QC Monitoring Program

1 Purpose

1.1 This protocol describes how to perform the steps necessary for the QC monitoring Program. See the Proficiency Testing Program section of the Quality Assurance / Quality Control Procedures Manual.

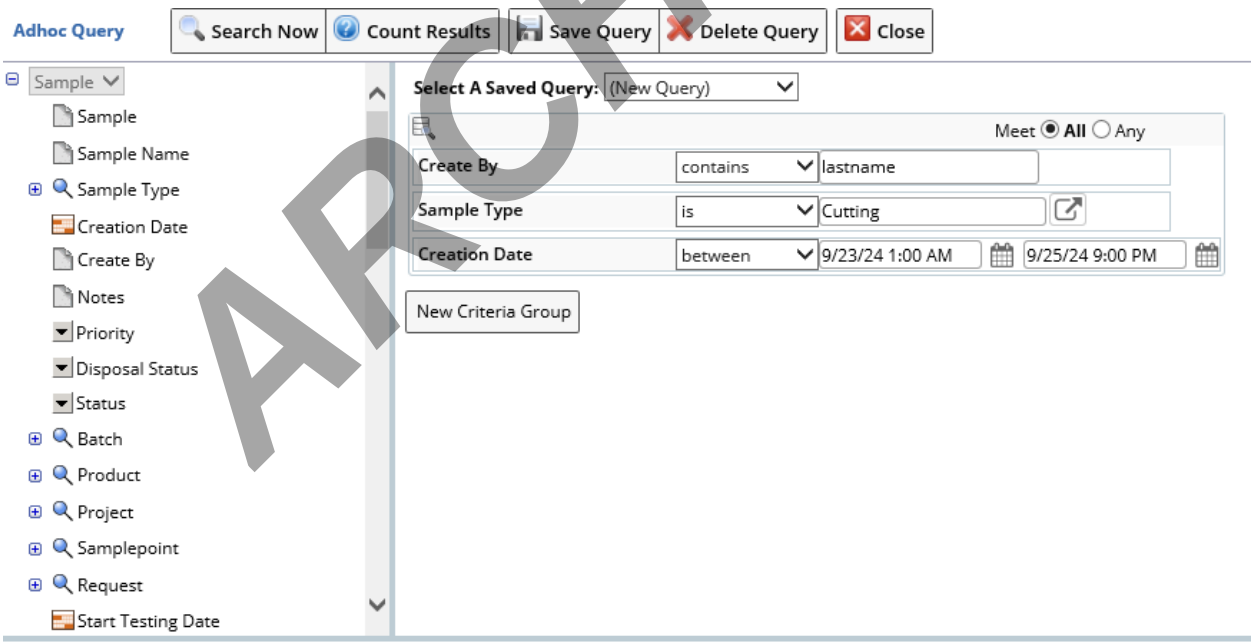
2 Creating the QC Monitoring Set

2.1 Run search query in LIMS to retrieve sample data

2.1.1 Navigate to Manage Sample tramstop

2.1.2 Create Ad Hoc query

2.1.3 Add three search criteria: “create by” = examiner last name following LIMS format, “sample type” = cutting, “creation date” = enter selected three-day range and the time (ex. 9/23/24 12:00AM – 9/25/24 9:00PM)



2.1.4 Click search (this ad hoc query can be saved to use for the future)

2.1.5 Select all samples, and navigate to View as Excel

2.1.6 Save Excel data in appropriate folder on the network (File format QC Query List examiner initials examination date)

2.2 Open a copy of the QC Monitoring Profile List Macro and save on the network (File format QC _examiner initials_examination date_QC Monitor initials, ex. QC_ABC_092424_XYZ). The examination date will be the second date of the three-day span (ex. if dates queried are 9/24/24 – 9/26/24, use 9/25/24 as the examination date.)

2.3 Initiate Qualtrax workflow – QC Monitoring Program Workflow

2.3.1 Fill in required fields. Refer to QC monitor transfer sheet where appropriate.

2.3.2 Save the workflow to notify the assigned QC monitor.

2.4 In LIMS, navigate to the case file pages for the cases included in the QC Monitoring Set.

2.4.1 Add note to the case file comments listing the QC Monitoring set name (QC_ABC_092424_XYZ).

3 Creating QC Monitoring Profile List Macro for STRmix™

3.1 During the write up process, the RA assigned to each case will evaluate the samples and profiles generated for their case. The RA will create an interpretation in LIMS for any profiles that meet the below criteria and add to the QC Monitoring Profile List Macro (**Samples with protective orders WILL NOT be used in this process)**:

3.1.1 Profiles (including exemplar and evidence profiles) with 11 or more fully deconvoluted loci regardless of CODIS eligibility.

3.1.1.1 Ensure that profiles are the most complete version from any of the samples in the case, whether or not it was directly derived from a cutting in the QC set.

3.1.1.2 For sexual assault cases, the victim's elimination profile should be added to the QC Monitoring Profile List Macro even if the samples were insufficient.

3.1.1.2.1 For other case types, if an elimination sample is typed, it should be included in the QC Monitoring Profile List Macro.

3.1.1.3 For single source profiles, a STRmix™ deconvolution needs to be performed.

3.2 Locate the appropriate QC monitoring folder and add profiles to the QC Monitoring Profile List Macro. Follow instructions in the QC Monitoring Profile List Macro.

3.3 Prior to submitting the case to technical review, the RA should assign the QC monitor listed in the case comments as the technical reviewer for their case.

4 QC Monitoring Using STRmix™

4.1 Ensure that QC702b- QC Monitoring Search Set-up protocol has been completed and reviewed before conducting the QC Monitoring process.

4.2 Generally, the QC Monitor will be assigned as the technical reviewer to cases within the QC Monitoring Set; if not, the QC Monitor will be notified when the case is submitted for technical review.

4.3 Cases must be technically reviewed before completing the QC monitoring process. See the Technical Review Section of the Evidence and Case Management Manual.

4.3.1 DB profiles and cases should remain in the Level 2 Review/Tech 2 stage until after the QC monitoring is completed. The technical reviewer should assign themselves to the Tech 2 line in the case report approvals tab.

4.3.2 DNA hits will not be approved until after the QC Monitoring Process is completed.

4.4 Review the data entry for the profiles in the QC Monitoring Profile List Macro and ensure they have been entered correctly. Refer to the instructions tab in the profile list to create the final .CSV file to be used for STRmix™ import.

4.5 Set up the STRmix™ profile search

4.5.1 Open the STRmix™ software by locating STRmix™ in the task bar or by double clicking on the STRmix™ icon on the desktop.

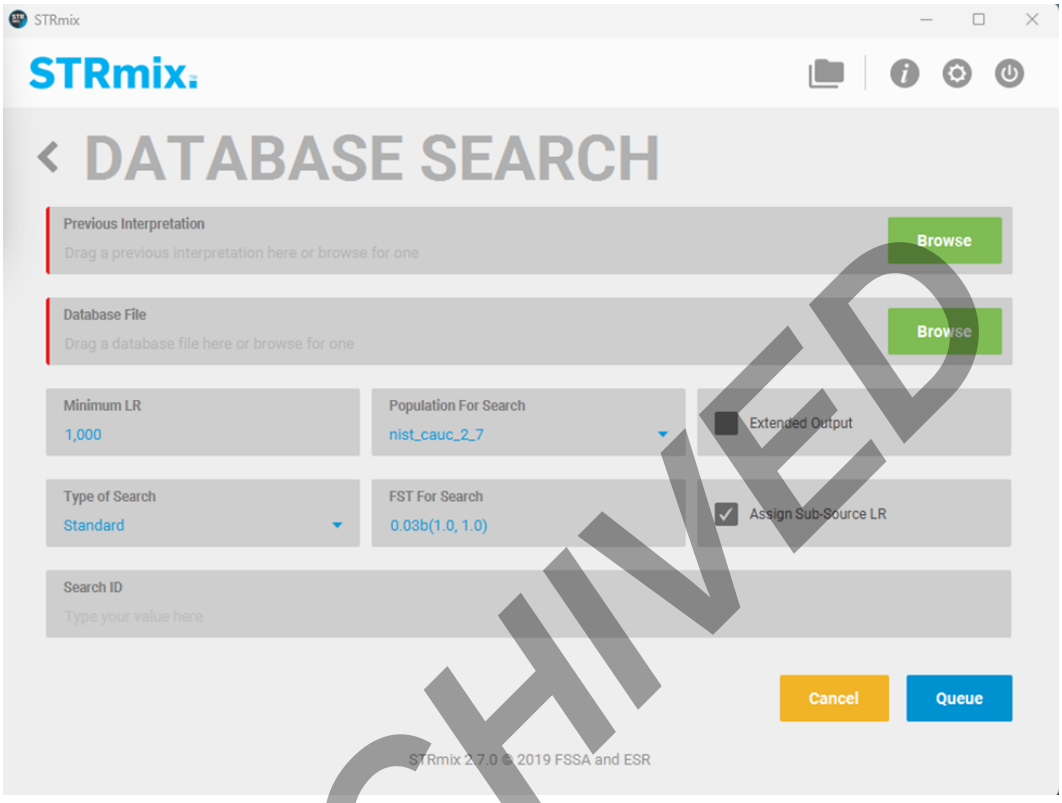
4.5.2 Select **Batch Mode** from the STRmix™ main window

4.5.2.1 Before setting up a batch, navigate to the OCME_STRmix_Fileshare folder (\\csc\ocme\OCME_STRmix_Fileshare). Create a new folder within the STRmix™ Fileshare folder with the name of "QC Batch Mode [date] [your initials]."

4.5.3 For the **Batch Directory**, select **Change** and navigate to and select the created folder inside the OCME_STRmix_Fileshare. This new folder will now appear at the top of the screen.

4.5.4 Use the drop-down arrow next to **Add to Batch** and select **Add Database Search** to set up each individual run.

4.5.4.1 Ensure your settings match the screenshot below



4.5.5 Select the **Previous Interpretation** file for a sample within the QC set.

4.5.6 Drag and drop the entire deconvolution run folder into **Previous Interpretation** field or **browse** and navigate to locate the deconvolution file, labeled as config.xml or results.xml (or settings.ini for older versions of STRmix™) within your run folder in the STRmix™ Data folder in the M drive.

4.5.7 For the **Database File**, select the QC Monitoring Profile List Macro.CSV file that was created for this QC batch set.

4.5.8 Drag and drop the QC Monitoring Profile List Macro.CSV file or **browse** and navigate to the appropriate folder and select the sheet to open.

4.6 After setting up the run, click **Queue** to return to the **Batch Mode** setup window.

4.6.1 Repeat steps 4.5.4-4.5.8 to add any additional runs.

4.6.1.1 To edit a sample set up, highlight the run listed, remove it, and redo the setup.

4.6.1.2 To remove a sample set up, highlight the sample, and select Remove.

4.7 Select **Start Batch** to start the batch run.

4.8 After completion of analyses, click **Open** to be directed to the Batch Mode folder you created.

5 Evaluate the STRmix™ Results

5.1 Navigate to the Reports folder for each sample and open the appropriate PDF.

5.1.1 Check that the database search setup is consistent with the following settings:

Interpretation chosen	Location of STRmix™ interpretation for sample
Profiling Kit	Kit is pulled in from the STRmix™ interpretation file: ex. OCME_Fusion_3500
Sample file	Sample data used for STRmix™ interpretation. This information is pulled in from the STRmix™ interpretation file.
Database searched	Location of QC Monitoring Profile List Macro for the QC set
Number of individuals in database	Dependent on number of donor and victim/exemplar profiles listed in the QC Monitoring Profile List Macro
Minimum LR	1,000
Population	nist_cauc_2_7
Type of search	Standard
FST	0.03b{1.0,1.0}
Assign sub-source LR	Y
Extended output	N
Search ID	[original name of sample STRmix™ interpretation]-DBSearch

5.1.2 Ensure Previous Interpretation Details are consistent with the STRmix™ interpretation that was performed for the sample.

5.1.3 Check that Data Validation indicates that all data passed validation.

5.2 Evaluate the LR results. LRs above the minimum LR threshold should be evaluated to determine if those results are concordant with the case results.

5.2.1 Some LRs greater than the minimum threshold may meet the concordance policy within or between cases. For example, a deconvoluted profile compared to the sample from which it was derived, an evidence profile compared to another sample in the same case where that

donor is qualitatively included, or suspect profile compared to an evidence sample for which the suspect was submitted for comparison.

5.2.1.1 A profile compared to a deconvolution for which that same profile is conditioned upon will return an LR of 0.

5.2.2 An LR greater than the minimum threshold that does not appear to be concordant with the case results should be evaluated to determine if it could be indicative of a contamination event, a new investigative lead, or adventitious support for inclusion. The nuclear Technical Leader and the Quality Assurance Manager must be notified of any non-concordant results.

5.3 Evaluate the information listed in the Verifying and reporting exact matches section in the Verifying and Reporting DNA Matches section of the CODIS manual.

5.3.1 Evaluate the order that the cuttings were made during examination.

5.3.2 A non-concordant LR may need to be rerun in STRmix™ to apply the HPD and Unified functions. Consult with the Technical Leader.

5.3.3 Exemplars or abandonment samples that were determined to be a mixture may require manual comparison to the other samples on the QC set.

5.3.4 If there is an indication of cross contamination in the set, it may be necessary to evaluate any samples determined to be 5p as part of the QC monitoring.

5.4 The QC monitor should initiate a non-conformity for any non-concordant results as necessary and notify the RA of the associated case(s) during this process.

5.5 Document results in the Qualtrax workflow

5.5.1 “OK” may be entered in the comment line for samples where no issues were detected.

5.5.2 Enter any further information for specific samples or the QC set as a whole as needed.

5.5.3 Assign a QC reviewer.

5.6 If any issues are detected during the QC monitoring, the nuclear TL or QAM will be assigned as the QC reviewer.

5.6.1 Approve the workflow when completed to send it to the assigned QC reviewer

5.7 Once the QC review is completed, the DB profiles and case reports for the cases will be final approved by the technical reviewer. Additionally, any DNA hit notifications can be approved.

6 QC Monitoring Review

6.1 Review the LR reports for the QC set. Ensure any LRs greater than the minimum threshold were evaluated.

6.2 Review the Qualtrax workflow to ensure any comments or other information were entered correctly.

6.3 When the review is complete, approve the Qualtrax workflow. This will send the workflow to the examining analyst for final acknowledgment.

6.4 Notify the QC monitor that the review is complete.

6.5 Fill out the QC Monitoring Program Memo to be included in the casefiles in the set. This memo must be signed by the QC monitor and the QC reviewer before being attached to each case.

6.6 If a case is distributed before the memo can be attached, the memo should be added to the casefile and the casefile should be recertified.