



Ames Procedural Requirements

APR 7100.10
Effective Date: June 6, 2019
Expiration Date: June 6, 2024

COMPLIANCE IS MANDATORY

Subject: Curation of Institutional Scientific Collections, Requirements for Curation of Non-human Biological Specimens

Responsible Office: D/Office of the Chief Scientist/Ext. 4-3261, Mail Stop 241-20

DOCUMENT CHANGE LOG

Status [Baseline /Revision /Cancelled]	Document Revision	Date of Change	Description
Baseline	0	6/6/2019	New document

TABLE OF CONTENTS

PREFACE

- P.1 Purpose
- P.2 Applicability
- P.3 Authority
- P.4 Applicable Documents and Forms
- P.5 Measurement/Verification
- P.6 Cancellation

CHAPTER 1 ROLES AND RESPONSIBILITIES

- 1.1 Ames Center Director
- 1.2 Ames Office of the Chief Scientist
- 1.3 Safety Officer
- 1.4 ISC Project Manager
- 1.5 ISC Repository Manager
- 1.6 The Funding Program Director

CHAPTER 2 REPOSITORY REQUIREMENTS AND PROTOCOLS

- 2.1 Repository Practices
- 2.2 Storage Facilities
- 2.3 Storage Equipment
- 2.4 Quality Management
- 2.5 Audits
- 2.6 Safety
- 2.7 Information Management Systems
- 2.8 Records Management
- 2.9 Security
- 2.10 Termination or Relocation of Repositories

CHAPTER 3 BIOSPECIMEN ACQUISITION, STORAGE, INTEGRITY VALIDATION, ACCESS AND DISTRIBUTION REQUIREMENTS

- 3.1 Acquisition
- 3.2 Storage
- 3.3 Integrity Validation
- 3.4 Access and Distribution

APPENDIX A. DEFINITIONS

APPENDIX B. ACRONYMS

PREFACE

P.1 PURPOSE

- a. This Ames Research Center Procedural Requirement (APR) implements Ames Research Center (ARC) Institutional Scientific Collections (ISC) curation requirements and procedures in accordance with NASA Policy Directive (NPD) 7100.10F Curation of Institutional Scientific Collections, NPD 8831.1E Maintenance and Operations of Institutional and Program Facilities and Related Equipment, and NPR 8831.2F Facilities Maintenance and Operations Management.
- b. This APR establishes the requirements for curation, acquisition, storage, integrity validation, request, and distribution of non-human biological and environmental specimens for the purpose of supporting science and serving as a long-term research asset, and, as appropriate and feasible, the associated specimen data and materials.
- c. This directive is to ensure specimens are stored for the required duration and under best practices to maintain sample integrity.
- d. This directive is to ensure specimens are made available for forensic, medical, occupational and scientific research activities.

P.2 APPLICABILITY

- a. In this directive, all mandatory actions (i.e., requirements) are denoted by statements containing the term "shall." The terms: "may" or "can" denote discretionary privilege or permission, "should" denotes a good practice and is recommended, but not required, "will" denotes expected outcome, and "are/is" denotes descriptive material.
- b. In this directive, all document citations are assumed to be the latest version unless otherwise noted.
- c. This APR is applicable to all current and future non-human biological and environmental specimens derived from flight and ground-based NASA funded research that have intrinsic value to the Institutional Scientific Collection (ISC) and should be made available to the general public.
- d. For collections deemed to be, in whole or in part, institutional scientific collections in the future, this APR shall be treated as a guide to best practices. Accordingly:
 - (1) The Program Manager shall assess the scientific and technical value of samples that are no longer needed for the initial project part of the ISC.
 - (2) Project collections with intrinsic value to the scientific and technical community will be considered for formal accessioning into the ISC.
 - (3) As appropriate, Project Plans should include periodic review and transition of collections into the ISC. Transition consideration from project to ISC is to make sure no useful project collections are lost due to Principal Investigator (PI) retirement/death, lab closure, mission completion, etc.
 - (4) Following a decision to accession a collection into the ISC, the requirements in this APR will apply. These requirements are guided by the International Society for Biological and Environmental Repositories (ISBER) Best Practices: Recommendations for Repositories, Fourth Edition, 2018.

P.3 AUTHORITY

a. This document addresses appropriate requirements outlined in:

(1) NPD 7100.10F, Curation of Institutional Scientific Collections

P.4 APPLICABLE DOCUMENTS AND FORMS

- a. NPD 2810.1, NASA Information Security Policy
- b. NPD 7100.10, Curation of Institutional Scientific Collections
- c. NPD 8831.1, Maintenance and Operations of Institutional and Program Facilities and Related Equipment
- d. NPR 1600.1, NASA Security Program Procedural Requirements
- e. NPR 1441.1, NASA Records Management Program Requirements
- f. NPR 2210.1, Release of NASA Software
- g. NPR 2810.1, Security of Information Technology
- h. NPR 2810.1, NASA Information Security Policy
- i. NPR 8831.2, Facilities Maintenance and Operations Management

P.5 MEASUREMENT/VERIFICATION

a. Verification of conformance to requirements in this directive are measured through Center and Responsible Organizational management reviews, self-assessments, and subsequent analysis and reports of conformance to requirements, as well as periodic internal audits

P.6 CANCELLATION

a. None.

Eugene Tu
Director

DISTRIBUTION STATEMENT:

CDMS

<https://www.nasa.gov/centers/ames/DMS>

CHAPTER 1 ROLES AND RESPONSIBILITIES

1.1 Ames Center Director is responsible for:

a. Institutional Science Collection and primary legal responsibility for safe operations and shall designate a Safety Officer.

1.2 Ames Office of the Chief Scientist is responsible for:

a. Oversight of the Project Manager ensuring implementation of the ISC plan and meeting the NPD and NPR 7100.10 NASA Policy for the Curation of Institutional Scientific Collections.

b. Determining if a new or existing Project collection qualifies as an ISC and concurring with the deaccession and/or transfer of collections outside of NASA under recommendation by the Project Manager.

1.3 Safety Officer is responsible:

a. Monitoring and maintaining compliance with the repository.

1.4 ISC Project Manager is responsible for:

a. Reviewing and approval of long-range plans and budgets for the management, operation and control of capabilities for the repository.

1.5 ISC Repository Manager is responsible for:

a. Overseeing day-to-day activities including:

(1) Receipt and shipment of biospecimens;

(2) Inventory control;

(3) Emergency response;

(4) Preparing and updating Standard Operating Procedures (SOP);

(5) Monitoring the facility;

(6) Freezer maintenance;

(7) Assuring personnel are appropriately trained;

(8) Monthly and quarterly radiation surveys;

(9) Annual Radiation Project renewal and compliance with all NASA regulations as they apply to tissue bound isotopes.

b. Providing periodic reports to the ISC project Manager.

1.6 The Funding Program Director shall:

a. Determine the criteria for access to non-human biological and environmental samples belonging to that particular program.

CHAPTER 2 REPOSITORY REQUIREMENTS AND PROTOCOLS

2.1 Repository Practices

- a. A variety of systems have been devised to allow for confidence and reproducibility in repository practices. Each system described in this section has been developed to ensure that good practices are in place, complete with careful documentation and traceability.
- b. The requirements by which NASA acquires, curates, stores, validates integrity and distributes specimens shall include:
 - (1) Ethical and legal considerations meeting the Institutional Animal Care and Use Committee (IACUC) regulations
 - (2) Respect to sensitivity of animal experimentation in descriptive text and outreach activities.
 - (3) Proper sample collection and corresponding data collection.
 - (4) Proper acquisition and storage of samples and associated data to maintain sample integrity and traceability.
 - (5) A process for making the specimens known to the research community, appropriate vetting of requests, and specimen retrieval and distribution.

2.2 Storage Facilities

- a. Ensure that all personnel are trained and that storage facilities are maintained in the most cost effective manner to minimize risk to processes and products, protect the safety and health of personnel and the environment, protect and preserve capabilities and capital investments, provide quality work places for NASA employees, and enable the Agency's mission.
- b. Each storage facility shall have a written disaster recovery/incident response plan for responding to a wide variety of emergency situations. This plan shall be tested periodically (i.e., at least annually) to verify the plan meets the anticipated needs.
- c. ISC specimens shall be stored in the Ames Biobank Repository.

2.3 Storage Equipment

- a. Storage equipment selection shall be based on the type of specimens to be stored, the anticipated length of time the specimens will be stored, the intended use for the specimens and the resources available for purchasing the equipment.
- b. Adequate backup capacity shall be maintained in the event of equipment failure.

2.4 Quality Management

- c. The Quality Management System (QMS) shall include Quality Assurance (QA) and Quality Control (QC) programs covering the full spectrum of the repository's operations. The implementation and maintenance of a QMS contributes to the long-term sustainability of repositories.

2.5 Audits

- a. Audits shall be conducted on a quarterly, semi-annual or annual basis, or in response to a non-compliant incident, accident or a change/deviation in procedure required in the light of new information and/or alterations to regulatory or health and safety issues.
- b. Audits shall cover the implementation of all SOPs that govern the repository and primarily directed at prevention of non-conformances as well as detection, corrective action and process improvement implementation.

2.6 Safety

- a. A safety plan shall be developed to protect employees.
- b. Employees shall be trained on the potential hazards associated with all biospecimens and sign-off on their agreement to handle all specimens with the necessary safety methods.
- c. Specimens considered dangerous due to radiation or infectious disease exposure shall be handled and stored in compliance with applicable local and federal regulation and with appropriate training.
- d. All persons, including visitors, shall wear appropriate personal protective equipment (PPE) when working in the repository (i.e., lab coats, long pants, eye protection, gloves, and covered shoes; not shorts, skirts, or open-toed shoes).

2.7 Information Management Systems

- a. A computer-based inventory system shall be in place to track the location and pertinent annotation of every specimen in the repository to ensure the maintenance of storage location and chain of custody.

2.8 Records Management

- a. A records management system shall be developed and maintained that permits detailed records to be made concurrently with the performance of each step in the collection, processing and distribution of specimens.
- b. Records shall be managed in accordance with Federal and NASA regulations and policies for Records Management.
- c. It may be necessary to either destroy or remove specimens. Under these circumstances, records shall be appropriately amended to indicate that the specimen is deaccessioned and no longer part of the collection, and the information management system shall be updated to document this event.

2.9 Security

- a. The repository shall follow the NPR 1441.1E, NPR 2810.1A, NPR 2810.1E, NPR 2210.1C and the NPR 1600.1A in meeting all necessary security requirements for sensitive but unclassified data, and quality assurance and integrity of the collections.

2.10 Termination or Relocation of Repositories

- a. A plan shall be developed for the disposition of specimens and/or data should the repository be terminated for any reason.
- b. In the event the repository must be relocated, a plan shall be prepared and approved by the Stakeholders and Quality Assurance Program.

CHAPTER 3 BIOSPECIMEN ACQUISITION, STORAGE, INTEGRITY VALIDATION, ACCESS AND DISTRIBUTION REQUIREMENTS

3.1 Acquisition

- a. All specimens that remain after completion of NASA-funded research shall be returned to NASA along with all associated descriptive metadata and sample integrity information.
- b. If NASA determines that a set of specimens is no longer required by the owning project, then these specimens may be designated by the Ames Chief Scientist to be accessioned into the ISC.

3.2 Storage

- a. Specimens shall be stored at Ames and maintained in accordance with ISBER Best Practices.

3.3 Integrity Validation

- a. Specimens shall be assessed for integrity on a regular basis (minimum of every 5 years). Specimens that are deemed to be no longer viable shall be reviewed by the Non-Human Biospecimen Storage Facility Process Management Board to determine whether they should be deaccessioned and discarded.

3.4 Access and Distribution

- a. Future use of samples shall be determined by the funding program and based on spaceflight human system risk assessment.
- b. The ISC shall have a defined process and set of conditions by which individuals may request biospecimens.
- c. Specimens shall be stored with the necessary metadata to allow for viable use by future users.
- d. All research biospecimens and associated metadata shall be listed on the Life Sciences Data Archive (LSDA) public website.
- e. A formal process shall be established to review requests for biospecimens.

APPENDIX A. DEFINITIONS

Acquisition. Materials (biospecimens) received by a repository and the catalog information about those materials. This acquisition may be tentative until the materials and catalog information can be assessed by the repository for suitability and integrity.

Accession. To take legal custody of the materials and the catalog information and to ingest into the existing repository systems. Accession would only occur if the particular acquisition is deemed suitable, viable and legally transferable to the repository.

Curation. The collection and archiving of assets, including selection, description, preservation, control, and maintenance.

The term “curation” is used in the e-science and biological science fields as a means of differentiating the additional suite of activities ordinarily employed by library and museum archivists to add value to their collections and enable its reuse from the smaller subtask of simply preserving the data, a significantly more concise archival task.

Principles. There are five commonly accepted principles that govern the occupation of curation:

- (1) Manage the complete birth-to-retirement life cycle of the asset.
- (2) Evaluate and cull assets for inclusion in the collection.
- (3) Apply preservation methods to strengthen the asset’s integrity and reusability for future users.
- (4) Act proactively throughout the asset life cycle to add value to the asset and the collection.
- (5) Facilitate the appropriate degree of access to users.

Institutional Scientific Collections. Objects in the custody of or owned by NASA that have been identified for long-term preservation and management for scientific research purposes, and that are made available through formal procedures to qualified parties within and outside the agency for such research. Such collections are subject to all of the requirements of this APR.

Quality Management Systems. support the delivery of high quality services to end-user communities and in doing so sustain the business, utility and research viability of collections.

APPENDIX B. ACRONYMS

ARC	Ames Research Center
IACUC	Institutional Animal Care and Use Committee
ISBER	International Society for Biological and Environmental Repositories
ISC	Institutional Scientific Collection
LSDA	Life Sciences Data Archive
NASA	National Aeronautics and Space Administration
NPD	NASA Procedural Directives
NPR	NASA Procedural Requirements
PI	Principal Investigator
PPE	Personal Protective Equipment
QA	Quality Assurance
QC	Quality Control
QMS	Quality Management System
SOP	Standard Operating Procedure