

Title: TR SOP-22 External Technical Review**A. PURPOSE:**

To define a means by which a case or a proficiency test that has been analyzed by a Division of Scientific Services (DSS) laboratory Examiner/Analyst within the Chemical Analysis Section (CAS) will be technically reviewed when an internal technical reviewer is not available. An outside entity can be utilized for technical review purposes if the scientist conducting such a review is from a properly accredited laboratory and has been deemed qualified to conduct such technical reviews within the appropriate discipline and category of testing.

B. RESPONSIBILITY:

Analysts/Examiners appropriately qualified within a particular discipline

Analyst/Examiner from an outside entity

Lead Examiner

Deputy Director

Quality Section/Quality Manager

C. DEFINITIONS:

1. External technical reviewer – Short term: When a technical reviewer from an outside agency is needed because another qualified analyst from the section is absent for a limited period of time (e.g., vacation).
2. External technical reviewer – Long term: When a technical reviewer from an outside agency is needed because another qualified analyst from the section is not currently available and/or there is no set date for their return (e.g., only one qualified Examiner is employed within the section, extended leave of absence).

D. PROCEDURE:

A case (or proficiency test) will be sent out of the laboratory for review when there is no available Examiner who is qualified within the specific field that the case encompasses.

External technical review – Short term

1. Analysts will ensure that the Lead Examiner or appropriate Deputy Director is aware when there is no individual available within the DSS laboratory to perform a technical review for a case or for a proficiency test within a particular discipline.
2. The Quality Section will be notified that there is a need for a technical reviewer based on the short term situation. They will also be advised of the need to possibly disseminate laboratory policies/procedures.

Approved by Director: Dr. Guy Vallaro

3. The Lead Examiner, Quality Section, and/or Deputy Director will contact an outside lab or other acceptable entity in order to find a technical reviewer who is currently qualified, and who has casework experience, within the applicable discipline and category of testing. The outside entity will have the appropriate accreditation to support a technical review which abides by DSS laboratory accreditation requirements.
4. Analysts will be informed as to who will be their external technical reviewer and will be responsible for arranging the technical review to be completed.
5. No additional or formal paperwork should be required for the need to use outside entities when only needed or utilized during limited time periods.
6. The Unit Lead or Deputy Director will ensure that updated information of currently-used outside technical reviewers is available upon request.

External Technical review – Long term

1. Analysts will ensure that the Lead Examiner or appropriate Deputy Director is aware when there is no individual available within the DSS laboratory to perform a technical review for a case or for a proficiency test.
2. The Quality Section will be notified. They will also be advised of the need to possibly disseminate laboratory policies/procedures.
3. The Lead Examiner, Quality Section, and/or Deputy Director will contact an outside lab or other acceptable entity to find a technical reviewer who is currently qualified and who has casework experience within the applicable discipline and category of testing. The outside entity will have the appropriate accreditation to support a technical review which abides by DSS laboratory accreditation requirements.
4. Appropriate paperwork (e.g., Memorandum of Understanding (MOU)) between the DSS laboratory and outside entities should be facilitated by the Deputy Director. Other divisions and units within the Department may be involved (e.g., Legal Affairs Unit).
5. Analysts will be informed as to who will be their external technical reviewer and will work with the Lead Examiner and/or Deputy Director for long-term use of the outside entity.
6. Once the relationship with outside technical reviewers is established, analysts will be responsible for arranging and ensuring that technical reviews are completed according to laboratory policy.
7. A copy of the MOU/contract and technical reviewer's qualifications should be provided to the Quality Section.
8. A copy of the contract is not required to be within each Analytical or Administrative Case File unless it is specifically requested.
9. The Quality Section does not need to be notified each time a technical review is required.
10. The Unit Lead or Deputy Director will ensure that updated information of currently-used outside technical reviewers is available upon request. They will also ensure that any required paperwork (e.g., MOU) will not expire and cause delays in DSS casework.
11. Obtaining recurring technical reviews for casework will be the responsibility of the analyst.

External Technical review – Both Short Term and Long Term

1. Analysts will be responsible for ensuring that there are no conflicts of interest during technical reviews (e.g., Proficiency Test-taking at the same time between analysts and technical reviewers). Analysts should work with the QA section when determining proficiency test scheduling in order to avoid conflicts with outside technical reviewers.
2. If a conflict exists with regards to proficiency testing, analysts will work with the Deputy Director and the Quality Section to come up with a viable solution.
3. Approved technical reviewers may come to the DSS laboratory to look at documents and conduct reviews. Outside technical reviewers will be supplied with appropriate documents/information (e.g., External Review form, Draft Copy of report, applicable SOPs, instrument data) and will be given an adequate working environment to conduct reviews.
4. Analytical Case File documents (or copies) may be sent to outside entities for technical review purposes. When such documents are mailed a complete number of document pages should be recorded (e.g., Table of Contents) and a trackable carrier/method will be used (e.g., FedEx).
5. Outside technical reviewers will conduct reviews according to their own policy and may be willing to follow DSS laboratory-specific requirements.
6. If additions or corrections are necessary on the draft report, the Technical Reviewer will make corrections and add their initials after each edit/addition.
7. Analysts will maintain notes on any technical changes when made via a verbal conversation with technical reviewers. These notes will be documented appropriately (e.g., placed in the case jacket).
8. Analysts and technical reviewers may work together to determine the best verbiage for final reports or to determine if additional work may be necessary.
9. Administrative reviews will not be done by external entities.
10. The initials of technical reviewers along with appropriate dates of technical reviews can be recorded on Analytical Case File jackets if the Technical Reviewer is unavailable.
11. When printing the final report on letterhead, technical reviewer's names and titles will be on reports. Technical Reviewer's laboratory affiliation may be listed on reports.
12. Technical reviewers will sign and return original-signed reports and all other documents back to the DSS laboratory analyst. Outside mailings involving the return of documents will be done via trackable carriers (e.g., FedEx) and outside reviewers should be provided pre-paid postage information (e.g., FedEx account number).
13. After receiving documents back from external reviewers, it is the responsibility of analysts to ensure that all pages of documents have been received and that the technical review has been satisfactorily completed.
14. Analysts can provide copies of appropriate documents to technical reviewers if requested (e.g., copy of signed report, copies of review forms, photographs). A 'copy' stamp may be used on documents sent to technical reviewers.

TR SOP-22 External Review

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Page 4 of 4

Revision #

Revision History

2

Title change. Modified contents within 'Definitions' section because of redundancy with GL procedures. Added and defined short term and long term technical review. Added steps and modified the 'Procedure' section. Added a revision history section.

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