

FDA STAFF MANUAL GUIDES, VOLUME III – GENERAL ADMINISTRATION

EXTERNAL RELATIONS

ACCESS TO RESULTS OF FDA-FUNDED SCIENTIFIC RESEARCH

Effective Date: July 12, 2017

1. Background and Purpose
2. Scope
3. Policy and Procedures
4. Responsibilities
5. Definitions
6. Legal Authority and References
7. Effective Date
8. History

1. BACKGROUND AND PURPOSE

On February 22, 2013, the [White House Office of Science and Technology Policy \(OSTP\)](#) issued a memorandum to the heads of executive departments and agencies entitled “[Increasing Access to the Results of Federally Funded Scientific Research](#)” (OSTP Memo or Public Access Memo). To increase public access to the results of research funded by the Federal Government, OSTP directed federal agencies (such as the FDA) with research and development budgets greater than \$100 million per year to provide free public access to federally funded, peer-reviewed, scientific publications and their associated data. The OSTP Memo also directed agencies to maximize public access, to the extent feasible and permitted by law, to digitally formatted data resulting from federally funded research.

This Staff Manual Guide (“Guide”) directly addresses FDA’s implementation of this memorandum, as related to FDA-funded research.

2. SCOPE

- A. This Guide imposes no requirements on researchers to publish research findings, although this is certainly encouraged, as appropriate. Publication and data access will be triggered if a researcher chooses to publish research findings in a peer-reviewed article. This Guide imposes no requirements to disclose digital data that is the result of FDA-funded research that is excluded from the definition of digital data (see Section 5.B for definition and exclusions).

- B. This Guide establishes the minimum expectations to maximize access to results of FDA-funded scientific research. However, individual Centers/Offices may prescribe additional requirements. Centers/Offices may supplement and expand upon the policy and procedures to meet their specific needs through issuance of written policies, standard operating procedures (SOPs), or template data management plans, so long as those documents support, and are consistent with this Guide.
- C. While FDA embraces the values of openness and transparency in the OSTP Memo, the agency is, in general, restricted by statute, regulation, and policy from disclosing certain categories of information and data, including, but not limited to:
- information that constitutes trade secret and confidential commercial information, or that otherwise must be protected to preserve intellectual property rights;
 - privileged information, including information related to ongoing product reviews, regulatory decision-making, and enforcement or ongoing criminal or administrative investigations;
 - personal privacy information; and
 - national security and other classified information.

D. Peer-Reviewed Articles: Intramural Research

The policy related to public access to the final published articles described in Section 3.A of this Guide applies to peer-reviewed articles accepted for publication on or after December 29, 2015, and authored, fully or in-part, by an FDA employee as part of their assigned duties.¹

E. Data Management: Intramural Research

The policy related to data management described in Section 3.B of this Guide applies to scientific research to be conducted by an FDA employee who proposes the research to managers for on or after December 29, 2015, including research to be conducted by an FDA employee involving data acquired, collected, or processed by a third party.

Section 3.B does not apply to research that only acquires, collects, or otherwise uses data excluded from the definition of digital data (see

¹ This Guide does not apply if the publication is not part of an FDA employee's assigned work. For guidance on non-assigned but FDA-related articles, please see Guide [2126.3: "Review of FDA-Related Articles and Speeches."](#)

Section 5.B for definition and exclusions). Furthermore, Section 3.B does not apply to research required to address immediate threats to public health and safety.

F. Peer-Reviewed Articles: FDA-funded Extramural Research

The policy related to public access to the final published articles described in Section 3.C of this Guide applies to all peer-reviewed articles accepted for publication that result from FDA-funded extramural research.

Program Officials shall ensure that extramural FDA-funded researchers comply with Section 3.C as a term and condition of a contract, grant, or assistance agreement related to scientific research that is initiated, or renewed, on or after December 29, 2015.

G. Data Management: FDA-funded Extramural Research

The policy related to data management described in Section 3.D of this Guide applies to scientific research to be conducted by an FDA-funded extramural researcher.

Program Officials shall ensure that extramural FDA-funded researchers comply with Section 3.D as a term and condition of a contract, grant, or assistance agreement related to scientific research that is initiated or renewed.

Section 3.D does not apply to research that only acquires, collects, or otherwise uses data excluded from the definition of digital data (see Section 5.B for definition and exclusions).

H. Peer-Reviewed Articles and Data Management: FDA Intramural-Extramural Collaborations

When more than one federal public access and data management policy could cover collaborative scientific research proposed to an FDA researcher's manager, compliance with this Guide is only required when an FDA researcher has primary responsibility (e.g., serves as the principal investigator or corresponding author) for the proposed scientific research pursuant to a written collaboration agreement.

3. POLICY AND PROCEDURES

A. Peer Reviewed Articles and Article Metadata: Intramural Research

1. Peer-Reviewed Articles

The final published articles covered by this policy must appear in the [National Library of Medicine's \(NLM\) PubMed Central \(PMC\)](#) for free public access to the full-text of the final published article within 12 months of the publication date. In order to ensure that the final published article is available through PMC within 12 months of the publication date, the final published article should be submitted to PMC within 10 business days of the date on which the final published article is available to either the journal's readership in print form or online, if the journal is electronic only.

A final published article can be submitted to PMC by:

- an FDA employee who is an author of the final published article, or their designee, via the [NIH Manuscript Submission System \(NIHMS\)](#), or
- the publisher of a PMC full participation journal carrying the final published article, pursuant to an agreement between the publisher and NLM.

To learn whether the publisher will submit the final published article or whether an FDA employee who is an author of the final published article has the responsibility for submission via NIHMS, please see the list of full participation journals² that submit final published articles directly to PMC.³

For directions on the use of NIHMS and completion of the submission process (including initial submission, processing, and final author review), see the NLM tutorials⁴ regarding use of NIHMS and PMC. FDA-specific tutorials for the submission of final published articles can be found on the website of the Office of the Chief Scientist.

Final published articles authored by agency employees do not carry copyright protections in the United States but may be protectable outside of the United States.⁵ Though not required, to avoid publisher confusion, employees should consider ensuring that any publication agreement or similar copyright transfer agreement with the publisher allows the final published article to be posted to PMC in accordance with this Guide.

² <http://www.ncbi.nlm.nih.gov/pmc/journals/>

³ Note also that authors using NIHMS to submit an article to PMC will receive a notice if the journal will submit or already has submitted that article to PMC.

⁴ <https://nihms.nih.gov/db/sub.cgi?page=stepbystep>

⁵ [17 U.S.C. § 105](#)

Once the PMC process for submitting a final published article is complete, PMC will ensure that the final published article is reviewable and searchable by, and freely available to, the public no later than 12 months after the date of publication.

2. Article Metadata

Article metadata covered by this policy must be made freely available to the public upon publication. Article metadata will be made available via NLM's PubMed index.

For final published articles in journals that are ordinarily indexed by MEDLINE, article metadata will appear automatically within PubMed without action by FDA or the authors.

For final published articles in journals that are not ordinarily indexed by MEDLINE, article metadata will appear within PubMed after the final published article is submitted to PMC via NIHMS.

3. Publication Tracking

To monitor compliance with agency publication access policies and to track agency publications, the FDA Library will maintain the catalog of FDA final published articles (Internal Article Catalog).

4. Compliance

At the conclusion of each calendar year, starting with calendar year 2016, the Office of the Chief Scientist will compare the number of final published articles deposited in the Internal Article Catalog to the number of FDA final published articles deposited into PMC over the same time period—the ratio will serve as a rough compliance rate that the Office of the Chief Scientist will publish on the website of the Office of the Chief Scientist.

At the conclusion of each calendar year, starting with calendar year 2016, the Office of the Chief Scientist will randomly audit 10% of the final published articles listed in the Internal Article Catalog. The Office of the Chief Scientist will determine which of the audited final published articles have been correctly deposited into PMC in accordance with this policy.

For those final published articles not in compliance, the Office of the Chief Scientist will request compliance with this policy, provide assistance in complying, and issue a deadline for compliance. If delinquent final published articles are not deposited by the deadline,

the Office of the Chief Scientist will notify the FDA researcher's supervisor. Previous non-compliance may be considered in decisions regarding future research.

B. Digital Data: Intramural Research

1. Data Management Plans

Researchers must submit a proposed Data Management Plan (DMP):

- when submitting a formal research proposal to receive approval from a manager or supervisor to conduct research that acquires, collects, or otherwise uses digital data (see Section 5.B for definition and exclusions);⁶ or
- prior to a decisional funding review for research as part of an intramural grant (for example, the Office of the Chief Scientist Intramural Grant programs).

The [Office of Scientific Integrity](#) will work with Centers/Offices to develop a [Data Management Plan template](#). However, Centers/Offices may implement their own Data Management Plan template with the approval of the Office of Scientific Integrity. A researcher's proposed DMP must include the following:

- types of digital data (see Section 5.B for definition and exclusions) to be produced or collected in the study;
- digital data metadata that will be made publicly available and used to describe any publicly stored data;
- the researcher's commitment to make digital data (see Section 5.B for definition and exclusions) supporting a final published article freely available to the public upon publication, if appropriate;
- digital data structuring (organization) and file formatting that will be used;
- data security measures that will be used and a description of the data that are private, privileged, or otherwise confidential; and

⁶ Refer to Section 2E. This Guide applies to an FDA employee conducting or primarily responsible for proposed research even if the FDA employee proposes to use a third party to acquire, collect, or otherwise process digital data (see Section 5.B for definition and exclusions). The FDA researcher should ensure that the agreement with the third party to acquire, collect, or process data establishes the expectations for data management as described in the approved data management plan.

- plans for digital data storage, archiving, and long-term preservation, as feasible, cost-effective, and appropriate (including, as applicable, an explanation why long-term preservation and access to data are not justified), in accordance with applicable records retention requirements.⁷

Researchers seeking research approval from management or seeking research funds via intramural grants should include planned data management costs in their proposals to ensure that they have the resources they believe are necessary to comply with proposed DMPs.

Researchers are expected to acquire digital data pursuant to approved data management plans. All formal status updates, progress reports, or reporting of results to management or the agency office providing intramural grant funding should include a statement of compliance with approved data management plans or a description of and reasons for any departures from approved data management plans.

Agency officials reviewing requests to conduct research or requests for funds will review data management plans on their merits in deciding whether to approve or fund research. In deciding whether to approve or fund research, reviewing officials will approve proposed DMPs as written or require changes to proposed DMPs as a condition of research approval or funding. Reviewing officials should consider the standards and common practices of the relevant scientific community or discipline regarding the value of public access to such data. Reviewing officials will consider the following in evaluating proposed DMPs:

- the value of long-term preservation of research data versus the associated cost and administrative burden—to the agency, Center, and specific agency strategic priorities or research program to which the research proposal relates;
- whether digital data (see Section 5.B for definition and exclusions) should be publicly accessible to search, retrieve, and analyze;
- restrictions regarding the disclosure of research data based upon agency regulations, statute, privacy concerns including HIPAA,

⁷ For questions regarding retention schedules or any other related questions, please contact your [Center/Office Assistant Records Liaison Officer \(ARLO\)](#).

proprietary interests, IRB requirements, or otherwise;⁸

- data storage, preservation, or records retention requirements; and
- available Center or agency resources—monetary, physical, human, technological or otherwise.

2. Public Access to Research Data

Researchers will provide public access to research data as provided in the approved data management plan. A researcher will provide access to the digital data (see Section 5.B for definition and exclusions) supporting the published research, consistent with the commitment in the approved data management plan, upon publication of a peer-reviewed article based on those data.

Digital data supporting the published research constitutes digital data and associated key digital data metadata needed to independently evaluate the data presented in the figures, images, charts, and tables in the final published article.

Given the presumption of openness of agency data, the agency will maximize access to digital data (see Section 5.B for definition and exclusions), while

- preserving the integrity of the data;
- adhering to applicable legal or regulatory restrictions on information disclosure; and
- balancing the value of public access to the data and the associated cost and administrative burden such as those related to modifying datasets to allow disclosure. For example, methods of disclosure may include creation of datasets that de-identify human subjects, or redaction or aggregation of datasets prior to sharing.

The Office of the Chief Scientist will support researchers seeking to make datasets freely available to the public by identifying methods and resources for providing public access to datasets. These methods might include:

⁸ In evaluating access to digital data, managers may consider the need to keep certain digital data confidential to ensure that research based upon that data can be published in the peer reviewed literature. Such evaluation does not supersede any policies or other considerations regarding access to data important to public health and safety, consistent with applicable statutes, regulations, and policy on information disclosure.

- depositing data in an existing public data repository (preferred);
- submission of supplemental information to the publishing journal (acceptable for smaller datasets);
- housing data on FDA webservers (acceptable); and
- making data available upon request (acceptable if there are considerations that would make storage in the public domain impractical or inappropriate—e.g., cost and resource limitations).

Information about available resources for making data freely available to the public can be found on the website of the Office of the Chief Scientist.

3. Compliance

FDA researchers are expected to acquire digital data pursuant to approved DMPs. As described in section 3.B.i, above, researchers should certify compliance with approved DMPs or note and explain any deviations from those DMPs whenever reporting results or providing status reports to management or the FDA office providing intramural funding. Managers and funding sources should consider deviations from approved DMPs and address any concerns to researchers. Where concerns with data management practices cannot be resolved, the managers or funding sources may consider whether to continue supporting the research. Managers may also consider whether deviations from approved DMPs should be considered in performance evaluations. Managers may consider prior compliance with this Guide in regards to future research and during performance appraisals.

C. Peer Reviewed Articles and Article Metadata: Extramural Research

Through the Statement of Work, Funding Opportunity Announcement, or similar instrument, Program Officials shall ensure, as a term and condition of a contract, grant, or assistance agreement, that extramural FDA-funded researchers provide, among other things:

- the final published article metadata to PubMed upon publication, and
- the final published article to PMC within 12 months of its publication date.

D. Digital Data: Extramural Research

1. Data Management Plan

Through the Statement of Work, Funding Opportunity Announcement, or similar instrument, Program Officials shall ensure that applicants for FDA funding provide a data management plan to the Program Official prior to commencing any related services or work. Elements of a data management plan should include, without limitation, the following:

- types of digital data (see Section 5.B for definition and exclusions) to be produced or collected in the study;
- digital data metadata that will be made publicly available and used to describe any publicly stored data;
- the researcher's commitment to make digital data (see Section 5.B for definition and exclusions) supporting a final published article freely available to the public upon publication, if appropriate;
- digital data structuring (organization) and file formatting that will be used;
- data security measures that will be used and a description of the data that are private, privileged, or otherwise confidential; and
- plans for digital data storage, archiving, and long-term preservation, as feasible, cost-effective, and appropriate (including, as applicable, an explanation why long-term preservation and access to data are not justified).

2. Public Access to Research Data

Through the Statement of Work, Funding Opportunity Announcement, or similar instrument, Program Officials shall ensure, as a term and condition of a contract, grant, or assistance agreement, that extramural FDA-funded researchers will provide public access to research data as provided in the applicable approved data management plan. In addition, an extramural FDA-funded researcher will provide access to the digital data (see Section 5.B for definition and exclusions) supporting any published research, consistent with the commitment in the approved data management plan, upon publication of a peer-reviewed article based on those data.

4. RESPONSIBILITIES

A. Office of Public Health Strategy and Analysis

[The Office of Public Health Strategy and Analysis \(OPHSA\)](#) provides strategic direction and data-driven analysis for the agency to more effectively and efficiently protect and promote the public health.

OPHSA will collaborate with the Office of Scientific Integrity to implement this Guide. This includes, without limitation, convening and leading steering committee meetings and implementation working groups, delegating tasks, orchestrating work performed by and input received from FDA Centers/Offices and operational components, directing implementation strategy, and developing training materials and additional instruction based on this Guide.

B. 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 collaborate with OPHSA to implement this Guide. This includes, without limitation, convening and leading steering committee meetings and implementation working groups, delegating tasks, orchestrating work performed by and input received from FDA Centers/Offices and operational components, directing implementation strategy, and developing training materials and additional instruction based on this Guide.

C. Senior Science Council

The [Senior Science Council \(SSC\)](#) provides advice and guidance to the agency and the Centers'/Offices' leadership on cross-cutting regulatory science planning, reporting, programs, policies, and communication.

SSC will review and provide expert input into agency implementation of the agency's data and publication access policy. Furthermore, OPHSA and OSI will likely recruit members of implementation working groups from the SSC or seek advice from the SSC on appropriate working group participants.

D. 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.

OHI will spearhead efforts related to management of FDA data resources, groups devoted to standardization of data or publication metadata, and otherwise serve as a liaison to HHS and interagency working groups related to development of standards for publication or data access. OHI will investigate various informatics strategies to serve as an agency-wide informatics solutions.

E. Program Official (PO)

Contracts: The PO is responsible for ensuring that the requirements of public access 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 of public access by the delivery date(s) and/or within the period of performance.

Grants: The PO is responsible for ensuring that the requirements of public access are clearly set forth in the Funding Opportunity Announcement and that the grant recipient meets the requirements of public access 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.

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.

FDA Centers/Offices may update, or create, policies and procedures required to comply with this Guide.

5. DEFINITIONS

A. Article Metadata

For purposes of this Guide, the phrase “article metadata” is defined as information that describes a peer-reviewed article, generally making the article uniquely identifiable and more easily searchable. Article metadata often include the article author, article title, publication title, publication date, article abstract, and unique identifying numbers or codes. For example, article metadata comprise the records found on PubMed or similar catalog.

B. Digital Data

Pursuant to the OSTP Memo and OMB Circular A-110, the term “digital data” is defined as the digitally recorded factual material that would be commonly accepted in the scientific community as necessary to validate published, peer-reviewed scientific articles. Moreover, the following are expressly excluded from the definition of digital data for the purposes of this Guide:

- preliminary materials underlying the data or factual information, including lab notebooks, preliminary analyses, drafts, plans for future research, peer-review reports, communications with colleagues, or physical objects such as lab specimens;
- data shared with FDA but owned by other organizations (e.g., aggregate electronic healthcare data from other parties used by FDA in product safety monitoring pursuant to FDA’s Sentinel program);
- data FDA received as part of an application for market authorization or application for exemption from marketing restrictions for investigational use;
- data obtained under licensing or data use agreements, or cooperative research and development agreements that include terms restricting the release and/or sharing of the data;
- data or information not available for disclosure pursuant to statute or regulation as described in Section 2 above; and
- technical and administrative data.

Nothing in this definition of data imposes requirements on researchers to digitize scientific data in order to comply with agency publication or data access policies.

C. Digital Data Metadata

“Digital data metadata” is defined as information describing the digital data and generally making the information/dataset uniquely identifiable and more easily searchable. Digital data metadata includes, but is not limited to, project title and abstract, collection dates, data format, and contact information.

D. Digital Repository

A digital repository is a focused collection of digital objects that can include text, visual material, audio material, and video material stored in electronic media formats along with means for organizing, storing, and retrieving the files and media contained in the library collection.

E. FDA Center/Office

For purposes of this policy, the terms, “FDA Center/Office” or “Center/Office” 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 conduct or fund scientific research, including offices within the Office of the Commissioner.

F. Final Published Article

For purposes of this plan, “final published article” is defined as a publisher’s copy of a peer-reviewed article, including all modifications from the publishing peer-review process, copy editing, stylistic edits, and formatting changes.

G. Full Participation Journal

Some journals commit to depositing the complete contents of each issue or volume, starting with a particular volume/issue or publication date, into PMC. PMC has a complete archive for many full participation journals going back to their first volume and issue.

H. Peer-Reviewed Article

For the purposes of this policy, the phrase “peer-reviewed article” is defined as an article published in a scholarly scientific journal that has been peer-reviewed prior to publication.

I. PubMed Central

PubMed Central (PMC) is a free digital repository of biomedical and life sciences journal literature at the U.S. National Institutes of Health's [National Library of Medicine \(NIH/NLM\)](#) developed and managed by NLM's [National Center for Biotechnology Information \(NCBI\)](#).

6. LEGAL AUTHORITY AND REFERENCES

Federal statute, regulations, and policy provide the authority, legal framework, and impetus for expanding public access to federally funded publications and digital data, including, but not limited to:

- [America COMPETES Reauthorization Act of 2010 \(Pub. L. No. 111-358\)](#), Section 103 sets out the OSTP Director's "responsibility to coordinate Federal science agency research and policies related to the dissemination and long-term stewardship of the results of unclassified research, including [...] peer-reviewed scholarly publications, supported wholly, or in part, by funding from the Federal science agencies."
- [Food and Drug Administration Modernization Act of 1997 \(Pub. L. No. 105-115\)](#), Section 113 (requiring establishment of a registry of clinical trials for both federally and privately funded trials of experimental treatments for serious or life-threatening diseases).
- Section 508 of the [Rehabilitation Act of 1973 \(29 U.S.C. § 794d\)](#), as amended by the [Workforce Investment Act of 1998 \(Pub. L. No. 105-220\)](#), Aug. 7, 1998.
- [Freedom of Information Act, 5 U.S.C. § 552](#).
- [Privacy Act, 5 U.S.C. § 552a](#).
- [Trade Secrets Act, 18 U.S.C. § 1905](#).
- [The Health Insurance Portability and Accountability Act of 1996 \(HIPAA\) \(Pub. L. No. 104-191\)](#).
- [Copyright Act, 17 U.S.C. § 101 et seq.](#)
- [Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq.](#)
- [Public Health Service Act, 42 U.S.C.](#)
- 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).
- Office of Science and Technology Policy, Memorandum for the Heads of Executive Departments and Agencies, [“Increasing Access to the Results of Federally Funded Scientific Research”](#) (Feb. 22, 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).
- Grants and Agreements, [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).
- FDA [Staff Manual Guide 2126.3, Review of FDA-Related Articles and Speeches](#) (Feb. 2, 2011) (“FDA encourages employees to share information that may benefit the public health by giving speeches and publishing articles in scientific or professional journals or other publications.”).

7. EFFECTIVE DATE

The effective date of this staff manual guide is July 12, 2017.

8. Document History - SMG 2126.4, Access to Results of FDA-Funded Scientific Research

STATUS (I, R, C)	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
Initial	12/22/2015	N/a	OC/OCS/ OSI	Walter S. Harris, FDA Chief Operating Officer
Revision	05/21/2017	N/a	OC/OCS/ OSI	Luciana Borio, Acting Chief Scientist