4.13 Control of Records
5.10 Reporting the Results

Forum on Laboratory Accreditation
February 2015

Silky S. Labie

Environmental Laboratory Consulting & Technologies, LLC

Topics in the Standard for Records

- ***4.13.1 Procedures***
  - 4.13.3
- ***4.13.2 Technical Records***
  - 4.13.3

Topics in the Standard for Reports

- ***5.10.1 General Reporting Requirements***
- ***5.10.2 Test Reports contents***
- ***5.10.3 Additional contents***
  - 5.10.11 Additional Requirements
- ***5.10.4 Calibration Certificates (not applicable)***
- ***5.10.5 Opinions and Interpretations***

- ***5.10.6 Results of subcontractors***
- ***5.10.7 Electronic transmission***
- ***5.10.8 Report Format***
  - 5.10.10 Exceptions

Topics in the Standard for Reports, cont.

4.13.1 General Requirements

4.13.1.1 You must have procedures for these activities related to quality and technical records:

- *Identification*
- *Collection*
- *Indexing*
- *Access*
- *Filing*
- *Storage*
- *Maintenance*
- *Disposal*

- *Quality Records include:*
  - *Internal audits*
  - *Management reviews*
  - *Corrective and preventive actions*

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4.13.1 General Requirements cont.

- ***4.13.1.2 Records must be***
  - ***Legible***
  - ***Stored/retained to***
    - ***be readily retrievable***
    - ***prevent damage or deterioration***
    - ***prevent loss***
  - ***Have a retention time***
    - **Retain for a maximum of 5 years after the last entry (4.13.3.3b)**

- ***4.13.1.3 Records must be held secure and in confidence***
  - **Records must be available to the accreditation body (4.13.3.c)**
  - **An access log must be used to document access to archived information (4.13.3.e)**

4.13.1 General Requirements cont.

- **4.13.1.4 Electronic records must**
  - **Be protected**
  - **Have a back-up system**
  - **Have a system to prevent unauthorized access or changes**
  - **Have the hardware and software needed to retrieve (if only electronic)(4.13.3.d)**

4.13.1 General Requirements cont.

4.13.2 Technical Records

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4.13.2.1 Universal Requirements

- ***You must retain records of:***
  - ***Original observations***
  - ***Derived data***
  - ***Enough information to establish an audit train***
  - ***Calibration***
  - ***Staff records***
  - ***Copy of each test report***
- ***Records must be retained for a specified time*** (5 years)

- ***You must retain sufficient information***
  - ***to identify factors that might affect the measurement uncertainty***
  - ***To repeat the test under the same conditions as the original***
- ***Identify the person(s) responsible for performance of each test and for checking results***

Universal Requirements, cont.

- You must have a system that allows the history of the sample and its associated data to be readily understood through documentation
  - Unequivocal, accurate records that document all laboratory activities such as
    - Facilities
    - Equipment
    - Analytical methods
    - Sample receipt and preparation
    - Data verification
    - Inter-laboratory sample transfers

Universal Requirements (4.13.3.a)

You must retain all information necessary for historical reconstruction

- Raw data for calibration, samples & QC
- Reference to method + data reduction
- Lab ID Code
- Analysis date
- Time of analysis (≤72 hrs) or time critical steps
- Instrument ID & operating conditions
- Manual calculations
- Analyst ID
- Sample prep including cleanup, ID codes, volume weights, instrument or meter readings, calculations & reagents
- Test results
- Standard & reagent origin, receipt, prep and use

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Universal Requirements (4.13.3.f i) - xix)

You must retain all information necessary for historical reconstruction

- Calibration criteria, frequency and acceptance limits
- Data and statistical calculations, review, confirmation interpretation, assessment & reporting conventions
- QC procedures & assessment
- Electronic data security, software documentation & verification, backups and records of changes
- Method performance criteria
- PT Results
- DOCs
- Record of names, initials & signatures of all individuals who sign/initial any lab records

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Universal Requirements (4.13.3.f i) - xix)

4.13.2.2

- **Observations, data and calculation must be recorded when they are made**
- **Must be identifiable to a specific task**

4.13.2.3 - Mistakes

- ***Cross out but do not obliterate***
- ***Enter correction next to error***
- ***Sign/initial***
- ***Electronic records must have an equivalent system (original data must be available)***

- Any entry (except automated data) must be legible and in indelible ink.
- Corrections must be initials and dated
- Corrections must specify the reason (except transcription errors)

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Mistakes 4.13.3 g)

4.13.3 h) Changes in Business

- If the lab goes out of business or transfers ownership you must have a plan:
  - Records must be maintained or transferred base on client requirements
  - Regulatory and state requirements applicable to records must be followed

5.10 Reporting the Results

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5.10.1 General Requirements

- ***Results must be reported***
  - ***Accurately, clearly, unambiguously and objectively***
  - ***In accordance with method specified requirements***
- ***Results are usually reported in a test report that must include***
  - ***Customer requested information***
  - ***Information necessary for the interpretation of the test***
  - ***Method-required information.***

General Requirements, cont.

- ***Reports usually contain items in 5.10.2 and 5.10.3 or 5.10.4***
- ***Reports to internal clients or written agreement***
  - ***May be simpler***
  - ***Information in 5.10.2 - .4 must be readily available***

- Provide information necessary to complete regulatory reports (MORs)
- Captive labs do not have to issue formal reports if
  - The lab is responsible for preparing the regulatory report or
  - The lab provides the information to another individual for report preparation
- All information as required in a formal report must be retained

General Requirements 5.10.10

5.10.2 Test Report

- *Title*
- *Lab name & address*
  - *Other locations*
- *Test Report ID*
  - *Each page must be linked to the report*
  - *Clear identification of last page*
- *Name & Address of Customer*
- *Method ID*
- *Sample ID including condition*
- *Date of receipt*
  - *Date of analysis / sample preparation*
- *Reference to sampling plan & procedures*
- *Results with units of measurement*
- *Name, function and signature of authorizing party*
- *Statement that the results relate only to the tested samples*

Required on all reports

- Sample preparation/analysis time when holding time is ≤ 72 hours
- Results reported on a basis than an received
- Clearly identify non-accredited tests if accreditation is required or if claims to such are included on the report (hard copy and electronic)
- Numerical results with values outside the calibration range

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Test Report 5.10.11

5.10.3 Test Report

5.10.3.1 Include the following where necessary to interpret the test results

- ***Modifications to the test method***
- ***Test Conditions***
- ***Statement of compliance/noncompliance with requirements or specifications***
- ***Estimated measurement uncertainty***
- ***Opinions and interpretations***
- ***Additional information required by method or customer***

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5.10.3.2 Include the following sampling information where necessary to interpret the test results

- ***Sampling date***
- ***Unambiguous ID of sample***
- ***Location of sampling***
- ***Reference to sampling plan and procedures***
- ***Environmental conditions***
- ***Standard for sampling methods, and modifications to the standard***

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Test Report, cont.

5.10.5 Opinions & Interpretations

- ***If made, document the basis upon which they are made***
- ***Clearly indicate any opinions or interpretations***

5.10.6 Subcontracted Results

- ***Clearly identify results from subcontractors***
- ***Subcontractor must report results in writing or electronically***

5.10.7 Electronic Transmission

- **Requirements of the TNI Standard must be met**

5.4.7 Control of Data

- **You must ensure that:**
  - **Computer software developed by the user is documented and validated**
  - **You have established and implement procedures for protecting the data; including**
    - **integrity and confidentiality of data entry or collection**
    - **data storage, transmission and processing;**
  - **Computers and automated equipment are maintained**
  - **Have the environmental and operating conditions necessary to maintain the integrity of test**

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5.10.8 Test Report Format

- **Format to minimize the possibility of misunderstanding and misuse**

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5.10.9 Amendments

- ***Must be a different document***
  - ***Clearly link the document with the original***
  - ***Ensure that the purpose (supplement, correction etc.) is stated.***
- ***Must meet the requirements of the TNI standard for reporting***
- ***A replacement must be clearly identified with a unique ID and reference to the original***