SMG 9005.1

FDA STAFF MANUAL GUIDES, VOLUME IV – AGENCY PROGRAM DIRECTIVES

GENERAL OR MULTIDISCIPLINE

SCIENTIFIC COLLECTIONS MANAGEMENT AND ACCESS POLICY

Effective Date: 10/05/2015

1. PURPOSE

Within the Department of Health and Human Services, the Food and Drug Administration protects the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation, as well as regulating tobacco products. In that role, FDA's permanent institutional scientific collections are agency assets that serve as important, primary resources for scientific reference, research, and discovery. The proper management and stewardship of the agency's scientific collections is critical to maintain their value. Public access to these valuable scientific collections is central to FDA's mission and the agency's regulatory science efforts. The availability of agency scientific collections advances public health by sparking scientific discovery and prompting the scientific community to address critical challenges in food safety, tobacco product regulation, and medical product development.

FDA shares the objectives of transparency and maximizing public access to FDA scientific collections, where feasible and appropriate. Accordingly, this document establishes policy, responsibilities, and procedures for the management of and access to scientific collections.

2. BACKGROUND

Beginning in 2005, the White House's Office of Science and Technology Policy (OSTP) and Office of Management and Budget (OMB) included in its priorities for interagency activity a call to "focus attention on integrated support and planning for the care and use of federally held scientific collections." This call gave rise to the formation of an Interagency Working Group on Scientific Collections (IWGSC) under the Committee of Science of the National Science and Technology Council (NSTC). The IWGSC issued a report in December 2008 that made seven recommendations for the improvement of management, accessibility, and impact of scientific collections owned by U.S. government departments and agencies.

On March 20, 2014, the White House Office of Science Technology and Policy (OSTP) issued a memorandum to the heads of executive departments and agencies entitled “Improving the Management of and Access to Scientific Collections.” In the memorandum, OSTP asks federal agencies that own, maintain or otherwise financially support permanent scientific collections to develop a scientific collections management and access policy.

3. DEFINITIONS

A. Scientific Collections

Scientific collections are sets of physical specimens, living or inanimate, and their supporting records and documentation. A collection is a set of specimens that are cataloged together in one database or using a single numbering system. Scientific collections are long-term research assets, as opposed to an expendable research supply. They are created for the purpose of supporting or doing science, rather than for their market value as collectibles or their historical, artistic, cultural, or other significance. For the purposes of this Staff Manual Guide (“Guide”), scientific collections are classified as follows:

1. Institutional Collections

This category of specimen-based scientific collections consists of specimens that have been identified for long-term preservation and management. Institutional collections are preserved, cataloged, and managed or supported for research, resource management, education, and other uses. Institutional collections serve as permanent or long-term research assets. Specimens in a federal research laboratory, or on federal property, are not necessarily, or automatically, part of an institutional scientific collection.

A key indication of whether a scientific collection constitutes an institutional collection is whether the collection has been, is intended to be, or should be well-managed for its long-term preservation as an important resource – that

is, whether the collection contains specimens that are, are intended to be, or should be:

- subject to a formal accessioning process when entering a collection, along with their associated documentation and archival material (e.g., notes, photographs, and maps);
- under the authority of scientific collection directors and housed in facilities devoted to long-term collection storage;
- inventoried on a schedule determined by the agency to ensure accountability of the collection;
- physically labeled in some way with catalog numbers or other unique identifiers linked to a corresponding record in a database or other record-keeping system;
- routinely made available to all qualified users, with certain exceptions;
- made available to qualified parties through formal loan procedures for research, education, or exhibition; and
- preserved long-term, except under certain infrequent conditions which may justify deaccessioning under a set of deaccessioning procedures.

2. Project Collections

Project collections are sets of specimens that are not intended for long-term preservation and management. Furthermore, these specimens are not being stored for future research, resource management, or educational value. Instead, these sets are less formal scientific collections that have been preserved as they relate to a discrete project, study, or because of the interest of a particular researcher or employee.

A key indicator of a project collection is that the collection is informally managed with no intention of long-term preservation for the benefit of the public or the institution. Project collections contain specimens that are, are intended to be, or should be:

- primarily used and managed by the research staff associated with a particular project or study;
- commonly housed in research spaces not designed for long-term collection storage;

- made accessible through informal sample sharing, Material Transfer Agreements, or loan procedures to the research community at the discretion of those associated with the project;

- completely expended or consumed by destructive analytical techniques used by the research project, or for other purposes such as education that may result in their degradation or destruction; and/or

- documented in non-standardized ways.

B. Specimen Metadata

Specimen metadata is information that describes a specimen that is part of a scientific collection. Generally, metadata makes a specimen uniquely identifiable and more easily searchable. Specimen metadata also often provides important scientific information about the specimen that may have its own research or educational value. Examples of specimen metadata include:

- source specific information (e.g., date of isolation, source, etc.);

- phenotypic and genotypic scientific information (e.g., toxin producer, serotype, PFGE or sequence type);

- species and strain identification; and

- digital images of macroscopic specimens or cultures of microscopic specimens.

C. Specimen Record

A specimen record is composed of all metadata for a single specimen in a scientific collection.

D. Scientific Collection Database

A scientific collection database is a listing or database of all specimen records.

E. Scientific Collection Record

A record of a scientific collection, or a scientific collection record, is a descriptive guide to a scientific collection. The record contains essential information such as the title of the scientific collection, contact information, and the physical location of the specimens. Each scientific collection record is made available to the public via an online registry and points to the location of the associated scientific collection database.

F. Scientific Collection Registry

A scientific collection registry is defined as an online digital repository that stores and makes publicly available agency scientific collection records, and as appropriate, the scientific collections database associated with the collection. The Interagency Working Group on Scientific Collections and the Smithsonian Institution have identified the registry of US Federal Scientific Collections (USFSC) (http://usfsc.GRSciColl.org) as an appropriate federal scientific collection registry and the agency has chosen to adopt USFSC as its scientific collections registry to host scientific collection records.

G. FDA Center/Office

The terms, “FDA Center/Office” or “Center/Office,” are used to refer to one of FDA’s core operating components—namely the Office of Regulatory Affairs, the Center for Food Safety and Applied Nutrition, the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, the Center for Devices and Radiological Health, the Center for Veterinary Medicine, Center for Tobacco Products, and the National Center for Toxicological Research, and other agency components that may own or manage institutional scientific collections, including offices within the Office of the Commissioner.

4. SCOPE

This Guide applies to all current and future institutional scientific collections that the agency owns or manages. This Guide does not apply to project collections.

This Guide does not apply to institutional collections that are owned by the agency, but managed by other federal agencies pursuant to an interagency agreement, provided the managing federal agency has in place a scientific collections policy developed pursuant to the 2014 OSTP *Improving the Management of and Access to Scientific Collections* memorandum.

This Guide applies to institutional collections that are owned by the agency, but managed by:

- non-federal third parties through a contract, grant, or assistance agreement; or

- federal third parties that have not issued a scientific collections policy pursuant to the 2014 OSTP memorandum that would directly govern the scientific collection at issue.

This Guide imposes no requirements on researchers to create an institutional scientific collection or to convert project collections into institutional scientific collections. The scientific collection policy requirements described herein will be

triggered only if a researcher, together with his or her Center/Office management, chooses to create and maintain an institutional scientific collection.

This Guide does not supersede existing, or future, policies, statutes, and regulations regarding the management, possession, use, and transfer of controlled substances, biological select agents and toxins, and radionuclides.

All new institutional collections created or acquired by the agency since the issuance of this Guide must comply with all requirements regarding the creation and management of, and access to, institutional collections as described, and pursuant to the timelines prescribed, in this Guide. Within one year of the effective date of this Guide, a scientific collection master plan must be developed for existing institutional collections and begin compliance with that plan (see §6.A). Furthermore, existing institutional scientific collections must comply with the annual reporting requirements (see §6.E) by October 1, 2016.

5. RESPONSIBILITIES

A. Office of Scientific Integrity

The Office of Scientific Integrity (OSI) reports to the Chief Scientist and works with others in the Office of the Commissioner and FDA's Centers/Offices to promote FDA’s public health mission by strengthening the credibility of the agency’s science and science-based decision-making.

OSI will provide substantial assistance to Centers/Offices to implement this Guide and provide input to Centers/Offices, as necessary, on implementation strategy. OSI will coordinate and monitor the management of institutional scientific collections and provide assistance in the formation of new institutional scientific collections.

B. Senior Science Council

The Senior Science Council provides advice and guidance to the agency and Center/Office leadership on cross-cutting regulatory science planning, reporting, programs, policies, and communication. The Senior Science Council will advise and assist with the reassignment of institutional collections in the course of deaccessioning.

C. Office of Acquisitions and Grants Services

The Office of Acquisitions and Grants Services is responsible for negotiating, awarding, and managing all contracts, grants, and assistance agreements. The Office of Acquisitions and Grants Services will ensure that contracts, grants, or assistance agreements are in compliance with this Guide —per the request of cognizant program requisitioning officials. If this Guide is applicable to any

contract, grant, or assistance agreement, it is the responsibility of the requisition official to identify this in their request for contract package/memorandum of need or request for funding announcement.

D. Program Official (PO)

Contracts: The PO is responsible for ensuring that the requirements of this Guide are clearly set forth in the Statement of Work or any similar document which describes the requirements that are to be performed by a contractor. The PO is also responsible to ensure that the contractor meets the requirements under this Guide by the delivery date(s) and/or within the period of performance.

Grants: The PO is responsible for ensuring that the requirements of this Guide are clearly set forth in the Funding Opportunity Announcement and that grant recipient meets the requirements under this Guide by the delivery date(s) and/or within the period of performance. The PO also ensures that the grant applications are in accordance with instructions provided by the DHHS awarding office.

E. Office of Health Informatics

The Office of Health Informatics (OHI), led by the Chief Health Informatics Officer, examines and employs innovative concepts, tools, and informatics solutions to support the agency's mission of promoting and protecting America's public health. OHI also has the primary goal of addressing the informatics and data needs and challenges of the FDA Centers/Offices, and providing the best possible support for their individual missions.

The Office will spearhead efforts related to digital management of FDA scientific collections, and otherwise serve as a liaison to HHS and interagency working groups related to development of standards for scientific collection metadata.

F. FDA Centers/Offices

FDA Centers/Offices promote the public health through the evaluation, surveillance, and review of FDA regulated products and the enforcement of the applicable statutes and regulations. The Centers/Offices are also the agency components primarily responsible for the conduct and funding of agency scientific research.

Center Directors and Associate Commissioner for Regulatory Affairs (ACRA) ensure compliance with this Guide through oversight of designated scientific collection directors. If an FDA Center/Office owns, manages, or funds, or expects in the near future to own, manage, or fund institutional scientific collections, the Center Director or ACRA shall develop specific internal policies and procedures for the implementation of the requirements of this SMG. Center/Office -wide policies should specifically address the criteria the Center/Office will use in

determining whether the creation of an institutional collection is justified in light of the Center's/Office's mission, and what steps the Center/Office will take in periodically evaluating project collections to determine whether they should be treated as institutional collections subject to this Guide. This Guide—as described (§6)—will be issued by October 1, 2015.

G. Scientific Collection Director

Each institutional scientific collection, owned, managed, and/or funded by FDA, will have a Scientific Collection Director, often a project principal investigator, who is responsible for:

- direction and planning of the scientific collection;
- establishment of a third party contract, grant, or assistance agreement, if necessary;
- establishment, review, submission, and revision of scientific collection master plan and standard operating protocols (SOPs);
- establishment of collecting priorities to guide the development of collections;
- control, monitoring, and documentation of all access to and use of collections;
- ensuring that the SOPs are stored in designated, accessible locations and available to personnel at all times;
- ensuring that personnel reviews the SOPs, and associated trainings are recorded;
- compliance with this Guide, SOPs, and the scientific collection master plan, and annual reporting on compliance;
- delegation of authority and assignment of collection responsibility to the appropriate project staff; and
- general scientific collection management and reporting.

6. POLICY AND PROCEDURES

A. Creation or Acquisition of an Institutional Scientific Collection:

To ensure policy compliance before acquiring an institutional collection or accessioning scientific specimens into an institutional collection, the scientific collection director must receive approval of a scientific collection master plan and scientific collection SOPs by Center/Office management. The scientific collection

master plan and SOPs will be submitted to Center/Office management for review and approval according to Center/Office developed scientific collection policies. Upon review and approval by the Center/Office, the scientific collection master plan and SOPs are submitted to the Office of the Chief Scientist for review.

1. Scientific Collection Master Plan

   The scientific collection master plan provides an overall vision and plan for the creation, expansion, long-term management, disposal, and accessibility of the scientific collection. The master plan will include the following components:

   - Collection Plan (see 6.A.i.a)
   - Budget Plan (see 6.A.i.b)
   - Access Plan (see 6.A.i.c)
   - Third Party Agreement (see 6.A.i.d)

   a. Collection Plan

      Developed by the scientific collection director, a collection plan will outline the scope, basic management, and projected growth of the scientific collection.

      - General information
        - Name, contact information, and operational division for the scientific collection director
        - Purpose of institutional scientific collection
        - Date scientific collection will be established
        - Any applicable statute, regulations, or policy that must be observed during the accession, management, and deaccession/disposal of specimens (e.g., Select Agent Regulations)
      - Accession Procedure
        - Scope of specimens to be potentially included into institutional collection
        - The estimated yearly growth of the scientific collection
      - Management Procedure
        - Standards for consistent documentation of metadata

- Infrastructure requirements and proposed compliance with best practices for preservation of specimens[1]

b. Budget Plan

- Scientific collection directors must develop a realistic cost projection for collection maintenance and operation for the intended life of the institutional scientific collection. A realistic cost projection may include, but is not limited to, the costs associated with the following activities:

- acquisition and growth, including specimens collected during agency research, specimens collections based on statutory requirements, and specimens acquired from other institutions or individuals;

- documentation of specimens (accessioning, cataloging, database input) and periodic inventorying;

- sharing and loaning physical specimens and samples;

- establishing and maintaining specimen and information security relating to data access;

- staffing (salary and benefits);

- overhead expenses for infrastructure to include building renovations, fixtures, cabinets, shelving, archival boxes, bags, labels, freezers, etc.;

- space (see OMB guidance and how this may impact budgeting for space, particularly to control environmental conditions);

- emergency or contingency planning, including backup power, specialized fire protection, as appropriate; and

- special infrastructure needs assessment, including any:

  - need for higher quality infrastructure than standard office, laboratory, or other standard space (e.g., humidity and climate control, plaster ceilings, etc.);

  - additional physical security or other infrastructure or services that would be required by applicable statute, regulations, or policy (e.g.,

[1] For an example of a source of best practices for collection management, see Best Practices for Repositories: Collection, Storage, Retrieval and Distribution of Biological Materials for Research International Society for Biological and Environmental Repositories. Third Edition. http://www.isber.org/

security and procedures necessary for management of controlled substances, BSL-3 infectious agents, etc.);

- additional specialized services (e.g., liquid nitrogen and other specialized gases);
- need to back up collections to protect against catastrophic event;
- additional fire safety considerations associated with storage of flammable substances; and
- special IT infrastructure.

Prior to approving a scientific collection master plan, Centers/Offices should:

- identify specific funds to be allocated to the creation and maintenance of, and access to, the collection; and
- incorporate projected costs for collection management and growth into planned expenditures for future years.

c. Access Plan

Physical and digital access to the collections must be balanced against human resources, preservation, and security concerns. Scientific collection directors, in consultation with their Center/Office and the Office of Scientific Integrity, may be required, or will have the discretion, to temporarily or permanently limit the access to institutional scientific collections and related catalogs, databases, and records in order to:

- safeguard individual privacy, confidentiality, trade secrets, copyright, and intellectual property rights;
- adhere to laws, regulations, treaties, and international or tribal agreements;
- protect national security; and
- address or accommodate
  - resource limitations,
  - specimen availability (e.g., whether the specimen is in active use or on loan and cannot be shared),

- preservation constraints (e.g., fragility of the specimen), or
- general security concerns.

Any limits to the public access to the institutional scientific collection must be disclosed in the scientific collections master plan (the collection master plan on file should be updated, as necessary, if access restrictions arise after initial submission of the collection master plan), including:

- restrictions on physical access to the scientific collection and justification for the restriction; and
- redactions to specimen metadata and information in scientific collection records and justification for the redactions.

All restrictions on digital access shall be limited to the minimal subset of specific records and metadata as possible, with all other collection content made publicly available as described in §6.C. Where possible, redaction of specific metadata should be favored over limiting digital and physical access to the entire specimen or subset of specimens.

d. Third Party Management

The scientific collection director should include all available information about any plan to enter into an agreement with a third party for the management of the institutional scientific collection, including the following:

- if the third party is a federal agency, then include the interagency agreement with this plan (see Appendix 2 for guidelines); and
- if the third party is a non-federal agency, then include with this plan the contract, grant, or assistance agreement that serves as the basis for the non-federal party managing the agency collection.

If the actual agreement is not immediately available, then that agreement should be included in the first annual report.

2. Standard operating protocol

The scientific collections standard operating protocol provides detailed instructions to be followed by all staff charged with the creation, expansion, long-term management, disposal, and accessibility of the scientific collection. These instructions must be followed at all times and by all scientific collections personnel. The SOP will include the following components:

a. Accession Protocol

- Transfer of custody of a specimen into the scientific collection
- Procedures used to process, handle, and store the specimen
- Protocol for the timely accession of the specimen
    - Standardized descriptive metadata into the record, including, but not limited to:
        - accession/voucher number;
        - physical location;
        - accession date; and
        - strain or species information, if applicable.
    - Insertion of the record into the database/catalog
- Assignment of physical storage space to the specimen

b. Management Protocol

- Procedures used to process, handle, maintain, track, ship, and share specimens
- Procedures used to store specimens in facilities devoted to long-term collection storage, including best practices for the long-term storage of institutional scientific collections
- Procedures used to annually inventory the collection to ensure accountability of the collection
- Procedures used to physically label specimens in some way with catalog numbers or other unique identifiers linked to the corresponding record in the institutional scientific collection database
- A document control program and policies for modifying or revising the SOP

c. Access Protocol

- Detailed instructions for publishing scientific collection records and databases online, including:

- step by step instructions and timelines for the process of providing digital access to newly accessioned specimen metadata; and

- a detailed description of which records and metadata are to be redacted from digital access.

- Detailed instructions for physical access to the scientific collection, including the following:

  - outline procedures to properly aliquot, or parse, biospecimens and analytes to ensure ease of distribution;

  - a detailed description of which specimens, records, and metadata will not be available for physical access;

  - procedures used to respond to and accommodate physical access and loan requests;

  - a standard timeline to responding to a request; and

  - a process to log and document physical access to the collection.

d. Deaccession and Disposal Protocol

- Guidelines for the decision to deaccession a specimen
- A procedure for the orderly transfer of specimens to a new collection
- The proper method of disposal of the specimen(s)

B. Accessioning

The FDA acquires specimens by a variety of methods, including purchase, transfer, and field collecting. The FDA recommends responsible, disciplined acquisition of collections, and the specimens within, through the following principles:

- the acquisition or creation of collections relevant to the mission and goals of the FDA and individual laboratories,

- clear delegation of collecting authority within laboratories to avoid duplication of efforts and mishandling, and

- strict adherence to all applicable laws and regulations relating to collections acquisition.

Collections may be acquired only in accordance with established authority and only when consistent with applicable law.

As a general rule, collection items are acquired and accessioned only when there is a good faith intention to retain them in the FDA collections permanently or for the long-term. Institutional scientific collections are retained as long as they continue to serve the mission and objectives of the FDA, and can be properly maintained and used.

C. Access and use

1. Scientific Collection Registry

A scientific collection record must be deposited into USFSC within 3 months of the acquisition of the institutional scientific collection, or accession of the first specimen of the institutional scientific collection. Furthermore, a scientific collection database, including all specimen records and metadata that are not restricted from public access, must be made available online within 6 months of the acquisition of the institutional scientific collection, or the accession of the first specimen in the institutional scientific collection. The posted institutional scientific collection record in USFSC must direct users to the location of the online database.

2. Metadata Format

When constructing and formatting the institutional scientific collection metadata, scientific collection directors must employ machine-readable and open formats, data standards, and common-core and extensible metadata for all new information creation and collection to facilitate search and discoverability and provide clear public guidance for accessing collections materials, consistent with the Executive Order on Making Open and Machine Readable the New Default for Government Information.

When available and where not limited by law or this Guide, make freely and easily accessible to the public all digital metadata in the highest available fidelity and resolution, including, but not limited to, photographs, videos, and associated records and documentation, that describe or characterize specimens in a scientific collection.

3. Physical Access

Specimens within an FDA scientific collection are the property of the United States Government. FDA will provide reasonable physical access to its institutional scientific collections to qualified researchers, academics, and others as feasible, appropriate, and consistent with applicable law, regulations, and policy, the agency mission, available resources, and

pursuant to the scientific collection's SOP and master plan. In order to receive physical access to specimens, those seeking physical access to the institutional scientific collection will adhere to the procedures outlined in the collection's SOP to the satisfaction of the scientific collection director. Furthermore, access to, and use of, collected patient or subject information or specimens must adhere to applicable rules, regulations and the policies of the Research Involving Human Subjects Committee (RIHSC).

D. Deaccessioning

Deaccessioning and disposal are a legitimate part of responsible institutional scientific collections management. Prudent institutional scientific collections management includes judicious consideration of appropriate deaccessioning and disposal. The periodic review, evaluation, deaccessioning, and disposal of existing institutional scientific collections, in part or in whole, is intended to refine and improve the quality and relevance of the collections with respect to the FDA's mission and purpose.

Deaccessioning and disposal occur for a variety of reasons, such as duplication or redundancy of institutional scientific collection material; insufficient relationship of collection items to the mission and goals of the FDA such that they are judged to be better placed elsewhere; and selection for consumptive research.

Centers/Offices may prescribe additional policies and procedures for the deaccessioning of individual specimens. The decision to deaccession a specimen should be made after careful review of the resources available to manage and maintain the collection, and the research and educational value of a collection. Scientific collection directors should also consult with researchers who have used the collection, parties interested in the collection's value for research, resource management, and educational purposes, and other subject matter experts, as needed.

If an entire institutional scientific collection is to be deaccessioned, then, via the Senior Science Council, other FDA Centers/Offices and laboratories shall be given an opportunity to accept ownership of the institutional scientific collection, in whole or in part, proposed for disposal, except as otherwise stipulated by authorizing legislation or other restrictions.

Collections, or specimens within, may be deaccessioned and destroyed only in accordance with established authority of the designated scientific collection director and only when consistent with applicable law.

A notification of deaccession of an entire institutional scientific collection is submitted through the management chain of command, including the Center Director or ACRA, for notification and approval. Once the Center Director or

ACRA approves the plan, the scientific collection director will notify the Office of Scientific Integrity of the proposed deaccession. The Office of Scientific Integrity will notify the Senior Science Council about the impending deaccessioning of an institutional scientific collection.

A notice of scientific collection deaccession must contain the following information:

- name of scientific collection director and contact information;
- itemized list of specimens to be deaccessioned;
- the disposition of the collection (e.g., transferred or destroyed);
- transfer recipient, if applicable;
- date(s) deaccession approved by Center/Office;
- proposed deaccession date; and
- proposed date of transfer or destruction.

A final notification must be sent to the Office of Scientific Integrity once the entire institutional scientific collection has been either transferred or destroyed.

E. Annual Reporting

To maintain proper oversight of the management of the scientific collection, the scientific collection director must submit an annual report to Center/Office management within 30 days prior to the start of the fiscal year. The report will be reviewed and approved through the management chain of command according to the policy and procedures set out in the Center/Office scientific collections policy. Once the report is accepted or approved within the Center/Office, a copy of the report will be provided to the Office of Scientific Integrity. The annual report must include:

- the current copy of SOP;
- the current scientific collections catalog;
- any changes to the digital or physical public access to the scientific collection;
- the link to the scientific collection record in USFSC (http://usfsc.GRSciColl.org);
- physical access log documentation, if any;
- annual inventory of specimens with a disclosure of any specimens that are missing;

- the current contract, grant, or agreement with a third party responsible with the management of the scientific collection, if applicable;

- previous fiscal year expenditures;

- upcoming fiscal year budget request; and

- a review of SOPs to determine if any significant changes in practices, procedures, technology, law, or regulation necessitate an update.

Prior to approving an annual report, Centers/Offices should identify specific funds to be allocated to the maintenance of, and access to, the collection for the upcoming fiscal year.

F. Third Party Management of Institutional Scientific Collections

Whenever practicable and appropriate, a scientific collection director may work with public or private third parties qualified to manage scientific collections owned by the FDA. Those third parties must agree to take responsibility for the management of and access to the institutional scientific collection. If this Guide is applicable to any contract, grant, or agreement, it is the responsibility of the Program Official to identify this in the Statement of Work (or other similar document) or Funding Opportunity Anouncement.

1. Other Federal Agencies

   If the third party managing the institution scientific collection is a federal agency, then the third party's scientific collections policy applies to the institutional collection, provided the managing federal agency has in place a scientific collections policy developed pursuant to the 2014 OSTP *Improving the Management of and Access to Scientific Collections* memorandum. An interagency agreement should be executed and submitted to the Office of the Chief Scientist and to the Center/Office pursuant to Center/Office specific policies.

   If the federal agency has not issued a scientific collections policy pursuant to the 2014 OSTP memorandum, then for the purposes of the Guide, they will be treated as a non-federal agency per §6.F.ii.

2. Non-Federal Agencies

   If the third party managing the institutional scientific collection is a non-federal agency, then the institutional scientific collection will be governed by this Guide.

Program Officials must include the requirements of this Guide in the Statement of Work (or any similar document) or the Funding Opportunity Announcement for any contract, grant, or assistance agreement for the management of specimens within an FDA institutional scientific collection. The Program Official shall ensure, as a term and condition to a contract, grant, or assistance agreement, that:

- specimens remain the property of the FDA;
- the orderly deaccession or transfer of specimens prior to the end of the period of performance; and
- the third party compliance with this Guide, including the sections relevant to:
    - creation or acquisition of an institutional scientific collection,
    - accessioning,
    - access and use,
    - annual reporting, and
    - deaccessioning.

The agreement or contract (if available) should be included with the scientific collections master plan and annual report. The contracting third party will identify a director for the collection who will be responsible for complying with the scientific collection requirements in this Guide.

7. LEGAL AUTHORITY AND REFERENCES

Federal statute, regulations, and policy provide the authority, legal framework, and impetus for the management of and access to scientific collections, including, but not limited to:

- Executive Order, “Making Open and Machine Readable the New Default for Government Information” (May 9, 2013)
- Office of Management and Budget, Memorandum for the Heads of Executive Departments and Agencies, “Open Data Policy—Managing Information as an Asset” (May 9, 2013)
- President Barack Obama, Memorandum for the Heads of Executive Departments and Agencies, “Transparency and Open Government” (Jan. 21, 2009)

- Office of Management and Budget Director, Peter Orszag, Memorandum for the Heads of Executive Departments and Agencies, “Open Government Directive” (Dec. 8, 2009)

- America COMPETES Reauthorization Act of 2010 (Pub. L. No. 111-358), §104 requires the OSTP Director to “develop policies for the management and use of Federal scientific collections to improve the quality, organization, access, including online access, and long-term preservation of such collections for the benefit of the scientific enterprise.”

- Freedom of Information Act, 5 USC § 552

- Privacy Act, 5 USC § 552a

- Trade Secrets Act, 18 U.S.C. § 1905

- The Health Insurance Portability and Accountability Act of 1996 (HIPAA) (Pub. L. No. 104–191)

- Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq.

- Public Health Service Act, 42 U.S.C. § 201 et seq.

- Office of Science and Technology Policy, Memorandum for the Heads of Executive Departments and Agencies, “Improving the Management of and Access to Scientific Collections” (Mar. 20, 2014)

- Office of Science and Technology Policy, Memorandum to the Heads of Executive Departments and Agencies, “Policy on Scientific collections” (Oct. 6, 2010)

- Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards, 45 CFR Part 75.

- Federal Acquisition Regulations System, Solicitation Provisions and Contract Clauses, 48 CFR Part 52

- FDA Regulations, Public Information, 21 CFR Part 20 (and other regulations cross-referenced therein)

- FDA Regulations, Protection of Privacy, 21 CFR Part 21

- FDA Staff Manual Guide 9001.1, Scientific Integrity at FDA (Feb. 3, 2012)

- Federal Accounting Standards Advisory Board (FASAB) (FASAB, 2005)

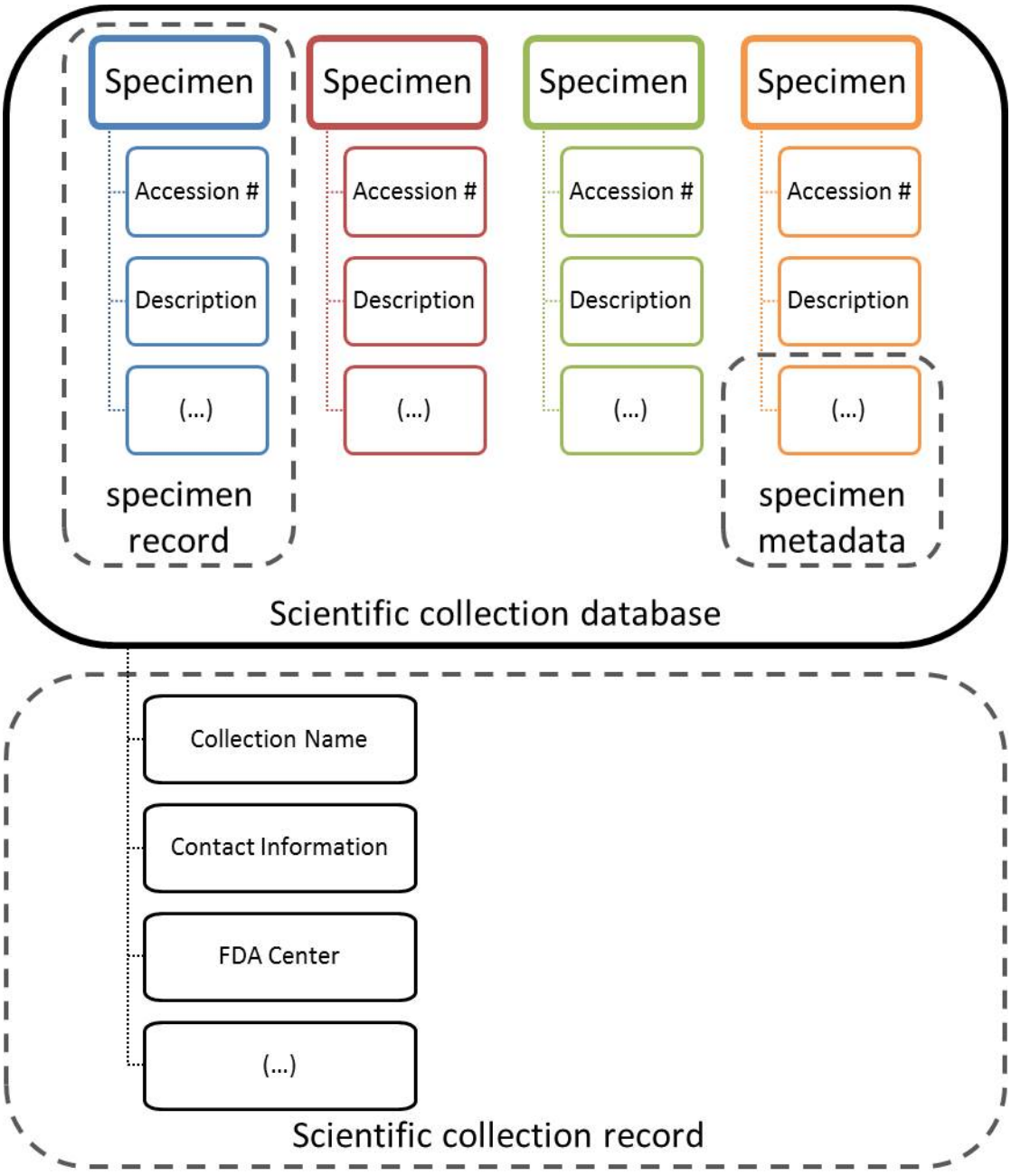
8. EFFECTIVE DATE

The effective date of this staff manual guide is October 5, 2015.

9. Document History – SMG 9005.1, Scientific Collections Management and Access Policy

STATUS (I, R, C)	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
Initial	10/05/2015	N/a	OC/OSI	Luciana Borio, Chief Scientist

APPENDIX 1- ELEMENTS OF AN INSTITUTIONAL SCIENTIFIC COLLECTION



APPENDIX 2 – INTERAGENCY AGREEMENT (IAA): GUIDELINES AND SAMPLE

Interagency[1] Agreement contents:

- Title of the project/collection;
- General background of the project/collection;
- Objective of IAA;
- Specific tasks detailing the roles and responsibilities of the parties involved with the IAA;
- Reporting requirements detailing any expected deliverables and a timeline for completion;
- Public access requirements for both digital and physical access;
- Term of agreement;
- A copy of the governing scientific collections policy developed pursuant to the 2014 OSTP Improving the Management of and Access to Scientific Collections memorandum;
- Funding details; and,
- FDA Program Official contact information.

[1] For more information on Interagency Agreements, see: http://inside.fda.gov:9003/Administrative/AcquisitionsGrants/InteragencyAgreements/default.htm

SAMPLE INTERAGENCY AGREEMENT

SCIENTIFIC SERVICES PROGRAM (SSP)

STATEMENT OF WORK (SOW)

1. TITLE

Commercial Seafood sample collection, identification, vouchering, storage, and gene-sequencing

2. GENERAL

CFSAN, in conjunction with the FDA Office of Regulatory Affairs, has the responsibility to develop, apply, and provide the necessary technology and methods for the effective identification of fish species for the purposes of protecting the public from improperly and illegally imported fish species that may constitute a health threat. The FDA is also responsible for having the necessary tools to detect and enforce regulations against substitution of one species for another in cases of economic adulteration (i.e., seafood fraud). The FDA is developing methods for species identification for various seafood commodities using a technique known as DNA barcoding that will address this problem. In order for the FDA to proceed with the use of the DNA Barcoding method, an authenticated sample library with validated DNA sequences is required. Any seafood species that are collected must be identified by appropriate experts in taxonomy, vouchered, and preserved in a curated location for use by subsequent scientific generations. DNA gene sequences must be obtained for each of the vouchered specimens.

The FDA does not have the capabilities to complete the identification, vouchering and storage of samples, nor does it make sense to develop them. The Smithsonian Institution, as a federally chartered museum and learning institution, has exactly the facilities necessary to help the FDA develop a seafood DNA database. The Smithsonian Institution regularly sends it scientists overseas to collect museum specimens, and thus has the experience and logistical capability to obtain samples from international locales and return them to the U.S. As experts in animal taxonomy, the Smithsonian Institution can identify seafood species and provide a voucher for the particular specimen in question. They can subsequently preserve that sample in a museum-quality storage area, retaining it for subsequent use should it become necessary. This repository can serve as the basis for a government-wide seafood library, a process that was recommended in the recent GAO report on seafood fraud. As a member of the Barcode of Life project, the Smithsonian Institution already has the capability for gene sequencing of the COI gene and can easily provide sequence information for the FDA. The FDA does not have the facilities itself to sequence these genes in an efficient way.

3. OBJECTIVE

The objectives of this task are to develop a collaboration with the Smithsonian Institution to: 1) Identify, voucher, store, and curate seafood specimens collected by the FDA or its collaborators, 2) Collect for the FDA seafood specimens from locations determined by the FDA in consultation with the Smithsonian Institution, 3) Sequence the COI gene in said specimens according to protocols established by the FDA, and 4) Aid the FDA in the continued development and refinement of DNA Barcoding methodologies.

4. SPECIFIC TASKS

The following tasks shall be performed independent of FDA supervision, direction, or control: Independently, and not as an agent of the FDA, the IAA partner shall furnish the necessary personnel, materials, transportation, services, facilities, and otherwise do all things necessary for or incident to the performance of the work as described below:

The IAA partner shall:

a. Provide expert taxonomic identification of fish species obtained in collection trips or given to the Smithsonian by the FDA. In 2010, SI established a 3 year MOU with the Department of Fisheries in the Philippines to collect scientific specimens for DNA barcoding from the major fish markets throughout the country. These markets are known to contain some of the greatest biological diversity in the world. Successful collecting trips were performed in both 2010 and 2011, funded through this FDA/SI – IAA, but inclement weather in 2011 prevented collections in the northern portion of Luzon. This area was visited for the third and final trip under the existing MOU with the Department of Fisheries in the Philippines in early 2013. For this year's task, SI will finish the authentication, vouchering, and sequencing of the over 800 specimens collected from these 3 trips, as detailed below.

[b. The management of and access to this institutional scientific collection will be governed by the Smithsonian Institution's scientific collections policy pursuant to the 2014 OSTP Improving the Management of and Access to Scientific Collections memorandum.]

c. Sequence the COI gene from fish and other samples identified by the FDA according to a protocol established by the FDA, as outlined in the Single Laboratory Validated method described in Handy et al. [2011, J AOAC, 94(1): 201-210].

d. Provide results of gene sequencing to FDA in FASTA file formats.

e. In addition to the development of a library for commercial fish described above, FDA is also developing methods and building standards libraries for other seafood commodities such as decapod crustaceans (shrimp, crab, and lobster). Under a separate contract, FDA is funding a crustacean taxonomic expert to provide FDA with tissues from vouchered crustacean standards housed at the University of Louisiana at

Lafayette. The IAA Partner will aid in the COI sequencing of these decapod crustacean specimens.

5. REPORTING REQUIREMENTS

The IAA partner will provide the project officer with:

a. Data from any sample collection efforts undertaken for the FDA, including location of sample acquisition (with geospatial coordinates), identification of the species, voucher ID number, storage location, and any COI gene sequence data there from.

b. Data from any fish specimens submitted to the Smithsonian Institution by the FDA under this agreement, including identification of the species, voucher ID number, storage location, and any COI gene sequence data there from.

c. Gene sequence data from any samples submitted for gene sequencing under this agreement.

All data shall be delivered in the form of a report via e-mail no later than thirty (30) days after completion of work.

6. TERM OF AGREEMENT

The data collection shall progress beyond fiscal year 2013 and is dependent on a successful project. The work is therefore non-severable and the period of performance shall be from the effective award date to July 31, 2014.

7. FUNDING

8. FDA PROGRAM OFFICIAL

APPENDIX 3 – SAMPLE STANDARD OPERATING PROTOCOL

A. PURPOSE
B. SCOPE
C. DEFINITIONS/ACRONYMS
D. RESPONSIBILITIES
E. POLICIES
F. PROCEDURES
G. DOCUMENT HISTORY
H. DISTRIBUTION/CLEARANCE SHEET
I. EFFECTIVE DATE
J. APPROVAL SIGN-OFF
K. REFERENCES
L. APPENDICES

A. PURPOSE

This document describes the procedures for maintaining the CFSAN Herbarium and Special Collections Laboratory (henceforth referred to as the Herbarium,) that is located in 2EL013, Wiley Building. The Herbarium is the depository for dried plants (either pressed or whole or plant fruiting bodies), insects, mushrooms, photomicrographs, hair and other materials that the FDA has used as authentic samples in regulatory cases and for research. These samples have been collected and used by the Agency over the past 110 years. For FDA Quality Assurance and Safety protocols, the Herbarium is to be considered a laboratory.

The FDA Herbarium/Collections Laboratory receives specimens from a wide variety of sources by purchase, trading, or collection by FDA personnel. This material is used for studying and supporting research projects related to filth, providing authentics to FDA field laboratories, and strengthening the filth and extraneous materials collections.

These specimens are the Agency's primary reference materials for the identification of plant materials and extraneous materials found in foods. Therefore, care should be used in the handling of specimens.

B. SCOPE

This Standard Operating Procedure (SOP) applies to Center for Food Safety and Applied Nutrition (CFSAN), Office of Food Safety (OFS), Division of Plant and Dairy Food Safety (DPDFS), Dairy and Egg Branch (DEB) laboratory personnel utilizing the Herbarium and Special collections

C. DEFINITIONS/ACRONYMS

- **Accessioning** is the acquisition, preservation, databasing, and integration of a new specimen into the collection.

- **Deaccessioning** is the permanent removal of the specimen from the collection.

- **Authenticated specimen** is a specimen unequivocally identified as belonging to a certain taxa.

- **Herbarium** is the depository for dried plants, insects, mushrooms, photomicrographs, hair, and other preserved materials.

- **Insectary** is a research and regulatory laboratory space for the study, maintenance, breeding, and/or observation of live arthropods.

- **Special Collections** consists of materials that can be found as adulterants in foods, e.g., hairs, plastic fragments, metal fragments, etc.

- **Herbarium** sheet is a dried press plant specimen suitably mounted on archival paper and annotated with the collection information of the plant.

D. RESPONSIBILITIES

The principal investigator (PI) ensures that the laboratory personnel have received training in and are knowledgeable of the use and maintenance of the herbarium. The PI and/or the designated laboratory personnel are responsible for the implementation of these procedures. The primary and the secondary backup personnel that are designated as responsible(s) can be found in the []. Responsibility for the Herbarium shall be noted as part of the responsibilities of the PI in their duties.

The designated laboratory member will be responsible for the following:

- Training branch members on the proper mounting, handling, accessioning, and deaccessioning of specimens.

- Troubleshooting problems related to accidental infestations of the Herbariums.

E. POLICIES

Security

The chain of custody for the materials in the Herbarium is to be maintained at all times. Entry to the Herbarium is controlled by an electronic security system which records the entry to the room. Entry is restricted to members of the Microanalytical team; their branch chief, division, and office directors; and appropriate facilities personnel management as determined by the building manager. FDA security is responsible for maintaining the electronic security log of the room.

Herbarium/museum cabinets shall be kept closed and locked when not in use. Herbarium specimens shall be treated like regulatory samples keeping in mind the rules for chain of custody.

Guests are to be escorted at all times by a Microanalytical team member.

Biosecurity for the Herbarium/Collections Laboratory

The greatest threat to the herbarium and other collections is the accidental introduction of live insects into the Herbarium/Special Collections Laboratory.

1. No food or beverages are allowed in the herbarium.

2. No live insects or mite cultures are allowed in the room under any circumstances.

3. New specimens or returned loaned specimens are not allowed back into the Herbarium or filed in the appropriate cabinet unless they have been frozen at -20°C or lower for at least one week unless they are preserved in 70% or greater ethanol or similar preservative media that would kill any live insects.

F. PROCEDURES

A. Plant Specimens

General Information

To prevent damage to the herbarium sheets they should be:

- **handled using both hands**
- **never be slid over each other**
- **never turned as pages in a book**
- **never be bent or folded**

Broken material known to come from the specimen is to be placed in the specimen packet.

Receipt of Specimens

New plant specimens or those returned from loans are to be received at a laboratory other than the Herbarium. The new specimens are to be frozen at -20°C or lower for at least one week before they are to be placed in the herbarium. Specimens shall be carefully stacked and sealed in plastic bags with a small satchel of a moisture absorbing crystal, e.g., dryrite crystals. The bundles shall not be thicker than three inches in height and spacers shall be placed between the bundles in the freezer to allow them to freeze rapidly. Fresh material is to be pressed and dried before being frozen (see Pressing

and Mounting). When taken out of the freezer, the samples are to be allowed to return to room temperature before the bags are opened. If the sample has not been processed (i.e., mounted and/or data entered into the herbarium data system), the sample shall be stored in the cabinet on the shelves designated for unprocessed specimens. If the sample data has already been entered into the Herbarium record system, the specimen shall be filed in its appropriate folder.

Specimens

Specimens may be obtained any number of ways: collecting, purchase, trade, remainder of regulatory samples, etc. The provenance of new materials shall be recorded as part of the record of the specimen.

Plant specimens collected by FDA employees may come from a variety of sources: plants grown in the wild (wildcrafted), plants grown under cultivation, or collected from markets. Enough material shall be collected to prepare at least two herbaria sheets.

Additional unmounted material may be retained for chemical and microscopic analysis. Both the mounted and unmounted material will be given the same acquisition number. One herbarium sheet will be used for vouchering of the specimen. Wildcrafted material shall be collected with permission of the property owner or with the proper permits from the appropriate local department of natural resources, or state or federal park official.

Pressing and Mounting Specimens

Fresh specimens may be preserved either by pressing to dryness and preserving in ethanol (70%) or in FAA solution (1:1:18 solution of 40% formaldehyde, glacial acetic acid, and 70% ethanol).

Care shall be taken to carefully arrange fresh material to be pressed so that those characters necessary for the accurate identification of the material are readily visible. Additional information on the pressing and preserving of specimens can be found in Liesner (2014), Bridson and Forman (1998), DeWolf (1968), Hill (1995), Smith (1971), and University of California (1975).

Pressed, dried specimens shall be archivally mounted on standard herbarium paper. Specimens may be mounted either by direct gluing of the specimen to the paper or by strapping the specimen to the paper using archival cloth tape. The preferred method is that the specimen be strapped.

On each herbarium sheet shall be a packet for the storage of any materials that have broken off of the mounted specimen.

U.S. Food and Drug Administration Herbarium
Genus species author - Family Common name (if any) Det. (ex descr. If applicable) John Smith 9/99 State, County, City. Detailed description of the locality that another person could use to find the exact spot. GPS co-ordinates, if available. Unusual features of the plant, and if only part of the plant was collect, how large was the plant originally. Identification characters not present on the mounted, dried specimen. Collector's name collector's number - date collected

Notes on the above:

Label width 5 inches max, length as long as necessary to include all pertinent information. Common abbreviations are allowed, legible typefont.

Line 1

Genus and species need to be in italicized font but the author does not. The family is put at the end of the same line as near as possible to the right hand border.

Line 2

Common name

Line 3

det. (determinavit) – he/she who determined (or identified) the plant. This is printed on the label and followed by the name of the botanist who made the identification and the date of determination. If the identification was made only by comparing the plant to a description of it (or by keying it out), add ex descr. (ex descriptione) between det. and the identifier's name. For ex descr., if possible, the specimen record in the database should record the key used to identify the plants and the step numbers used to determine the identity of the plant.

Line 4

Location. Start with the largest geographical organization, State, then county, and then town. Include as well directions to the collection site from a local landmark near the plant. This should be as exact as possible so that another person can find the exact location again. For example, Cobble stone beach on the south side of Maine 195 (Corea Rd.) approximately 1 mile east of the intersection of Maine 186 and Maine 195 on the north end of the town of Prospect Harbor. If available, include the GPS co-ordinates. These can be from a hand held GPS detector or extrapolated from a map or a computerized mapping program.

Line 5

Any other features of the plant or the location. Include features that would be lost or unavailable in the mounted specimen. Some examples are: flower color, sap color or texture, size of the plant if only part of the plant is collected, other plants growing in the area but only if you can correctly identify them. For example, brown algae collected on sandy/gravel beach in intertidal zone. Length 1.5-2 m and width 0.75 m.

Line 6

Collector’s name and the collector’s number for the specimen. The date of collection at the right hand margin in international format, dd month yyyy, e.g., 2 September 1999.

Mounting the Label

The label should be typed or printed on the highest quality rag bond paper, preferably 100% rag paper and mounted in the lower left hand corner of the herbarium sheet approximately 1/4" from the edge of the sheet. If the label could obscure part of the specimen, only glue one edge of the label so that it can be folded back so the specimen can be reviewed. NEVER glue the label over part of the specimen (See Bridson and Forman, Hill, and Liesner).

Tracking of Specimens

New specimens shall be given an unique sequential number. Herbarium sheets will be labeled with an accession tracking number. Bulk material associated with the herbarium sheet shall also be labeled with the same number. Existing collection numbers will be incorporated into the new numbering system, e.g., the Eli Lily, McCrone slides, grain seed contaminant collections.

An electronic database shall be maintained on all specimens in the collection containing at least the genus, species, author, family, unique sequential

number and bar code. Once the database is fully operational, no specimen can be filed into its appropriate family folder until it has first been numbered and recorded in the electronic database.

Filing of Specimens

The plants in the Herbarium shall be divided into four broad groupings and then filed alphabetically (first by family then genus and species) under these four groupings. The first is the seaweed; second, primitive tracheophytes (non-flowering plants); the third, angiosperms (flowering plants); and the fourth, mushrooms. The primitive tracheophytes include those families of the lycopodiophytes, psilotophytes, equisetphytes, leptosproangiante ferns, cycads, conifers, and gnetophytes. The angiosperm families shall be organized according to the classification system of Cronquist (1988) and species within the families according to Mabberley's The Plant Book: A Portable Dictionary of the Higher Plants. For those families covered under article 18.5 of the International Code of Nomenclature for algae, fungi, and plants (Melbourne, 2011), *Arecaceae (Palmae), Poaceae (Gramineae), Brassicaceae (Cruciferae), Fabaceae (Leguminosae), Clusiaceae (Guttiferae), Apiaceae (Umbelliferae), Lamiaceae (Labiatae), or Asteraceae (Compositae)*, the plants shall be filed using the -aceae name with a family folder filed under the synonym directing the investigator to the appropriate synonym. Each family shall have one or more folders labeled with the family name. More than one folder may be used per family to prevent crowding of the specimens. If multiple folders exist per family, the outside of the family shall be labeled in pencil with the letters of the alphabet that the folder contains, e.g., A-L, M-Z. Within each family folder shall be a genus folder with the specimens of that genus arranged alphabetically. The genus folder may contain reprints of any articles or work sheets that refer to specimen(s) that have been used and cited in those article(s) or worksheet(s). Alternatively, instead of the actual worksheet or article, there may be a notation as to where copies of the worksheet or article can be found both in the genus folder and in the electronic database.

Loaning of Specimens

The Herbarium is primarily intended to serve as reference materials for the regulatory and research activities of the Agency. All of the plants in the collection are readily available from other larger herbaria, e.g., Missouri Botanical Gardens, Field Museum of Chicago, Smithsonian Institute, Harvard Herbaria, and the New York Botanical Gardens. Since chain of custody must be maintained for the samples, requests for material from the Herbarium from outside the Agency will be considered on a case by case basis and may be only granted if the requestor cannot obtain the material from any other source and the request will not significantly alter or decrease the amount of the

specimen. Any specimen used for regulatory purposes and noted as such cannot be loaned.

[Digital Access to Specimens]

[Detailed instructions for publishing scientific collection records and databases online, including:

- **step by step instructions and timelines for the process of providing digital access to newly accessioned specimen metadata; and**

- **a detailed description of which records and metadata are to be redacted from digital access.]**

Use of Specimens

Each specimen represents a significant investment by the Agency. Therefore, research proposals to use Herbarium specimens must be clearly outlined and clearly state the benefits to the Agency when the research involves the destruction of a specimen or its associated materials.

When used for regulatory purposes, the entire specimen must not be destroyed so that part of it can be retained as a reserve sample. A notation must be made on the reverse side of the herbarium sheet in pencil or India ink with the unique sample number of the regulatory sample that was compared to the specimen.

In both cases, a notation of the use of the specimen shall be noted in the appropriate genus folder and in the electronic database.

B. Other Materials/Special Collections

Other materials/collections shall be stored in the best available way as determinated by the Microanalytical Team based on their experience and recommendations in published literature or contacts with museum curators.

These materials are subject to the biosecurity recommendations.

C. Corrective Action in Case of a Live Insect Infestation

Precaution offers the greatest protection against accidental insect infestation of the collection.

Care should be used not to bring into the Herbarium anything that has been used in the Insectary. If absolutely necessary, then the item must be thoroughly sanitized beforehand.

All light fixtures, ceiling ports, and any opening must be sealed with a caulking compound. If opened, any ceiling panel shall be resealed once any necessary work is completed.

The UV light trap shall be monitored on a regular basis.

Within the capacity of the Wiley Building air handling system, the room shall be maintained at 20°C or less and a relative humidity of 50%. These conditions retard the growth and development of commonly found storage pests.

The accidental infestation of the Herbarium by insects, especially *Anthrenus scrophulariae* (carpet beetle)*, Trogoderma inclusum, Dermestes sp., Lasioderma serricorne* (tobacco beetle)*, and Stegobium paniceum* (drugstore beetle), is best avoided by good housekeeping, isolation of newly received specimens from the collection, and the use of common sense.

Should a cabinet in the collection become infested, all specimens in the cabinet shall be removed and treated as new specimens being frozen at -20°C or lower for a minimum of a week, but preferably for a month. The cabinet shall be thoroughly washed and sanitized (Edwards et al., 1981). Before any new samples are placed in the cabinet, a petri dish with a glycerol soaked piece of filter paper will be placed in the cabinet. After 24 hours, the filter paper will be examined for any insect excreta or traces of insect activity. If any insect presence is detected, the cabinet will be resanitized. If no additional insect activity is observed, then the cabinet can be refilled with the specimens provided they have been frozen as per above. Cabinets adjacent to the infested cabinet shall be inspected to verify that the contamination has not spread.

In the event of a severe insect infestation, the entire room can be sealed and fumigated via the fumigation port located next to the door. Any such fumigation shall be done with the knowledge and consent of the CFSAN Safety Office.

The room housing the herbarium shall be regularly inspected for any signs of infestation.

D. Deaccessioning a specimen

A sample may be deaccessioned for a variety of reasons, e.g., destructive sampling as part of a regulatory case, extensive damage due to accidental destruction caused by insect infestation. All deaccessions shall be noted on the specimen record in the database with the reason for deaccession recorded. The specimen record should note the reason why the specimen was deaccessioned, any attempts made to find a replacement specimen, and, in the case of destructive sampling of the entire specimen as part of a regulatory action, concurrence of the Branch Chief and Division Director. In the latter case, the

results from the destructive sampling and the outcome of any legal proceedings shall also be added to the specimen record in the database, if they become available from the district or regional laboratory.

E. DOCUMENT HISTORY

Version:	Revision Date:	Author:	Reason for Change:
1231.133.4.v2	8/28/2014	GCZ	To conform with Center SOP for SOPs Addition of section on deaccessioning

F. EFFECTIVE DATE

10/01/2014

G. APPROVAL SIGNOFFS

H. REFERENCES

Anon, International Code of Nomenclature for algae, fungi, and plants (Melbourne, 2011) in press

Bridson, D, and L. Forman (ed.), (1998). The Herbarium Handbook, 3rd ed., Royal Botanical Gardens, Kew. pp. 46-51, 193-260

Croat, T.B., (1978). Survey of Herbarium Problems, Taxon 27:203-218.

Cronquist, A. (1988). The Evolution and Classification of Flowering Plants, 2nd ed. The New York Botanical Garden, Bronx, New York.

DeWolf, G.P. (1968). Notes on Making an Herbarium, Arnoldia 28:69-111.

Edwards, S.R., B.M. Bell, and M.E. King (1981). Pest Control in Museums: A Status Report (1980). The Association of Systematics Collections.

Greuter, W., F.R. Barrie, H.M. Burdet, W.G. Chaloner, B. Demoulin, D.L. Hawksworth, P.M. Jorgensen, D.H. Nicholson, P.C. Silva, P. Trehane, J. McNeill. (1994). International Code of Botanical Nomenclature (Tokyo Code), Koeltz Scientific Books, Konigstein, Germany

Hill, S.R. (1995). How to Make a Plant Collection, Herbarium Supply Co., Menlo Park, CA.

Liesner, R. (ed.), Field Techniques Used by Missouri Botanical Garden, accessed on-line August 25, 2014, http://www.mobot.org/MOBOT/Research/Library/liesner/tpage.html

Mabberley, DJ (1993) The plant-book: A portable dictionary of the higher plants, Cambridge University Press, Avon, England

Nevling, Lorin I, Jr., (1973) Report of the Committee for Recommendations in Desirable

Procedures in Herbarium Practice and Ethics, Brittonia 25:307-10

Smith, C.E. (1971). Preparing Herbarium Specimens of Vascular Plants, Agriculture Information Bulletin No. 348, Agricultural Research Service, United States Department of Agriculture

University of California, Berkeley, Herbarium. (1975). Selecting and Preparing Flowering Plant Specimens. Leaflet 2787. Division of Agricultural Sciences, University of California.

I. APPENDICES

none