SOP Title: Document Control	
SOP #: 101	Version 04-22-09
Approved by: TVB	Date: 4/22/09
Author: Patricia Lukens	Department: Quality Control

1.0 Purpose

1.1 To ensure that documents are uniquely identified, only current versions of the correct documents are in use in the laboratory, and that all documents are available for staff to perform their work.

1.2 To provide policies for how laboratory documents that affect the quality of tests are reviewed, approved, issued, tracked, updated, revised, amended, retained, archived, and discarded.

1.3 To require that amendments to documents are clearly marked, and that all documents are approved only by authorized, qualified personnel.

2.0 Document Control Procedures

2.1 Document Review, Approval and Issue

2.1.1 All documents that affect the quality of testing are reviewed and approved by the appropriate Laboratory Section Head or other approved laboratory staff member and/or the Director. These documents include manuals, policies, SOP's, procedures, instructions, test methods, worksheets, forms, international standards, and regulations.

2.1.2 After documents are approved, they are issued using the following procedures:

2.1.2.1 Approved documents are submitted to the Quality Systems Manager who assures the document has a unique ID number and revises the version number and date if applicable. Document identification numbers are assigned using the following system:

- SOP 0100's Quality System Procedures
- SOP 0200's Serology
- SOP 0300's Bacteriology
- SOP 0400's Virology
- SOP 0500's Molecular Diagnostics
- SOP 0600's Histopathology
- SOP 0700's Pathology
- SOP 0800's Immunohistochemistry
- SOP 0900's Aquaculture

- SOP 1000's Electron Microscopy
- SOP 1100's Central Processing
- SOP 1200's Avian Health and Food Safety
- SOP 1300's Parasitology
- SOP 1400's TSE Laboratory

2.1.2.2 Version numbers are the date of posting of the document to the WADDL web site. For example 07-17-09 indicates the revision posted on July 17, 2009.

2.1.2.3 Approved documents are placed in web folders by the Quality Systems Manager. These folders are accessible to all WADDL personnel. These folders are entitled:

- Standard Operating Procedures
- Forms
- WADDL Safety Program
- WADDL Emergency Program

2.1.2.4 Hard copies of documents are also issued in manuals that are present in each laboratory. These hard copies are printed with an approval box in the bottom left corner saying "Approved / Controlled Document" QM: PLukens". When the SOP is submitted to the appropriate laboratory section or WADDL department, the responsible Section Head, Laboratory Manager or other designated staff member will stamp the SOP with a red "Entered" stamp and write their initials and date. This red stamp indicates the SOP has been placed into the SOP manual by the responsible person and is controlled. If a Standard Operating Procedure does not contain this approval box and stamp, it is considered invalid and is not controlled by the WADDL document control system.

NOTE: Older documents are stamped by the Quality Manager on the first page, with a red stamp saying "Authorized Copy", with the Quality Manager's initials and date. These SOPs will continue to be used and acceptable as they are fazed out of the system.

2.1.2.5 The red "Entered" stamps are issued to each Laboratory Section or WADDL department and assigned a WADDL lab ID number in order to keep track of where the stamps are assigned and who is authorized to use them.

2.1.2.6 WADDL personnel are not encouraged to print procedures from the web site, however if they do (for

training purposes for example), these are not controlled procedures ("Uncontrolled Document" appears on each page) and the staff members are responsible to see that these procedures are not confused with the official procedures and are not referred to during testing. If an employee requires a controlled approved document in printed form they must request an official printed copy from the Quality Systems Manager or his/her designee. This controlled copy will be marked as indicated above.

2.1.3 Any printed copies of documents in use that do not have the Controlled / Approved box and the red Entered stamp or contain a different version number than the current one on the WADDL web site are considered invalid and must be immediately removed and recycled, retained off the bench in the staff members personal training file with appropriate status designation, or appropriately stamped and identified by the Quality Manager.

2.1.4 Exception to the above: The WADDL Safety Manual is made up of several individual procedures and appendixes. These individual documents are combined into the WADDL Safety Manual. The reverse of the Safety Manual's cover page will be stamped by the QC Manager as in 2.1.3 indicating the entire manual is controlled. When individual procedures within the manual or the entire manual are revised an additional stamp will be placed on the cover page. This procedure will pertain only to WADDL Laboratory Safety Program documents.

2.1.5 In the instance that it is necessary to retain an outdated document in use, it will be clearly stamped in red "Obsolete Document" and initialed and dated by the Quality Manager, or in green "Uncontrolled Copy of Document".

2.1.5.1 The Immunohistochemistry (IHC) Laboratory has a need to refer to obsolete SOP's on a regular basis. The IHC laboratory retains obsolete SOPs as a reference material in the Developmental Summary Notebooks. They are NOT kept in the current procedures manuals. This reference material is used in retrospective analysis of a case when additional samples may be submitted from the same animal or from different animals in the same herd and the protocol has since changed [as a change in primary antibody affecting test specificity]. For this reason, printed copies of their obsolete SOP's are properly marked and maintained in a separate manual in that laboratory for use as a reference.

2.1.6 The Quality Systems Manager has the responsibility of maintaining current documents with the correct version numbers in the WADDL web files. Only the Director, the Quality Systems Manager and the Medical Informatics staff have read / write access to these web files.

2.1.7 Manufacturer's manuals for laboratory equipment are maintained in the equipment file in the laboratory section or Quality office, as needed. If the equipment manual is used in preference to creating an SOP for operation or maintenance procedures, the manual will be controlled and numbered as an SOP or reference document.

2.1.8 If the instructions accompanying a laboratory test kit are used to perform a test with no changes, the test kit instructions may be identified as the SOP with an appropriate cover page, or may be scanned as an appendix or reference to the testing procedure. Test kit instructions may be used directly from the box if the posted controlled copy on the WADDL web is the identical version.

2.1.9 Documents may be periodically reviewed by the Director or his designee.

2.2 Document Version Tracking

2.2.1 SOPs: The SOP Master List is electronically produced from the WADDL web site system. Current documents are listed by name and last modified date, which is the version number of the SOP. This last modified date is the date the SOP was placed on the WADDL web site for access to all WADDL employees. This list is automatically updated when obsolete documents are replaced on the system by the Quality Systems Manager. When saving the SOP onto the WADDL web site system, the file should be named as follows: SOP title and number. For example: "Document Control SOP 101".

2.2.2 Forms: The Forms Master List is electronically produced from the WADDL web site system. The name, and ID number of the form, is listed with the last modified date. This last modified date is the version number and reflects the date the form was placed on the WADDL web site for access to all WADDL employees. This Master list is automatically updated when obsolete forms are replaced on the system by the Quality Systems Manager. When saving a form onto the WADDL web site system, it should be named as follows: Form number and title. For example: "Daily Worksheet IHC 001.

2.2.3 Manuals: The Master Manual List is maintained in an Excel file by the Quality Systems Manager. This list contains the manual name, manual ID number, date created, and link to the manual's Table of Contents.

2.3 Document Updates, Revisions and Amendments

2.3.1 When documents require changes, the Director or the Quality Systems Manager will issue the Microsoft Word version of the document electronically to an authorized laboratory section head or other approved laboratory staff member. The changes to the document will be made using the "Track Changes" function in Word. In this way the most recent specific changes in the document are clearly identified. In addition, the changes are listed at the end of each SOP. Each time a SOP is revised, the changes from the previous version are accepted by the Quality Systems Manager. Copies of previous versions are stored in a snapshot file and can be accessed by the Quality Systems Manager.

2.3.2 When the amendments to the document are complete, the Section Head or other approved laboratory staff member will return the document electronically to the Quality Systems Manager for posting to the WADDL web site. The Quality Systems Manager will change the version number, and place the new version in the appropriate web file and convert it to a pdf for staff viewing.

2.3.3 The Quality Systems Manager provides new hard copies electronically to the Section Head, Laboratory Manager or other designated staff member, as well as a SOP Training form (see Forms Section 3.0). They are instructed to print only the number of copies needed for their SOP manual(s). Each manual contains a Document Change Record form in the front of the manual. When sections or individual documents in a manual are changed, the change is recorded on the form allowing a quick reference to changes made in the manual.

2.3.4 Handwritten amendments to WADDL documents are not permitted. Printed copies of WADDL documents that are amended by hand are considered invalid and should be destroyed or recycled immediately.

Note: The Immunohistochemistry Laboratory's SOP's have the potential to change on a daily basis. For this reason, the normal procedure for changing SOP's is not reasonable. Therefore, this laboratory is permitted to make hand-written amendments to their SOPs for a period of time until the SOP's are deemed ready to

rewrite by the Section Head. These hand-written amendments are documented, dated and maintained with the SOP until the SOP is rewritten. At that time the SOP would undergo revision according to the normal policies given here.

2.4 Document Retention, Archival, and Discard

2.4.1 Obsolete or invalid electronic documents will be immediately removed from the WADDL web site files which automatically places the document in the "Obsolete WADDL Documents" folder. The date the document was transferred to the obsolete file is also archived in the system. Only the Director, Quality Systems Manager and WADDL Information Systems staff have access to this folder.

2.4.2 Printed copies of obsolete documents will be returned by the laboratory staff to the Quality Systems Manager to be destroyed or recycled except as noted in 2.1.5 above.

2.4.3 Authorized and archived document directories are copied and archived indefinitely as described in SOP 102: Information Systems.

3.0 Associated Forms

Form QC 1: Document Change Record
Form QC 021: SOP Training Documentation Form

4.0 References

Essential Requirements for an Accredited Veterinary Medical Diagnostic Laboratory, American Association of Veterinary Laboratory Diagnosticians Inc., current version

OIE *Quality Standard and Guidelines for Veterinary Laboratories: Infectious Diseases*, Office of International Des Epizooties, Paris, 2002

ISO/IEC 17025:1999(E), *General requirements for the competence of testing and calibration laboratories*

5.0 Distribution

5.1 Electronic distribution: Placed in the "Standard Operating Procedures" folder on the WADDL web site accessible to all WADDL employees.

5.2 Hard copy distribution: Issued to each laboratory in the SOP Manual.

SOP Changes

12/11/06	All applicable sections	- changed Quality Control Manager to Quality Systems Manager
	Section 2.1.2.1	- changed General System Procedures to Quality System Procedures and BSE Laboratory to TSE Laboratory
	Section 2.1.2.3	- updated folder names
	Section 2.1.2.4	- added description of stamp procedure and purpose of text in footer
	Section 2.1.3	- added text to allow uncontrolled copies of SOPs in staff personal training files
	Section 2.1.4	- added exception to document control procedures for safety manual
	Section 2.1.5	- added green Uncontrolled Document stamp
	Section 2.1.6	- added Medical Informatics staff as having read / write access to SOPs
	Section 2.1.7	- added Quality Control office as location for equipment manuals
	Section 2.3.1	- added acceptance of previous changes to SOPs and how obsolete SOPs are stored
04-22-09	Entire SOP	- Changed Director of Laboratory Services to Director
	Section 2.1.2.2	- Updated version dates to 2009 dates
	Section 2.1.2.3	- Added WADDL Emergency Plan
	Section 2.1.2.4	- Revised to include the new document control indication on each SOP and a note about the old method
	Section 2.1.2.5	- New section
	Section 2.1.2.6	- Revised to include instructions for what do to with printed SOPs from the web
	Section 2.1.3	- Added new control system
	Section 2.1.7	- Revised location of equipment manuals
	Section 2.1.8	- Added sentence regarding test kit instructions
	Section 2.3.1	- Added changes listed at the end of the SOP
	Section 2.3.3	- Changed distribution process
	Section 3.0	- Added SOP Training form