



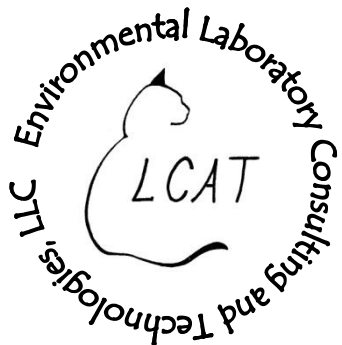
4.13 Control of Records

5.10 Reporting the Results

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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***





- **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 General Requirements cont.





- **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)



- **4.13.1.4 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



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

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





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)



Mistakes 4.13.3 g)



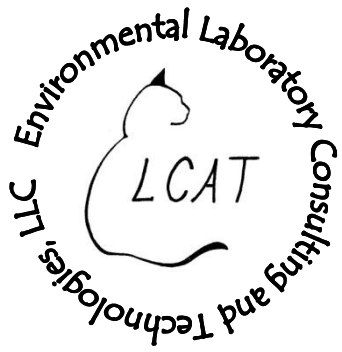
4.13.3 h) Changes in Business

- 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





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.***





- ***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





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**

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***



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**





5.10.8 Test Report Format

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



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***

