Document Control		
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Document Control

1 Guiding Principles and Scope

1.1 The Department of Forensic Biology controls all documents that comprise its management system in order to ensure that invalid and/or obsolete documents are not used. This procedure describes how controlled documents are created, revised, distributed, and archived.

2 General Structure of Management System Documents

2.1 **Internal Documents.** All controlled internal documents are maintained in Qualtrax. The internal documents that comprise the management system are structured as follows:

2.1.1 **Management System Manual:** The Management System Manual is the top tier document in the management system. It provides an overall guide to the management/quality system of the Department of Forensic Biology. It contains references to other management system documents that have more detailed information.

2.1.2 **Scientific Procedures Manuals:** These manuals contain current procedures pertaining to the analytical testing of biological specimens. The manuals are: Serology Procedures Manual, Molecular Serology Procedures Manual, the Protocols for Forensic STR Analysis Manual, and the Protocols for Mitochondrial DNA Analysis Manual.

2.1.3 **CODIS Manual**: This manual details the protocols associated with verifying, uploading, and reporting of forensic profiles in relation to the CODIS System

2.1.4 **LIMS Process Manual:** This manual contains procedures for the operation of the Laboratory Information Management System (LIMS) within the Department.

2.1.5 **Administrative Manual:** This manual contains procedures with laboratory-wide application pertaining to laboratory planning, organization, and documentation.

2.1.6 **Quality Assurance/Quality Control Manual:** This manual contains procedures pertaining to the Department's quality assurance and quality control activities, for example, proficiency testing, reagent preparation and performance testing, validation, and equipment calibration and maintenance programs.

2.1.7 **Evidence and Case Management Manual:** This manual contains procedures related to (1) evidence intake, distribution, and return; and (2) case handling, including evidence examination guidelines; handling, evaluation, and troubleshooting of cases which are in progress; report writing and reviews.

2.1.8 **Training Manual:** The Training Manual details in-house training in the Department.

2.1.9 **Forms Manual:** Forms are used to record information. Their use is specified in various procedures. Official forms and/or their links are maintained in Qualtrax within the Forms folder. The Quality Assurance (QA) Reagent Sheets are maintained within a folder under the Quality Assurance / Quality Control (QA/QC) Procedures manual. Some controlled forms exist as Workflows in Qualtrax.

2.1.10 **Workflows:** Workflows are used to gather information within Qualtrax in lieu of the use of electronic or paper forms. Workflows can be used to transform paper forms into electronic databases. Workflows that are created to replace and/or aid with controlled forms will be tested and/or reviewed before use by the corresponding approver, as determined by the area of the lab to which the workflow relates.

2.1.11 **Memos:** There are three types of memos used within the Department:

- Operational Memos
- Non-Conforming Work Memos
- Memos to File.

See Section 6 below for more detail concerning memos

2.1.12 **Master List:** The current revision status and distribution of all documents that are part of the management system, whether internal or external are recorded in various Master Lists. These Master Lists are produced via Reports by Qualtrax.

2.2 **External Documents.** External documents are also part of the management system documentation. These may include, but are not limited to, accreditation requirements, OCME and Department of Health and Mental Hygiene (DOHMH) policies and procedures, and instrument manuals. References to applicable controlled external documents are found in internal management system documents.

3 Responsibility and Authority for Document Control

3.1 The **Laboratory Director**, in conjunction with the Nuclear DNA Technical Leader, is the approving authority of the Management System Manual as the overall guide to the management/quality system of the Department of Forensic Biology.

3.2 **The Deputy Director** has the primary responsibility and authority for approval of all guiding principles and procedures that are under the Administrative Manual. The Deputy Director also oversees the management and upload of Forensic Biology documents to the NYC.gov/OCME website. The Director and Deputy Director may act as back-up approvers for all other management system documents; however, where DNA Technical Leader authorization is needed, the approval can be done only where the Deputy Director is acting as the designated deputy Technical Leader in the absence of the primary DNA Technical Leader.

3.3 **The Quality Assurance Manager (QAM)** has the primary responsibility and authority for implementation and maintenance of the document control system. The QAM is also the primary approver of all guiding principles and procedures that are under the Quality Assurance/Quality Control Manual and the Evidence and Case Management Manual.

3.4 **The Nuclear DNA Technical Leader** has the primary responsibility and authority for approval of the Management System Manual as well as the procedures in the Protocols for Forensic STR Analysis Manual and the Serology Procedures Manual; is principal or co-approver of the proficiency testing program; and is principal or co-approver of the Nuclear DNA training program content in the Training Manual.

3.5 **The Mitochondrial DNA Technical Leader** has the primary responsibility and authority for approval of procedures in the Mitochondrial DNA Analysis Manual; principal or co-approver of the proficiency testing program; and principal or co-approver of mitochondrial DNA training program content in the Training Manual.

3.6 **The Molecular Serology Technical Leader** has the primary responsibility and authority for approval of procedures in the Molecular Serology Procedures Manual; principal or co-approver of the proficiency testing program; and principal or co-approver of molecular serology training program content in the Training Manual.

3.7 **The Training Manager** has the responsibility and authority for approval of the Training Manual.

3.8 **The CODIS Manager** has the responsibility and authority for approval of the CODIS Manual.

3.9 **The LIMS Manager** has the responsibility and authority for approval of the LIMS Process Manual.

3.10 **The Document Control Coordinator (DCC)** works under the direction of the Quality Assurance Manager and is responsible for the overall function of Qualtrax. The DCC has the primary responsibility and authority to ensure that: guiding principles and procedures are in the correct format, the most current approved internal management system documents are available in Qualtrax and/ or on the Forensic Biology server, and the OCME website as applicable. The DCC ensures that obsolete documents are suitably marked and archived.

3.11 **Assistant Directors** have the authority and responsibility to propose new and revised guiding principles and procedures and to provide expertise for the review of document proposals.

3.12 **All Forensic Biology staff** has the authority and responsibility to propose new and revised management system documents.

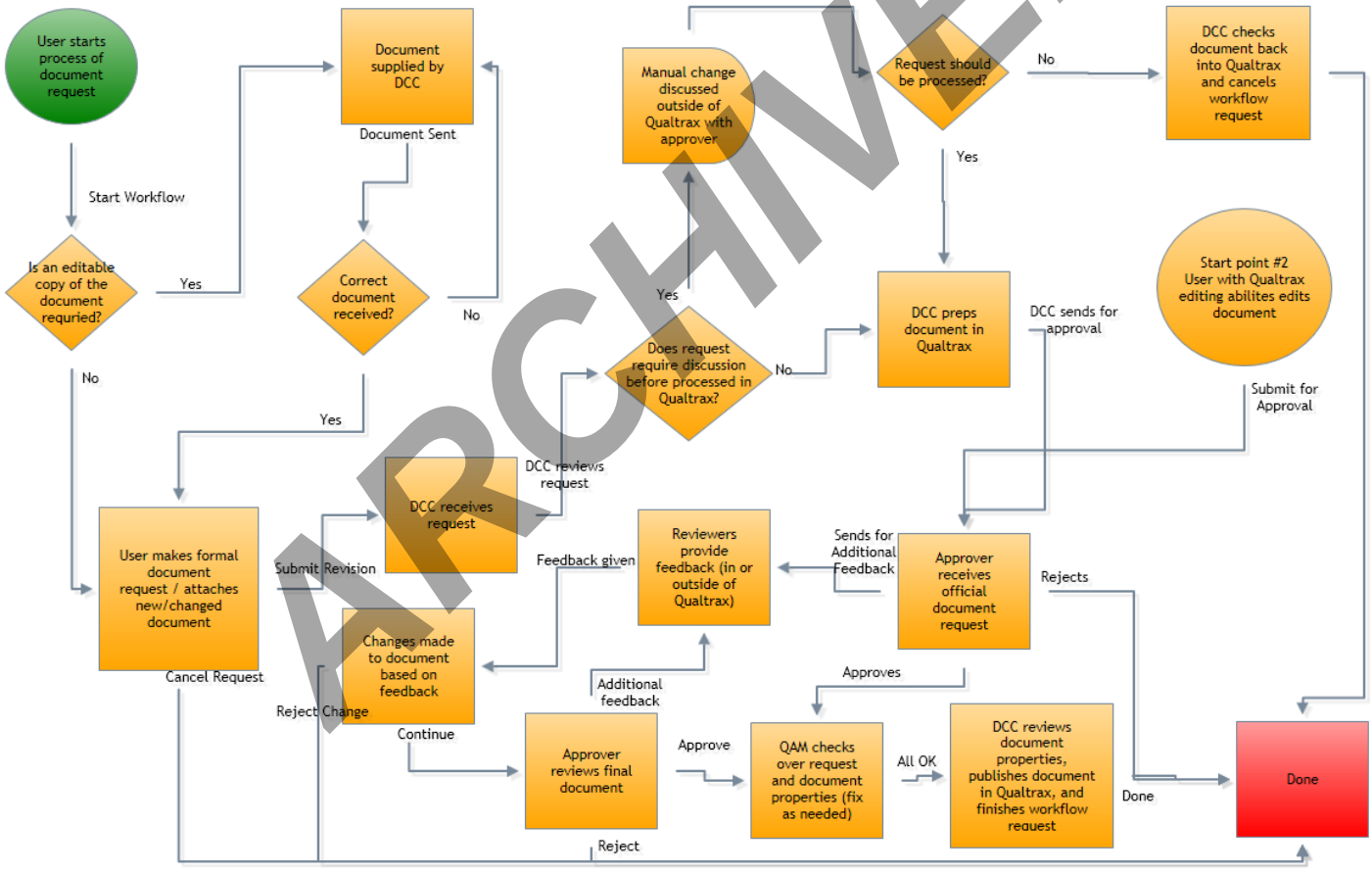
4 Document Format

4.1 All management system documents generated by the laboratory are marked with:

- Name or title of the document
- The name and/or title of the approving authority
- The effective date and/or date of approval
- Page numbering in a “page x of x” format when applicable

4.2 The revision history of all controlled documents can be found in the Properties tab of each document contained in Qualtrax.

5 Creation, Revision, and Approval of Manuals, Procedures and Forms



5.1 The overall process for creating new or revised manuals, procedures, and forms is outlined in the chart above.

5.2 Most document creation/ revision requests will follow the process listed below in its entirety. Some personnel, such as Manual Approvers, the Document Control Coordinator, Training

Coordinator, and CODIS Administrator may edit a document directly in Qualtrax, and therefore will not follow the entire process as described below. All document changes are recorded in Qualtrax, no matter the process followed, and are distributed to the laboratory via email.

5.3 **Step 1.** Draft document written & submitted

5.3.1 If the requestor cannot directly edit a document in Qualtrax, or if a new document has been requested:

5.3.1.1 Document Change Request Workflow is initiated by the Requestor via Qualtrax.

5.3.1.2 For ease of document or form creation, the preferred format for a draft document is an electronic "Word" or "Excel" file.

5.3.1.2.1 If revising an already existing document, staff should request an unprotected electronic copy of the document(s) for revision from the Quality Assurance Manager or Document Control Coordinator.

5.3.1.2.2 "Track changes" will be active for document revisions when checked out of Qualtrax. They should be kept on so proposed changes are apparent to the document reviewer and so track changes function will be utilized in Qualtrax.

5.3.1.3 If the request is for a new document, the Document Control Coordinator or QAM should be consulted to determine who the approver will be.

5.3.1.4 Requested changes are then submitted to the Document Control Coordinator. The Document Control Coordinator may consult with the appropriate Approver before making requested changes to the actual Qualtrax document.

5.4 **Step 2**. Document prepared and formatted by Document Control Coordinator

5.4.1 The document is prepared/formatted for Qualtrax.

5.4.2 Formatting includes ensuring that the document has the correct header and footer layout. The document Revision History should be updated as applicable.

5.4.3 If the requestor can directly edit in Qualtrax, the Document Change Request workflow is not required:

5.4.3.1 The document is checked out of Qualtrax by the editor

5.4.3.2 The document is edited and saved to the editor's computer.

5.4.3.2.1 Document name should not be changed so it will match the document name as checked out of Qualtrax

5.4.3.2.2 Documents checked out of Qualtrax will have the "track Changes" function on. This function should not be turned off. All changes should also be highlighted

5.4.3.3 Once changes have been made, the document is checked back into Qualtrax.

5.4.4 The document is sent to the appropriate Document Approver for review and/or approval.

5.4.4.1 Most Manuals will go to approval by clicking the button "Submit for Approval".

5.4.4.2 If the Manual approver wishes for Reviewers to submit feedback first via Qualtrax, the designated editor of the Manual is changed to the Approver, giving the approver control over the ability to send for review or approval. (the "Submit for Approval" button is not utilized in this instance.

5.4.4.3 The "Changes Made" field at this step is required and should be used to explain exactly what was changed. This is the field that is sent to the laboratory to explain changes.

5.4.4.3.1 Note: If changing the editor, the "Changes Made" field is not required, but is accessible via the document properties tab and should also be filled out.

5.5 **Step 3**. Evaluation of Request; Interim reviews & revisions

5.5.1 The Approver reviews the document changes made by the Document Control Coordinator and/or editor to ensure the correct changes were processed and updates the revision history as necessary.

5.5.1.1 If a workflow exists for the request, the workflow should be utilized as it contains the original document with tracked changes.

5.5.1.2 The "view with Tracked Changes" button at the top of the document should be used to see the changes made. Checking this tracked changes version against the workflow version may be helpful to ensure the request was carried over into Qualtrax as requested.

5.5.2 Performance checks must be conducted for forms containing macros, and the documentation of the performance checks will be provided to the Quality Assurance Manager, or Technical Leader, as appropriate.

5.5.3 Feedback should be sought from knowledgeable staff members who would be affected by the requirements of the document.

5.6 **Step 4**. Approval

5.6.1 If the Document Approver feels that the request has merit, they will approve the new version of the document and the document will be submitted to the Quality Assurance Manager.

5.6.1.1 The Quality Assurance Manager also checks the document changes made by the Document Control Coordinator and/or editor to ensure the correct changes were processed and updates the revision history as necessary.

5.6.1.2 The Quality Assurance Manager then approves the document for the Document Control Coordinator to publish.

5.6.1.3 The Quality Assurance Manager may also reject the document, communicating to the Document approver as to the reason why.

5.6.2 If the Document Approver disagrees with the document change request, they can reject the change request outright, or send the request back to the original requestor for changes and further considerations. Feedback should be included if a request is rejected.

5.7 **Step 5**. Approved document placed on server

5.7.1 The Document Control Coordinator or designee places the new or revised document in Qualtrax or on the Department server.

5.7.1.1 If the Document Control Coordinator was not the original editor of the document, they must check the formatting of the document, rejecting the document for further editing if needed, or approving the document and then fixing the format (see5.8.4).

5.7.1.2 The documents in Qualtrax are the official “controlled copies” for internally generated Management System documents.

5.7.1.3 The documents in Qualtrax are protected against unauthorized changes due to the permissions granted in the software.

5.7.1.4 The date the Document Control Coordinator approves the document for publishing will be recorded on the new/revised document either manually or via the Qualtrax template macro(s). This is the date that the document is available for use by the laboratory and is denoted by the Date Effective on the document.

5.8 **Step 6**. Staff notified; Document Control Coordinator completes updates

5.8.1 Qualtrax is set to automatically send notifications to all laboratory personnel when edits are made to documents and/or new documents are created in Qualtrax.

5.8.2 The Document Control Coordinator or designee performs the following tasks:

5.8.2.1 Archives and Retires out-of-date documents, as applicable.

5.8.2.1.1 Pre-Qualtrax documents that are archived are marked with "Archived", the date archived and the identity (by position or name/initials) of the person who archived the document.

5.8.2.1.2 When a document is revised in Qualtrax, the previous version is automatically replaced by the Qualtrax system and watermarked as "Archived". The new revised version is now available for staff use and previous versions are available to those with permissions to see them via the History tab of the document.

5.8.2.1.3 "Retired" in Qualtrax means the document is no longer in effect and there is no current "published" version. Retired documents are removed from the system such that only those with permission to access the retired document can do so. The information associated with the retirement of the document, such as date retired and who retired the document, can be seen in the document Properties tab.

5.8.2.1.4 Documents that are retired in Qualtrax are marked with a "Retired" Watermark the Qualtrax Software.

5.8.2.2 Closes the Documents Change/Request Workflow

5.8.2.3 Provides documents for the OCME website.

5.8.3 Staff discards printed copies of obsolete versions of documents.

5.8.4 Non-technical updates to documents such as typographical errors, formatting, correction to a hyperlink, or minor changes in the header/footer (i.e. document property in Qualtrax did not update correctly) can be made without the document going through the approval process or additional notification to laboratory personnel.

5.8.5 Other Interim revisions to controlled documents are not allowed.

5.9 Retention and accessibility of Archived and Retired documents

5.9.1 Electronic copies of archived internal management system documents are retained indefinitely.

5.9.2 Documents that are publicly available online will be sent to the NYC Department of Information Technology to be made available as described in the Submission of Documents to the Forensic Biology Website section of the Administrative Manual.

5.9.3 Staff and other personnel may access archived and retired documents in .PDF format via the Department of Forensic Biology Manuals section on the agency website.

(https://www1.nyc.gov/site/ocme/services/technical-manuals.page)

5.9.4 Access to archived or retired non-public documents, or non-.PDF versions of archived and retired documents is restricted to the Quality Assurance Manager, Technical Leaders, Document Control Coordinator, Director, and Deputy Director, if such copy exists.

5.9.5 Requests by staff to access a non-public or an editable version of an archived or retired document, must be submitted in writing to the Quality Assurance Manager with a reason for request.

6 Memos

6.1 There are three types of memos that the Department utilizes:

6.1.1 **Operational Memos** are used to document the distribution of operational information to staff and operational agreements between the Department and its customers. Operational Memos may also be used to convey changes in Standard Operating Procedures, or to outline new techniques before the associated manual is officially modified. Some memos convey guidelines for issues that do not fall under the Department's management system, e.g., dress codes. However, other memos may address issues that do have an operational impact and are considered to be controlled documents.

6.1.1.1 Operational Memos are typically authorized by top management of the Department (Director, Deputy Director(s), Assistant Director(s).

6.1.1.2 Operational memos are prepared on Department letterhead and must identify the author and date of issue.

6.1.1.3 Memos are usually marked with a memo number. This is the year of issue followed by the sequential number of the memo (YYYY-###).

6.1.1.4 Operational memos are protected against unauthorized changes, are retained in Qualtrax.

6.1.1.5 Memos located in Qualtrax that are out-of-date are marked as retired. Only those with the ability to see retired documents can access these Memos. The information associated with the retirement, such as date retired and who retired the document, can be seen in the document's Properties tab.

6.1.1.6 Memos located in Qualtrax that have been updated will be marked as "archived" and may be replaced with a new memo number. In this instance the old memo number should be referenced on the new memo.

6.1.2 **Non-Conforming Work Memos** are used to document Type I non-conformances.

6.1.2.1 Non-Conforming Work Memos are authorized by any Forensic Biology personnel acting

as the Principle Investigator of the non-conformance.

6.1.2.2 Memos pertaining to Type 1 non-conformances are placed on the left side of the hardcopy case record and/or attached to the LIMS case record. See the Non-Conforming Work section of the QA/QC Manual for more detailed information.

6.1.3 **Memos to File** are used to document case specific matters that are not readily apparent in the body of the case record (ex. samples from different cases are deemed inconclusive due to sample switches by the submitting agency discovered during testing) or are of a complex nature requiring detailed documentation (ex. pull-up left in a previous STRmix analysis was subsequently removed and new STRmix analysis were performed resulting in no change to the previously reported results).

6.1.3.1 Memos to File are authorized by the Reporting Analyst. Memos to File are placed on the right side of the case record and attached to the LIMS case record.

7 Periodic Document Review

7.1 The Quality Assurance Manager creates a document review schedule to ensure that all documents that form part of the management system are reviewed at least once during a calendar year.

7.2 The schedule lists the documents, the staff responsible for review, and the proposed date(s) by which the review is to be completed.

7.3 The staff member responsible for the review of a document is the approving authority. For example, the review of technical DNA procedures is assigned to the appropriate DNA Technical Leader.

7.4 The approving authority may designate other reviewers but retains the ultimate responsibility for ensuring that the document is current and correct or is revised as needed.

7.5 To maintain the schedule created, documents in Qualtrax are set to “expire” at a set time each year. This still allows analyst’s access to the documents, which are still current, but notifies the document approver that the document needs to be reviewed.

7.6 After reviewing the Document in Qualtrax, the Document Approver can determine if (1) the document is satisfactory by choosing “Verify up to date”, (2) revisions are needed, or (3) the document is no longer needed.

7.7 Records of the yearly document review are maintained in Qualtrax.

7.8 Document revisions, if needed, are completed as per the process described in the Creation, Revision, and Approval of Manuals, Procedures and Forms section of this manual.

8 Release of Management System Documents to External Parties

8.1 Requests for the release of Department of Forensic Biology management system documents that are not publicly available to parties external to the Department must be made in writing. If the external party is an attorney making a discovery request, refer to the ATTORNEY / CUSTOMER REQUESTS section of the Administrative Manual.

8.2 The Quality Assurance Manager has the authority and responsibility to consider all such requests and may require documentation from the requestor with regard to their proposed use of the document(s).

8.3 The Quality Assurance Manager may consult with an OCME Legal Counsel.

8.4 Records of all requests and their dispositions are maintained by the Quality Assurance team.