A. **PURPOSE**:

Documents that are part of the Management System for the Division of Scientific Services are controlled to assure 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 Laboratories will have Management System Documents, (specifically SOPs) available in electronic form to all Division employees. ~~The number of controlled paper copies will be minimal with preferably only one controlled paper copy maintained by the Quality Section.~~

B. **RESPONSIBILITY**:

Director: responsible to review the Management System documents at least annually to assure that they meet the needs of the laboratory

Deputy Directors: responsible to review the Management System documents at least annually to assure that they meet the needs of the laboratory. Additionally they are responsible assure that when changes are required to controlled documents within their section that the proper processes are followed.

Quality Manager and Assistant Quality Manager: responsible for assuring the latest version of all General Laboratory Management System documents are issued ~~(electronic or paper)~~ and outdated versions are removed from use. Additionally they are responsible to assist laboratory sections to properly document changes to controlled documents within the sections.

Forensic Science Examiner 3/Forensic Science Examiner 2 : responsible to assure that all employees they supervise (and they themselves) are using the most up to date version of Management System documents. Additionally if they discover the need to edit a controlled document within their section they communicate this to their Deputy Director and assure that they follow the document control procedure for making those changes.

Forensic Science Examiners 1/Chemists 1 and 2: responsible to adhere to the policies set forth in the current Management System Documents and that they are using the current version of any laboratory form. Additionally if they discover the need to edit a controlled document within their section they communicate this to their Section Lead ~~Supervisor~~.

Administrative Staff (however titled)/Support Staff: responsible to adhere to the policies set forth in the current Management System Documents.

C. **DEFINITIONS**:

MSD: Management System Documents - all documents contained in the Quality Manual, Division Standard Operating Procedures, Safety Manual, section Standard Operating Procedures and Work Instructions as applicable.
SOP: Standard Operating Procedure – these can either be section specific or Division wide

WAN: Wide Area Network

Qualtrax – compliance software used to assist in functions such as but not limited to document control. Qualtrax uses "groups" to allow for certain permissions in the document control workflow. Personnel in groups will be designated as an editor, reviewer(s) and/or approvers. (i.e. separate groups are prepared for each laboratory section and job type).

Editors may be section Leads, Deputy Directors, the AQM, QM or Director. Editors can request edits to SOPs.

Reviewers can be any person within a group that they wish to have preview the document changes. Reviewers can suggest changes.

Approvers are members of the Quality Section and the Director. Members of the Quality Section are approvers to orchestrate the publishing of documents. The Director is the overall approver of the document.

D. **PROCEDURE**:

1. General Laboratory (GL) SOPs are approved for use, prior to their implementation, by the Director or their designee.
   a. Changes to General Laboratory SOPs will be directed through the Quality Section.
2. Laboratory specific SOPs which have been validated, are reviewed and accepted ~~approved~~ for use by the sections Deputy Director or their designee and approved by the Director. Each Laboratory section may only use procedures that have been approved for use in the specific laboratory section. Each Laboratory has a specific SOP detailing the method development/validation and documentation process.
   a. Changes to section specific SOPs will be directed through the Quality Section for reviews, approvals and publishing.
3. Qualtrax will be used to direct the flow of document changes, review, and approvals.
4. **Document Approval and Issue:**
   a. Approval: Approval for all MSD will flow through Qualtrax. ~~will be indicated by signing and dating the header page of the printed document.~~
      i. General Laboratory (GL) SOPs: approval by Director or their designee.

ii. Management System Documents: approval by Director or their designee.

iii. Section specific SOPs: reviewed/accepted by the Deputy Director approval by ~~Deputy Director and~~ Director.

(a) Note: in the DNA laboratory the DNA Technical Leader (TL) will ~~co-sign for approval~~ also be responsible to edit and review ~~section specific~~ DNA SOPs in Qualtrax. Edits of a technical nature by the TL will be incorporated.

(i) The General Flow of SOP changes in Qualtrax for the DNA section will be from the TL (or their designee), to the Deputy Director for Review and acceptance, to the Director for approval and to the Quality Section for approval/publishing.

(ii) The DNA TLs edit and/or review in Qualtrax is documentation of their approval of the document.

b. Preparation – preparation of section specific MSD will, in general, be performed by the Section Lead ~~Supervisor~~ or their designee (the preparer of the document will be designated as the editor in Qualtrax). ~~The preparer will sign and date the header page of the document.~~

i. Section specific SOP changes can be prepared by a member of the section as appointed by the section Supervisor, the ~~Change Order form~~ changes will be directed through Qualtrax to the Quality Section as noted above.

ii. Quality Records (QR) and worksheets which are not considered controlled documents and are not maintained in Qualtrax, will be edited, reviewed and approved through email documentation maintained by the Quality Section. The person making an edit and updating the QR will notify (by email) the Deputy Director (and TL if DNA) and the Quality Section. Once reviewed and approved by the necessary personnel, the section affected will be notified of the changes through an email before the updated QR or worksheet is put into effect. The current versions of QRs and worksheets not in Qualtrax will be maintained on a shared drive in the "Controlled SOP" folder.

c. Distribution – the Quality Section is responsible to issue the most recent versions of all MSD. Part of this responsibility includes the removal of the prior version. Issuance or SOPs and removal from use will all be directed by the Quality Section through Qualtrax.

i. Laboratory SOPs (General or Section Specific) will be published through Qualtrax. When the Quality Section Publishes a SOP an email notice will be sent through Qualtrax to those responsible for the changes.

ii. The Quality Section will maintain the Controlled and Obsolete SOPs within Qualtrax.

iii. Laboratory employees receiving notice are responsible to log into Qualtrax to review the changes.

(a) Employees should contact their leads if there are questions concerning the changes.

iv. All current SOPs are available to employees through Qualtrax.

(a) Once printed SOPs are not controlled.

~~General Laboratory SOP will be issued as follows:~~

(b) ~~The QM or designee will print a single original copy of the SOP. This will be signed by the preparer (generally the QM) and the "approver" the Director.~~

(c) ~~The document will then be stamped "Controlled" in red.~~

(d) ~~The original signed controlled copy will be maintained by the QM.~~

(e) ~~The QM or designee will upload the current SOP to the WAN shared drive in the "Controlled SOPs" folder.~~ ~~**Only SOPs currently in use will be placed in this folder**~~. ~~Outdated SOPs are removed when a new version is designated as current.~~

(i) ~~This folder is maintained as 'read only' for all laboratory employees except for the Quality Section members who will have edit capabilities.~~

(ii) ~~SOPs in this folder will not have the signatures filled in or a controlled stamp, however the location of the SOP in the "Controlled SOPs" folder designates it as the current version for use.~~

(f) ~~The Quality Section will notify all employees of the update(s) electronically.~~

(g) ~~When SOP changes are sent to employees, the employees are responsible to read the document changes.~~

(i) ~~The employee should contact their supervisor if there are questions concerning the updates.~~

(ii) ~~Employees are responsible to destroy all printed non-controlled copies of the outdated version. Supervisors are responsible to assure that only the current SOP is present in the laboratories.~~

(h) ~~The "Controlled SOPs" folder on the shared drive will also contain a copy of the current document control list.~~

~~Section Specific SOPs will be issued as follows:~~

(i) ~~The Quality Section will print a single copy of the SOP, this will be signed by the preparer and the "Approver" generally the Deputy Director and Director and the TL in DNA .~~

(j) ~~The original signed copy will be stamped "controlled" and will be maintained by the Quality Section.~~

(k) ~~The Quality Section will upload the SOP to the appropriate WAN and LAN servers.~~

~~(i) Section analysts will have access to section specific SOPs on the WAN Shared drive in the "Controlled SOPs" file and on the LAN server specific to their section. (Due to each laboratory section having access to different computers on different servers specific laboratory SOPs will also be available on specific drives of specific servers.) The Quality Section will work with the Section Supervisors to determine the best server for the individual laboratory sections.~~

~~(ii) The Quality Section will designate a file on the LAN section server to contain the current SOPs. **Only SOPs currently in use will be placed in this folder**. Outdated SOPs are removed when a new version is designated as current.~~

~~(iii) SOP in this folder will not have the signatures filled in or a controlled stamp, however the location of the SOP in the specified folder designated it as the current version for use.~~

(l) ~~The Quality Section will notify the Section Deputy Director and/or Supervisor when a SOP is updated and the file is uploaded on the appropriate servers. Supervisors will inform their employees of any changes affecting their section and they will document that the communication has occurred. Documentation of the communication will be forward to the Quality Section.~~

~~(i) Employees are responsible to read all section SOP changes and to contact their Supervisor if there are questions regarding the changes.~~

~~(ii) Employees are responsible to destroy all printed non-controlled copies of the out dated version.~~

~~(iii)Section Supervisors are responsible to assure that all non-controlled copies within the section are the current version.~~

(m)~~The folder containing the SOPs will also contain a copy of the current document control list.~~

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

vi. ~~The master copy of all~~ All MSD will be maintained thru Qualtrax by the Quality Section.

~~The Management System Documents list will contain the following information:~~

(a) ~~Document Title~~

(b) ~~Document ID~~

(c) ~~Current Version/Revision Number~~

(d) ~~Date issued~~

(e) ~~Number of Controlled Copies~~

(f) ~~Location of Controlled Copies~~

vii. When a controlled document is software or a manufacture's manual, the original will ~~live~~ be maintained in the section that uses the document. This will be notated in the Management System Document list. Example: Computer Crimes will maintain the software used for their imaging process ~~investigations~~.

5. **Identifiers**:

a. All MSD will be uniquely identified. ~~When possible~~ Each page of the controlled document will have a designator. ~~in the upper right hand corner which will include the Document ID, Version/Revision number and Revision date. The first page of the printed document will have a header which includes the name of the document, who it is controlled by and a red 'Controlled' stamp distinguishing the document as a controlled copy. The header will also include who prepared the document and who approved the document with the corresponding dates.~~ When a controlled document is software or a manufacturer's manual, the original (or the case for the original) will have a sticker designating it as a controlled copy with the Document ID, and version noted, unless otherwise noted on the cover.

b. Each laboratory section will have a unique prefix identifier as part of the documents ID these are designated as:

GL: General SOPs applicable to all sections

CC: Computer Crimes Electronic Evidence Laboratory

DNA: DNA laboratory

~~DD: DNA Database~~

FB: Forensic Biology

CH: Chemistry

FLIN: Instrumentation

TR: Trace

QD: Questioned Documents

LP: Latent Prints

MMIE:Video/Multi Media

FT: Firearms/Tool marks

Note: the Firearms/Tool Marks section has 4 acceptable identifiers, FT, TM, FA and CW

~~IP: Imaging/Photo~~

IM: Imprints

TX: Toxicology

CS: Controlled Substance

CM: Case Management

The complete identifier will include the prefix with a number designation for the specific document in the section. Worksheets/ appendixes that are specific to documents will be designated with the complete identifier and a second number for the worksheet.

Example: CC-1 (this would be the first SOP for the Computer crimes Laboratory)

CC-1.1 (this is the 1st appendix related to the 1st SOP for Computer Crimes)

CC-1.2 (this is the 2nd appendix related to the 1st SOP for Computer Crimes)

c. When software and published manuals are referred to in an SOP or work instruction ~~order~~ as part of the method they must also be controlled documents. For these items the version that is being used will, when possible, be marked with a control sticker by the Quality Section ~~SQM~~ this sticker will include the same information as the designator for documents. If the software or manual is only referred to as a reference it does not need to be controlled. Software used to run instrumentation need not be controlled as long as the name and version number are referenced either in the equipment inventory list, the specific SOP or in the maintenance manual.

d. The document title, current version/revision and document history of all MSD will be maintained in the Qualtrax system. ~~The Quality Section will maintain a list of all MSD through Qualtrax, this will include the name of the document, the current version/revision number. and where controlled copies are maintained (what section or individual).~~

6. **Changes to Management System Documents:**

a. When a change is required to a MSD, for any reason, the change will be directed through the section Supervisor or the Laboratory Director(s). Section Leads, Deputy Directors, the QM, AQM and the Director have permission levels in Qualtrax to edit documents. Edit permissions are set based on sections assigned (i.e. a DNA Lead cannot edit a Toxicology SOP). ~~The person requesting the change must complete a "Controlled Document Change~~

~~Request form (GL-19.1 or GL-19.2). If the change only affects a specific laboratory section use form GL-19.2 if it affects general laboratory policies use form GL-19.1~~.

b. Hand written changes to Controlled Copies of all MSD are not acceptable as official changes. ~~At no time should a controlled copy of a document be annotated with hand written notes/instructions~~.

c. Review:

   i. The individual that prepared the original document (or the individual in that position) should be consulted concerning the change. They must review the information to verify that the change will not adversely affect any other component of the procedure.

   ii. The individual that approved the original document (or the person in that position) will review the changes to the document. It is important that the "approver" of the document have access to all background information concerning the change.

d. Approval:

   i. Changes to General Laboratory MSD will be reviewed by the the Deputy Directors and the Quality Section. ~~Manager~~. Overall approval of the changes will be by the Director or their designee.

   ii. Changes to section specific SOP will be reviewed ~~and approved~~ by the Deputy Director, and approved by the Director and a member of the Quality Section through Qualtrax. ~~Note that the Quality Section Review will be cursory for format only unless noted.~~

e. When possible, changes to documents will be distinguished using red font ~~(or other distinguishing color)~~ so that the change is easily identified by those using the document. This will not be done when a document goes through a major revision.

   i. When a major revision occurs, those affected by the changes (those that use the document) will be informed that the changes have occurred. The section Leads ~~Supervisor~~ or designee will be responsible to review the changes with their section and assure they understand the changes. Notification of changes will be through Qualtrax. The section ~~supervisor~~ leads are ~~is~~ responsible to assure that the changes are implemented when the document is issued.

   ii. The Quality Section or the Deputy Directors or their designee are responsible to inform laboratory staff of changes to General Laboratory MSD. This will generally be communicated electronically through Qualtrax. ~~The QS will maintain a record of this communication.~~

f. The Quality Section is responsible to maintain controlled documents through Qualtrax. Current versions of general laboratory SOPs are available to all employees. ~~for removing the old controlled copy of the document and issuing the current version.~~ All personnel are responsible for the destruction of any uncontrolled printed copies of SOPs, when new versions are made available.

g. ~~Note that the above procedure for MSD changes is also applicable to electronic management system documents.~~

7. **Archiving**:

a. The Quality Section is responsible for maintaining an archive of old versions of MSD, this will be achieved within Qualtrax. Out of Service SOPs will accessible only to the Quality Section or their designee. The effective/published date and the date retired from service will be maintained in the document properties.

~~The Quality Section will maintain the archive of all MSD. When removed from use a copy of the MDS will be filed and "Out of Service", "Removed from Service" (or similar wording) with the date will be written on the header page. This will allow personnel to verify what version was used for specific cases.~~

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, after September 1, 2014 these will be maintained thru Qualtrax.

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.

8. Non-Controlled Documents:

a. It is recognized that analysts may desire copies of SOPs for work that they perform. The current copies on Qualtrax print with a notation that printed versions are not controlled. ~~the servers are set so when printed there is no controlled stamp or approval signatures therefore the copies are non-controlled documents.~~

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

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

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

~~GENERAL LABORATORY CONTROLLED DOCUMENT CHANGE REQUEST~~

~~Request Submitted by:_____ to:_____ Date:_____~~

~~1. Requested change:~~

~~Give a general description of the proposed changes. Attach a copy of the SOP with changes.~~

~~Version _____ to Version____~~

~~2. Investigation~~

~~Documents affected by change:~~

~~(when proposing change you must be thorough determining the systems that will be affected)~~

~~Quality Manual: Document Section(s):~~

~~SOP: Document Section(s):~~

~~Form: Document Section(s):~~

~~Other: Document Section(s):~~

~~3. Reviewed by:~~

~~Quality Manger: _____date:_____~~

~~Deputy Director: _____date:_____~~

~~Deputy Director: _____date:_____~~

~~Other if appropriate: _____date:_____~~

~~_____~~

~~4. Approval:~~

~~Director: _____ date: _____~~

~~**5. Distribution:**~~

~~Date put into effect: _____ by: _____~~

~~CONTROLLED DOCUMENT CHANGE REQUEST- Laboratory Specific~~

~~Request Submitted by: _____ to: _____ Date: _____~~

~~**1. Requested change:**~~

~~State the nature of the proposed change and the expected impact to the QS. Attach a copy of the proposed changes (marked up copy showing changes).~~

~~**2. Investigation**~~

~~Documents affected by change:~~ ~~(when proposing change you must be thorough determining the systems that will be affected)~~

~~Quality Manual: _____ Document Section(s):~~

~~SOP: _____ Document Section(s):~~

~~Form: _____ Document Section(s):~~

~~Other: _____ Document Section(s):~~

~~Is this change affected by or does it affect any General Laboratory Policies? Y N If yes use form. GL 19:1~~

~~**3. Review/Approval:**~~

~~Quality Section Representative Manager: _____ date: _____~~

~~Laboratory Deputy Director: _____ date: _____~~

4. Distribution:

Date put into effect: _____ by: _____

CONTROLLED DOCUMENT CHANGE REQUEST- Laboratory Specific

Request Submitted by: _____ to: _____ Date: _____

1. Requested change: The Section Supervisor should review changes and sign below prior to forwarding to the Quality section.

a. Give a general description of the proposed changes.
b. Attach a copy of the SOP with proposed changes.
c. Provide Quality Section with an electronic version.

Version _____ to Version _____

2. Investigation

Documents affected by change: (when proposing change you must consider the systems that will be effected)

SOP: _____ Document Section(s):

Form: _____ Document Section(s):

Other: _____ Document Section(s):

Does this change affect any General Laboratory Policies? Y N If yes use form. GL 19:1

3. Review

Section Supervisor: _____ Date: _____
(if not preparer of the document)

~~Quality Section representative:~~ _____ ~~Date:~~ _____
~~(QS review for format only unless noted)~~

~~4. Approval:~~

~~DNA TL (if Applicable):~~ _____ ~~Date:~~ _____

~~Deputy Director:~~ _____ ~~Date:~~ _____

~~Director:~~ _____ ~~Date:~~ _____

~~5. Distribution:~~

~~Date put into effect:~~ _____ ~~by:~~ _____