	Intermountain Forensics	**SOP #**	DOC-200
		Revision #	01
Forensic DNA Technical Leader Approval		**Issue Date**	
		6/1/20	

Standard Operating Procedure Management

1. Purpose

This procedure describes the initiation and revision process for standard operating procedures (SOP)

2. Summary

The mechanism to initiate an SOP, revise an SOP are laid out. Storage of raw SOPs, active SOPs and obsolete SOPs is identified.

3. Procedure

New Standard Operating Procedure
1. The need for a new SOP may come as the result of corrective action, preventative action, implementing new technology, an audit or DNA Technical Leader review or by suggestions from staff or external entities.
    a. The DNA Technical Leader (DNA TL) will have the ultimate authority on whether to approve the request for a new SOP

2. A SOP request form (DOC-303) can be used to document the need for and approval of a new SOP

3. The DNA TL or designee must approve the request and assign a SOP number
    a. SOP numbers should reflect approved naming convention
        i. XXX-### format

4. The following information should be documented
    a. Reason for the new SOP
        i. Include audit, validation or corrective/preventative action information if appropriate
    b. Whether the change is major or minor
    c. The date of form submission to DNA TL
    d. Signature and approval date of DNA TL to initiate revision

5. Upon approval, a template file (DOC-300 or DOC-301) will be utilized to create the new SOP
    a. This SOP will be saved as a new file name to the "In Revision" folder until complete and ready for approval by DNA TL
    b. The SOP request form will be named as per the SOP number _DR and saved within the SOP Requests folder
        i. New SOPs will not have a revision number in the file name

6. An entry for the SOP will be made in the SOP Reference (DOC-302) log

7. While the SOP is being created, it will remain in the "In Revision" folder and the status in the log should be "in revision"
    a. Where possible, initials of the staff member responsible for the revisions should be noted in the log
    b. When complete, the log can be changed to "ready for review" to facilitate DNA TL review

8. DNA TL will review the completed SOP and revise (if necessary) for approval

9. Upon approval by DNA TL
    a. SOP request form (if applicable) will be signed/dated by the DNA TL
    b. If the SOP is a 100 or 200 level SOP it will be saved as a PDF in the applicable active folder, If the SOP is a 300 level SOP a copy of it will be saved in the applicable active folder
        i. Active folder includes
            1. Administrative (policy, human resources and organizational structure)
            2. Operations (maintenance, reagents, non-assay instructions)
            3. Processing (assay specific instructions)
            4. Analysis (instructions on analysis and interpretation)
            5. Documents (300 level SOP's)
    c. Log form should be set to "active" and the date of sign off should be noted
        i. Revision number is set to 1 as a new SOP
    d. If major change

   i. Documented notification is given to the staff
     1. Documentation should be added to the SOP request form
     2. DNA TL may require documented review of the SOP by all staff members (added to the SOP request form)
  e. A non-PDF, editable version of the SOP should be stored for future revision
   i. A _RAW should be added to the end of the filename to ensure this is not used in casework

Revision to an Existing Standard Operating Procedure

10. The need for a revised SOP may come as the result of corrective action, preventative action, implementing new technology, an audit or DNA Technical Leader review or by suggestions from staff or external entities.
  a. The DNA Technical Leader will have the ultimate authority on whether to approve the request for a revision to an SOP

11. A SOP request form (DOC-303) can be used to document the need for and approval of a revised SOP

12. The SOP number should be retained
  a. A revision number will be added (Rev2, Rev3 etc.)

13. The following information should be documented
  a. Reason for the revision
   i. Include audit, validation or corrective/preventative action information if appropriate
  b. Whether the change is major or minor
  c. The date of form submission to DNA TL
  d. Signature and approval date of DNA TL to initiate revision

14. Upon approval, the _RAW file will be utilized to create the revision
  a. This SOP will be saved to the "In Revision" folder until complete and ready for approval by DNA TL
  b. The SOP request form will be named as per the document number _DR and saved within the SOP Requests folder
   i. The revision number should be included in this file name

15. An entry for the revision number of the SOP will be made in the SOP Reference (DOC-302) log

16. While the SOP is being revised, it will remain in the "In Revision" folder and the status in the log should be "in revision"
  a. Where possible, initials of the staff member responsible for the revisions should be noted in the log
  b. When complete, the log can be changed to "ready for review" to facilitate DNA TL review

17. DNA TL will review the completed SOP and revise (if necessary) for approval

18. Upon approval by DNA TL
  a. SOP request form (if applicable) will be signed/dated by the DNA TL
  b. If the SOP is a 100 or 200 level SOP it will be saved as a PDF in the applicable active folder, If the SOP is a 300 level SOP a copy of it will be saved in the applicable active folder
   i. The revision number should be included in the file name
   ii. Active folder includes
     1. Administrative (policy, human resources and organizational structure)
     2. Operations (maintenance, reagents, non-assay instructions)
     3. Processing (assay specific instructions)
     4. Analysis (instructions on analysis and interpretation)
     5. Documents (300 level SOP's)
   iii. The replaced version of the SOP should be removed from "Active" and placed in the "obsolete" folder structure
  c. Log form should be set to "active" and the date of sign off should be noted
   i. Revision number is set to 1 as a new SOP
  d. If major change
   i. Documented notification is given to the staff
     1. Documentation should be added to the SOP request form
     2. DNA TL may require documented review of the SOP by all staff members (added to the SOP request form)
  e. A non-PDF, editable version of the SOP should be stored for future revision

      i.   A _RAW should be added to the end of the filename to ensure this is not used in casework

4.   References

ADM-103 Documents

5.   Definitions

N/A