Module 6:

REPORTING

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**Introduction**

The outcome of a sample analysis is presented in the form of a written report prepared by laboratory officials. The report is intended to inform the requesting authority of the laboratory’s findings regarding whether or not LMOs are present in the sample, and when suitable, estimated quantities are informed. The report is written according to laboratory policy[[1]](#footnote-1) in compliance with national and international regulations and practices.

A well drafted report is a vital component of the laboratory’s work. It is the primary channel of communication between the laboratory and the requesting authority. A well written report aims to present the results of each test carried out by the laboratory shall be reported accurately, clearly, objectively, unambiguously and in accordance with any specific instructions in the methods

While the format of the report may be presented in numerous ways, there are, nonetheless, several key elements that should be included to ensure that the report is thorough and comprehensive. Additional information can be included to supplement the information contained in the report, based on the national regulatory requirements and the laboratory’s policy.

**Laboratory documentation requirements**

A well compiled laboratory case file is a key component in facilitating the drafting of an informative and through report. It allows for efficient traceability from the raw data to the final report and is therefore important to ensure that the case file is complete and contains all the relevant information needed. All the information in a case file should be compiled in such a way that any other trained laboratory member can follow and understand all the steps and decisions taken during the analysis.

While variations do exist between laboratories in with respect to the level of detail included in a case file, there are a few basic pieces of information that comprise a thorough case file. This may include:

* *Case submission information:* This is a standard form that is to be submitted along with the samples by the authority requesting the testing. The form should include date of sample receipt, name and contact information of the requesting authority, a general description of the items received such as sample type, sample matrix and sample weight, the name and contact information of the laboratory receiving officer, as well as information on the sample’s chain of custody and packaging. Upon the submission of a case to the laboratory a file number should be assigned in order to facilitate administrative follow up and as part of laboratory good management practices.
* *Test record information:* raw data from laboratory testing is normally recorded on standard work forms that are developed by the laboratory. Such forms encourage consistent and standard recording of required information and facilitate the traceability of raw data. The forms are compiled in the relevant laboratory case file along with relevant references to the location of electronic data which can be referred to as needed while drafting a report.
* *Case report:* once the report is written, it also becomes a component of the case file and a copy is retained within the file.

**Report writing sections and contents**

The contents and scope of the report may vary based on the specific requests made by the national authority that is requesting the testing. This will influence both the types of tests carried out and the specificity of the details included in the report in order to adequately answer the questions posed by the requesting authority. The following points are guidelines for the minimum content that may be considered for inclusion in the report. Several of these pieces of information also make up a major component of the case file, which highlights the importance of ensuring that the case file is complete as the analysis takes place.

The minimum content of a report is described in the ISO 17025:

(a) a title (eg "Test Report" or "Calibration Certificate");

(b) the name and address of the laboratory and the place where the tests and / or calibrations were carried out, if different from the address of the laboratory;

(c) unambiguous identification of the test report or calibration certificate (such as a serial number), and on each page an identification which ensures that the page is recognized as a part of the test report or calibration certificate and a clear identification of the end of the test report or calibration certificate;

d) the name and address of the customer;

e) identification of the method used;

f) a description, condition and unambiguous identification of the tested or calibrated item (s);

(g) the date of receipt of the test or calibration item (s) when this is critical to the validity and application of the results and the date (s) of the test or calibration;

(h) reference to the sampling plan and procedures used by the laboratory or other bodies, where these are relevant to the validity or application of the results;

(i) the results of the test or calibration with the units of measurement where appropriate;

(j) the name (s), function (s) and signature (s) or equivalent identification of the person (s) authorized to issue the test report or calibration certificate;

(k) where relevant, a statement that the results refer to items tested or calibrated.

In addition, test reports shall, where necessary for the interpretation of test results, include:

(a) deviations, additions or exclusions from the test method and information on specific test conditions, such as environmental conditions;

b) where relevant, a declaration of conformity / non-compliance with the requirements and / or specifications;

(c) where applicable, a statement on the estimated measurement uncertainty; information on uncertainty in test reports is required when it is relevant to the validity or application of test results when required in the customer's instruction or when uncertainty affects compliance to a specification limit.

d) where appropriate and necessary, opinions and interpretations;

(e) additional information that may be required by specific methods by customers or groups of customers.When opinions and interpretations are included, the laboratory should document the basis on which opinions and interpretations have been made. Opinions and interpretations should be clearly highlighted as such in the test report.

**Technical and administrative review**

A *technical review* is an in-depth review of the analysis records that is carried out prior to the issuance of a report to confirm the validity of results and conclusions.

The technical review is carried out with the view to:

* Ensure that the appropriate analyses have been conducted.
* Ensure that the conclusions of the reporting analyst are reasonable, consistent with the documented data, and within the constraints of validated scientific knowledge.
* Confirm that verifications have been documented.
* Ensure that technical language in the report is clear, accurate, and complete.
* Ensure there is sufficient supporting documentation.

In addition, the technical reviewer and the analyst who drafted the report are equally responsible for ensuring the accuracy of the technical aspects of the case record.

An *administrative review* is a procedure that checks the case file documentation and reports for consistency with laboratory policy and for editorial correctness prior to issuing a report to the requesting authority.

An administrative review ensures that the content of the report follows laboratory policy and procedure by ensuring that the language in the report is clear, accurate, and complete, in addition to proofreading the report for clerical errors. Furthermore, the administrative review checks that the technical review has been properly conducted and documented.

Technical and administrative reviews may be combined as one process and carried out by the same person. However, neither the technical nor the administrative reviews are to be conducted by the analyst who completed the work.

**Report issuance**

Once the technical and administrative reviews have been completed and documented in the case file the report is signed by an authorised signatory as the person(s) accepting responsibility for the content of the report, as per laboratory policy. The authorised signatory is to include their signature and title, or equivalent identification, printed name and laboratory of employment.

Laboratories must retain an exact copy of all reports issued within the relevant case files. These copies must be retained securely and be readily available for the time period specified in the laboratory’s documented policies, since they are subject of audit and review.

In the event that an amendment has to be made to a report after it has been issued, it has to be communicated in the form of a supplementary report that quotes the original report as a reference. If it is necessary to issue a replacement report, this should be uniquely identified and should contain a reference to the original document that it replaces.

**References**

National Accreditation Board for Testing and Calibration Laboratories, India; Specific Criteria for Biological Testing Laboratories; 2012

United Nations Office on Drugs and Crime (UNODC); Guidance for the Implementation of a Quality Management System in Drug Testing Laboratories; 2009

National Association of Testing Authorities, Australia; Biological Testing ISO/IEC 17025 Application Document, Annex D: Accreditation of facilities testing for genetically modified organisms (GMO); March 2013

National Association of Testing Authorities, Australia; Criteria for Accreditation of Laboratories Testing Genetically Modified Organisms; 8.G13 GMO Guidelines / Issue 2 / March 2006

1. Write something about this in QA section and reference (MQ: Reference to module addressing implementation of quality (system) in the laboratory and/or accreditation) [↑](#footnote-ref-1)