A. **PURPOSE**:

Documents that are part of the Management System for the Division of Scientific Services 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. Qualtrax is the management software used as part of the Quality System of the DSS ~~Laboratory~~ for document control.

The DSS Laboratories will have Management System Documents, (specifically SOPs) available in electronic form to all Division employees.

B. **RESPONSIBILITY**:

Director: responsible to review the Management System documents at least annually to assure that they meet the needs of the laboratory. Responsible for final approval of Management System Documents.

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 to 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responsible for assuring the latest version of all General Laboratory Management System documents are issued and outdated versions are removed from use. Additionally they are responsible to assist ~~Laboratory~~ Sections/units to properly document changes to controlled documents within their respective units.

Forensic Science Examiner 3: 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 Unit they communicate this to their Deputy Director and assure that they follow the document control procedure for making those changes.

Forensic Science Examiner 2/Principal Chemist : responsible to assure that all employees they lead (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 Unit 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/Evidence Control Officers/Laboratory Assistants: 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~~ DSS form. Additionally if

they discover the need to edit a controlled document within their Unit they communicate this to their Unit Lead.

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/Unit Standard Operating Procedures and Work Instructions as applicable.
SOP: Standard Operating Procedure – these can either be Section/Unit 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 may be designated as an editor, reviewer(s) and/or approvers. (i.e. separate groups are prepared for each laboratory section/unit and job type).

Qualtrax Specific Definitions:

Group: created in Qualtrax to allow for specific permissions to be assigned; these are created based on the various laboratory sections and units. In general, Groups are based on the laboratory sections, units and job title.
Mass Import Tool and Automatic File Transfer: features of Qualtrax that allow for documents to be transferred into and out of Qualtrax from a linked computer.
Editor: an individual assigned permissions that allow them to edit documents. A member of the Quality Section will be the editor for all General Laboratory SOPS.
Reviewer: individuals assigned permissions to review edited documents 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 Qualtrax "document properties" tab for each DNA SOP. Deputy Directors are reviewers of GL SOPs.
Approver: the Director, Deputy Directors and Quality Section are approvers All documents require the Director (or designee) approval. ~~The Deputy Director (DD) is the first approver. Once the Deputy Directors have approved the document, it will flow to the Director for final approval, the Quality Section then approves the document purely to allow the document to be published.~~

Section/Unit SOPs: the Deputy Director 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.

General Laboratory SOPs: The Director is the approver and a member of the Quality Section approves the document purely to all the document to be published.

Published Document: this is the equivalent of an authorized, controlled document.

Inbox: this is the main page in Qualtrax; each person has their own inbox. The inbox lists what tasks are assigned to the individual. The inbox also has a calendar for displaying scheduled tasks.

Properties: each document in Qualtrax has a related properties tab. 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 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~~ Unit specific SOPs which have been validated, are reviewed and accepted for use by the Section's Deputy Director or their designee and approved by the Director. Each ~~Laboratory~~ DSS Unit may only use procedures that have been approved for use in the specific ~~Laboratory~~ DSS Section. Each ~~Laboratory~~ DSS Unit has a specific SOP detailing the method development/validation and documentation process.
   a. Changes to Unit 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. (See section 9 below for Use of Qualtrax).
4. **Document Approval and Issue:**
   a. Approval: Approval for all MSD will flow through Qualtrax.
      i. Management System Documents (includes GL SOPs): approval by Director or their designee.
      ii. Section/Unit specific SOPs: reviewed/accepted by the Deputy Director and approval by Director or their designee.
         (a) Note: in the DNA unit ~~laboratory~~ the DNA Technical Leader (TL), will also be responsible to edit and review DNA SOPs in Qualtrax. Edits of a technical nature by

the TL will be incorporated. The TL will document his/her review/approval of DNA SOPs in Qualtrax.

(i) The General Flow of SOP changes in Qualtrax for the DNA Unit 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 publishing.

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

b. Preparation – preparation of Section/Unit specific MSD will, in general, be performed by the Unit Lead or their designee (the preparer of the document may be designated as the editor in Qualtrax).

i. Unit specific SOP changes can be prepared by a member of the Unit as appointed by the Unit Lead, the 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 Unit 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 of SOPs and removal from use will all be directed by the Quality Section through Qualtrax.

i. DSS ~~Laboratory~~ SOPs (General or Section/Unit 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.

(a) Tests may be set up in Qualtrax that relate to changes in specific controlled documents. When this is done employees assigned to the unit will be notified that there is a document change and a test to take. The analyst is required read, and understand the changes and to complete this test prior to using the procedure.

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

iii. DSS ~~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.

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.

v. All MSD will be maintained thru Qualtrax by the Quality Section.

vi. 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. Example: Computer Crimes will maintain the software used for their imaging process.

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.

5. 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 ~~Laboratory~~ DSS Unit will have a unique prefix identifier as part of the documents ID these are designated as:

GL: General SOPs applicable to all Units

Case Support Section

CM: Case Management Unit

ER: Evidence Receiving Unit

Identification Section

CC: Computer Crimes Unit

QD: Questioned Documents Unit

LP: Latent Prints Unit

IM: Imprints Unit

MMIE: Video/Multi Media Unit

FA/TM: Firearms/Tool marks Unit

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

Forensic Biology and DNA Section

DNA: DNA Unit

mtDNA: Mitochondrial DNA Unit

FB: Forensic Biology Unit

~~Controlled Substance/Toxicology/Chemistry Section~~

Chemistry Section

CH: Chemistry Unit

FLIN: Instrumentation Unit

TR: Trace Unit

TX: Toxicology Unit

CS: Controlled Substances Unit

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

Example: CC-1 (this would be the first SOP for the Computer Crimes Unit)

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

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

c. When software and published manuals are referred to in an SOP or work instruction as part of the method they must also be controlled documents. For software that is available only through the"cloud" see note in section 4. C.vi. For these items, the version that is being used will, when possible, be marked with a control sticker by the Quality Section. 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.

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 Unit Lead or the Deputy Director for Section/Unit specific SOPs or through the Quality Section for GL SOPS. Unit Leads (or designees), Deputy Directors, the QM, AQM and the Director have permission levels in Qualtrax to edit documents. Edit permissions are set based on assigned Units (i.e. a DNA Lead cannot edit a Toxicology SOP).

b. Hand written changes to Controlled Copies of all MSD are not acceptable as official changes.

c. Review:

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

   ii. The individual that approved the original document (or the person in that position) should 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/approved by the Deputy Directors and the Quality Section. Overall final approval of the changes will be by the Director or their designee.

   ii. Changes to Section/Unit specific SOP will be reviewed/approved by the respective Deputy Director, final approval by the Director and then approved by a member of the Quality Section for publishing through Qualtrax.

e. To track changes made between revisions of controlled documents the properties/history tab in Qualtrax will be used. The editor is responsible to detail what changes are being made to the document in this tab. The editor must be detailed enough for the user to understand the overall meaning of changes made. This need not contain changes such as typographical changes, grammatical changes, or other minor clarifications.

i. Note: as this is a change to procedure the use of the properties/history tab will be introduced to controlled documents as new revisions are made. Past changes as defined in note 2 below will remain until a new revision is required.

ii. Note 2: As of the effective date of revision 4 of this document, this practice is no longer in effect for new changes, new changes will be addressed as in section e above. When possible, changes to documents will be distinguished using red or blue font for additions and strikethroughs for deletions 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.

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

iv. The Quality Section or the Deputy Directors (or their designee) are responsible to inform ~~Laboratory Section~~ DSS staff of changes to General Laboratory MSD. This will generally be communicated electronically also through Qualtrax.

f. The Quality Section is responsible to maintain controlled documents through Qualtrax. Current versions of General Laboratory SOPs are available to all employees. All personnel are responsible for the destruction of any uncontrolled printed copies of SOPs, when new versions are made available.

7. <u>Archiving</u>:

a. The Quality Section is responsible for maintaining an archive of old versions of MSD, these will be archived 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" tab in Qualtrax.

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

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.

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 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.

9. Use of Qualtrax:

All DSS employees are entered in Qualtrax as users of the system and each has a profile. Employees are designated into a group with specified group permissions. The Quality Manager and Assistant Quality Manager have administrator privileges. Issues with the system; including adding new employees and changing groups must go through the Quality Section.

a. Logging into Qualtrax:
   i. Open Qualtrax (http://dps-qualtrax01/Qualtrax) and click on Log In
   ii. This prompts the user for the User Name and Password.
      (a) The User Name is the users employee number
      (b) The Password is the same as that for the LAN computer.

      Note: To simply view a document you do not need to log in to Qualtrax, but must be on a computer that has access to the Qualtrax server.

b. Qualtrax Groups: Qualtrax is set up to contain "groups" which assigns permissions for individuals based on the needs of the Section/Unit. Permissions are given to these groups according to the level of access and control they require in the system.

   i. Each laboratory unit has a designated group. A group can contain many individuals or just one individual.
   ii. Other groups have been made depending on laboratory needs; for example there is a group named DNA Technical Lead and a group named Deputy-Identification.
   iii. Individuals within each group inherit the group permissions.

iv. The Quality Section is in every group as a group "manager" so that data reports can be run in Qualtrax.

c. Adding Documents to Qualtrax:
   i. This is performed by the Quality Section using the Mass Import Tool or the Automatic File Transfer Tool. Once documents are uploaded they are given a laboratory generated header. All documents must be saved as a macro-enabled document to be uploaded.
   ii. Open the Mass Import Tool and log in.
   iii. A box will open with multiple Sections. First a box labeled "Qualtrax Folders", next a box labeled "Your Folders" and a box labeled "Files to be Imported".
      (a) Pick the location the document is to be imported to from the "Qualtrax Folders" box.
      (b) Find the document(s) that need to be imported from the "Your Folders" box. Drag these into the "Files to be Imported" box.
      (c) On the bottom navigation bar check off the box labeled "Generate PDF for View Extension" then click the import button.
      (d) A pop up box will appear labeled Import Settings. First pick the editor of the document (from the drop down list). Click the "Edit Groups" button and pick the group(s) this document is related to.
         (i) In selecting the groups that are assigned; the approver, reviewer and those to be notified can be designated at this time. The document will only upload if an approver is designated.
      (e) Then click the Import button on this box. (Not Import and Publish) Click OK button.
      (f) The editor will have a notice in the In Box that the document is in edit.
   iv. Adding the Header – the Qualtrax Header Footer Tool is used. The link to this tool is located on the Shared Drive in the Qualtrax folder. Open this tool and log in.
      (a) A box will open with 3 Sections. The 1st box is labeled "Select Qualtrax Template", the 2nd is labeled "Select Qualtrax Files to Update", the 3rd is labeled "Comments to add to Revision History"
         (i) Select the appropriate template.
         (ii) Select the file that is to be updated.
         (iii) Add a comment to the revision history
         (iv) Check the box labeled "Increment Qualtrax Revision Number"
         (v) Click "Apply Template"
         (vi) A box will appear showing the progress of the update, when it is complete click close.

(vii) The document will now be in Qualtrax with the Header.

(viii) Qualtrax automatically assigns a document ID to the document; this will be a unique number located at the bottom of the screen when a document is opened and in the top right hand corner of the header. This number is used internally by Qualtrax.

d. Opening a Document: All employees can open general and section/unit specific SOPs to read or view them.
   i. Opening a document without logging in:
      (a) Click on the Qualtrax link. The main page will open.
      (b) In the blue navigation bar two options are listed Documents and Personnel. Click on Documents.
      (c) The Document Tree will open.
      (d) The Document Tree lists the various Laboratory Sections.
         (i) DSS Quality Manual
         (ii) Forensic Biology/DNA Section
         (iii) Identification Section
         (iv) Toxicology/Controlled Substances/Chemistry Section
         (v) Laboratory Case Support Section
      (e) Within each Laboratory Sections are Units, in each Unit are the current approved procedures.
      (f) Click on the needed document to view the document.
      (g) Note that from the document list only the current approved/published documents will open.
   ii. Opening a document when logging in:
      (a) Open Qualtrax and Login and follow the steps above.
      (b) Note this is needed when a document is to be checked out for editing.

e. Editing a Document: Editing can only be performed through Qualtrax by those with editing permissions. In general, the path is to edit, review, approve, then publish the document.
   i. Log into Qualtrax and open the document to edit.
   ii. In the gray option bar click on 'EDIT' – this will open a dialogue box labeled 'Edit Reason' –type in the reason for the edit. Then click the blue 'Check Out' button.
   iii. A dialogue box will open asking to 'Open or Save' the document – click Open. (you must have previously downloaded the Automatic File Transfer (AFT) tool)

iv. If you are using the AFT for the first time, you will be asked to make a working folder. Browse to a location on your computer or make a new folder for Qualtrax edits. Once this folder is made, do not move this folder from its original location.

v. Qualtrax will open the document in word format.

(a) Important: this is the document that is to be edited, do not move it (i.e. save it in a new location). Qualtrax needs to know this path to be able to check the document back in with the changes made to it.

vi. Edit the document as needed. All added text should be in red or blue text. Deleted information should be crossed out and turned to red text. Do not use track changes. Qualtrax will not recognize track changes in Microsoft Word.

vii. When edits are completed, save the document (remember just 'save' (not 'save as') so the location is the same) and close the document.

viii. Open Qualtrax and Log In.

ix. Go to the 'INBOX' – a list of the documents in edit assigned to the user will be on the top left corner of the screen.

x. Click open the needed Document.

xi. On the gray options bar click 'Check In' – this imports the edited document from your working folder; this does not publish the document.

xii. On the gray options bar click 'Release for Review' – this releases the document to the "Reviewers" (and TL in DNA) for review of the edits.

xiii. A box will appear labeled "Changes Made" – type in a listing of the edits. The editor should give details of the overall reason for the edits, but may not need to be as detailed to list added commas or semi-colons. The information entered at this time will become the document history and the manner to track the changes made to the document. It is important to be detailed enough to allow the user of the updated document to understand what has been updated.

(a) Example: Edited to allow for new equipment to be used for this procedure.

xiv. Emails are automatically sent via Qualtrax informing the reviewers that a document has been assigned to them for review. The information included in the "Changes Made" box are sent with this email notification.

xv. "Tests" may also be associated with document changes. If a test is associated with a document revision an email notification will be sent.

f. Reviewing a Document:

i. From the inbox open the document to review by clicking on the link.

ii. The reviewer assesses the edits made to determine if they are appropriate and do not conflict other procedures.
iii. The reviewer cannot edit this document, they can only make comments.
iv. When the document is reviewed, click on the 'Review' button on the gray navigation bar. This opens a box labeled "Comments"
v. Type in comments concerning accepting or not accepting the edits.
   (a) Accepting: the comments can be simple – such as edits acceptable.
   (b) Not Accepting: the comments should include changes to be made.
      (i) Example: need to add Quality Control measures for the new instrument.
vi. Click the blue 'Review' button. This sends the document back to the editor, and sends an email to the editor to inform them of document status.
vii. The editor then clicks on the link in their Inbox to open the document.
viii. Open the Properties link to view the reviewer's notes. This will be in the 'Reviewer History' on the General tab.
   (a) If the reviewer has accepted the edits, the editor can now release the document for approval.
      (i) On the gray navigation bar click 'Release for Approval' (note if this is not present click on the 'More' button and a drop down menu will appear with this option).
   (b) If the review has not been accepted: incorporate the needed information by repeating the 'Editing a Document' steps above.
   (c) At any point the editor can cancel release from review and place the document back into "edit".
   (d) If a collaborative effort is needed, a document in edit can have a "change in editor". If the current editor would like another individual to continue edits to the document, then they can do so by selecting "change in editor", selecting the person's name and clicking save. The document in edit will then appear in the new editor's inbox and the new editor can "check out" the document to continue editing.

g. Approving Documents:

The Director is the final approver of all Procedures. The Quality Section approves documents only in the role of publishing the Director approved document.

i. From the email notification or from the Qualtrax 'Inbox' click on the link to the document to be approved.
ii. Review the changes to the document.

(a) If acceptable click the 'approve' button on the gray navigation bar.
  (i) A comments box will appear; a comment can be added here. Click the 'Approve' button.
  (ii) This will send the approval to an individual in the Quality Section for publication. Publication is performed in the same manner as the approval.
  (iii) When this approval is given, the document is published. All individuals assigned to this document (based on groups) will be informed of the newly released document via an automated email.
  (iv) It is the responsibility of all employees receiving the email to open the link and review the changes.

(b) If not accepted:
  (i) Click the 'Reject' button on the gray navigation bar.
  (ii) A comments box will appear, add comments as to why the document edits are rejected.
  (iii) Click the blue 'Reject' button.
  (iv) This sends the document back to the Editor. Additionally an email notification will be sent saying the document rejected by the approver and the reason.
  (v) The editing process is followed again until approval is gained.

h. Document Properties:

This contains information about the document including editing, reviewers and approval notes and dates.

i. Log in and open the appropriate document.
ii. Click on Properties in the gray navigation bar. A Document Properties page will open with several tabs:
  (a) General: contains information of dates, and notes of edits, reviewers and approvals for the current version.
  (b) History: contains information of dates, and notes of edits, reviewers, and approvals for all past versions. The out of date revisions can be opened from this area by clicking on "view" next to the revision number.
  (c) Custom Fields: Only used when there are "child" documents related to the parent.
  (d) Document Lists: this shows what groups have responsibilities for this document (approvers, editors, and those to notify). These responsibilities can be edited in this field only by those with the permissions to do so.
  (e) Locations: shows where on the document tree this document is located.

(f) References: if there are references, such as accreditation criteria, linked to the document they are listed here.
(g) Security: lists what groups can view or edit the document.

E. **REFERENCES**:

4. Qualtrax 'Help Guide'