US Environmental Protection Agency
Office of Pesticide Programs

Office of Pesticide Programs
Microbiology Laboratory
Environmental Science Center, Ft. Meade, MD

Standard Operating Procedure for
Maintaining, Tracking and Archiving of Records

SOP Number: ADM-03-07

Date Revised: 03-07-18

SOP Number	ADM-03-07
Title	SOP for Maintaining, Tracking and Archiving of Records
Scope	This SOP provides guidance for maintaining, tracking, labeling and archiving of records generated by the Microbiology Laboratory Branch.
Application	This procedure applies to all records generated by the laboratory staff and the quality assurance unit.

	Approval Date
SOP Developer:	_____ Print Name: _____
SOP Reviewer	_____ Print Name: _____
Quality Assurance Unit	_____ Print Name: _____
Branch Chief	_____ Print Name: _____

Date SOP issued:	
Controlled copy number:	
Date SOP withdrawn:	

TABLE OF CONTENTS

1. Definitions	1. Record: All books, papers, maps, photographs, machine readable materials, or other documentary materials, regardless of physical form or characteristics, made or received by an Agency of the United States Government under Federal law or in connection with the transaction of public business and preserved or appropriate for preservation by that Agency or its legitimate successor as evidence of the organization, functions, policies, decisions, procedures, operations, or other activities of the Government or because of the informational value in them (see section 15.1). 2. Electronic Versions of the Record Copy: Electronic versions of records may be created with office automation applications. 3. Records Schedule or Series: EPA's official schedule for retention and disposal of Agency records. MLB records fall in the following record series; 1004 (procurement and contracts), 1016 (proficiency testing and GLP related files), 1023 (policy and guidance documents), and 1035 (efficacy test reports, research reports, QA related documents, lab notebooks, quality control records etc.). Refer to attachment 1. 4. File Closure: When a record is no longer actively in use, it may be closed, designating the record as inactive. File closure marks the beginning of the record retention schedule. 5. NARA: National Archives and Records Administration.
2. Health and Safety	Not applicable.
3. Personnel Qualifications and Training	1. Refer to SOP ADM-04, OPP Microbiology Laboratory Training.
4. Instrument Calibration	Not applicable.
5. Sample Handling and Storage	Not Applicable
6. Quality Control	1. The records management practices of the Microbiology Laboratory Branch conform to the Agency's records schedules and to the policies of the Agency's National Records Management Program.
7. Interferences	None.
8. Non-conforming	1. Any instances of non-compliance with this SOP will be corrected upon discovery.

Data	
9. Data Management	1. Product efficacy test reports and research studies are catalogued according to the numbering system in the Master Schedule. Records are filed consecutively following the Master Schedule. 2. The MLB Master List (MLB share file – Master List – document control) is used to track other relevant lab documents (standard operating procedures, equipment manuals, quality records, records (e.g. QMP, QAPP and QAARWP), procurement records, contract records and external documents (e.g. AOAC and ASTM standard methods). The Master List specifies the location of documents.
10. Cautions	1. Confidential or sensitive information is maintained by the recipient in a secure location consistent with the Agency's requirements. CBI is not filed in the common file areas (D217 and D219).
11. Special Apparatus and Materials	1. 3" or 5" accordion folders 2. Fiberboard Box Special, Purpose (Records Retiring); purchase through GSA
12. Procedure and Analysis	1. Staff and management all have record keeping responsibilities. The procedures outlined below are organized by type of record.
12.1 Studies Tracked on the Lab Master Schedule	a. Research Reports: Consolidate all test sheets and supporting documentation for a study in a study binder. Once the study memo summarizing the data is finalized, the Branch Chief (BC) will note the date on the master schedule. The analyst will return the complete binder including the final study memo to the QAU. The QAU will file the binder in D217 according to the "R" number. Maintain these files for 20 years after file closure. b. For Product Efficacy Reports and Proficiency Test Exercises, once the memo is finalized (refer to ADM-01), the BC will note the date on the master schedule. The analyst will file the blue book copy including the Biological Report of Analysis and supporting test sheets, in D217 by the registration number assigned to the product. Maintain these files for 10 years after file closure. c. Three years after retiring the fiscal year master schedule, the documents will be boxed, labeled and stored in an alternate secure location (for example, D219) or sent to the Federal Record Center in order to free space in D217 (limited) for new and active files. d. If records are maintained on site, they may be destroyed at the point in time consistent with the record retention schedule.

	e. Place a pocket folder indicating the number/name of the record as a place holder for the record when removing records from D217 or satellite storage.
12.2 **Documents Tracked on the Master List**	a. Standard Operating Procedures, QMP, QAPP, QAARWP, procurement records, contract records, and external references (e.g. AOAC and ASTM standard methods) are tracked on the master list. b. SOPs are updated on a three-year cycle or more frequently as necessary to keep the documents current. The QAU is responsible for maintaining SOP related updates. Refer to ADM-02 for the procedure for tracking and maintaining copies of the SOPs. c. The official 'O' version of an SOP is filed in D217 by SOP number for one review cycle. After the cycle is complete, the 'O' versions may be boxed, labeled and stored in an alternate location (D219) by SOP number. d. The laboratory's Quality Management Plan and annual report (QAARWP) are reviewed on an annual basis. The Master List is updated as necessary to reflect the most recent version. These documents are provided to the Office of Pesticide Programs Director of Quality Assurance to compile into an overarching office wide document. The documents are for one review cycle. e. Quality Assurance Project Plans are project specific. The Master List is updated as necessary to reflect the most recent version. QAPPs are closed upon completion of the project. f. Upon receipt of a new piece of equipment, place a sticker with the current date (month/year) and update the master list. Place the manual in the bottom drawer of the file cabinet outside D206 or keep the manual with the piece of equipment. Manuals may be discarded when the equipment is no longer actively in use. g. Publications and copies of standard methods are tracked in the master list and maintained as long as they are useful to the laboratory. h. Documents developed by the laboratory in this category are subject to a 10 years retention schedule after file closure.
12.3 **Quality Control Records**	a. Quality control documents such as calibration certificates, equipment logs, microorganism transfer logs, etc. are maintained in binders by activity. b. Once a binder is full or three years have elapsed (whichever comes first), archive the records in D217 by activity (e.g. autoclave QC logs). If space is constrained, box and move to a satellite storage

	area in the facility. c. Maintain these files for 10 years after file closure.
12.4 **Routine Procurement Files**	a. Routine procurement files consist of routine acquisitions and contract management records for program related procurements (e.g. Montana State University) maintained by contracting officers (COs) and contracting officer's representatives (CORs), including correspondence and other documents related to the award, administration, receipt, inspection, payment, review, and audit of contracts. b. Routine procurement files documenting the acquisition of goods and non-personal services (e.g., printing services) maintained by the procurement organization, including purchase documents such as purchase requisitions, credit card and bank card slips, direct deposit forms for vendors, specifications, bids, schedules of delivery, initiating requisitions, records of receipt, inspection, and payment. c. Records for routine procurements – requests for procuring items, approval from the divisional budget officer, orders, and receipts are filed in the Agency's Payment Net (PNET) system. PNET constitutes the Agency's official record keeping system for these transactions. It is not necessary or desirable to maintain paper copies of these records once filed and approved in PNET. d. Actions initiated through EAS are electronically stored and EAS constitutes the official repository for these documents (e.g. documents for purchases above the purchase card limit, with terms and conditions etc.) EAS records are maintained for six years. e. Contract records maintained by the on-site COR include the contract, task orders written against the contract, invoices, final deliverables, requests to exercise a contract option, and files closing out the contract. These files are maintained by the COR. Contract records are maintained for six years after the contract is complete or terminated.
12.5 **Policy and Guidance Documents**	a. Guidance documents and supporting documentation are maintained in the D217 archives. If records are uploaded to regulations.gov as part of a public docket file, the lab copies do not need to be maintained. The retention of records on regulations.gov are under control and management of the docket staff and ds are subject to the public docket retention schedule. b. Documents leading to decisions supporting testing guidance and

	guidelines are indexed and maintained for 20 years.
12.6 Retirement of Records	a. If space permits, all records will be maintained at the Environmental Science Center for the length of their retention schedule. If file and storage space is constrained, the files will be boxed and sent to the Federal Record Center (FRC). b. The US EPA National Records Management Program EPA Series Website (see ref 15.1) provides guidance on how to send records to the FRC (e.g., paperwork to complete, etc.). The laboratory will seek assistance from an Agency records management specialist to complete the steps necessary to ship the records to the FRC.
13. Data Analysis/ Calculations	1. None.
14. Forms and Data Sheets	1. Attachment 1: Microbiology Laboratory Branch's File Structure. 2. Microbiology Laboratory Branch: Master list of Documents kept on the shared drive.
15. References	1. List of EPA schedules in final status: US EPA National Records Management Program Website: https://www.epa.gov/records/list-epa-records-schedules-final-status 2. EPA Records schedules in final status: https://www.epa.gov/sites/production/files/2017-07/documents/20170707_epa_records_schedules_in_final_status.pdf 3. US. EPA Records Schedule, EPA Series No. 1035, Test Method Evaluation Records. 4. US EPA Records Schedule, EPA Series No. 1016, Controls and Oversight 5. US EPA Records Schedule, EPA Series No. 1004, Acquisitions and contracts. 6. US EPA Records Schedule, EPA Series No. 1023; Regulatory Development and Implementation, and Dockets.

ATTACHMENT #1: MICROBIOLOGY LABORATORY BRANCH'S RETENTION SCHEDULE

Schedule #	Function #	NARA Disposal authority	Description/Disposition
1035	108 Environmental Management	Item c. Routine environmental programs and project records DAA-0412-2013-0021-0003	Product efficacy test reports (ATP) and supporting documentation. Items related to the receipt and tests made on pesticide samples and supporting documentation, including raw data, media reagent preparation records, quality and control records, chain of custody, test results, sterilization and calibration records, temperature and air sampling records, inspection records, standard operating procedures and other reports and assessments. Collections of lab standard operating procedures (SOPs) used to assure quality of analytical procedures used by EPA laboratories to assess environmental measurement activities or document the quality system of the organization conducting the environmental collection activities. Collection of approved or accepted quality assurance project plans (QAPPs) and quality management plans (QMP) that describe procedures to assess environmental measurement activities or document the quality system of the organization conducting the environmental data collection activities. Quality control records such as equipment calibration, monitoring water, detergent residue, EMAS etc. Record retention is 10 years after file closure.
		Item b. Long term environmental program and project records DAA-0412-2013-0021-0002	Scientific research project files related to basic, exploratory research for projects conducted by EPA personnel in the Office of Chemical Safety and Pollution Prevention (OCSPP) that provide demonstration or proof of concept projects including collaborative and method validation studies. Research studies records may be destroyed 20 years after file closure.
1023	306	Regulatory Development and Implementation; and Dockets	General dockets and non-substantive rulemaking records. Background material for the establishment of public dockets for guidance materials for testing. Materials

		Items a thru d DAA-0412-2013-0010-0001 thru 0004	posted to regulations.gov for the purposes of a public comment period are maintained by the docket staff following the docket record retention schedules. Destroy 20 years after file closure.
1004	405	Acquisition and Contracts Items b and d DAA-0412-2013-0014-0002 DAA-0412-2013-0014-0004	Routine procurement files relating to orders for supplies and materials. Contract related records for contracts that have been completed or terminated. Destroy 6 years after file closure.
1016	301	Item b. Long term controls and oversight records DAA-0412-2013-0015-0002	Records related to Good Laboratory Practice (GLP) and audit report files for audits of laboratories involved in performing studies and analyses of environmental programs, including inspector worksheets, supporting documentation, correspondence and related records. Destroy 20 years after file closure.
		Item c. Routine control and oversight records DAA-0412-2013-00015-0003	Laboratory performance evaluation studies and proficiency testing (PT) records. Destroy 10 years after file closure.