.13 Control of Records

4.13.1 General

4.13.1.1 ISO/IEC 17025:2005(E), Clause 4.13.1.1

4.13.1.1.1 The FSMO shall have a plan to ensure that the records are maintained or transferred according to the clients' instructions in the event that the FSMO transfers ownership or goes out of business. In addition, in cases of bankruptcy, appropriate regulatory and state legal requirements concerning FSMO records shall be followed.

4.13.1.2 ISO/IEC 17025:2005(E), Clause 4.13.1.2

4.13.1.3 ISO/IEC 17025:2005(E), Clause 4.13.1.3

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4.13.1.4 ISO/IEC 17025:2005(E), Clause 4.13.1.4

The laboratory shall have procedures to protect and back-up records stored electronically and to prevent unauthorized access to or amendment of these records.

4.13.1.4.1 Records that are stored only on electronic media shall be supported by the hardware and software necessary for their retrieval.

4.13.1.4.2 Records that are stored or generated by computers or personal computers shall have hard copy or secure backup copies.

~~4.13.1.4.3 Access to archived information shall be documented with an access log. These records shall be protected against fire, theft, loss, environmental deterioration, vermin and in the case of electronic records, electronic or magnetic sources.~~

4.13.2 Technical Records

4.13.2.1 ISO/IEC 17025:2005(E), Clause 4.13.2.1

4.13.2.1.1 The technical records to be maintained shall include the ~~audit trail~~ chain of custody form of ~~samples~~ transferred samples between organizations.

4.13.2.1.2 All records shall be retained for a period as specified by the client or regulatory authority or in the absence of such specificity for a minimum of five (5) years from generation of the last entry in the records. ~~or for long duration projects five (5) years from project completion.~~

4.13.2.2 ISO/IEC 17025:2005(E), Clause 4.13.2.2

4.13.2.2.1 All generated data records, except ~~that those~~ which are generated by automated data collection systems or equipment, shall be recorded directly, ~~and~~ promptly, and signed by the person responsible for producing the records. Hand written records must be made and legibly in permanent ink.

4.13.2.3 ISO/IEC 17025:2005(E), Clause 4.13.2.3

4.14 Internal Audits

4.14.1 ISO/IEC 17025:2005(E), Clause 4.14.1

4.14.1.1 The FSMO shall, ~~as a minimum requirement, at least annually and in accordance with documented procedure(s)~~, conduct internal audits of its activities that are covered under the FSMO's scope of accreditation, in accordance with a documented procedure(s) every year.

4.14.2 ISO/IEC 17025:2005(E), Clause 4.14.2

4.14.3 ISO/IEC 17025:2005(E), Clause 4.14.3

4.14.4 ISO/IEC 17025:2005(E), Clause 4.14.4

4.15 Management Reviews

4.15.1 ISO/IEC 17025:2005(E), Clause 4.15.1

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NOTE 4: A management review includes an annual review of the FSMO's quality manual in accordance with a documented procedure.

4.15.2 ISO/IEC 17025:2005(E), Clause 4.15.2

5.0 TECHNICAL REQUIREMENTS

5.1 General

5.1.1 ISO/IEC 17025:2005(E), Clause 5.1.1

5.1.2 ISO/IEC 17025:2005(E), Clause 5.1.2

5.1.3 Field samples and measurements ~~have value to data users only to the degree that the sample or measurement is representative of a specified~~ shall be representative of the environment, setting or process sampled or measured. Therefore, ~~the~~ FSMO shall address representativeness by identifying the subject of the sampling or measurement; select and documenting a each observationsampling or measurement location and time, that represents ~~the~~ that target identified subject; and documenting the subject, location, and time sufficiently to demonstrate whether the sample or measurement represents the same subject as other samples or measurements from the vicinity.

5.2 Personnel

5.2.1 ISO/IEC 17025:2005(E), Clause 5.2.1

5.2.2 ISO/IEC 17025:2005(E), Clause 5.2.2

5.2.2.1 The FSMO shall have sufficient personnel with the necessary education, training, technical knowledge and experience for their assigned functions.

5.2.2.2 Management shall be responsible for ~~ensuring~~ assuring that the training of ~~each member of their~~'s technical staff is kept up-to-date (on-going) by:

- a) Documenting training courses or workshops on specific equipment, techniques or procedures.
- b) Demonstrating that each employee has read, acknowledged and understood data integrity procedures. ~~There are four required elements within a data integrity system:~~
 - ~~□ data integrity training;~~
 - ~~□ signed data integrity documentation for all FSMO employees;~~
 - ~~□ in-depth, periodic monitoring of data integrity issues with confidential reporting of issues to management; and~~
 - ~~□ data integrity procedures documentation.~~
 - ~~i. The data integrity procedures shall be signed and dated by senior management~~
 - ~~ii. These procedures and the associated implementation records shall be properly maintained.~~
 - ~~iii. The data integrity procedures shall be annually reviewed and updated by management.~~
- c) Ensuring that the employee training file contains a signed attestation that technical personnel have read, understood and agreed to perform environmental sampling and field

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measurements in accordance with the most recent version of the methods and standard operating procedures.

5.2.3 ISO/IEC 17025:2005(E), Clause 5.2.3

~~3.1.4~~ 5.2.4 ISO/IEC 17025:2005(E), Clause 5.2.4

~~3.1.25~~ 2.5 ISO/IEC 17025:2005(E), Clause 5.2.5

5.3 Accommodation and Environmental Conditions (ISO/IEC 17025:2005(E) Clause 5.3)

5.3.1

NOTE: Field personnel should document sampling and measurement conditions that may affect the quality of results including, but not limited to, air temperature, weather conditions, tides, stream stage, etc. Descriptions of sample conditions (e.g. turbidity, odor, less than optimal sample quantity, etc.) should also be noted.

5.3.3

NOTE: During field tests and while handling samples, personnel should avoid areas where activities or conditions may adversely affect results, such as temporarily storing samples near volatile liquids, or transporting test items between areas of high temperature contrast.

5.4 Methods and Method Validation

5.4.1 General (ISO/IEC 17025:2005(E), Clause 5.4.1)

5.4.2 Selection of Methods (ISO/IEC 17025:2005(E), Clause 5.4.2)

~~5.4.2.1~~ Methods particularly important to FSMOs include those for The FSMO shall establish and maintain procedures for the following activities: selection and documentation of field observation sampling and measurement points; collection, preservation, and transportation of samples; and operation of measurement instruments under variable conditions in the field environment. Records shall be maintained for these activities. Decisions may be needed in each instance to select a representative observation point or the necessary equipment to collect a representative sample. The FSMO shall establish and maintain procedures to make and document these decisions. Program specific rRegulations, sampling protocols, project specific procedures, client-specified data quality objectives, reference methods or test method requirements shall be followed if more stringent than this Standard.

5.4.3 Laboratory-Developed Methods (ISO/IEC 17025:2005(E), Clause 5.4.3)

5.4.4 Non-Standard Methods (ISO/IEC 17025:2005(E), Clause 5.4.4)

5.4.5 Validation of Methods (ISO/IEC 17025:2005(E), Clause 5.4.5)

5.4.6 Estimation of Uncertainty of Measurement (ISO/IEC 17025:2005(E), Clause 5.4.6)

5.4.7 Control of Data (ISO/IEC 17025:2005(E), Clause 5.4.7)

5.5 Equipment

5.5.1 ISO/IEC 17025:2005(E), Clause 5.5.1

5.5.2 ISO/IEC 17025:2005(E), Clause 5.5.2

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5.5.2.1 Equipment for attended or unattended measurements at a selected observation point shall be capable of maintaining calibration throughout the range of environmental conditions that occur during the period of measurements.

5.5.3 *ISO/IEC 17025:2005(E), Clause 5.5.3*

NOTE: This Standard applies to measurements made and samples collected with equipment operated by attending staff, as well as to measurements made and samples collected discretely, continuously or at intervals by unattended equipment.

5.5.4 *ISO/IEC 17025:2005(E), Clause 5.5.4*

5.5.4.1 ~~The specific items or types of equipment used to collect a sample or complete a measurement shall be documented by the FSMO. Records shall be maintained for the specific items or types of equipment used to collect a sample or complete a measurement.~~

5.5.5 *ISO/IEC 17025:2005(E), Clause 5.5.5*

5.5.6 *ISO/IEC 17025:2005(E), Clause 5.5.6*

5.5.6.1 Equipment for field sampling and measurement are of necessity portable ~~or transportable~~ and may be used in multiple locations under variable environmental conditions. The FSMO shall establish and maintain procedures for selection, identification, preparation, calibration before use, during use, and maintenance ~~after use of all its field portable~~ equipment.

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5.5.7 *ISO/IEC 17025:2005(E), Clause 5.5.7*

5.5.8 *ISO/IEC 17025:2005(E), Clause 5.5.8*

5.5.9 *ISO/IEC 17025:2005(E), Clause 5.5.9*

5.5.10 *ISO/IEC 17025:2005(E), Clause 5.5.10*

5.5.11 *ISO/IEC 17025:2005(E), Clause 5.5.11*

5.5.12 *ISO/IEC 17025:2005(E), Clause 5.5.12*

5.6 Measurement Traceability

5.6.1 General (*ISO/IEC 17025:2005(E), Clause 5.6.1*)

5.6.2 Specific Requirements

5.6.2.1 Calibration (*ISO/IEC 17025:2005(E), Clause 5.6.2.1*)

5.6.2.1.3 Special calibration procedures may be necessary for measurements made ~~discretely, continuously or at intervals~~ by unattended equipment. ~~In these circumstances, the~~ FSMO ~~should shall~~ establish and maintain procedures for servicing ~~such unattended~~ equipment ~~before and after each series of measurements at appropriate intervals in time~~ in order to ~~independently identify and~~ quantify ~~any environmental fouling and~~ calibration drift. Measurement ~~values results~~ that ~~indicate fouling or may be affected by calibration~~ drift shall be evaluated for usability based on specified acceptance criteria. ~~before they are reported to the customer as final.~~

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- 5.6.2.1.4 Instruments/equipment used for environmental sampling and field measurement activities shall be calibrated (where applicable) prior to use. The following items are essential elements of initial instrument/equipment calibration:

- a) The details of the initial instrument/equipment calibration procedures including calculations, integrations, acceptance criteria and associated statistics shall be documented.
- b) Sufficient raw data records shall be retained to permit reconstruction of the initial instrument/ equipment calibration (e.g., calibration date, method, instrument/equipment ID, analyte(s) being calibrated, calibrator's initials or signature, concentration and response, calibration curve or response factor, or unique equation or coefficient used to reduce instrument/equipment responses to concentration).
- c) Criteria for the acceptance of an initial instrument/equipment calibration [and calibration verification](#) shall be established. The criteria used shall be appropriate to the calibration technique employed.
- d) If the initial instrument/equipment calibration [or applicable calibration verification](#) results are outside established acceptance criteria, corrective actions shall be performed and all associated samples reanalyzed [if possible](#). ~~reanalysis of the samples is not possible, data associated with an unacceptable initial instrument/equipment calibration shall be reported with appropriate data qualifiers.~~
- e) When continuing calibration checks are needed to maintain confidence in the calibration status of the instrument/equipment, these checks shall be carried out according to a defined procedure.
- f) [Data associated with an unacceptable initial or continuing instrument/equipment calibration shall be reported with appropriate data qualifiers.](#)
- g) [Records of reference standard used for calibrations and reference material certificates shall be retained.](#)

[5.6.2.2 Testing \(ISO/IEC 17025:2005\(E\) Clause 5.6.2.2\)](#)

5.6.3 Reference Standards and Reference Materials (ISO/IEC 17025:2005(E) Clause 5.6.3)

5.7 Sampling

5.7.4 The FSMO shall document the sampling subject, location and time sufficiently to allow data users to determine ~~whether the sample represents the same subject as other samples or measurements from the vicinity~~ [representativeness](#), as described in *Clause 5.1.3*.

5.7.5 The FSMO shall document the [sample type](#), methods and equipment used to collect a sample or complete a measurement, as described in *Clauses 5.4.2.1, 5.5.4.1, and 5.5.6.1*.

5.8 Handling of Test and Calibration Items

~~5.8.3.1~~ [5.8.1](#) *ISO/IEC 17025:2005(E), Clause 5.8.1*

~~5.8.4.2~~ [5.8.2](#) *ISO/IEC 17025:2005(E), Clause 5.8.2*

~~5.8.5.3~~ [5.8.3](#) *ISO/IEC 17025:2005(E), Clause 5.8.3*

~~5.8.4~~ [5.8.4](#) *ISO/IEC 17025:2005(E), Clause 5.8.4*

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NOTE 4: For Field Sampling and Measurement Organizations, the requirements for "test and calibration items" apply equally well to "field samples". That is, these requirements apply to both FSMO "field samples" and "test and calibration items".

5.9 Assuring the Quality of Test and Calibration Results (ISO/IEC 17025:2005(E) Clause 5.9)

5.9.1

- f) [Verification of a measurement calibration using a second source](#)
- g) [The FSMO shall establish a proficiency testing program that is applicable to it's scope.](#)

5.10 Reporting the Results

5.10.1 General (ISO/IEC 17025:2005(E) Clause 5.10.1)

NOTE 3: Periodic samples or measurements at one site or parallel samples or measurements at a number of sites for the same customer may constitute a single series of tests that are appropriately included in a single test report, provided the various subjects are clearly identified.

5.10.2 Test Reports and Calibration Certificates (ISO/IEC 17025:2005(E) Clause 5.10.2)

- f) such as sample type (grab, composite etc.), including an identification of the matrix sampled (aqueous, solids etc.).
- j) including phone number [of person authorizing](#).
- l) results for any field blanks, spikes and duplicates and if applicable, any confirmation samples.

5.10.3 Test Reports

5.10.3.1 ISO/IEC 17025:2005(E) Clause 5.10.3.1

~~5.8.4.4~~ 5.10.3.2 ISO/IEC 17025:2005(E) Clause 5.10.3.2

- d) including a description of sample preservation, transportation and storage and sample containers as on a chain of custody for example; see *Clauses 5.4.2.1, 5.5.4.1, and 5.5.6.1*;

~~5.8.5~~ 5.10.4 Calibration Certificates (ISO/IEC 17025:2005(E) Clause 5.10.4)

~~5.8.6~~ 5.10.5 Opinions and Interpretations (ISO/IEC 17025:2005(E) Clause 5.10.5)

5.10.6 Testing and Calibration Results Obtained from Subcontractors (ISO/IEC 17025:2005(E) Clause 5.10.6)

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- 5.10.7 Electronic Transmission of Results (*ISO/IEC 17025:2005(E) Clause 5.10.7*)
- 5.10.8 Format of Reports and Certificates (*ISO/IEC 17025:2005(E) Clause 5.10.8*)
- 5.10.9 Amendments to Test Reports and Calibration Certificates (*ISO/IEC 17025:2005(E) Clause 5.10.9*)
- 5.10.10 Reports of Sampling

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~~When the FSMO transfers samples to an independent laboratory for analysis, the FSMO shall provide a unique identification identifier for each sample taken. All relevant information, including special conditions, and adequate information concerning sampling and/or measurement dates and times, methods, all sampling and handling procedures used and items as described in sections 5.7.4 and 5.7.5 must be retained in the sampling records. sampling dates and times, methods, all sampling and handling procedures used and items as described in sections 5.7.4 and 5.7.5, must be retained in the sampling records. (preservation, extraction, analysis or hold times for example), methods, and preservation as described in Clauses 5.7.4, 5.7.5, and 5.8.~~

- 5.10.11 Reports of Monitoring Instruments

~~Reports of data from monitoring instruments are sometimes most valuable when available in near real time. Any report Reports shall indicate whether the data are raw instrument readings or have been adjusted for sensor calibration, drift or fouling. The reports Reports should include or indicate the availability of the categories of supporting and methodological information listed in Clause 5.10.1.~~