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.** 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. In terms of Standard 4.2.2 of ISO 17025:2005, this is our "quality manual."

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

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

2.1.4 **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.

2.1.5 **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.

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

2.1.7 **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.

2.1.8 **Workflows:** Workflows are used to gather information 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 approved before use by the corresponding approver, as determined by the area of the lab to which the workflow relates.

2.1.9 Official Memos: Official memos are used within the Department to document the distribution of operational information to staff and operational agreements between the Department and its customers. Official 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.

2.1.10 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 and/or Deputy Directors** have the primary responsibility and authority for approval of the Management System Manual and all guiding principles and procedures that are under the Administrative Manual. The directors may also act as back-up approvers for all other documents; however, where DNA Technical Leader authorization is needed, the approval can be done only where the director is acting as the designated deputy Technical Leader in the absence of the primary DNA Technical Leader.

3.2 **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.

3.3 **The Nuclear DNA Technical Leader** has the primary responsibility and authority for approval of 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.

3.4 **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.

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

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

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

3.8 **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.

3.9 **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.

3.10 **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:

4.1.1 Name or title of the document

4.1.2 The name and/or title of the approving authority

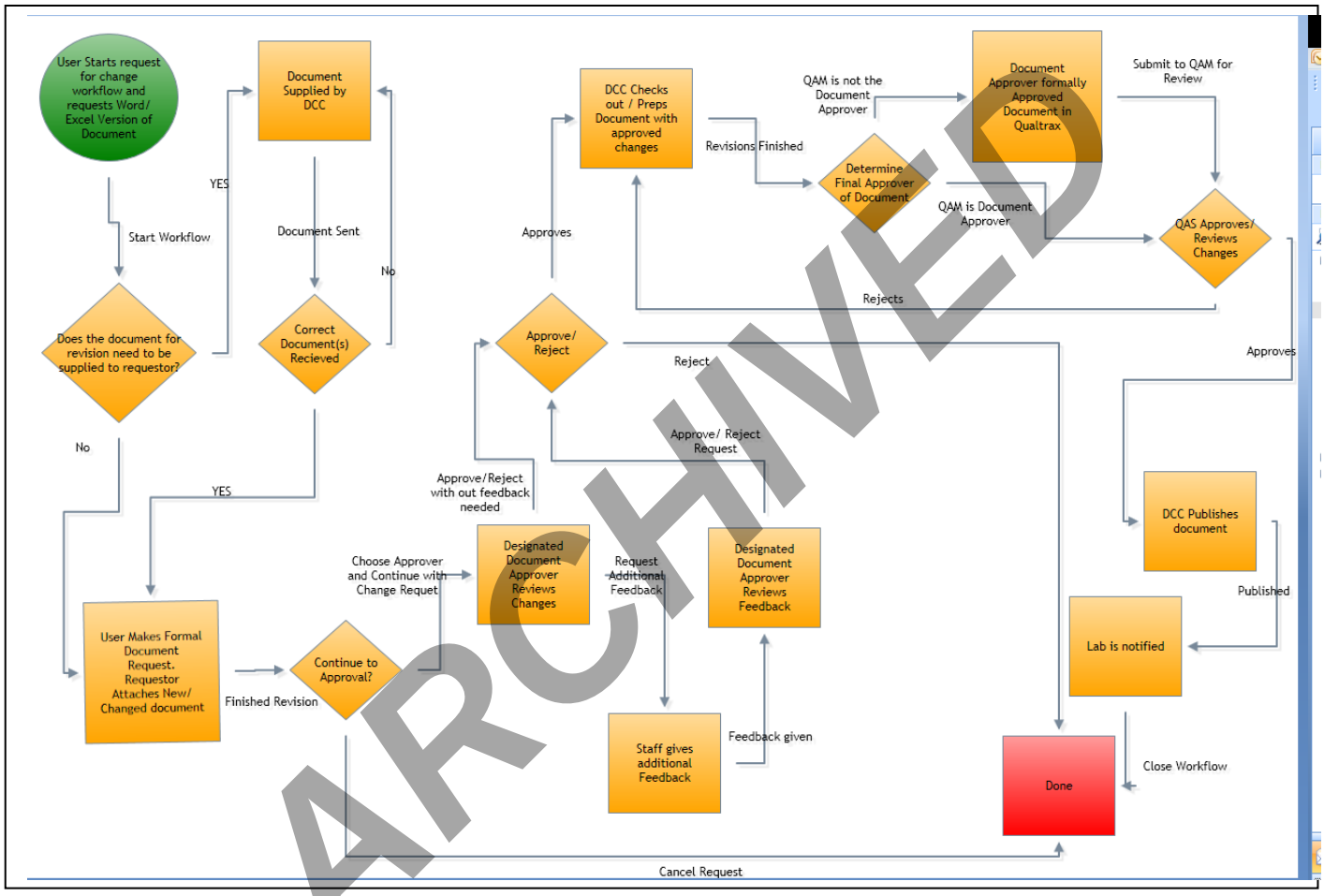
4.1.3 The effective date and/or date of approval

4.1.4 Page numbering in an “page x of x” format

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:



5.2 Most document creation/ revision requests will follow the process listed below in its entirety. Some personnel, such as Manaul Approvers, the Document Control Coordinator, and CODIS Administrator may edit a document directly in Qualtrax, and therefore will not follow all of the process listed 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 Revision Workflow is initiated by the Requestor.

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" should be active for document revisions so that the proposed changes are apparent to the document reviewer.

5.3.1.3 Requested changes are then submitted to the listed Document Approver

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

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

5.3.2.1 The document is checked out of Qualtrax by the editor

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

5.3.2.2.1 Document must be saved as macro enabled

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

5.3.2.2.3 All changes must be highlighted

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

5.3.3 The document is sent to the appropriate Document Approver for review and approval by clicking the button "Submit For Approval".

5.3.3.1 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 **Step 2**. Evaluation of Request; Interim reviews & revisions

5.4.1 The appropriate Document Approver reviews requests for new and revised documents. If a workflow exists for the request, the workflow should be utilized as it contains the document with tracked changes.

5.4.2 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.

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

5.5 **Step 3**. Approval

5.5.1 If the Document Approver feels that the request has merit, they will approve the request and the request will be submitted to the Document Control Coordinator.

5.5.2 If the Document Approver disagrees with the 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.

5.6 **Step 4**. Document prepared and formatted by Document Control Coordinator

5.6.1 The document is prepared in Qualtrax, or in a format outside of Qualtrax as necessary to reflect the approved request.

5.6.1.1 Note: Documents for Qualtrax should be in macro-enabled format.

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

5.7 **Step 5**. Final review(s)

5.7.1 After prepared by the Document Control Coordinator, the Document Approver will officially approve the document in Qualtrax.

5.7.2 The Quality Assurance Manager also 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.

5.8 **Step 6**. Approved document placed on server

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

5.8.1.1 The documents in Qualtrax are the official "controlled copies" for internally generated Management System documents.

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

5.8.1.3 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.

5.9 **Step 7**. Staff notified; Document Control Coordinator completes updates

5.9.1 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. All notification emails are maintained by the Quality Assurance Group.

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

5.9.2.1 Retires (aka. Archives) out-of-date documents, as applicable.

5.9.2.1.1 NOTE: "Retired" in Qualtrax means the document is no longer in effect and there is no "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.

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

5.9.2.1.3 When a document is updated in Qualtrax, the previous version is automatically replaced by the Qualtrax system. 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.

5.9.2.1.4 Documents that are retired in Qualtrax will be approved for retirement and edited by addition of an "Archived Watermark" by the Document Control Coordinator.

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

5.9.2.1.6 Access to archived documents is restricted to the Quality Assurance Manager, Document Control Coordinator, Director and Deputy Directors.

5.9.2.1.7 Requests by staff for copies of archived documents must be submitted in writing to the Quality Assurance Manager.

5.9.2.2 Closes the Documents Change/Request Workflow

5.9.3 Staff discards printed copies of obsolete versions of documents.

5.9.4 Non technical updates to documents such as typographical errors, formatting, 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.

5.9.5 Note: Other Interim revisions to controlled documents are not allowed.

6 Official Memos

6.1 Official memos are used within the Department to document the distribution of operational information to staff and operational agreements between the Department and its customers. Memos fall under the Department's document control system only when the content impacts testing or the management system. This procedure describes the parameters by which official memos are created and archived.

6.2 The authority and responsibility to issue official memos is restricted to managers (assistant directors, deputy directors, and director).

6.2.1 Official memos are prepared on Department letterhead and must identify the author and date of issue.

6.2.2 Official memos are protected against unauthorized changes, are retained in Qualtrax, and are grouped in folders by year of distribution.

6.2.3 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.

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" on or about November 1st of 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.

8 Release of Management System Documents to External Parties

8.1 Requests for the release of Department of Forensic Biology management system documents 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 REQUESTS procedure.

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.