US Environmental Protection Agency
Office of Pesticide Programs

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

SOP for Maintanining, Tracking and Archiving Records

SOP Number: ADM-03-08

Date Revised: 03-15-21

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Title	SOP for Maintaining, Tracking and Archiving of Records
Revisions Made	• Provided guidance for archiving previous versions of forms upon their revision (section 10). • Section 1: added new definitions. • Section 9: added details regarding the storage of electronic and paper records. • Section 12.1: a timeframe for scanning completed study binders and reports was established. • Section 15: new references added. • Minor editorial changes.

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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
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1. Definitions	1. National Records Management Program (NRMP): Policies and procedures are based on the Agency's NRMP (see section 15.1). 2. Record: Recorded information, in any format, that is created in the course of business, received for action, or needed to document EPA activities. See the NRMP's Records Management Basics for New Employees for information on how to identify records (section 15.2). 3. Electronic Versions of the Record Copy: Electronic versions of paper records created with office automation applications. 4. Office of Management and Budget (OMB)/National Archives and Records Administration (NARA) Memorandum, Transition to Electronic Records (M-19-21), dated June 26, 2019: Directs federal agencies to transition to electronic records. Beginning January 1, 2023, all transfers of permanent records must be in electronic format (section 15.4). 5. 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. 6. 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.
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 NRMP (see section 15.1).
7. Interferences	None.

8. Non-conforming Data	1. Any instances of non-compliance with this SOP will be corrected upon discovery.
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. Quality Management Plan, Quality Assurance Project Plan and QA Annual Report and Workplan), procurement records, contract records and external documents (e.g. AOAC and ASTM standard methods). The Master List specifies the location of documents. 3. Federal Agencies' business processes and recordkeeping is transitioning to a fully electronic environment. NARA will end the acceptance of paper records by December 31, 2022 (see section 15.4). Federal agencies must ensure that all records are created, retained and managed in electronic format. 4. Paper versions of the documents may be boxed, labeled and stored on site 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. Note that after December 31, 2022, only electronic copies of documents may be sent to the FRC. 5. If paper records are maintained on site, they may be destroyed at a point in time determined by the Branch Chief (BC).
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. 2. Review Records Management Basics for New Employees (section 15.2) for an overview on how to identify a record and to learn EPA employees' responsibilities regarding all records.

	3. The procedures outlined below pertain specifically to maintaining, tracking, labeling and archiving MLB laboratory records. The procedures are organized by type of record. 4. When leaving Federal service, government employees need to take steps to ensure all federal records are properly managed and preserved until their authorized disposition. No materials can be removed without authorization. Follow NRMP guidelines for separating employees.
12.1 Studies Tracked on the Lab Master Schedule	Research Reports: Consolidate all test sheets and supporting documentation for a study in a study binder. a. Once the study memo summarizing the data is finalized, the BC will note the date on the master schedule. b. Within 10 business days following completion of the study memo, the analyst must scan the study binder/memo and file it on the shared drive according to its research protocol number (e.g., R-2021-XX). c. The analyst will return the complete binder including the final study memo to the QAU d. The QAU will file the binder in D217 according to the research protocol number. e. Maintain the electronic files for 20 years after file closure. 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. a. Within 10 business days following completion of the memo, the analyst must scan the blue book copy, memo, and Biological Report of Analysis (BRA) and file it on the shared drive according to the registration number assigned to the product. b. The analyst will return the blue book copy including the BRA and supporting test sheets to the QAU. c. The QAU will file the blue book and supporting documentation in D217 by the registration number assigned to the product. d. Maintain the electronic files for 10 years after file closure.
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 electronic versions of SOP related updates. Refer to ADM-02 for the procedure for tracking and maintaining copies of the SOPs. i. The official 'O' version of an SOP is filed in D217 by SOP number for one review cycle. After the cycle is complete, the QAU must scan and file the 'O' versions on the shared drive. c. The laboratory's Quality Management Plan (QMP) and QA annual report and workplan (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. After the cycle is complete, the QAU must scan and file the documents on the shared drive. d. 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. Upon completion of the project, the QAU must scan and file the QAPP on the shared drive. e. Upon receipt of a new piece of equipment, affix an EPA property decal if applicable 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. f. Publications and copies of standard methods are tracked in the master list and maintained electronically so long as they are useful to the laboratory. g. Maintain electronic versions of documents in this category for 10 years after file closure.
12.3 Quality Control Records	a. Maintain quality control documents such as calibration certificates, equipment logs, microorganism transfer logs and EMAS records etc. by activity. b. Each year, scan records and maintain an electronic version, by calendar year, on the shared drive. For large set of records (e.g., EMAS), it may be necessary to scan quarterly or monthly. c. Maintain electronic 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) are 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 must be maintained electronically by the purchase card holder and uploaded to the Agency's official record keeping system (e.g., CitiManager, Purchase Card Order Request System [PCORS]) as directed by the Agency's Purchase Card Team (see section 15.9). It is not necessary or desirable to maintain paper copies of these records once stored or uploaded electronically. d. Actions initiated through EPA's Acquisition System (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 electronically or in paper form, by the COR, 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 electronically or in paper form, by the COR, 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 are subject to the public docket retention schedule. b. Documents leading to decisions supporting testing guidance and

	guidelines are indexed and stored electronically on the shared drive for 20 years.
12.6 Retirement of Records	a. If space permits, paper records may be maintained at the Environmental Science Center for the length of their retention schedule (see section 9). Disposal of paper records is at the discretion of the BC b. The EPA NRMP website (see ref 15.1) provides guidance on how to send records to the FRC (e.g., paperwork to complete, etc.) and is available until Dec. 2022. The laboratory will seek assistance from an Agency records management specialist to complete the steps necessary to ship the records to the FRC. c. Once the end of the retention schedule for maintenance of electronic records has been reached, the laboratory may forward the electronic records to the FRC or dispose of them, at the discretion of the BC.
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. EPA's National Records Management Program (NRMP) Website: https://intranet.epa.gov/records/ 2. EPA's NRMP Website, Information on identifying records and employees' records responsibilities: https://intranet.epa.gov/records/files/new_employee_flyer.pdf 3. EPA's NRMP Website, EPA Records Schedules in Final Status: https://intranet.epa.gov/records/schedule/final/ 4. OMB/NARA Memorandum, Transition to Electronic Records (M-19-21), dated June 26, 2019: https://www.archives.gov/files/records-mgmt/policy/m-19-21-transition-to-federal-records.pdf 5. US. EPA Records Schedule, EPA Series No. 1035, Test Method Evaluation Records. 6. US EPA Records Schedule, EPA Series No. 1016, Controls and Oversight 7. US EPA Records Schedule, EPA Series No. 1004, Acquisitions and contracts.

	8. US EPA Records Schedule, EPA Series No. 1023; Regulatory Development and Implementation, and Dockets. 9. Environmental Protection Agency Acquisition Guide (EPAAG), Chapter 13, Simplified Acquisition Procedures; Subsection 13.3.1, Government-Wide Commercial Purchase Card.

ATTACHMENT #1: MICROBIOLOGY LABORATORY BRANCH'S RECORD 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 Items a thru d DAA-0412-2013-0010-0001 thru 0004	General dockets and non-substantive rulemaking records. Background material for the establishment of public dockets for guidance materials for testing. Materials 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.