Section7.4 “Handling of Test or Calibration Items” & Section 7.11 “Control of Data and Information Management”

Wednesday August 14, 2024 – 1:00pm EST

Presented by:

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Section7.4 “Handling of Test or Calibration Items” & Section 7.11 “Control of Data and Information Management”

This webinar is being recorded

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All attendees are muted. However, feel free to utilize the questions tab and they will be answered at the end of the session.

Section 7.4 “Handling of Test or Calibration Items”

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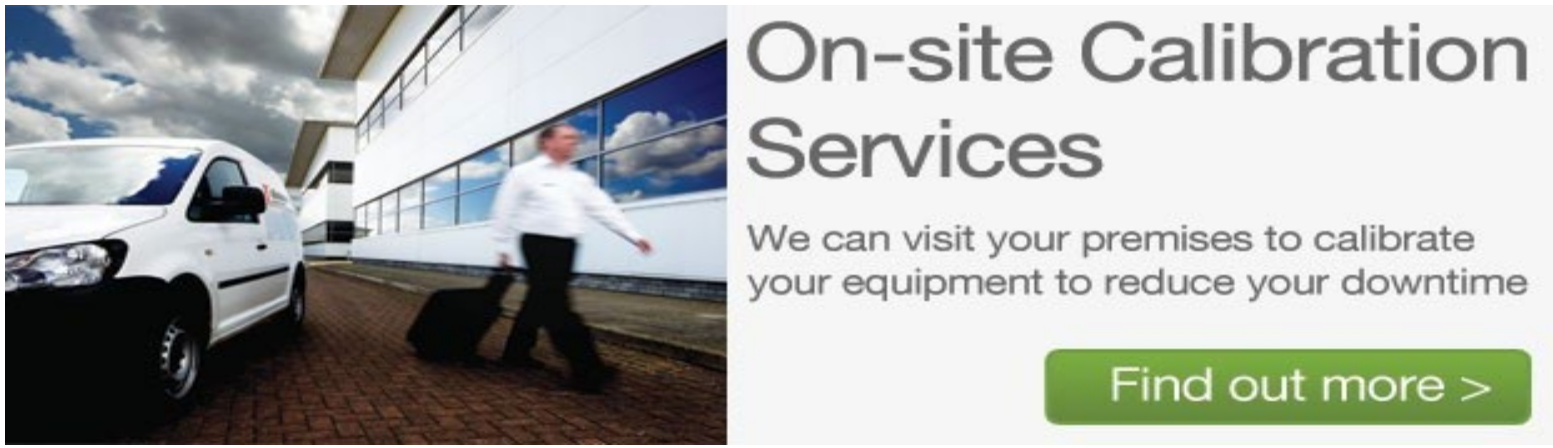
This section is also applicable to tests or calibrations performed on site at the customer location.



Section 7.4 “Handling of Test or Calibration Items”

7.4.1 The laboratory **shall have a procedure** for the transportation, receipt, handling, protection, storage, retention, and disposal or return of test or calibration items, including all provisions necessary to protect the integrity of the test or calibration item, and to protect the interests of the laboratory and the customer. Precautions **shall** be taken to avoid deterioration, contamination, loss or damage to the item during handling, transporting, storing/waiting, and preparation for testing or calibration. Handling instructions provided with the item **shall** be followed.

Procedure: a set of actions that is the official or accepted way of doing something. The quality management system should have a procedure addressing all applicable elements stated in 7.4.1.

Section 7.4 “Handling of Test or Calibration Items”

the transportation, receipt, handling

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protection, storage, retention and/or disposal

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including all provisions necessary to protect the integrity of the test or calibration item, and to protect the interests of the laboratory and the customer;

Section 7.4 “Handling of Test or Calibration Items”

7.4.2 The laboratory **shall** have a system for the unambiguous identification of test or calibration items. The identification shall be retained while the item is under the responsibility of the laboratory. The system **shall** ensure that items will not be confused physically or when referred to in records or other documents. The system **shall**, if appropriate, accommodate a sub-division of an item or groups of items and the transfer of items.

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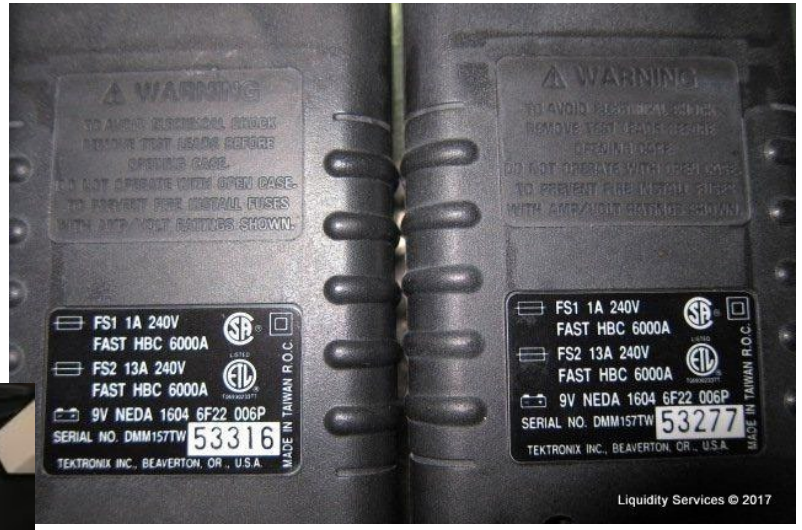
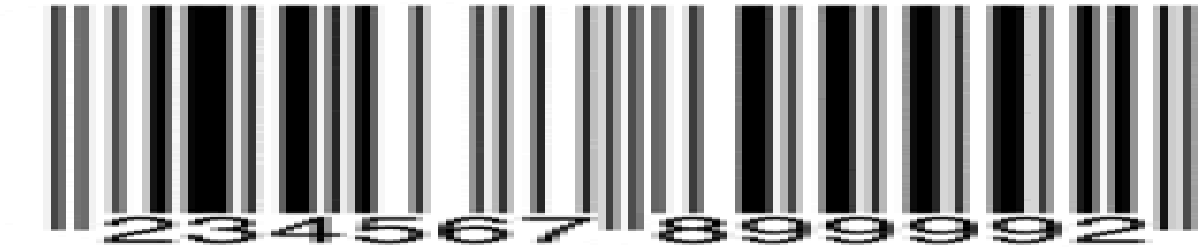
a system for identifying test and/or **calibration items.**



Section 7.4 “Handling of Test or Calibration Items”

a system for identifying **test** and/or calibration **i**tems



Section 7.4 “Handling of Test or Calibration Items”

The method used for identification of test samples must ensure that the ID method is unique, and the ID tag or other ID method is not likely to come off resulting in a mis-identification or confusion with other samples ;

Section 7.4 “Handling of Test or Calibration Items”

7.4.3 Upon receipt of the test or calibration item**, deviations from specified conditions shall be recorded**. When there is doubt about the suitability of an item for test or calibration, or when an item does not conform to the description provided, the laboratory **shall** consult the customer for further instructions before proceeding and **shall record** the results of this consultation. When the customer requires the item to be tested or calibrated acknowledging a deviation from specified conditions, the laboratory **shall** include a disclaimer in the report indicating which results may be affected by the deviation.

Section 7.4 “Handling of Test or Calibration Items”

Key Points

Deviations from specified conditions shall be recorded, asking the customer for further instructions and record the results of the consultation, and inclusion of a disclaimer

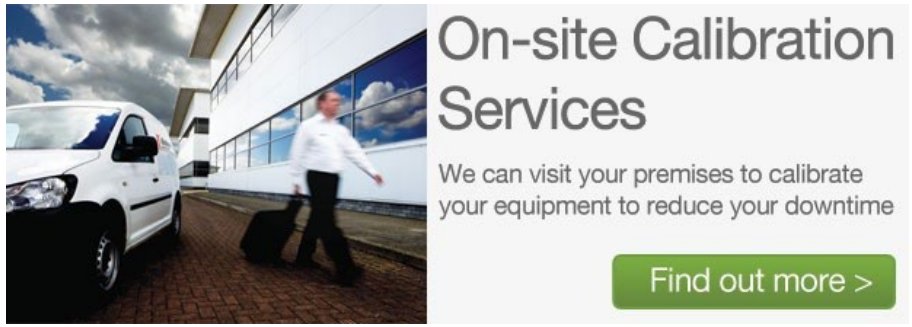
- If the customer wants the items tested or calibrated anyway, the lab needs to include a statement with the results

Section 7.4 “Handling of Test or Calibration Items

deviations from specified conditions shall be recorded.

For example within the internal procedure

Environmental conditions required:



Temperature to be within the range of 68 ºF +/- 2 ºF.

Relative Humidity to be less than 50 % RH

The UUT must remain in the laboratory for a minimum of 12 hours prior to calibration to permit thermal stabilization.

Note: Calibrations are not to be performed if the environmental conditions are outside the allowable limits stated above

Section 7.4 “Handling of Test or Calibration Items”

Untestable/deviating samples are items which have been received by a laboratory, but which are not in an appropriate condition to truly reflect the original sample. This could be due to the samples not being handled correctly during transport or in the way prescribed in the relevant standard or that lack essential information for a quality analysis to be undertaken. Consequently, the validity of the reported results may be jeopardized.

Sampling Clover Seed

Section 7.4 “Handling of Test or Calibration Items”

Such untestable/deviating sample may:

- not been preserved adequately (e.g. not cooled, not acidified),

- have exceeded its maximum preservation time,

- in the case of microbiological analyses, lack the date and time of sampling,

- be denatured through heat, light or humidity,

- have rotted or suffered microbiologically, or

- have become cross contaminated.

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When a sample is taken by the customer or on the customer’s behalf by an external provider and transferred to the laboratory, the laboratory cannot be responsible for verifying if the sample was taken in accordance with the relevant requirements. Just a statement that the results relate to the item tested/analyzed as received, which is used by many laboratories is certainly not enough. In such a case, the laboratory shall contact the customer, inform them of the problem and ask for further instructions. Clause 7.1.4 has to be considered in this context (Review of Request Tenders and Contracts)

Section 7.4 “Handling of Test or Calibration Items”

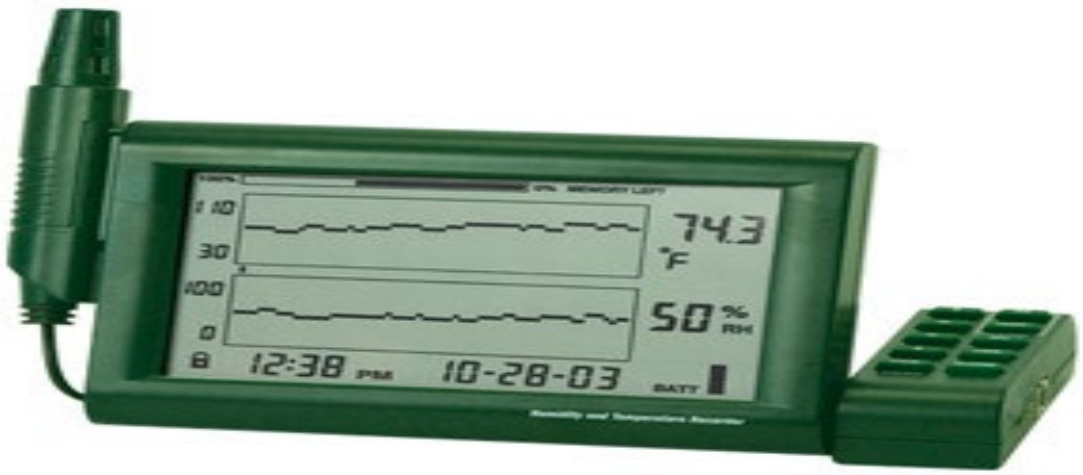
7.1.4 Any differences between the request or tender and the contract shall be resolved before laboratory activities commence. Each contract shall be acceptable both to the laboratory and the customer. Deviations requested by the customer **shall not impact the integrity of the laboratory or the validity of the results;**

Section 7.4 “Handling of Test or Calibration Items”

If the customer still requires the sample to be tested anyway: This general finding could be further specified e.g. by stating that the sample was supplied in packing which was inappropriate for the relevant analysis or that the sampling date was unknown or that the sample condition had deteriorated.

Section 7.4 “Handling of Test or Calibration Items

7.4.4 When items need to be stored or conditioned under specified environmental conditions, these conditions **shall** be maintained, monitored and recorded.



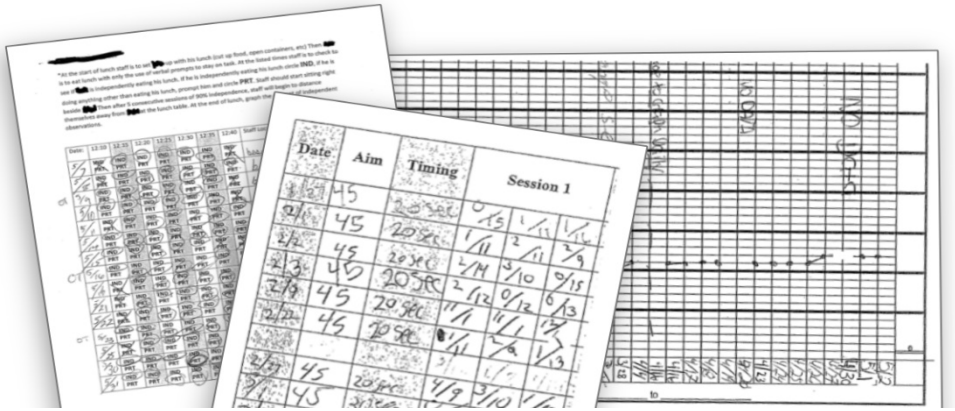
Section7.11 “Control of Data and Information Management”

What ISO/IEC 17025:2017 brought forth “Section 7.11 Control of Data Information System

This section has been adapted for the handling electronic information.

Section7.11 “Control of Data and Information Management”

7.11.1 The laboratory **shall** have access to the data and information needed to perform laboratory activities



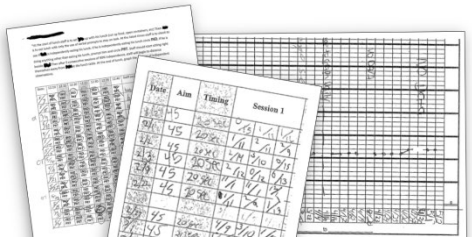
The requirements for information management systems are not restricted only to computerized systems (LIMS) but to any kind of system handling information

Section7.11 “Control of Data and Information Management”

7.11.2 The laboratory information management system(s) used for the collection, processing, recording, reporting, storage or retrieval of data **shall** be validated for functionality, including the proper functioning of interfaces within the laboratory information management system(s) by the laboratory before introduction. **Whenever there are any changes, including laboratory software configuration or modifications to commercial off-the-shelf software, they shall be authorized, documented and validated before implementation**

7.11 Control of Data and Information Management

NOTE 1*: In this document "laboratory information management system(s)" includes the management of data and information contained in both computerized and non-computerized systems. Some of the requirements can be more applicable to computerized systems than to non-computerized systems*



Still recognizes paper systems for data collection and management;

NOTE 2: *Commercial off-the-shelf software in general use within its designed application range can be considered to be sufficiently validated*

7.11 Control of Data and Information Management

7.11.3 The laboratory information management system(s) **shall:**

a) be protected from unauthorized access;

b) be safeguarded against tampering and loss;

c) be operated in an environment that complies with supplier or laboratory specifications or, in the case of non-computerized systems, provides conditions which safeguard the accuracy of manual recording and transcription;

d) be maintained in a manner that ensures the integrity of the data and information;

e) include recording system failures and the appropriate immediate and corrective actions.

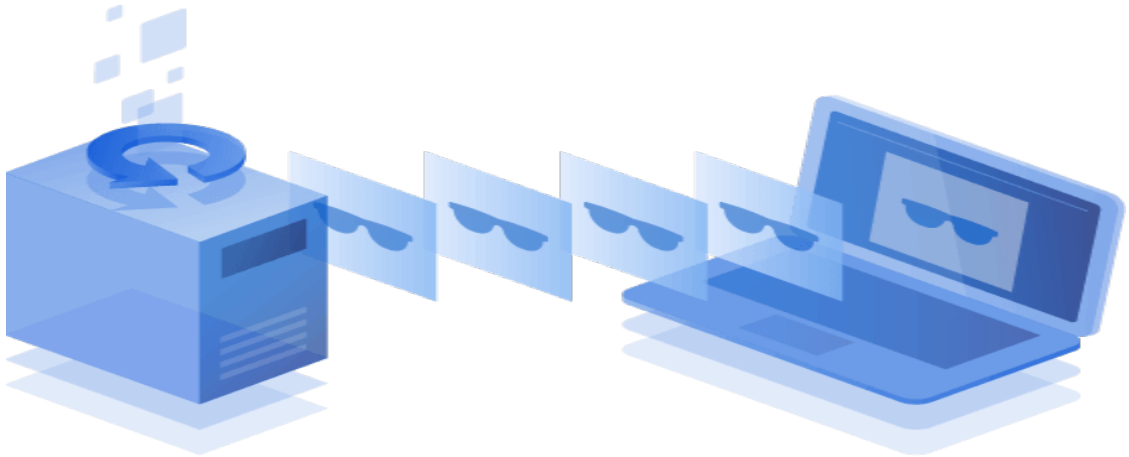
(e would address system crashes)

7.11 Control of Data and Information Management

7.11.4 When a laboratory information management system is managed and **maintained off-site** or through an external provider, the laboratory **shall** ensure that the provider or operator of the system complies with all applicable requirements of this document;

7.11 Control of Data and Information Management

7.11.5 The laboratory **shall** ensure that instructions, manuals and reference data relevant to the laboratory information management system(s) are made readily available to personnel



The staff shall have access to instructions to the LIMS

7.11 Control of Data and Information Management

7.11.6 Calculations and data transfers **shall** be checked in an appropriate and systematic manner;

Section7.4 “Handling of Test or Calibration Items” & Section 7.11 “Control of Data and Information Management

This time is allocated for questions. You should have a space provided for submitting questions.

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If a question is not answered, please submit directly to webinar@pjlabs.com

SAVE The Date

Thursday, September 12, 2024 – 1:00pm ET

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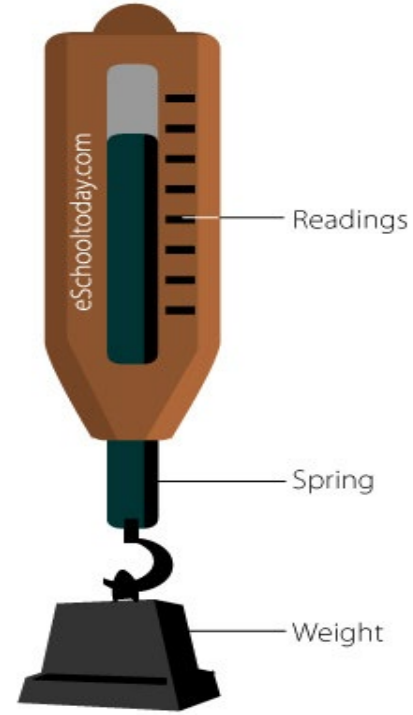

Presented BY:

Henry Zumbrun | Morehouse Instrument Company