United States Environmental Protection Agency

Scientific Collections Policy:

Improving the Management of and Access to Scientific Collections

Office of the Science Advisor

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Outline

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I. PURPOSE

U.S. Environmental Protection Agency (EPA) scientific collections are assets of the federal government and their ownership carries with it trust responsibilities. This policy is intended to improve the development, management, accessibility, legal and ethical use, and long-term preservation of scientific collections owned, directly managed, or financially supported by the EPA.

This document is intended exclusively as guidance for employees of the EPA. It is not a regulation and does not create new legal obligations or limit or expand obligations under any federal, state, tribal or local law. It does not create any substantive rights for any persons.

II. BACKGROUND

Beginning in 2005, federal agencies were requested by the White House Office of Science and Technology Policy (OSTP) and Office of Management and Budget (OMB) to focus attention on integrated support and planning for the care and use of federally held scientific collections. This call for interagency coordination prompted the formation of an Interagency Working Group on Scientific Collections (IWGSC) under the White House National Science and Technology Council's (NSTC) Committee on Science, Life Science Subcommittee. In 2008, the IWGSC created a report titled *Scientific Collections: Mission-Critical Infrastructure for Federal Science Agencies* [1], which made seven recommendations to improve the management, accessibility, and impact of scientific collections owned by the federal government. In response to this report, in 2010 OSTP released a memorandum [2] to federal agencies requesting their implementation of three recommendations: budgeting for collections, developing best practices, and making collections more accessible. In 2011, Congress enacted 42 U.S.C. Section 6624 [3] on scientific collections as part of the America COMPETES (Creating Opportunities to Meaningfully Promote Excellence in Technology, Education, and Science) Reauthorization Act of 2010. Section 6624 addressed management of scientific collections, development of an online clearinghouse, disposal of collections, and development of methodologies for projecting costs associated with the management and preservation of scientific collections. EPA has developed this policy in response to the March 20, 2014 OSTP memorandum on *Improving the Management of and Access to Scientific Collections* [4].

III. APPLICABILITY AND SCOPE

EPA Program Offices and Regions that own, directly manage, or financially support scientific collections are subject to this policy. The policy only applies to physical sample collections and the information associated with the sample collection. This policy does not apply to the data or publications that may result from examination and analysis of the sample and/or collection. Each EPA Program Office and Region should determine, as part of its existing program planning and management processes, if they have or plan to have collections subject to this policy. EPA Program Offices and Regions with scientific collections covered by this policy should comply with this policy to the greatest extent practicable.

This policy complies with the 2014 OSTP memorandum on *Improving the Management of and Access to Scientific Collections* that directs federal agencies to include certain topics and address recommended topics where applicable. In addition, this policy is designed to take into account the scope, nature, and purpose of the scientific collections owned and/or funded by the Agency. This policy is, and implementation of this policy shall be, consistent with all applicable federal laws, EPA's mission and resource allocations.

IV. EFFECTIVE DATE

The effective date of this policy is 30 days after this policy is finalized.

V. SCIENTIFIC COLLECTION DEFINITION

EPA's definition of the term "scientific collection" is consistent with the definitions used in Section 6624 of U.S.C. 42, the 2008 IWGSC report, and the 2014 OSTP memorandum.

> *A scientific collection is a set of living or inanimate physical objects, and as appropriate and feasible the associated specimen data and material, that is created for the purpose of supporting science, and is preserved, cataloged, and managed as a long-term research asset rather than for its market value as a collectible or its historical, artistic, or cultural significance.*

In accordance with this definition and the documents previously mentioned, the collections under the purview of this policy are characterized by meeting all four of the following criteria:

1. Physical Object
   Physical objects can be either living or inanimate (e.g., tissue or whole body specimens, soil core samples, water samples, air particulate samples); including their supporting records, documentation and materials.
2. Owned, Managed, or Financially Supported by EPA
   Scientific collections that are owned and financially supported by the Agency but managed by non-Agency entities through a grant, contract, or cooperative agreement

are covered by this policy. Collections created from an Agency grant or cooperative agreement but managed and financially supported by the grantee or cooperative agreement principal investigator are not covered by this policy.

3. Scientific Study
   Scientific collections are used for research or science related educational purposes and not for aesthetic or market value as collectibles.
4. Long-term
   Long-term refers to a collection's purpose of providing scientific value for an extended period of time rather than for short-term use. Each Program Office and Region is responsible for determining a collection's long-term or short-term designation.

The term "scientific collection" as defined and used in this policy may also be referred to as an "institutional collection". These terms differentiate from the terms "project collections" or "working collections" which are for short-term use and relate to a discrete project or study, and are not intended for long-term preservation. Project or working collections are not under the purview of this policy.

The term "associated specimen data" used in the definition of scientific collection refers to the metadata associated with the physical object. Metadata may include but is not limited to: object/sample identification number, field collection date and location, collection/sampling technique, object name (common and scientific), collector name and organization, and preservation agent/chemical fixative.

Some Agency scientific collections were created intentionally to support programs that have been in operation for decades and are used to analyze for long-term trends. Other Agency scientific collections were initially created to support only a discrete or short term project but are kept after project termination for potential use by other efforts. In these cases, project collections convert to scientific collections by definition. This policy imposes no requirement to convert project collections to scientific collections, but rather encourages Program Offices and Regions to consider the need and feasibility of converting the project collection to a scientific collection during the planning of the project collection. The conversion of project collections to scientific collections is a means to efficiently manage resources because of the extensive time and funding needed to create them. These scientific collections may be kept for several years or they may be kept longer depending on the continued interest and use by the originating organization, other EPA organizations or interested external parties. There is no predetermined length of time that scientific collections need to be kept until transfer or disposal.

VI. SCIENTIFIC COLLECTION MISSION STATEMENT

EPA develops, maintains, and archives scientific collections for the intended purpose of supporting the programs under which they were constituted, thereby supporting the Agency's mission to protect human health and the environment.

EPA's scientific collections contribute to advancing the Agency mission by providing a source of scientific study for determining the presence, concentration, and trends of toxic chemicals in air, soil, water and entire ecosystems and the effects on human health and the environment.

EPA scientific collections may serve the function of a voucher collection, which is defined as a collection "from earlier observations or findings. A voucher specimen is one on which critical analysis and observations have been performed, and it is likely that future researchers will want to either repeat these analyses to corroborate published findings or to apply new analytical techniques" [1]. During the study extra samples and specimens may be collected and stored/archived for future use. Archived samples have been used as standards (type specimens, reference collections), for example to ensure consistent identification of species. EPA scientific collections could also consist of specimens/samples/materials that were prospectively collected for future analysis or experimental use in line with the Agency mission.

VII. LEGAL AUTHORITY

EPA's authority to develop scientific collections is found in the statutes that EPA implements. These statutes do not require and are not specifically directed towards scientific collections, but rather scientific collections support programs that are operated under the Agency's authority. Major legislation under which EPA could develop, manage, and archive scientific collections includes, but is not limited to

- Clean Air Act (1963), Public Law 88-206
    - Clean Air Act Amendments: 1966, Public Law 89-675; 1977, Public Law 95-95; 1990, Public Law 101-549)
    - Clean Air Act Extension, 1970, Public Law 91-604;
- Motor Vehicle Air Pollution Control Act (1965), Public Law 89-272;
- Air Quality Act (1967), Public Law 90-148;
- Water Pollution Control Act (1948), Public Law 80-845 (Amendment,1972, Public Law 92-500);
- Water Quality Act (1965), Public Law 89-234;
- Clean Waters Restoration Act (1966), Public Law 89-753;
- Water Quality Improvement Act (1970), Public Law, 91-224;
- Safe Drinking Water Act (1974), Public Law 93-523 (amendments of 1986 and 1996);
- Clean Water Act (1977), Public Law 95-217; Clean Water Act (2000) 65 FR 24641;
- Water Quality Act (1987), Public Law 100-4;
- Great Lakes Water Quality Agreement of 2012, Annex 3, Section C, Number 4;
- Toxic Substances Control Act(1976), Public Law 94-469;
- Federal Insecticide, Fungicide, and Rodenticide Act (1947), Public Law 61-152;
- Food Quality Protection Act (1996), Public Law;
- Solid Waste Disposal Act (1965), Public Law 89-272 (Hazardous and Solid Wastes Amendments Act 1984, Public Law 98-616);
- Resource Recovery Act (1970), Public Law 91-512;
- Resource, Conservation and Recovery Act (1976), Public Law 94-580; and
- Comprehensive Environmental Response, Compensation, and Liability Act ("Superfund") (1980), Public Law 96-510 (Superfund Amendments and Reauthorization Act, 1986, Public Law 99-499).

VIII. POLICY AND PROCEDURES

EPA Program Office and Regional scientific collection managers/custodians should follow this agency policy and their Office's or Region's appropriate scientific collection policies and procedures. In the absence of specific Program Office or Regional procedures for biological materials (human, animal, plant) they should use, where feasible, the International Society for Biological and Environmental Repositories' (ISBER) Best Practices for Repositories [5]. These best practices are updated periodically. The Program Office or Region should use the most up to date guidance available for biological materials. ISBER best practices includes sections on

- repository planning considerations;
- facilities;
- storage equipment and environments;
- quality management;
- safety;
- training;
- records management;
- cost management;
- biological material tracking/ inventories;
- packaging and shipping;
- specimen collection, processing and retrieval;
- legal and ethical issues; and
- specimen access, utilization and destruction.

Scientific collections do not have record keeping requirements. The National Archives and Records Administration (NARA) does not consider laboratory or field samples and materials to be records; therefore, their storage/archiving is not covered under records policies. However, scientific collections that are converted from project collections may have been initially retained to confirm, reconstruct, or support research or other program activities. These samples and materials that are retained should be managed in accordance with the procedures of the collecting EPA Program Office and Region.

Agency Level Policy and Procedures

a. Policy Implementation and Collection Oversight

EPA does not operate an agency-wide physical repository that receives, processes, stores, or distributes specimens contained in its scientific collections; nor has it designated a Scientific Collections Director or centralized scientific collection management structure to provide oversight. These activities are delegated to each Program Office and Region that owns, directly manages, or financially supports a scientific collection(s). Because of differing organizational structures in each Program Office and Region, each Program Office and Region is responsible for determining the organizational and management level that will best provide oversight for each scientific collection, as well as collective oversight of all scientific collections within that organization, to ensure compliance with this policy.

To assist in determining implementation of and compliance with this policy, the manager/custodian of each scientific collection, in concurrence with the appropriate management level, must annually submit to their Assistant Administrator or Regional Administrator, a statement verifying that their scientific collection is managed in

accordance with this policy. This verification is to be provided to the Director of the Office of the Science Advisor upon request.

The Office of the Science Advisor will annually review the status of EPA's scientific collections and update the record of these collections in the registry of US Federal Scientific Collections (USFSC) (http://usfsc.grscicoll.org/), and be responsible for managing EPA's contributions to the IWGSC Clearinghouse (https://usfsc.nal.usda.gov/). See Section e., Communication Strategy for additional information on the registry and clearinghouse.

Requirements listed in this policy help ensure that activities associated with implementation of this policy follow existing laws and regulations. Appendix 2 lists these requirements, and are fully described in detail throughout the policy.

b. Policy and Collection Funding

The EPA does not budget at the specific line item level for scientific collections nor does it have a standalone process for determining resources solely devoted to scientific collections. Scientific collections are typically not funded directly, but rather as support to activities or programs. Therefore, the appropriate organizational level to budget for and fund scientific collections as well as implement this policy is determined by each respective Program Office and Region. Any associated resources would be contained in the activity or program's base budget.

c. Organizational and Collection-Specific Policy Discrepancies

In the event that there is a discrepancy between this policy and those of the Program Offices and Regions, the policies and procedures described in this policy should generally take precedent over those of the Program Offices and Regions unless this policy indicates that Program Offices and Regions have the flexibility to determine how or whether to perform a specific action.

d. Safeguards for Privacy, Confidentiality, and Intellectual Property

Individual Privacy and Confidentiality - Human Subjects Research

EPA research on human subjects must comply with Title 40 of the Code of Federal Regulation, Part 26 (Protection of Human Subjects) [6], and EPA Order 1000.17 Change A1 (Policy and Procedures on Protection of Human Research Subjects in EPA Conducted or Supported Research) [7]. Collection and future use of human biospecimens as part of a human subjects research project must comply with this Regulation and Order to protect individual privacy and confidentiality until transfer or disposal of the specimen/collection. Questions should be directed to the Human Subjects Research Review Official.

Intellectual Property and Confidential Information

A scientific collection or, more particularly, the information associated with the collection, may include subject matter that could be protected under intellectual property law. In

these cases, Program Offices and Regions should consider the effect that disclosing the collection or associated information would have on intellectual property rights. For example, a scientific collection may reveal a potentially patentable method, but the method's inventor has not yet applied for patent protection; or information associated with the collection may be used by the author in an article that has not yet been published. EPA Program Offices and Regions should consult with whomever may be able to claim intellectual property rights when deciding on the appropriate time to release/allow access (see Subsection h. Scientific Collection Access) to the collection and associated information. Potential rights owners would include grantees, contractors and research collaborators, in addition to EPA employees.

Program Offices and Regions must also determine whether releasing/allowing access to a scientific collection and associated information would disclose confidential business information, personal privacy information or other privileged information. Program Offices and Regions should consult the Agency's public information regulations in 40 CFR Part 2 to ensure that access to scientific collection and associated information is conducted in accordance with the applicable information disclosure laws.

To assist in safeguarding intellectual property associated with the collection, maintenance, and/or storage of a scientific collection, Program Offices and Regions must execute a Material Transfer Agreement (MTA) before releasing or receiving any physical material from the collection. An MTA is a widely accepted vehicle for governing the movement of physical material between a provider and a recipient, who will then use the material for its own research purposes.

The Agency enters into MTAs under the authority of the Federal Technology Transfer Act (FTTA) [8]. Like most MTAs, the standard Agency MTA requires the recipient to acknowledge the provider when publishing research results based on the material. The standard Agency MTA also protects intellectual property by requiring the recipient to allow the provider to review any draft manuscripts before their publication. The Agency's MTA template is located at http://www2.epa.gov/ftta/document-templates-federal-technology-transfer-act-agreements.

This is in contrast to situations when a Program Office or Region wants to move materials from a scientific collection to a recipient to fulfill a Government purpose which would be funded by appropriated funds. For example, EPA may want to provide water samples from a scientific collection to a laboratory that EPA has contracted with to perform analyses on the samples, and provide the resulting data to EPA. Or EPA may wish to contract with an entity to store a scientific collection because the entity has necessary climate-controlled facilities. In these situations, a contract rather than an MTA would be used to specify the materials to be transferred, and the contractor's obligations with respect to them, including obligations related to intellectual property. Similarly, if EPA uses appropriated funds to acquire a

scientific collection from an external source, a procurement contract rather than an MTA, would be the appropriate instrument to effectuate the movement of the collection.

e. Communication Strategy

After EPA Program Offices and Regions discuss intellectual property rights with the Office of General Council (OGC) and OGC determines that intellectual property rights for their scientific collections have been secured, and that disclosing the collection will not reveal confidential business, personal privacy or other privileged information (see Subsection d. Safeguards for Privacy, Confidentiality, and Intellectual Property), information about their collections should be communicated to the Office of the Science Advisor, who will register their scientific collections in the USFSC Registry (http://usfsc.grscicoll.org/).

This registry is a community-curated, comprehensive clearinghouse of information about object-based scientific collections that are owned and/or managed by US Federal Government departments and agencies. Each collection record includes information such as: collection name; collection description; collection content (e.g., sediments, fish tissue, human biosamples); preservation type (storage environment and sample treatment; and, primary contacts. The USFSC Registry automatically transfers collection information into the Global Registry of Scientific Collections (GRSciColl) (http://www.grscicoll.org). GRSciColl is an online portal through which researchers can search for and access information about collections across all scientific disciplines. It is operated by Scientific Collections International (SciColl) (http://www.scicoll.org), a global consortium that promotes the use and impact of object-based scientific collections to promote international and interdisciplinary collaboration.

The Office of the Science Advisor will also be responsible for reviewing and entering EPA information placed in the IWGSC Clearinghouse (https://usfsc.nal.usda.gov/). This online clearinghouse serves as a central location for IWGSC documents and federal agency documents related to scientific collections (e.g., agency policies, best practices, and standard operating procedures).

EPA Program Offices and Regions should maintain similar identifying, detailed and descriptive information or metadata on their intranet and/or internet webpages. If deemed appropriate, each Program Office and Region will develop and display information regarding the scientific collection in the appropriate format. Formats should be consistent with Open Data Executive Order 13462, *Making Open and Machine Readable the New Default for Government Information* [9]. The information displayed may include, but is not limited to

- collection name,
- collection status (e.g., active, inactive),
- collection content,
- collection description,
- preservation type,
- access eligibility,

- contact information, and
- specimen database (e.g., metadata).

Collection Level Policy and Procedures

f. Scientific Collection Metadata

Metadata associated with scientific collections should comply with EPA's Enterprise Information Management Policy (EIMP) [10]. The EIMP establishes a standard Agency approach for managing information it produced or funded. The purpose of EIMP is to improve the ease of which information is found, understood, accessed, and used.

The Agency's Enterprise Information Management (EIM) Minimum Metadata Standards [11] provides a scalable metadata template that can be used to develop common metadata elements for Scientific Collections. To strengthen EPA's ability to manage its scientific collections, the minimum set of metadata requirements should be used by each Program Office and Region that owns, directly manages, or financially supports a scientific collection. These minimum metadata standards are extensible and can be expanded to the extent needed to comply with the 2014 OSTP memorandum on Improving the Management of and Access to Scientific Collections or to address specific programmatic or scientific collection requirements.

To enhance discovery, access, and sharing of EPA's scientific collections, Program Offices and Regions that own, directly manage, or financially support scientific collections should follow the EIMP Cataloguing Information Procedure [12] which states that datasets under the purview of the EIMP must be registered in EPA's Environmental Dataset Gateway (EDG). EDG is the EPA enterprise metadata catalogue that generates the data inventory in accordance with Open Data EO 13462 [9].

g. Scientific Collection Costs

A major component of costs incurred by scientific collections is the cost of physical housing or storage of the collection samples/specimens. Program Offices and Regions should consider the costs associated with the storage options available as part of the scientific collection planning process. The primary options are listed below:

- Collections can be maintained at an EPA facility at the Program Office or Regional expense.
- When permitted by law, collections may be stored by organizations outside of the Agency pursuant to an MTA, and if appropriate, a Memorandum of Understanding (MOU), between the Program Office or Region and the organization. By agreement, the costs for maintenance and preservation of these collections could be the responsibility of the organization.
- When permitted by law, collections may be stored by contract facilities. The costs to fund this contract would be responsibility of the Program Office or Region.

- Where permitted by law, hybrid arrangements may be used where, for example, space is contracted in a facility, with maintenance of the collection performed by EPA personnel.

h. Scientific Collection Creation or Acquisition

Initial Considerations

EPA Program Offices and Regions should address the following considerations while planning the creation or acquisition of a scientific collection, as well as the conversion of a project/working collection to a scientific collection:

- accessioning information form template; create a template based on necessary accessioning information to standardize descriptive metadata, including, but not limited to
  - accession/voucher number,
  - accession date,
  - physical collection location and date,
  - taxonomical information (e.g., strain, genus, species), and
  - project/program information;
- placement of accessioning information into the database/catalog;
- anticipated collection size;
- assignment of physical storage space to the collection;
- collection maintenance requirements (e.g., temperature, back-up power);
- anticipated collection retention time;
- contact(s) for collection supervision and information;
- location collection resides while being developed;
- location collection resides once research is complete;
- organization funding maintenance and preservation of the collection;
- transfer of custody of a specimen into the scientific collection; and
- need for an MTA.

Newly created scientific collections should follow specific Program Office or Regional requirements for sample/specimen storage, retrieval, and retention. Metadata generated through the creation of a scientific collection or the transfer of a scientific collection should be maintained electronically. Access to this information may be made public according to the requirements of the Program Office or Region that maintains the scientific collection (see Subsection h. Scientific Collection Access). Electronically accessioning into a standardized database should also be considered because it will enable tracking and public access of digital information for new collections as previously discussed in Subsection e. Communication Strategy.

Need for Quality Assurance Project Plans

EPA requires that all environmental data used in decision making be supported by an approved project specific Quality Assurance Project Plan (QAPP) [13, 14]. The collection of objects/specimens for a scientific collection must be conducted using approved QAPPs.

QAPPs integrate all technical and quality aspects of a project, including planning, implementation, and assessment, and typically describe the environmental conditions under which samples must be maintained/stored. Organizations that conduct environmental data operations on behalf of EPA through contracts, financial assistance agreements, and interagency agreements must follow *EPA Requirements for Quality Assurance Project Plans* [13]. The same Agency requirements are also found in *The EPA Quality Manual for Environmental Programs* [14], which must be followed by internal EPA organizations. QAPPs are developed and followed for each project. An ongoing program, which may be composed of multiple projects, may retain the samples beyond the length of the project to support the larger program, thereby creating a scientific collection. Consequently, the owner of the scientific collection must make a determination whether the existing QAPP adequately addresses any additional requirements for long term storage of the samples/specimens.

Acquisition of Collections from External Organizations

Acquisition of a scientific collection or samples/specimens means they are either obtained via donation or purchased. Program Offices and Regions are responsible for developing an MTA when a scientific collection or samples/specimens are obtained from an external organization, such as another federal agency. A contract is needed when appropriated funds are used to purchase a collection or samples/specimens. For additional information on MTAs see Subsection d. Safeguards for Privacy, Confidentiality, and Intellectual Property.

i. Scientific Collection Access

EPA Program Office and Regional scientific collections are for the purpose of supporting the scientific program under which they were created and are maintained. Scientific collections are a finite resource. Access to the physical material from a scientific collection, via direct access, may be made available to requestors only when there is a mutual benefit to both the program that owns the collection and the requestor. Access means the scientific collection or samples are temporarily provided to the requestor for a determined period of time such as a loan. Material given to a requestor permanently is considered a transfer. For additional information on transferring samples/specimens or entire scientific collections see Subsection j. Scientific Collection De-accession, Transfer and Disposal.

Access requests should be made in writing to the manager of the program (typically the contact person) outlining the material requested and the purpose of the research. Requests, both internal and external to the Agency will be considered by the appropriate scientific collection Program Manager and any appropriate additional managers. Program Offices and Regions will determine the appropriate level, or levels, of approval needed prior

to the release of any scientific collection material. To support transparency and accessibility of the scientific collections, Program Offices and Regions should comply with the EPA Scientific Integrity Policy [15], which expects timely responses to requests for information, by the media, the public or the scientific community.

Requests should be evaluated against a predetermined set of criteria according to the Program Office's and Region's mission, and a response should be made to the requestor in a timely manner regarding the access or release of samples. Criteria to allow access to collection materials include, but are not limited to

- Purpose of the requestor's research is consistent with the purpose under which the scientific collection was created, efforts of the activity or program, or other EPA efforts.
- Potential significance of research/investigation.
- Requestor will share research results, including data and analysis with the donating Program Office or Region.
- Quantity of the requested sample or specimen is within the total allowable quantity identified by the providing program (allowable quantity to be loaned is determined on a sample/specimen by sample/specimen basis depending on the amount needed to be reserved to maintain a sufficient quantity of the collection for the providing program's purposes; allowable quantity to be loaned equals the total sample or specimen quantity minus the reserved quantity).
- Quantity of samples or specimens requested does not exceed over half the allowable quantity to be loaned.
- Access to the sample will not result in the total sample's integrity being compromised.
- Access to the collection and its metadata does not compromise national interests or security, or violate copyright, international or tribal agreements, confidentiality, privacy or other laws and regulations.

In the event that access must be restricted, access shall be limited to the minimal subset of specific objects and data possible, with all other collection content made public; where possible, redaction of specific metadata fields should be favored over limiting access to the entire collection or subset.

Program Offices and Regions may find it advantageous to develop detailed instructions for physical access to their scientific collections, such as

- procedures to properly aliquot, or parse, specimens and analytes to ensure ease of distribution;
- procedures used to respond to and accommodate physical access and loan requests;
- a standard timeline for responses to a request;
- preparation of the MTA; and
- a process to log and document physical access to the collection.

If the Program Office or Region decides to allow the external requestor physical access to specific scientific collection specimens/samples, it must develop an MTA prior to the material being temporarily given to the requestor. For additional information on MTA see Subsection d. Safeguards for Privacy, Confidentiality, and Intellectual Property.

When available and where not prohibited by law, Program Offices and Regions should consider making all digital files describing or characterizing the object in the collection, freely and easily accessible to the public in the highest available fidelity and resolution, including but not limited to, photographs, videos, and digital 3D models, and associated records and documentation, describing or characterizing objects in their scientific collections. They may also find it advantageous to develop detailed instructions to allow digital access to the scientific collection, such as

- step by step instructions and timelines for the process of providing digital public access to newly accessioned specimens,
- a detailed description of which records or specimen metadata fields are restricted from disclosure and why,
- a timeline from accession of a specimen to digital public access, and
- a detailed description of which records and metadata to be redacted.

j. Scientific Collection Management

EPA does not have agencywide standards for the long-term preservation, maintenance, and accessibility of its scientific collections, but rather, allows these elements to be addressed by the collecting and/or managing Program Office or Region because of the variety of program needs and collections that that may have specific requirements. For example, the Office of Research and Development Policy and Procedures Manual (Section 13.4 Quality Assurance/Quality Control Practices for ORD Laboratories Conducting Research) provides directions on storing samples, in both the short term for projects or in the long term for scientific collections. The Office of Pesticide Programs addresses sample storage, retrieval, and retention in general, whether or not for a long term scientific collections, under 40 CFR Part 160, Good Laboratory Practice Standards [16]. More specific standard operating procedures (SOPs) may be used by sub-organizations within the Program Offices and Regions that cover the collections specific to their purpose.

Program Offices and Regions should create and/or follow SOPs that address the following components to assist in the management of scientific collections:

- procedures used to process, handle, maintain, track, and transfer specimens;
- procedures used to store specimens in facilities devoted to long-term collection storage, including best practices for the long-term storage of scientific collections;
- procedures used to periodically conduct an inventory to ensure accountability of the collection;
- procedures used to physically label specimens with catalog numbers or other unique identifiers linked to the corresponding record in the scientific collection log/database; and

- a contract agreement and/or an MTA and, if appropriate, an MOU between Program Office or Region and a non-agency custodial facility, or contract facility such as university or contract repository.

k. Scientific Collection De-accession, Transfer and Disposal

The decision to de-accession for the purpose of transferring or disposing of a whole collection or individual samples/specimens is made by the collection owner, in accordance with the appropriate procedures in the Program Office or Region, after careful review of the research and educational value of the collection and resources needed to maintain the collection. There are multiple reasons for transferring or disposing of these scientific collections, many of which are discussed below. Generally, these collections are maintained as long as they remain useful to the Agency. The procedures described below adhere to the requirements listed in 42 U.S.C. Section 6624 [3] that must be taken prior to the transfer or disposal of Federal scientific collections.

Scientific collection managers/custodians should annually consider the status of their collection(s). This could be done as part of the annual process in which they submit a statement to their management verifying that their scientific collections are managed in accordance with this policy (see Subsection a. Policy Implementation and Collection Oversight). It is recommended that they consider the following conditions to assist in determining whether to transfer or dispose of a sample(s) or the entire collection. These conditions should also be considered when a requestor would like to permanently obtain a sample(s)/specimen(s), which is done through a transfer:

- lack of significance, relevance or usefulness to the mission and goals of the Program Office, Region, or Agency regarding research or education;
- opportunity to upgrade or reduce duplication in a collection;
- deterioration, damage, or alteration occurred that is beyond repair or requires excessive resources to repair, considering the significance of the collection;
- lack of proper storage capacity within current Agency facilities;
- lack of funding to adequately maintain collections;
- lack of sample/specimen documentation and metadata; thereby significantly reducing usefulness for research or education;
- destructive sampling procedures occurred during previous use that rendered the sample/specimen(s) useless for its intended purpose; and
- consumption of most of the sample/specimen, thereby leaving an insignificant quantity of sample/specimen; or consumption of the entire sample/specimen.

Once the determination to transfer or dispose has been made, but prior to removal of scientific collection material, the managing Program Office or Region should announce their intent to transfer or dispose both internally and externally to the Agency. This intent could be announced on an associated EPA website as described in subsection e. Communication Strategy, or among stakeholder groups such as the relevant research and teaching community. Collection owners should also notify the Office of the Science Advisor who will announce the intent to de-accession the collection in the USFSC Registry (http://usfsc.grscicoll.org/) and the IWGSC Clearinghouse (https://usfsc.nal.usda.gov/). If Program Offices and Regions announce their intent to dispose of a scientific collection they

should wait a minimum of 60 days from the time of the announcement until disposal occurs. This allow interested parties sufficient opportunity to contact collection owners of their interest in obtaining the collection via transfer.

The managing Program Office or Region has final authority in deciding which entity shall receive the entire collection or part of it. However, EPA Program Offices and Regions must be given priority in the event external parties are also interested in owning the collection or individual sample material. If there is no Agency interest, then priority is given to other Federal agencies, then non-Federal institutions that will continue to make the collections and its metadata accessible for research and education.

Transfer

Transfer of a scientific collection infers not only the permanent physical transfer of specific samples/specimens or the entire collection, but also future ownership and responsibilities associated with the maintenance of these collections. Transfer of the physical material between Agency Program Offices and/or Regions should be accomplished according to an agreed upon protocol, to ensure continued integrity of the material during transfer from one collection/facility to another. Transfer to an external organization requires an MTA (and if, appropriate, an MOU) between the Program Office or Region and the receiving external organization. For additional information on MTAs see Subsection d. Safeguards for Privacy, Confidentiality, and Intellectual Property. An external transfer infers the abdication of Agency ownership and responsibility. Upon transfer of a sample or collection, any lists, databases, or records of the scientific collection material should be updated to reflect the transfer of the sample(s) or collection, and the Office of the Science Advisor should be notified (see Subsection a. Policy Implementation and Collection Oversight).

Disposal

EPA Program Offices and Regions are responsible for determining whether to dispose/destroy the entire collection or individual specimens/samples. This determination can be made based on the considerations listed above. Disposal should be conducted according to the procedures or standards used by the managing Program Office or Region. Disposal must be done according to Federal Management Regulation 41 CFR Part 102-36 [17], which allows the disposal of government property. Disposal options must comply with applicable laws and regulations including hazardous waste rules if there are high contaminant concentrations (i.e., samples stored in formalin or ethanol). Upon disposal of a sample(s) or collection, any lists, databases, or records of the scientific collection material should be updated to reflect disposal of the sample(s) or collection, and the Office of the Science Advisor should be notified (see Subsection a. Policy Implementation and Collection Oversight).

IX. SIGNATURE

Thomas A. Burke, Ph.D., MPH
EPA Science Advisor

11/30/15
Date

Appendix 1: SUMMARY OF EPA SCEIENTIFIC COLLECTIONS

Freshwater Fish Samples

- Great Lakes Fish Monitoring and Surveillance Program: Homogenized whole body lake trout and walleye collected annually as a composite of each of the Great Lakes from 1972 - Present
  The Great Lakes Fish Monitoring and Surveillance Program (GLFMSP) has been collecting whole fish tissue samples for chemical analysis at set locations in all five Great Lakes. The GLFMSP Archive is a collection of approximately 4000 sample jars consisting of homogenized whole body lake trout and walleye as composites. Samples are maintained at the Great Lakes Water Institute at the University of Wisconsin at Milwaukee. Collection is owned by EPA's Great Lakes National Program Office.

- 2010 Great Lakes Human Health Fish Tissue Study
  The Great Lakes Human Health Fish Tissue Study was initiated in 2010 under the Agency's National Coastal Condition Assessment (NCCA) and is the first statistically based study of fish contamination in the Great Lakes Study. Fish samples were collected from 157 randomly selected sites throughout the five Great Lakes, and fillet tissue samples were analyzed for mercury, polychlorinated biphenyls (PCBs), polybrominated diphenyl ethers (PBDEs), and perfluorinated compounds (PFCs). The fillet samples were also analyzed for omega-3 fatty acids. Results for PFCs were published in 2014. Other results are expected to be reported in 2016. The archive contains 375 jars of fish fillet tissue samples being stored at a contracted facility. Collection is owned by EPA's Office of Water.

- 2013–14 National Rivers and Streams Assessment Fish Tissue Study
  The 2013-14National Rivers and Streams Assessment (NRSA) included a national study of contaminants in the fillet tissue of fish collected from 361 randomly selected sampling locations in the Nation's rivers. Fillet samples are being analyzed for mercury, polychlorinated biphenyls (PCBs), and perfluorinated compounds (PFCs). EPA anticipates having fish tissue results available to report during 2017. Samples are being stored at a contracted facility. The archived tissue collection is under development through the end of 2015. Collection is owned by EPA's Office of Water.

Freshwater Biota Samples

- Great Lakes Plankton and Benthos Monitoring Program: Zooplankton, phytoplankton and benthos samples collected biannually in each of the Great Lakes from 1983 - Present
  The Great Lakes Plankton and Benthos Monitoring Program conducts biannual surveys within all of the five Great Lakes. During each survey, approximately 150 zooplankton and between 75 and 125 phytoplankton samples are taken, analyzed and archived. The samples are part of a long term trends program to determine the biological health of the Great Lakes. Samples are stored at the Great Lakes Water Institute at the University of Wisconsin at Milwaukee. Collection is owned by EPA's Great Lakes National Program Office.

- Freshwater Genetic Biodiversity Collection
  EPA's Freshwater Genetic Biodiversity Collection contains various freshwater (lakes, rivers, and streams) benthos samples from around the U.S. The bulk of this material is used in DNA barcoding and/or other genetics/genomics research (e.g., using genetic diversity as an indicator of ecosystem condition and sustainability). DNA extracts are maintained long term, however, the originating physical specimen is only maintained for several years until analysis is completed. Collection is owned by EPA's Office of Research and Development.

Marine Fish and Invertebrate Samples

- Histopathology Microslides and Paraffin Blocks
  The EPA Atlantic Ecology Division (AED) histopathology microslide collection contains over four decades of fish and invertebrate tissue samples representing most groups of marine species. The slides span years 1967 through present, and paraffin tissues blocks from 1980. Slides of over 81400 animals comprise both reference and affected marine animals, including 381 cases of disease in marine animals that have been accepted into the Registry of Tumors in Lower Animals (RTLA). These were first described in the animals within the collection dating from 1967-1997. Samples were obtained from field collection, toxicology experiments, and referred pathology and disease cases from around the world. This collection represents historical progression and records of the state of marine animal health, which aids studies that predict risk to marine populations into the future. Samples are currently maintained at AED, Narragansett, RI. Collection is owned by EPA's Office of Research and Development.

Air Deposition Samples

- Integrated Atmospheric Deposition Network (binational): Residuals of processed samples collected at five sites from 2006 - Present and raw samples collected at two sites from 2003 - Present
  The Integrated Atmospheric Deposition Network (IADN) is a long-term binational air deposition monitoring network that has been in continuous operation since 1990. IADN determines the loadings of toxic contaminants to the Great Lakes, tracks the effectiveness of toxic reduction efforts, and identifies sources for additional reduction efforts. Through a cooperative agreement with Indiana University, IADN collects air and precipitation samples at five sites along the shores of the Great Lakes. Air and particle samples are collected for 24 hours every 12 days. Precipitation samples are integrated over a month. Every sample is extracted, concentrated, cleaned up and fractionated, and then analyzed for a broad suite of toxic contaminants using gas chromatography and gas chromatography mass spectrometry. There are two types of samples in the collection. The first is a residual of each processed sample. There are about four archived vials (4ml and 2ml) per sample depending on the solvent fractionation and analytical methods applied. The 4 ml vials are generally kept for a minimum of 5 years (current archive dates back to 2006) while the 2 ml vials date back to 2005. The second type of archived sample is raw subsamples from a high volume air samplers at Chicago and Cleveland sampling sites consisting of approximately 25 grams of XAD resin. Raw samples date back to about 2003. Archived samples are stored and managed by Indiana University. Collection is owned by EPA's Great Lakes National Program Office.

Aerial Photographs

- Remote Sensing Archive
  The EPA Environmental Photographic Interpretation Center (EPIC) provides a wide range of remote sensing and aerial photographic analyses in support of investigations under Superfund, the Resource, Conservation and Recovery Act (RCRA), or the Clean Water Act (CWA). EPIC completes approximately 150 site characterizations annually using current and historical aerial photographs. Site characterization provides detailed information about a site and its history, often going back as many as 70 years. Collection is owned by EPA's Office of Research and Development.

Appendix 2: SCIENTIFIC COLLECTIONS CHECKLIST: Requirements and Recommendations for Creating, Managing and Disposing of Scientific Collections

Applicability and Scope

- ☐ Each EPA Program Office and Region should determine, as part of its existing program planning and management processes, if they have or plan to have collections subject to this policy. *(page 2)*
- ☐ EPA Program Offices and Regions with scientific collections covered by this policy should comply with this policy to the greatest extent practicable. *(page 2)*

General Policy and Procedures

- ☐ Scientific collection managers/custodians should follow this Agency policy and their Program Office's or Region's appropriate scientific collection policies and procedures. *(page 5)*
  - ☐ In the absence of specific Program Office or Regional procedures for biological materials (human, animal, plant), they should use, where feasible, the International Society for Biological and Environmental Repositories' (ISBER) Best Practices for Repositories. *(page 5)*
  - ☐ Samples and materials originally collected as part of a project but that are retained beyond project completion are considered scientific collections; therefore, they should be managed in accordance with the procedures of the collecting EPA Program Office and Region. *(page 5)*

Policy Implementation and Collection Oversight

- ☐ Each Program Office and Region is responsible for determining the organizational and management level that will best provide oversight for each scientific collection, as well as collective oversight of all scientific collections within that organization, to ensure compliance with this policy. *(page 5)*
- ☐ To assist in determining implementation of and compliance to this policy, the manager/custodian of each scientific collection, in concurrence with the appropriate management level, must annually submit to their Assistant Administrator or Regional Administrator, a statement verifying that their scientific collection is adhering to this policy. *(page 5)*
- ☐ The Office of the Science Advisor will annually review the status of EPA's scientific collections and update the record of these collections in the registry of US Federal Scientific Collections, and will manage EPA's contributions to the IWGSC Clearinghouse. *(page 6, 8)*

Policy and Collection Funding

- ☐ Each Program Office and Region determines the appropriate organizational level to budget for and fund scientific collections as well as implement this policy. *(page 6)*

Organizational and Collection-Specific Policy Discrepancies

- ☐ In the event that there is a discrepancy between this policy and those of the Program Offices and Regions, the policies and procedures described in this policy should generally take precedent over those of the Program Offices and Regions unless this policy indicates that Program Offices and Regions have the flexibility to determine how or whether to perform a specific action. *(page 6)*

Individual Privacy and Confidentiality – Human Subject Research

- ☐ Collection and future use of human biospecimens as part of human subjects research must comply with Title 40 of the Code of Federal Regulation Part 26 (Protection of Human Subjects) and EPA Order 1000.17 Change A1 (Policy and Procedures on Protection of Human Research Subjects in EPA Conducted

or Supported Research), to protect individual privacy and confidentiality until transfer or disposal of the specimen/collection. *(page 6)*

Intellectual Property and Confidential Information

- [ ] Program Offices and Regions should consider the effect that disclosing the collection or associated information would have on intellectual property rights, and should consult with whomever may be able to claim intellectual property rights when deciding on the appropriate time to release/allow access to the collection and associated information. *(page 7)*
- [ ] Program Offices and Regions must also determine whether releasing/allowing access to a scientific collection and associated information would disclose confidential business information, personal privacy information or other privileged information, and should consult the Agency's public information regulation to ensure that access to scientific collection and associated information is conducted in accordance with the applicable information disclosure laws. *(page 7)*
- [ ] A Materials Transfer Agreement (MTA) must be executed prior to the release or receipt of any scientific collection physical material to or from an entity external to EPA. *(pages 7, 11, 13, 15)*

Communication

- [ ] Program Offices and Regions should maintain identifying, detailed and descriptive information about their scientific collections on their intranet and/or internet webpages, and it should be consistent with the Executive Order on *Making Open and Machine Readable the New Default for Government Information*. *(page 8)*

Scientific Collection Metadata

- [ ] Metadata associated with scientific collections should comply with EPA's Enterprise Information Management Policy (EIMP). *(page 9)*
- [ ] To strengthen EPA's ability to manage its scientific collections, the minimum set of metadata requirements, as found in the Agency's Enterprise Information Management (EIM) Minimum Metadata Standards, should be used by each Program Office and Region that owns, directly manages, or financially supports a scientific collection. *(page 9)*
- [ ] Program Offices and Regions that own, directly manage, or financially support scientific collections should follow the EIMP Cataloguing Information Procedure which states that datasets under the purview of the EIMP must be registered in EPA's Environmental Dataset Gateway (EDG). *(page 9)*

Scientific Collection Costs

- [ ] Program Offices and/or Regions should consider the costs associated with the storage and maintenance options available as part of the scientific collection planning process. *(page 9)*

Scientific Collection Creation or Acquisition

- [ ] Program Offices and Regions should address the 12 considerations found in Subsection g. while planning the creation or acquisition of a scientific collection, as well as the conversion of a project/working collection to a scientific collection. *(page 10)*
- [ ] Newly created scientific collections should follow specific Program Office or Regional requirements for sample/specimen storage, retrieval, and retention. *(page 10)*
- [ ] Metadata generated through the creation of a scientific collection or the transfer of a scientific collection should be maintained electronically. *(page 10)*
    - [ ] Access to this information may be made public according to the requirements of the Program Office or Region that maintains the scientific collection. *(page 10)*
    - [ ] Electronically accessioning into a standardized database should be considered. *(page 10)*
- [ ] The collection of objects/specimens for a scientific collection must be conducted using approved Quality Assurance Project Plans (QAPPs). *(page 11)*

- ☐ The owner of the scientific collection must make a determination whether the existing QAPP adequately addresses any additional requirements for long term storage of the samples/specimens. *(page 11)*

Scientific Collection Access

- ☐ Program Offices and Regions will determine the appropriate level, or levels, of approval needed prior to the release of any scientific collection material. *(page 11)*
- ☐ Access requests should be evaluated against a predetermined set of criteria, and a response to requested access should be given in a timely manner. *(page 12)*
- ☐ In the event that access must be restricted, access shall be limited to the minimal subset of specific objects and data possible, with all other collection content made public; where possible, redaction of specific metadata fields should be favored over limiting access to the entire collection or subset. *(page 12)*
- ☐ Program Offices and Regions should consider making all digital files describing or characterizing the object in the collection, freely and easily accessible to the public in the highest available fidelity and resolution. *(page 13)*

Scientific Collection Management

- ☐ Program Offices and Regions should create and/or follow SOPs that address the components listed in Subsection i., to assist in the management of scientific collections. *(page 13)*

Scientific Collection De-accession, Transfer and Disposal

- ☐ The procedures described on page 15 adhere to the requirements listed in 42 U.S.C. Section 6624 that must be taken prior to the transfer or disposal of Federal scientific collections. *(page 14)*
- ☐ Program Offices and/or Regions should annually consider the conditions listed in Subsection j., to assist in determining whether to transfer or dispose of a sample(s) or the entire collection. *(page 14)*
- ☐ Once determination to transfer or dispose has been made, but prior to removal of scientific collections material, the managing Program Office or Region should announce their intent to transfer or dispose both internally and externally to the Agency and should also notify the Office of the Science Advisor. *(page 14)*
- ☐ Program Offices and Regions should wait a minimum of 60 days from the time of the announcement of their intent to dispose until disposal. *(page 15)*
- ☐ Priority transfer must be given to EPA Program Offices and Regions over external entities, and transfer should be accomplished according to an agreed upon protocol. *(page 15)*
- ☐ Disposal should be conducted according to the procedures or standards used by the managing Program Office or Region and must be done according to Federal Management Regulation 41 CFR Part 102-36, which allows disposal of government property. *(page 15)*
- ☐ Disposal options must comply with applicable laws and regulations. *(page 15)*
- ☐ Upon transfer or disposal of a sample(s) or collection, any lists, databases, or records of the scientific collection material should be updated to reflect transfer or disposal of the sample(s) or collection, and the Office of the Science Advisor should be notified. *(page 15)*

Appendix 3: TERMS AND DEFINITIONS

Accessioning refers to the process of recording the addition of a new specimen(s) into the scientific collection.

Associated Specimen Data refers to the metadata associated with the physical object in the scientific collection.

De-accessioning is the process of removing a specimen(s) or whole collection from ownership through transfer or disposal.

Human Subject is a living individual about whom an investigator (whether professional or student) conducting research obtains (1) Data through intervention or interaction with the individual, or (2) Identifiable private information, as defined in 40 CFR Part 26 Protection of Human Subjects.

Intellectual Property includes patentable inventions, copyrighted works, trade secrets and trademarks. For purposes of this policy, intellectual property also includes information that will be safeguarded before intellectual property rights are established.

Metadata are structured information describing content, data resources, or objects, which help locate, use, understand, share, and manage these information sources. Metadata should answer questions about the scientific collection content such as its purpose, date, location, and means collection, object/specimen descriptors, and name of the organization and collector.

Project Collection (or working collection) refers to a set of physical objects intended for short-term storage and use, relates to a discrete project or study, and are not intended for long-term preservation.

Quality Assurance Project Plans integrate all technical and quality aspects of a project, including planning, implementation, and assessment, and typically describe the environmental conditions under which samples must be maintained/stored.

Scientific Collection (or institutional collection) is a set of living or inanimate physical objects, and as appropriate and feasible the associated specimen data and material, that is created for the purpose of supporting science, and is preserved, cataloged, and managed as a long-term research asset rather than for its market value as a collectible or its historical, artistic, or cultural significance.

Voucher Collection is a set of physical objects previously collected and which critical analysis and observations have been performed, and are preserved with the intent of being used in future research, to either repeat original analysis to corroborate published findings or to apply new analytical techniques.

Appendix 4: REFERENCES

[1] National Science and Technology Council, Interagency Working Group on Scientific Collections (2008) *Scientific Collections: Mission-Critical Infrastructure for Federal Science Agencies* http://www.whitehouse.gov/sites/default/files/sci-collections-report-2009-rev2.pdf

[2] Executive Office of the President, Office of Science and Technology Policy (2010) Memorandum: *Policy on Scientific Collections* http://www.whitehouse.gov/sites/default/files/microsites/ostp/ostp-2010-scientific-collections.pdf

[3] United States Code (2011) Title 42, Chapter 79, Subchapter II, Section 6624 *Federal Scientific Collections* http://www.gpo.gov/fdsys/pkg/USCODE-2011-title42/html/USCODE-2011-title42-chap79-subchapII-sec6624.htm

[4] Executive Office of the President, Office of Science and Technology Policy (2014) Memorandum: *Improving the Management of and Access to Scientific Collections* http://www.whitehouse.gov/sites/default/files/microsites/ostp/ostp_memo_scientific_collections_march_2014.pdf

[5] International Society for Biological and Environmental Repositories (2012) *Best Practices for Repositories: Collection, Storage, Retrieval and Distribution of Biological Material for Research* http://c.ymcdn.com/sites/www.isber.org/resource/resmgr/Files/ISBER_Best_Practices_3rd_Edi.pdf

[6] Code of Federal Regulations (2010) Title 40, Part 26 *Protection of Human Subjects* http://www.gpo.gov/fdsys/pkg/CFR-2010-title40-vol1/xml/CFR-2010-title40-vol1-part26.xml

[7] U.S. Environmental Protection Agency (2011) Order 1000.17 Change A1 *Policy and Procedures on Protection of Human Research Subjects in EPA Conducted or Supported Research* http://www.epa.gov/osa/phre/pdf/epa-order-1000_17-a1.pdf

[8] U.S. Government Printing Office (1986) Public Law 99-502 *Federal Technology Transfer Act* http://www.gpo.gov/fdsys/pkg/STATUTE-100/pdf/STATUTE-100-Pg1785.pdf

[9] Executive Order of the President (2013) *Making Open and Machine Readable the New Default for Government Information* http://www.whitehouse.gov/the-press-office/2013/05/09/executive-order-making-open-and-machine-readable-new-default-government-

[10] U.S. Environmental Protection Agency (2015) Information Policy, *Enterprise Information Management Policy (EIMP)*, (Chief Information Officer Transmittal No. 15-004, Classification No. CIO 2135.0, Approval Date 3/3/2015) http://www2.epa.gov/sites/production/files/2015-08/documents/cio-2135-0.pdf

[11] U.S. Environmental Protection Agency (2015) Information Standards, *Enterprise Information Management (EIM) Minimum Metadata Standards*, (Chief Information Officer Transmittal No. 15-004, Classification No. 2135-S-01.0, Approval Date 3/3/2015) http://www2.epa.gov/sites/production/files/2015-08/documents/cio-2135-s-01-0.pdf

[12] U.S. Environmental Protection Agency (2015) Information Procedure, *Enterprise Information Management Policy (EIMP) Cataloguing Information Procedure*, (Chief Information Officer Transmittal No. 15-004, Classification No. 2135-P-01.0, Approval Date 3/3/2015) http://www2.epa.gov/sites/production/files/2015-08/documents/cio-2135-p-01-0.pdf

[13] U.S Environmental Protection Agency (2001) EPA/240/B-01/003 *EPA Requirements for Quality Assurance Project Plans* (EPA QA/R-5) http://www.epa.gov/quality/qs-docs/r5-final.pdf

[14] U.S. Environmental Protection Agency (2000) CIO2105-P-01-0 (formerly 5360 A1) *The EPA Quality Manual for Environmental Programs* http://www.epa.gov/irmpoli8/policies/2105P010.pdf

[15] U.S. Environmental Protection Agency (2014) *Scientific Integrity Policy* http://www.epa.gov/research/htm/scientific-integrity.htm

[16] Code of Federal Regulations (2011) Title 40, Part 160 *Good Laboratory Practice Standards* http://www.gpo.gov/fdsys/pkg/CFR-2011-title40-vol24/xml/CFR-2011-title40-vol24-part160.xml

[17] Code of Federal Regulations (2006) Title 41, Part 102-36 *Federal Management Regulation; Disposition of Excess Personal Property* https://federalregister.gov/a/E6-15042