

A. PURPOSE:

The Division of Scientific Services uses a process of technical and administrative reviews of case records and reports as a quality assurance measure. Technical review allows for the monitoring of test results on a continuous basis to ensure the validity of the results.

Technical reviews are performed on case files prior to reports being issued to the submitting agencies. Technical reviews are performed by authorized analysts to verify that the appropriate methods were used, and conclusions made in the case are reasonable and are supported through the documentation within the case file.

Technical reviewers are authorized by the Director or their designee. In general the DSS requires all cases to be technically reviewed prior to administrative review and release to the customer(s). The Director may designate certain disciplines to have less than 100% technical review based on the needs of the DSS.

Administrative reviews are performed on all case files prior to the reports being issued to the submitting agency. Administrative reviews are used to ensure that the case demographics are correct and that there are no typographical errors.

B. RESPONSIBILITY:

All laboratory personnel are responsible to ensure compliance with this procedure.

C. DEFINITIONS:

Qualified analyst: any individual who has competency in the discipline the case requires. This individual is proficiency tested in the discipline.

Analyst (or authorizer of results): the individual(s) who performed the case work, and/or who generated the results. The analyst is also the author of the final issued report. The analyst is responsible to ensure that the case file contains all the appropriate documentation, and to review the draft report for errors prior to submission for technical review.

Specific to the Toxicology Unit cases are not assigned to a single analyst. Analysts perform specific portions of the casework. Batch technical reviewers review the batch documentation for technical merit and the Authorizer of the Report ensures the file contains the appropriate documentation and authorizes the report to be released; noting that an administrative review will be performed prior to release.

Technical Reviewer: Responsible to ensure that the data in the case file folder supports the report findings and that the proper DSS procedures were followed. The technical reviewer cannot be the author(s) of the report or analyst(s) in the case. A technical reviewer must have been competency tested in the task(s) being reviewed and must be authorized to perform technical reviews.

Batch Technical Reviewer: the use of a batch technical reviewer is specific to areas where casework is batched. The Technical Reviewer of this data/batch must have been competency testing in the work

being reviewed. This is a review of the overall batch for technical compliance (use of controls, calibrators, blanks and other components as required). This reviewer must be authorized to perform technical reviews.

Authorizer of Report: This title is used specific to the Toxicology Unit. The Individual will have experience in the discipline. The Authorizer of the Report will update the technical review milestone in LIMS-plus within the Toxicology Unit.

Note for Units other than Toxicology, the act of authorizing a report is performed by the analyst after all appropriate results are performed. This is designated by the analyst's signature (handwritten or electronic) on the final report.

Administrative Reviewer: an individual who reviews the case file for non-technical errors (typographical in nature) the administrative reviewer cannot be the author(s) of the report or analyst(s) in the case. If an administrative reviewer notes an error that is technical in nature they must notify the technical reviewer and analyst.

Report Author or Co-Author (authorizer of results): the analyst, or any other analyst responsible for generating results for an assigned case. An individual, who verifies a critical finding, is not a Co-author of a case. In areas that batch casework and where the case is not "assigned" to an individual may have multiple authorizers of results.

Verification: an act of either 1) reviewing data, results or an item and forming an opinion as to the result to confirm or disagree with the analyst's results or 2) performing independent testing to form an opinion as to the result that confirms or disagrees with the analyst's results.

Report Co-Signer: The individual that performs the technical review of a case. The co-signer is not an author of the report.

D. **PROCEDURE:**

1. Technical review of cases can be achieved in two ways.
 - a. Traditional 'Technical Review': here cases are assigned to one analyst and one technical reviewer. In this case the technical reviewer looks at the case on a whole and all parts of the testing performed.
 - b. 'Batch Technical Review' combined with an Authorizer of the report: Note this is only used within the Toxicology Unit. In this process components of testing are assigned to multiple analysts; each analyst is the authorizer of the results related to the work they perform. Each component (or batch) is individually technically reviewed (this is a batch approach to analysis). For these cases an Authorizer of the Report reviews the draft report and the already technically reviewed case specific data compiled for a case. In this type of review the Authorizer of the Report is responsible to update the technical review milestone in LIMS-plus. The report will not list a technical reviewer.

Approved by Director: Dr. Guy Vallaro

- i. Technical Reviewers and Batch Technical Reviewers must have been competency tested in the task(s) being reviewed and must be authorized to perform technical reviews.
 - ii. Authorizers of Reports use technical data that has already been technically reviewed and perform an overall review of the results to ensure the completeness of the case records. The Authorizer of the Report will have experience in the discipline but not necessarily in all the current techniques of the discipline.
2. Analysts (also defined as the authorizer of results) must review their own case work prior to submitting it for technical review. They must verify that the required documentation is present in the case file and they must review the case report for typographical errors or transcription errors. Ultimately, the contents and completeness of the case file is the responsibility of the case analyst(s).
 - a. Once a case file is passed from the analyst to a reviewer any changes made to the report must be tracked. Tracking includes initialing and dating any changes made. For Units using electronic records the Unit will designate in their Unit SOPs how this will be achieved.
 - b. Draft reports used in the review process are considered examination records and will remain in the case file with any appropriate annotations. The draft report should be treated as any other case documentation with case number and analyst's initials present on the page(s); additionally any cross outs or notes must be initialed and dated by the person making the change.
 - c. Division personnel that issue findings or testify in court based on another examiner's work must review and document the review of the generated data. The documentation of the review will generally be demonstrated by the initialing of the specific paperwork related to the analysis.
 - d. The analyst is responsible to ensure that for sexual assault cases that only the initials of the victim are used in the report.
 - i. Example: Jane Doe report as JD
Jane Smith Doe report as JSD
Jane Joan Doe report as JJD
3. The following are general guidelines as to the information that needs to be checked on each case. Some units may find it necessary to change what is reviewed during which review (administrative or technical) based on the needs of the unit. For example a unit in which the case description is important may decide that the review of the description is an important part of the technical review instead of the administrative review. In these cases the Unit specific SOPs detail what is to be reviewed during each review.
 - a. What cannot be changed is that the technical reviewer must be current or previously competent in the task being reviewed and must be familiar with the technical procedures of

- the unit and they cannot have produced any data for the case. Additionally, they must be authorized for technical review in the discipline.
- b. For administrative reviews the reviewer cannot be the authorizer of results/analyst of the case.
 - c. In general Technical reviews are performed on all DSS cases unless noted in Unit specific SOPs. This may be achieved in 1 of 2 ways as described in this document.
 - i. The Director may authorize some disciplines to have less than 100% technical review based on the needs to the DSS. This authorization will be in writing and will identify the minimal number (or percentage) of cases to be reviewed for the Unit per a specified time period.
4. **Technical Review** – The DSS breaks technical reviewers into two types as listed above. Technical Review and a combined technical review which utilizes Batch Technical Review and an Authorizer of Reports.
- a. Technical Reviews: This is a review of the case (draft) report and the documentation that supports the findings presented. The technical information that supports the case findings will be reviewed to ensure that the results listed in the case reports are supported by the documentation.
 - i. Technical reviews of examination data or test reports shall not be conducted by the author or co-authors of report or examination data of the case.
 - ii. An individual reviewing a case for technical review will:
 - (a) Ensure that the documentation in the case is adequate to support the conclusion made by the analyst(s).
 - (b) Check all manual calculations made that affect the reported conclusions. Verify that transcription of the data is correct.
 - (c) Ensure that the analysis performed is adequate to support the reported conclusion.
 - (i) If associations are made, ensure that the association is clearly documented and ensure that the association on the report is properly qualified.
 - (ii) For units that perform verifications, ensure that the case file contains the verification documentation including who performed the verification.
 - (iii) If the results are not definitive (such as with inconclusive findings) ensure that the reason for reporting the result is documented in the case file and on the report.
 - (iv) For units reporting Uncertainty verify that the uncertainty statement is correct.
 - (v) If eliminations are made ensure the report clearly communicates the elimination.
 - (d) Ensure that proper controls and/or calibration requirements as set forth in the SOPs used were met.

- iii. Ensure that the appropriate worksheets were used and are completed as required by Unit specific SOPs.
- iv. Ensure that information required by the specific Unit SOPs is included as required.
 - (a) Review the findings, including observations, photographs, instrumental data etc... to determine if the minimum requirements to make the reported conclusions are met. Where multiple techniques are applied, review correlation of results.
- v. Review the draft report and ensure that the findings represented on the report are accurate, complete, and represent what was documented in the case file.
 - (a) Ensure that all evidence related to the Unit request is addressed on the report.
 - (b) Ensure that any evidence that is related to the Unit request that is not analyzed is designated as such in the report.
 - (c) In the event a deviation requiring customer approval was authorized and used, a reference to that deviation is reported.
- vi. Review the case report and ensure that all required information is contained in the report, including:
 - (a) Title
 - (b) Name and address of the Division
 - (c) Name and address of the submitting agency
 - (d) Division Case Number
 - (e) Agency Case Number
 - (f) Methods used in analysis of the case materials
 - (g) Evidence description
 - (h) Date of case receipt
 - (i) Items analyzed (with a reference to a sampling plan if applicable) with a statement to the effect that the results only relate to the items tested
 - (j) Results with appropriate units of measure if applicable
 - (k) The Name and title of the authorizer of the report (i.e. the analyst) and co-signer (technical reviewer)
 - (l) Presence of the opinion/conclusion statement.
 - (i) Results apply to the evidence as received by the Division of Scientific Services and relate only to the items tested. This report reflects the test results, conclusions, interpretations and/or the findings of the analyst as indicated by their signature below.

- (m) Presence of a statement that the results apply to the sample(s) as received by the DSS.
- vii. Review the Request for Analysis form and any other documentation submitted by the client to ensure that the work performed is what was required of the submitted agency.
- viii. To document that the technical review was performed the Technical Reviewer will complete a case review sheet (however named) specific to that Unit. The case review sheet (however titled) will minimally capture the components reviewed, the initials of the reviewer and the date of the review. This sheet will remain in the case records to document the review.
- (a) The technical reviewer may choose to initial pages in the case file.
- (b) Any notes added, by the technical reviewer, to case documentation will be initialed and dated by the technical reviewer.
- ix. All technical reviews will be minimally documented in LIMS-plus by updating the milestone in LIMS-plus. By approving the technical review the reviewer agrees that the results within the report are supported by the data within the case file/records.
- (a) Documentation of the technical review in the case file can be achieved by including a notation in the case file such as on a technical review checklist or the use of milestone stickers to track the case progression.
- x. Generate and sign the final report if the report is acceptable (this step may be performed at the administrative review step). The technical reviewer is the co-signer of case reports; except as noted above.
- (a) For units using LIMS-plus to electronically sign reports no handwritten signatures are required.
- xi. Upon reviewing the case file, any issues, transcription errors, errors in calculations etc... must be noted to properly document the reviewer's opinion. The case file is then returned to either the analyst or the analyst's Supervisor/Lead to have the issues addressed prior to the case being marked as Technically Reviewed in LIMS-plus. Individual units may have preferences in the flow of the case reviews; therefore it will be at the discretion of the Assistant Director or Deputy Director if they want case issues being given back directly to the analyst or to have them flow through the Unit Lead or Supervisor. .
- xii. The Chain of Custody for all the reported evidence will be checked in LIMS. This check may also be done as part of the administrative review.
- xiii. Draft reports must stay in the case file. This is to allow for the tracking of changes to the case report after it is marked draft complete by the analyst. If any notes were made by the technical reviewer they must become a permanent part of the case documentation; notes must be initialed by the person adding them to the case.
- (a) Note: * In the Toxicology Unit cases are worked in batches. Refer to SOP TX-5 for guidance.

- (b) Note: * In the DNA Unit cases are worked in batches. Refer to DNA SOP-21 and DNA SOP-23 for guidance.
- b. Batch Technical Reviews: This is a review of results from a specific method/technique within a Unit. This in general will include multiple samples tested in a sequence with the same quality control samples (blanks, calibrators, controls as appropriate) relating to the complete batch. The batch technical reviewer is reviewing the batch as a whole for compliance to the current related Unit SOP(s).
- i. A batch technical reviewer will review batch instrumentation data for completeness, and for conformance with the Unit specific method to include:
- (a) Appropriate use, result(s) and documentation of controls and/or calibrators.
 - (b) Appropriate use, results(s) and documentation of blanks (reagent and/or method blanks).
 - (c) Appropriate use, results, and documentation of other method specific SOPs.
 - (d) Batch is documented per Unit specific guidance.
 - (e) Verify that the result(s) identified as listed in LIMS-plus is substantiated by the data reviewed.
 - (f) Other information as required by Unit specific SOPs.
- ii. Documentation of the review will be documented as per Unit specific SOPs. This will usually be on a batch review form (however titled). The batch technical reviewer does not have a milestone to update in LIMS-plus.
- iii. Batch technical reviewers identifying an issue will document the issue as per Unit SOPs. Each notation or change made as part of this process will be initialed and dated.
- c. Authorizer of Reports: The combination of batch technical reviews with Authorizer of Reports is unique to the Toxicology Unit; refer to TX-5 for additional guidance.
- This is a review of the draft report and data specific to a case, where the technical data has been previously technically reviewed during batch technical review(s). The Authorizer of Reports is using the accumulated technically reviewed results to ensure that the data is appropriately reported.
- The Authorizer of Reports cannot be the author of any data that is part of the case to be reviewed, but can have performed a batch technical review.
- i. The Authorizer of Reports will be provided with documentation of the batch reviews to verify that the batches were accepted by the batch technical reviewer.
- ii. The Authorizer of the Report will:
- (a) Ensure that the documentation in the case is adequate to support the conclusion made by the analyst(s).

- (b) Ensure that the analysis performed is adequate to support the reported conclusion.
 - (i) If the results are not definitive (such as with inconclusive findings) ensure that the reason for reporting the result is documented in the case file and on the report.
 - (ii) Verify that the uncertainty statement is correct.
- (c) Ensure that proper controls and/or calibration requirements as set forth in the SOPs used were met. This will be done by verifying the batch technical reviewer's acceptance of the applicable batch/batches that are a part of the case file.
- iii. Ensure that the appropriate worksheets were used and are completed as required by Unit specific SOPs.
- iv. Ensure that information required by the specific unit SOPs is included as required.
- v. Review the data to determine if the minimum requirements to make the reported conclusions are met. Where multiple techniques are applied, review correlation of results.
- vi. Review the draft report and ensure that the findings represented on the report are accurate, complete, and represent what was documented in the case file.
 - (a) Ensure that all evidence related to the unit request is addressed on the report.
 - (b) Ensure that any evidence that is related to the unit request that is not analyzed is designated as such in the report.
 - (c) In the event a deviation requiring customer approval was authorized and used, a reference to that deviation is reported.
- vii. Review the case report and ensure that all required information is contained in the report, including (this may be performed as part of the administrative review):
 - (a) Title
 - (b) Name and address of the Division
 - (c) Name and address of the submitting agency
 - (d) Division Case Number
 - (e) Agency Case Number
 - (f) Methods used in analysis of the case materials
 - (g) Evidence description – where applicable the condition of the evidence as received
 - (h) Date of case receipt
 - (i) Items analyzed (with a reference to a sampling plan if applicable) with a statement to the effect that the results only relate to the items tested
 - (j) Results with appropriate units of measure if applicable

- (k) Name and title of the analyst(s); authorizer of report will be electronically added at the final report stage
 - (l) Presence of the opinion/conclusion statement
 - (m) Presence of a statement that the results apply to the sample(s) as received by the DSS.
 - (i) Results apply to the evidence as received by the Division of Scientific Services and relate only to the items tested. This report reflects the test results, conclusions, interpretations and/or the findings of the analyst as indicated by their signature below.
 - viii. Review the Request for Analysis form and any other documentation submitted by the client to ensure that the work performed is what was required of the submitted agency.
 - ix. The Chain of Custody for all the reported evidence will be checked in LIMS. This check may be done as part of the technical or administrative review, as per Unit guidance.
 - x. To document that the review was performed the Authorizer of the Report will complete a case review sheet.
 - (a) Upon reviewing the case file, any issues, transcription errors, errors in calculations etc... must be noted to properly document the reviewer's opinion.
 - (i) The case file is then returned to the Unit Supervisor or Lead to have the issues addressed.
 - (ii) The Authorizer of the report may choose to initial pages in the case file that they feel are important to the conclusions made.
 - (iii) Any notes added, by the reviewer, to case documentation will be initialed and dated by the reviewer.
 - xi. The Authorizer of the Report will update the 'Technical Review' milestone in LIMS-plus. Note the setting of the technical review milestone is performed since there is no "Authorization of Report" milestone within LIMS-plus. Setting this milestone in the Toxicology Unit does not relate to the action of a technical review being performed.
5. **Administrative Review** – This is a review of general case information performed by someone other than those authoring/co-authoring the case. Since the information being reviewed in an Administrative Review is not analytical in nature the person performing this review is not required to be competent in the testing method. Administrative reviewers will be authorized by the Director to perform these reviews.
- a. Administrative reviews are performed on all case reports prior to their release.
 - b. An Administrative Reviewer will:
 - i. Check each page of the case file and ensure that the case number is on each page in the file and that where appropriate the analyst's initials are present.

Note 1: There are certain documents that can be added to a file after the release of the case that will require the case number but not necessarily the initials of the analyst; these documents will be administrative in nature.

Note 2: Unit forms will generally have a spot for the person performing the work (analyst) to initial. The administrative reviewer should verify these are complete.

- ii. Check the case documentation to ensure that the Technical Reviewer has annotated the review of the case as appropriate per unit guidance (i.e. on unit case review sheet, in LIMS-plus or on a milestone sticker).
- iii. Review the demographics of the case: this includes at a minimum - submitting agency, agency case number, name of source, address of source (if applicable).
 - (a) For sexual assault cases ensure that only the initials of the victim are included on the case report.
- iv. Review the case for typographical errors. The administrative reviewer will read the case report to look for typographical or major grammatical errors in the final report.
- v. If the Administrative reviewer finds an issue, they will return the case file to the analyst for correction. If the administrative reviewer can fix the issue (such as addition of a case number) they can do so without involving the case analyst. The Unit Supervisor may require all issues be addressed to them and not the analyst; this will be left to the discretion of the Unit Supervisor.
- vi. The reviewer will document that the review was performed on the unit case review sheet and by updating the milestone in LIMS-plus. By documenting the administrative review the reviewer indicates that they have reviewed the case for the items listed above and everything was as expected.
- vii. For Units using electronically signed crystal reports in LIMS-plus the updating of the milestone to administratively reviewed in LIMS-plus indicates that the report can be issued.
- viii. Analysts are responsible to forward the completed report to Evidence Receiving with any applicable evidence within 5 working days of the Administrative Review. In Units that issue their own reports, the Unit will issue the report to the appropriate submitting agencies and others within 5 working days; or as per Unit specific guidance; not to exceed 5 business days.
 - (a) It is recognized that there may be rare instances when submission of the report to Evidence Receiving cannot be achieved within 5 business days. When this occurs inform your Assistant Director or Deputy Director and document the reason in the case synopsis.
 - (b) GL-11 provides additional guidance on issuing reports.

- c. It is recognized that individual Units may combine the responsibilities for the Technical and Administrative review based on the Unit's personnel requirements. Such combined functionality is detailed in individual unit SOP's.
- d. When no report is created administrative review is not required; such as for duplication cases in Multi-Media.

6. Outsourcing Review –

An outsourcing case review will be performed on reports from contract laboratories where the contract laboratories report is being submitted directly to the submitting agency. This review will take place of the traditional Technical and Administrative reviews listed above.

Case Management or the assigned reviewer will:

- a. Verify evidence returned from the contract laboratory is what was sent.
- b. Verify that the report matches the Division case number and represents what was submitted to the contract laboratory.
- c. Verify that the requested testing was performed.
- d. Mark the appropriate request in LIMS-plus as draft complete.
- e. Units may have additional guidance in their SOPs.