A. **PURPOSE**:

Documents that are part of the Management System for the Division of Scientific Services (DSS) are controlled to ensure that the most up to date version is being followed at all times. Control includes a method for distributing controlled documents, identifying controlled documents, making changes to controlled documents and archiving past versions of controlled documents. The DSS uses Quality Management Software (QMS) as part of the Quality System for document control.

The Division of Scientific Services has Management System Documents, (specifically SOPs) available in electronic form to all Division employees.

Documents maintained outside of the QMS, that require control will be tracked within the Unit by the Unit Manager or their designee. These may include some Quality Records and reference manuals required for case work.

B. **RESPONSIBILITY**:

1. Managers: Responsible to provide direction to subordinate staff under their purview as indicated by the organization chart.
2. Supervisors: Responsible to provide supervision to subordinate staff under their purview as indicated by the organization chart.
3. FSE2: responsible as a working lead to subordinate staff as indicated on the organizational chart.
4. FSE1 and Lab Assistants: Responsible to adhere to this procedure as it pertains to their Unit.
5. ECO: Responsible to adhere to this procedure as it pertains to their Unit.
6. Support Personnel (however titled): Responsible to adhere to this procedure as it pertains to their Unit.

C. **DEFINITIONS**:

1. MSD: Management System Documents – include documents maintained as controlled within the QMS or maintained as controlled externally based on the need of the document. These include but are not limited to, all GL procedures, all section/unit procedures, all unit work instructions and quality records.
2. SOP: Standard Operating Procedure – these can either be Section/Unit specific or Division wide.
3. General Laboratory SOPs: The Director is the approver. A member of the Quality Section approves the document purely to allow the document to be published.
4. Section/Unit SOPs: the Unit Manager(s) is the 1st approver, the Director is the final approver. A member of the Quality Section approves the document purely to allow the document to be published.
5. WI: Work instruction – similar to SOPs and used in conjunction with SOPs these tend to provide more in-depth instruction.

6. QR: Quality Record, generally a form
7. QMS: Quality Management Software – compliance software used to assist in functions such as but not limited to document control. The QMS uses "groups" to allow for certain permissions in the document control workflow. Personnel in groups may be designated as an editor, reviewer(s) and/or approvers. (I.e. separate groups are prepared for each Section/Unit and job type) of documents.

QMS Specific Definitions:

8. Group: created in the QMS to allow for specific permissions to be assigned; these are created based on the various Sections and Units and job titles.
9. Automatic File Transfer: feature of the QMS that allow for documents to be transferred into and out of the QMS for editing purposes.
10. Header/Footer Tool: this tool allows for header/footer templates to automatically be applied within the QMS. This will apply the title, revision number, effective date and other information as applicable based on the template used. Documents must be added to the QMS as a macro enabled word document (or other formats as revisions to the QMS occur) for this tool to work.
11. Editor: an individual that is able to edit documents in the QMS. A member of the Quality Section will be the editor for all General Laboratory SOPS.
12. Reviewer: individual assigned to review edited documents and make suggestions prior to final approval and publishing. In the DNA Unit, the Technical Leader is a document reviewer. The TL's documented review/approval for DNA SOPs is viewable in the QMS "document properties" tab for each DNA SOP. Managers are reviewers of GL SOPs.
13. Approver: the Director, Section Manager (DD and/or AD) and Quality Section are approvers. All documents require the Director's (or designee when not available) approval.
14. Published Document: this is equivalent to an authorized, controlled document.
15. Inbox: this is the main working page in the QMS; each person has their own inbox. The inbox lists what tasks are assigned to the individual.
16. Properties: each document in the QMS has a document properties button which contains multiple tabs which includes a tab labeled "History". From this tab, the history of the document can be viewed to identify items such as changes made, and the dates specific revisions were in effect.

D. **PROCEDURE**:

1. **General Information**:

a. Laboratory procedures (general or Unit Specific) will be maintained in the QMS.

b. The processes of uploading new procedures, edit, review and approval of procedures will be performed through the QMS. The documentation related to these steps will be maintained with the document history in the QMS.

i. The QMS tracks the revision number and effective dates and other information for MSD that are entered in a manner that allows for the use of the header/footer tool.
ii. To track changes made between revisions of controlled documents, there is a "View Tracked Changes" feature in the tool bar. Clicking on this option allows review of the changes made to that document. Previous versions edited after 07/31/18 will have the tracked changes document available as well in the archive.

c. General Laboratory (GL) SOPs and Section or Unit SOPs must be approved for use by the Director prior to their implementation.

d. Hand written changes to procedures are not acceptable as official changes. Changes must go through the proper reviews and approvals in the QMS.

e. All procedures (GL or Unit) will be reviewed at least annually (once per calendar year) to ensure that they are still suitable for the task and are compliant to any applicable requirements. The review will be documented through the QMS. Documents will be set to "expire" annually to the document manager or last editor.
i. The term "expire" in this manner is meant to mean it is due for review within the QMS. It does not mean the document is not appropriate for use. Anyone accessing a SOP in this status will see the current published version only.
ii. When the review is required the document will be in the needed reviewers 'Documents in Edit' in the QMS inbox. After review the document the options are to 'Verify Up to Date' or to check out and edit any needed changes.

f. Employees are encouraged to bring suggested edits to their Unit Lead or Supervisor for Unit SOPs or to the Quality Section for General Laboratory SOPs.

g. Changes to SOPs are communicated via automated emails through the QMS. Any DSS employee listed as 'notify' for a SOP will received an email when a SOP is newly released. It is the responsibility of the employee to review updates to SOPs in a timely manner, and before performing work related to that SOP.

h. Quality Records that are embedded in LIMS, such as report templates, require a QMS 'LIMS Report Template Substantive Changes' workflow to obtain approval for the edit. The workflow should be initiated to instruct the LIMS Administrator what change is required, the change will be approved by the Unit Manager and the Director prior to being put on line.

i. Some Units maintain QRs externally from the QMS; generally this is due to the complex nature of the form.
i. The current versions of QRs and worksheets not in the QMS will be maintained on a shared drive in the "Controlled SOP" folder. Note there is a folder for each Unit, it is the responsibility of the Unit Manager(s) to maintain these records.
ii. Units are responsible to track the revisions on a Unit management system document List, however titled. The tracking needs to minimally contain the document ID, the revision number and the date the revision was put into use.

iii. In general the approval of changes to these will be by the Unit Manager. In DNA the TL must additionally approve of the changes.
iv. Notification of changes to QRs to staff will be through email.
v. Unit Supervisors and Lead are responsible to ensure that the current version of QRs and worksheets are being used by Unit analysts.

j. When a controlled document is software or a manufacturer's manual, the original will be maintained in the Unit that uses the document. This will be notated in the Management System Document list for that Unit. (Example: Computer Crimes will maintain the software used for their imaging process).

i. Note: There will be occasions when "hard" copies (paper or CD) of software is not available (i.e. the purchase of the document is such that a copy is available only in the cloud or electronic manuals saved on a Division server). For these cases the Section will record the title, version, date in service and other pertinent information on the section instrument/software list.

k. The general path for SOPs within the QMS:
i. Upload (new SOPs)
ii. Edit
iii. Review
iv. Approval
v. Publish with notification to needed personnel

2. **<u>Uploading new MSD</u>**:
a. When new documents need to be added to the QMS the Unit Manager can add the document or will provide the document to the Quality Manager (or designee) saved as the name of the needed title.
i. Example: FB SOP-28 MK2 IR Crime-lite.
b. SOPs and WI are added as macro enabled word documents (or other if currently allowed by the current version of the QMS) into the folder for the specific Unit.
i. Refer to QMS WI-8 for guidance on uploading documents within the QMS.
c. Once added the document will be set to be edit, review or approve based on the need of the document. If provided as a fully reviewed document it can be sent straight to the approval step. Note that the QMS automatically assigns a unique ID number to all documents that are uploaded.
d. QRs: it is preferred that QRs be added as macro enabled word documents to allow the automated tracking of revisions via the header/footer tool.

i. QRs placed into the QMS that are not macro enabled word documents do not allow for an automated header updates. This means when the QR is edited the revision must be updated by hand as part of the edit. This edit is the responsibility of the individual editing the document. There will not be a revision date on these QRs but the date approved (i.e. revision date) can be found in the QMS either in the properties for the QR

or when the QR is open on the bottom of the screen. A field with title, ID, Revision, status, editor and date published is at the bottom of the screen.

ii. Quality Records (QR) and worksheets should be maintained in the QMS. Those that are not maintained in the QMS, will be edited, reviewed and approved through email documentation.

3. **Editing Documents in the QMS:**

a. SOPs and QRs may be edited as needed.

b. General Laboratory Procedures:

c. Edits to GLs are generally performed by the Quality Section.

d. All Managers are provided the opportunity to review GL edits, the QMS will send an email notification when the GL is in the review stage.

e. Section/Unit specific Procedures:

i. When a change/edit to a Unit SOP is required, for any reason, the change will be directed through the Unit Supervisor, Technical Lead in DNA, or appropriate Manager.

(a) In the QMS edit permissions are given to those as required by the Unit regardless of title, this will be determined by the Unit Manager(s).

f. SOPs will be edited so that the tracked changes versions can be reviewed as needed within the QMS.

g. The header and footer of SOPs and QRs that utilize the header/footer tool cannot be adjusted during the editing phase; doing so will negatively affect the automated tool.

h. The editor is responsible to forward the in edit document to the review stage, once reviewed they move the document to the approval stage.

i. When the editor of an SOP releases the document for review, a note is to be made providing a general description of the change or a reference to view the tracked changed version can be used. An example of the note is; “Refer to Tracked Changes version”. The QMS will be the **only** location to find a current controlled copy of an SOP.

i. Refer to QMS WI-8 for guidance on editing documents within the QMS.

4. **Reviewing Documents in Edit Process:**

a. All Managers are designated as reviewers of GL SOPs.

i. The editor of the document has the option to forward the document to approval without 100% review. The Quality Manager (or their designee) will be a reviewer for all GL SOPs.

b. Reviewers of Unit/Section SOPs will be dependent on the need of the Unit.

i. In the DNA Unit the TL and CODIS administrator, FSE3 and Unit Managers are reviewers. The TL is a required reviewer of all SOPs this review may be captured in the Approval stage.

ii. In ID and CAS Units the Unit Managers, FSE3 and the Unit FSE2 are reviewers, FSE1 may be designated as reviewers.

c. Once a document is in review it is the responsibility of the reviewer to review and provide suggestions for edits, if required, in a timely manner.

d. Once the reviewers comments are reviewed and if needed incorporated into the edits, the editor moves the document to the approval stage.

i. The editor of the document has the option to forward the document to approval to the Unit Manager without obtaining 100% review.

5. **Document Approval and Publishing:**

a. General Laboratory SOPs and QRs are approved by the Director (or designee).Unit/Section SOPs, WI and QRs are approved by the Unit Manager(s) and the Director.

i. Note: in the DNA Section, the DNA Technical Leader (TL), will also be responsible to edit and review DNA SOPs in the QMS. Edits of a technical nature by the TL will be incorporated. The TL will document his/her review/approval of DNA SOPs in the QMS.

b. All SOPs are published by the Quality Section as the last approver of the document.

c. Publishing – the Quality Section is responsible to issue the most recent versions of all MSDs.

d. Issuance of SOPs and removal from use will all be directed by the Quality Section through the QMS, this is through the approval step in the QMS.

i. DSS SOPs (General or Section/Unit Specific) will be published through the QMS. When an SOP is published an email notice will be automatically sent through the QMS to those accountable for the changes.

ii. Tests may be set up in the QMS that relate to changes in specific controlled documents. When this is done employees assigned to the related Unit will be notified that there is a document change and a test to take. Each appropriate analyst is required to read and understand the changes and to complete this test prior to using the procedure.

iii. DSS employees receiving an email notice are responsible to log into the QMS to review the changes. This must be performed in a timely manner to ensure that the latest guidance is being followed.

iv. Employees should contact their Supervisors or Leads if there are questions concerning the changes.

e. All current SOPs are available through the QMS.

f. Once printed, SOPs are not controlled.

g. Any Unit analyst that prints a copy of a current SOP is responsible to ensure they are working from the current SOP and that they destroy the paper copy when new versions are made available.

6. **Identifiers**:
   a. All MSD will be uniquely identified. Each page of the controlled document will have a designator (with the exception noted above). When a controlled document is software or a manufacturer's manual, the original (or the case for the original) will have a sticker (when possible) designating it as a controlled copy with the Document ID, and version noted, unless otherwise noted on the cover.
   b. Each DSS Unit will have a unique prefix identifier as part of the documents ID these are designated as:
      i. GL: General SOPs applicable to all Units
      ii. Support Services Section
         (a) CM: Case Management Unit
         (b) ER: Evidence Receiving Unit
         (c) QMS: Quality Management Software
         (d) LIMS: Laboratory Information Management System
      iii. Identification Section:
         (a) CC: Computer Crimes Unit
         (b) LP: Latent Prints Unit
         (c) MMIE: Multi Media Unit
         (d) FA: Firearms Unit
         (e) LTY: Lottery
      iv. Forensic Biology and DNA Section
         (a) FB: Forensic Biology Unit
         (b) DNA: DNA Unit
      v. Chemical Analysis Section
         (a) CH, CHEM: Chemistry Unit (Fire Debris and GSR)
         (b) TX: Toxicology Unit
         (c) CS: Controlled Substances Unit
         (d) BA: Breath Alcohol
         (e) SNR: Serial Number Restoration

      Note that the ID designations are subject to change based on the needs of the DSS such as due to restructuring.

   c. The complete identifier will include the prefix with a number designation for the specific document in the Unit. Worksheets/Appendixes may be designated in 1 of 2 ways.
      i. QR can be used to identify worksheets as Quality Records (example DNA QR-123 or QR FA 11).

ii. Worksheets/appendixes that are specific to documents (if applicable) maybe designated with the complete identifier and a second number for the worksheet/appendix. (Example CS 1.1 would be a form or appendix related to the SOP CS 1).

7. **Retiring a Controlled Document in the QMS**:
   a. Retiring a controlled document will go through the same approval process as publishing a document. Doing this will document the approval of the managers and Director to retire the document.
      i. Place the document in "Edit" under "Edit Reason" type in "No Change to Retire Document Only"
      ii. Click "Edit Later" this moves the document to the editors Inbox under "Documents in Review"
      iii. Click on the document from the Inbox and place into the "Release for Approval" stage.
      iv. In the "Changes Made' text box type in the same phrase "No Change to Retire Only" then click "Release for Approval".
      v. The document will go through the same approval path as for publishing the procedure. Generally this is the Unit Manager(s), the Director then Quality Manager.
      vi. The Quality Manager will publish the document and immediately retire the document.

8. **Archiving**:
   a. The Quality Section is responsible for maintaining an archive of old versions of MSD, these will be archived within the QMS. Out of Service SOPs will be accessible to members of Management. The effective/published date and the date retired from service will be maintained in the "document properties" tab in the QMS.
      i. Members of Case Management have permissions in the QMS to allow them to retrieve historical versions of General and Unit specific SOPs; this is for the purposes of preparing discovery packets and responses to FOIAs.
   b. The archived MSDs will be maintained for a period not less than 10 years from the date of removal from service. Revisions prior to September 2014 will be maintained by paper or electronically on the LAN. Revisions after September 1, 2014 will be maintained within the QMS.
   c. One copy of each archived document will be stored with the Quality Section in either paper or electronic format based on the dates listed above. Individuals that need to access these documents should go through a member of the Quality Section to retrieve the needed documents. The Case Management Unit may have access to archived MSD for the purposes of discovery and FOIA requests.
   d. Unit Managers are responsible to archive MSD controlled outside of the QMS. When QRs are to be edited a copy of the QR should be placed in the "Document Morgue" allowing for

the tracking of revisions. For documents such as electronic user manuals a copy will be moved to the "Document Morgue". Each Unit has a file within the 'Document Morgue" folder.

6. <u>Non-Controlled Documents</u>:

a. It is recognized that analysts may desire copies of SOPs for work that they perform. Any SOP printed from the QMS will contain a statement that the SOP is not controlled.

b. If the Management of the DSS requires that all or specific analysts be given an uncontrolled copy of a SOP, then the copy will be printed from the QMS and as stated above, will not be controlled.

c. When new versions of SOPs are issued, copies of old versions must be destroyed; this is the analysts' responsibility.

d. When copies of MSDs are required for Freedom of Information Act or Discovery requests, refer to SOP GL-11 "Control of Records" for guidance.

7. Other QMS Documents:

a. Other records and documents may be maintained within the QMS that are not published/controlled documents. These records are maintained within the QMS for organizational purposes only. Documents such as safety data sheets, references, personnel records, audit reports and others may be found within the QMS.

b. Generally if these are updated the 'replace' function will be used. This allows the QMS software to archive the older version and display the new version when opened.

E. **REFERENCES**:

1. QMS: 'Help Guide'
2. CT Division of Scientific Services QMS Operating Manual
3. QMS WI-8 'Document Control Features'