	Technical Review	
Status: Published		Document ID: 990
DATE EFFECTIVE	APPROVED BY	PAGE
04/27/2021	Quality Assurance Manager	1 OF 10

Technical Review

1 Guiding Principles and Scope

- 1.1 Technical review is an evaluation of reports, notes, data, and other documents to ensure that there is an appropriate and sufficient basis for the scientific conclusions. The Department of Forensic Biology uses a program of technical review for case reports issued by the Department in order to ensure that all appropriate testing was conducted, that reports accurately reflect the results of testing, and that all opinions are based upon objective scientific observations.
- 1.2 This document describes the technical review procedure of the Department.
- 1.3 If differences of opinion arise during the technical review process and cannot be resolved by the analyst, reviewer, their supervisor(s), and/or manager(s), the "Discrepancies in Interpreted Results" procedure in the Administrative Manual must be followed.

2 Procedure

- 2.1 Technical review will occur at two points in the lifecycle of a case: Point one is referred to as *test* batch technical review and point two is referred to as case technical review.
 - 2.1.1 **Test Batch Technical Review** may occur as individual test batches, such as extractions and amplifications, are completed or may be done together after multiple batches are completed. These reviews occur on a batch level and are not necessarily tied to a specific case.
 - 2.1.1.1 An individual case must have all test batches tied to the current assignment reviewed before the associated case file and report may be finalized and submitted to case technical review (See the Case Management Procedure).
 - 2.1.2 **Case Technical Review** is the overall review of a completed case in which the analysis results summary, notes, data, and other documents are checked to verify that the Department's analytical, case management and QA/QC procedures were followed; data was interpreted correctly; and the final case report accurately reflects the supporting data. Technical review is performed on all cases prior to the release of the report, except for those that are eligible for Administrative Completion (see the <u>Administrative Completion</u> of Cases procedure).
 - 2.1.2.1 If non-conforming work is pending, technical review of the case should not be performed. Technical Reviewers should email the LIMS Super Users to roll back the approvals to put the status back to "Pending RA".
- 2.2 The case record contains all the case documentation needed for interpretation of results and conclusions, and the technical review of those interpretations and conclusions. Prior to

	Technical Review	
Status: Published		Document ID: 990
DATE EFFECTIVE	APPROVED BY	PAGE
04/27/2021	Quality Assurance Manager	2 OF 10

submitting a case for technical review, the reporting analyst will ensure that all necessary technical and administrative records have been compiled. See the <u>Case File</u> procedure for further details on the technical and administrative records that are required.

2.2.1 Data associated with individual test batches, such as reagent lot numbers, are reviewed as part of the test batch technical review and are not all contained in the case record. However, all data is contained in the LIMS system and is available for review. The case record will contain documentation of each test batch technical review associated with the case including the name of the person who performed the review and the date of the review. All data needed to interpret results and draw conclusions will be contained in the case record.

3 Technical Reviewer Requirements

- 3.1 The reporting analyst may not perform a technical review of their own case. Technical reviews may not be performed by the author or co-author of any examination records within the associated case record.
- 3.2 The technical reviewer must be or have been an analyst qualified in the method, technology, typing test kit, platform and interpretation software being reviewed.
 - 3.2.1 "Analyst" includes those whose sole analytical responsibility is technical review.
- 3.3 Analysts may technically review cases written by analysts of the same title and lower level staff. Analysts may not review the work of higher-level staff.
- 3.4 Criminalist II or above may technically review Simple Cases: Serology cases; DNA cases where no DNA testing past the quantitation step is attempted.
- 3.5 Criminalist III or above may technically review Moderately Complex Cases: Cases containing simple interpretation of STR typing results and do not require STRmixTM analyses or calculations (e.g. cases with only single source profiles, mixtures amplified with less than 75 pg of total input DNA, or mixtures of four or more contributors), suspect cases with cross-referenced evidence where all samples are insufficient and/or not suitable for comparison, and suspect cases without cross-referenced evidence.
- 3.6 Criminalist IV or above may technically review Highly Complex Cases: All of the above, as well as cases that contain complex interpretation of STR typing results and/or require STRmixTM analysis or calculations (e.g. deconvolutions of DNA mixtures, comparisons to exemplars requiring the use of STRmixTM, and likelihood ratio calculations). Criminalist IV or above should be performing all test batch technical reviews.

	Technical Review	
Status: Published		Document ID: 990
DATE EFFECTIVE	APPROVED BY	PAGE
04/27/2021	Quality Assurance Manager	3 OF 10

4 Elements of Technical Review

- 4.1 This section will detail the two main points of tech review: Test Batch Technical Review and Case Technical Review.
- 4.2 Forensic Biology case work is often processed in batches where samples from unrelated cases are worked through specific laboratory protocols, such as extraction and amplification, together for efficiency of human effort, time, and resources. These protocols are referred to as test batches in the LIMS system. To build upon this efficiency, the technical review of these test batches will also occur in a batched form. This review will be called Test Batch Technical Review. Analysts who meet the requirements for a technical reviewer (see section 3) will review the completeness of basic elements of test batches and sign off on this review. This review will include ensuring that all parameters for passing detailed in those specific protocols are met, including the results of all control samples.
 - 4.2.1 Use queries available on the Historical Test Batch List page in LIMS to search for and select test batches that need technical review.
 - 4.2.2 Review the test batches via their edit page in LIMS to ensure that:
 - 4.2.2.1 Testing conforms to proper technical procedures and applicable laboratory policies and procedures. Specific requirements for each batch type are documented in their relevant sections of the manual.
 - 4.2.2.2 All required reagents have been properly recorded.
 - 4.2.2.3 Any required instrument log has been recorded.
 - 4.2.2.4 All 'performed by' steps apart from the final review have been completed.
 - 4.2.2.4.1 In most instances, the same individual will perform all lab processing steps of a multi-step procedure. If multiple analysts performed lab steps, the batch reviewer will document the name and date of the additional individuals in the batches' notes/comment section. This is because the Analysis Results Summary will only display the analyst who completes the first laboratory 'performed by' step within the test batch. Incubation steps will be displayed separately, and no note is needed regarding that step.
 - 4.2.2.5 For batches with plate names, ensure the plate has been named properly including that the date/time matches the appropriate control sample(s).
 - 4.2.2.6 All required witnesses are completed.
 - 4.2.2.7 All required QC Batch Parameters are completed and meet passing requirements such as temperature or other ranges.

	Technical Review	
Status: Published		Document ID: 990
DATE EFFECTIVE	APPROVED BY	PAGE
04/27/2021	Quality Assurance Manager	4 OF 10

- 4.2.2.8 For quantitation batches, open the experiment results report attachment to confirm that all parameters were transcribed over correctly.
- 4.2.2.9 For STR batches, all required controls, such as positive controls, negative controls, internal lane standards and allelic ladders are accounted for and yielded expected results in the GeneMarker HID software. Check internal lane standards for all controls and samples. Ensure controls are correctly marked pass/fail in the plate data entry screen and any ILS failures for samples are appropriately indicated. Mark the "ILS Checked?" box for the appropriate analysis set on the "Plate Analysis Set" tab to indicate all ILS were checked. Check STR edits for controls only. STR edits for individual case samples will be evaluated by the reporting analyst and the technical reviewer who performs the case technical review.
- 4.2.2.10 Additionally, for STR batches, confirm that all appropriate samples were scheduled for rerun or reinjection.
- 4.2.3 If it is determined that the test batch is not complete, contact the appropriate analyst to have those elements corrected and/or completed. If it is determined that the test batch fails, check that a note of the failure has been made in the notes/comments section of the batch and confirm scheduling of any necessary rework. For STR batch failures, the STR failure deviation will be used as documented in the LIMS process manual. The tech reviewer will be responsible for approving the deviation which was logged by the batch analyst. When the test batch technical review is completed, fill in the final test batch review 'performed by' task in LIMS.
 - 4.2.3.1 For STR batches, pass or fail, the reviewer will perform the test approval step as documented in the "Test Batch Analysis, Review and Approval" section of the LIMS manual. Select the next applicable test for the samples under the "Next Process" column as needed for reruns/reamps. Add rerun/reamp samples to a new batch for processing as needed. For reinjections, follow the "STR Reinjections" section of the LIMS manual.
 - 4.2.3.2 It may at times be necessary to tech review an older test batch which has not been updated with a test batch review 'performed by' task in LIMS. For these batches, it is acceptable to document technical review by placing a note in the notes/comments section of the batch including the name of the reviewer and date of the review. Example: "Batch tech reviewed by *Name* on *Date*."
- 4.3 Case technical review is a thorough review done of specific completed cases that have been submitted for review by an interpreting analyst. There are two basic types of case technical review: full technical review and limited scope technical review. Within LIMS, there are two technical review designations: "Tech1" and "Tech2". If both "Tech1" and "Tech2" are performed, it is expected that the full technical review is designated by the "Tech1" notation and a limited scope review is designated by the "Tech 2" notation. It is not the intention that a case record be subject to two full technical reviews.

	Technical Review	
Status: Published		Document ID: 990
DATE EFFECTIVE	APPROVED BY	PAGE
04/27/2021	Quality Assurance Manager	5 OF 10

- 4.4 **Full Technical Review.** At a minimum, a full technical review includes the following steps. Some steps will not be applicable to technical review of serology cases or DNA cases that do not proceed past the quantitation step.
 - 4.4.1 The case report and the case record are reviewed to ensure that:
 - 4.4.1.1 Testing conforms to proper technical procedures and applicable laboratory policies and procedures. It is not expected that this tech review includes test batch level data previously reviewed during the test batch technical review. Rather, only test batch data specific to the results, interpretations and conclusions of the case displayed on the Analysis Results Summary in the case file should be reviewed.
 - 4.4.1.2 The reported results and conclusions are accurate and supported by the technical records:
 - 4.4.1.2.1 DNA profiles are consistent with the raw or analyzed data (e.g., electropherograms, sample sequences).
 - 4.4.1.2.2 Because all required controls have been previously reviewed during test batch technical review, it is not required to re-review this data. Ensure that all test batches in the case have had a test batch technical review. This review, as well as the pass/fail status of all controls is documented on the Analysis Results Summary in the electronic case file.
 - 4.4.1.2.3 Inclusions, exclusions, and results reported as inconclusive comply with Department guidelines.
 - 4.4.1.2.4 Associations must be properly qualified in the case report with either a quantitative or qualitative statement as appropriate.
 - 4.4.1.2.5 When no definitive conclusions can be reached, the case report must clearly communicate the reason(s).
 - 4.4.1.2.6 Examination notes and supplemental records meet Department requirements with respect to dates of examination and analyst and case identifiers.
 - 4.4.1.3 The following elements are verified as present in the report:
 - Description of the DNA technology
 - Description of the DNA loci or amplification system
 - The results and conclusions
 - A quantitative or qualitative interpretative statement
 - The signature and title of the analyst of record
 - 4.4.1.4 A database review is completed if not already done (See Section 8 Database Review)

	Technical Review	
Status: Published		Document ID: 990
DATE EFFECTIVE	APPROVED BY	PAGE
04/27/2021	Quality Assurance Manager	6 OF 10

4.4.2 The following four checklists detail the specific items which will be checked as part of the full technical review or test batch technical review. Each full technical review list applies to one of three categories of file: positive cases (any sample is amplified in any system), negative cases (results up to and including quantitation which results in all samples insufficient for amplification), and suspect cases. Not all items will apply to every case and will be checked as necessary. These checklists may be printed out by the analyst and/or tech reviewer to facilitate the tech review process via hand-checking the boxes; however, they will not be retained in the case record and will be discarded after use. Printed checklists are an aid only and are not formal documentation of technical review. See

Section 7 for Documentation of Technical Review.

- Case Management Checklist Positive Cases
- Case Management Checklist Negative Cases
- Case Management Checklist Suspect Cases
- Case Management Checklist Test Batch Tech Review
- 4.5 **Limited scope technical review**. A **technical review** is of limited scope if it follows a full technical review. The intent is to verify the most critical elements of a case, including:
 - The informative DNA typing results, including review of controls
 - Deconvolutions of mixed DNA profiles and/or STRmix analysis documentation
 - Statistical calculations
 - The comparisons made
 - The conclusions which are relayed in the case report
- 4.6 Problems identified during technical review must be corrected. The majority of corrections are the responsibility of the reporting analyst; however, technical reviewers have discretion to make minor administrative corrections that do not alter the results and/or conclusions. The following list contains corrections that the tech reviewer may make without having the reporting analyst make the changes. If any other corrections are needed, the technical review must be rejected and the reporting analyst must make the corrections. See chart below:

	Technical Review	
Status: Published		Document ID: 990
DATE EFFECTIVE	APPROVED BY	PAGE
04/27/2021	Quality Assurance Manager	7 OF 10

Corrections that the Tech Reviewer can fix

Updating printed paperwork on lefthand side of case file

Top Block of Report

Minor report fixes/typos that don't affect conclusions or statistics

Order of sections on report

Consumption footnote (*)

Deleting extraneous sections left in or blank pages/spacing in the report

Bolding or Unbolding in the report

Add in headers if missing

Typos in DB profile Spec ID, matching cases, etc.

DNA HITS fixes

Distribution list updates in LIMS - wrong borough, missing ECMS, CMS, etc.

Delete unnecessary attachments in LIMS

Numbering pages & Setting priority status in LIMS

5 Update NYPD DEMP (DNA Evidence Management Program)

- 5.1 The Department of Forensic Biology has agreed with the NYPD to check their DNA Evidence Management Program (DEMP) for additional evidence that may exist pertaining to a sexual assault case currently undergoing technical review by the Department of Forensic Biology. It has been further agreed that DEMP will be updated before completion of the technical review of that case. This is the only situation where a tech reviewer must check and update DEMP.
- 5.2 If the goals of the case have not been met by testing the kit (e.g. no semen has been found or no male profile has been developed), the technical reviewer will check DEMP for the existence of additional evidence pertaining to that case.
 - 5.2.1 If there is additional evidence, select "send to OCME if the case is still active" and update the LIMS communication log for that case to indicate that this request was made.
 - 5.2.2 For kits, if there is a listed suspect, attempt to contact the assigned ADA to determine if additional evidence still warrants testing.
 - 5.2.3 If DEMP indicates that there is no additional evidence for that case, update the LIMS communication log for that case to indicate that DEMP was checked and no additional evidence exists.
- 5.3 If the goals of the case have been met by testing the kit (e.g., a male profile was developed), the technical reviewer still needs to check DEMP for the existence of additional evidence pertaining to that case.

	Technical Review	
Status: Published		Document ID: 990
DATE EFFECTIVE	APPROVED BY	PAGE
04/27/2021	Quality Assurance Manager	8 OF 10

- 5.3.1 If there is additional evidence, select "do not send to OCME" and update the LIMS communication log for that case to indicate that this request was made.
- 5.3.2 If DEMP indicates that there is no additional evidence for that case, update the LIMS communication log for that case to indicate that DEMP was checked and no additional evidence exists.

6 Number of Technical Reviews

- 6.1 Test batch technical review will be performed on all test batches which have samples and/or controls from casework and proficiency tests. One review will be performed per test batch.
- 6.2 Completed case files are reviewed via a Case Technical Review. One full technical review is sufficient for most cases; however, heightened scrutiny is required in some circumstances. Heightened scrutiny is:
 - 6.2.1 One full technical review conducted by a manager OR
 - 6.2.2 One full technical review conducted by a Criminalist Level III or IV and one limited scope technical review conducted by a Criminalist Level IV or above.
- 6.3 Heightened scrutiny is required:
 - 6.3.1 For cases that were tested using Identifiler or Fusion, the following requirements apply:
 - 6.3.1.1 Cases that require kinship analysis or paternity analysis
 - 6.3.1.2 Cases that require partial match analysis (suspect to case only, not within a case
 - 6.3.2 For cases that were tested using Identifiler, the following legacy requirements apply:
 - 6.3.2.1 Cases that require the calculation of a likelihood ratio using FST, except when an identical likelihood ratio was previously calculated (e.g. for an abandonment sample profile)
 - 6.3.2.2 Cases where a comparison of the DNA profile of a suspect, victim, elimination sample, or other known/deduced donor to a sample results in an inconclusive result ("no conclusion can be drawn").
 - 6.3.2.3 Cases containing mixtures that exhibit more than one "Z" or "INC" in the deconvoluted profile (unless the "Z" or "INC" is due to dropout/degradation rather than ambiguity in the deconvolution)
 - 6.3.2.3.1 The requirement for heightened scrutiny technical review does not apply to cases that contain only mixtures where the DNA profile of the deconvoluted contributor

	Technical Review	
Status: Published		Document ID: 990
DATE EFFECTIVE	APPROVED BY	PAGE
04/27/2021	Quality Assurance Manager	9 OF 10

is unambiguous. Characteristics of simple (unambiguous) DNA mixtures may include:

- The presence of a clear major contributor with the addition of just a few other called alleles.
- A completely deconvoluted major contributor with no more than one "Z" or "INC".
- A completely deconvoluted major or minor contributor, with no more than one "Z" or "INC", obtained by assuming a contributor to the mixture.
- 6.3.3 **Note:** An analyst or technical reviewer may request a heightened scrutiny for review of any

7 Documentation of Technical Review

- 7.1 Technical review is documented within the LIMS.
- 7.2 Test batch technical review is documented in the individual test batches via the **final** review 'performed by' task or by a note in the batch's notes/comments section if the 'performed by' task does not exist. Test batch technical review is not accepted or rejected but is simply completed regardless of pass/fail status. If a test batch fails, that will be documented either in the batch's notes/comments section or in the case of STR plates via an STR failure report.
 - 7.2.1 Note: Only the final 'review' task is used to document technical review. This is distinct from all other 'review' or 'setup review' tasks which designate the creation or completion of the batches for processing or proceeding to the next test batch and do not constitute a technical review.
- 7.3 Each stage of a completed case's full technical review accept/reject, and limited scope technical review accept/reject must be documented in LIMS.
 - 7.3.1 If a case record and report are accurate and complete, approve by selecting "accept" in LIMS.
 - 7.3.2 If a case requires analyst corrections to any part of the case record (notes, database profiles, statistical calculations, reports, etc.), disapprove by selecting "reject" in LIMS. The reason for the rejection shall be included in the comments section when rejecting the technical review in LIMS. The reporting analyst is responsible for checking LIMS to determine if corrections are needed.
 - **7.3.3** Once corrections have been made following a rejection in LIMS, the technical reviewer completes the review and approves as described above.
- 7.4 Cases with completed technical review are ready for administrative review.

	Technical Review	
Status: Published		Document ID: 990
DATE EFFECTIVE	APPROVED BY	PAGE
04/27/2021	Quality Assurance Manager	10 OF 10

8 Database Review

- 8.1 DNA profiles that are eligible for LDIS, SDIS and/or NDIS must undergo a database review by a Criminalist III or above.
 - 8.1.1 Database review can be included as part of a full or limited-scope technical review or it can be conducted as a stand-alone review in order to expedite profile entry into a database.
 - 8.1.2 At a minimum, a database profile review includes:
 - 8.1.3 A review of the database profile and interpretation (LIMS) and supporting documentation to ensure that:
 - All required fields within the form have been completed
 - The DNA profile(s) is accurate
 - The specimen identification number and specimen categories are correct
 - The positive and negative control results are acceptable
 - The DNA profile(s) is eligible for entry into the applicable database(s)
- 8.2 Database review is documented within the LIMS.

9 Corrections to DNA Profile Evaluation Forms prior to entry into CODIS.

- 9.1 Corrections to database profiles are shown to the reporting analyst, who verifies the changes prior to entry into LDIS.
- 9.2 If the profile is needed for immediate upload and the reporting analyst is not available, the corrections can be approved by a Criminalist IV or above. The corrected database profile is later shown to the reporting analyst.

10 Corrections to DNA Profile Evaluation Forms after CODIS entry.

- 10.1 Modifications may be made by the reporting analyst or the CODIS group.
- 10.2 If modifications have been made by the CODIS group, they will involve the reporting analyst as necessary, particularly if doing so provides training value to the reporting analyst.