Chapter 2 – Notes, Records, and Information

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2.1 – Regulatory Notes

2.1.1 – Definition

Regulatory notes are the contemporaneous, sequential record of your daily investigatory efforts. They record your observations relevant to violations and active cases. They are the vital link between your findings and your subsequent testimony in court. Your regulatory notes are confidential because of the data they contain (e.g., information pertaining to open investigatory files, trade secrets, and personal information protected under the Privacy Act). Regulatory notes are government property and are releasable under the FOIA following FDA's procedures (See IOM 2.3).

2.1.2 –Difference between Regulatory Notes and Administrative Notes

Regulatory notes should not be confused with administrative notes. Administrative notes are purely administrative in nature and may include information related to travel, expenses, fiscal data, timekeeping, and documentation of meetings outside of regulatory operations. Regulatory notes should not contain purely administrative information, and they should not be maintained together. Administrative notes can be documented in a separate section of the same bound notebook where your regulatory notes are kept or in a separate administrative diary.

2.1.3 – Use of Regulatory Notes

Accurate regulatory notes are to document evidence and to refresh your memory when reporting certain important details of a field operation, such as a sample collection, consumer complaint, inspection, or investigation. Regulatory notes are the source record upon which your reports will be prepared. Regulatory notes also support the principle of "presumption of regularity" (that is, in the absence of clear evidence to the contrary, courts presume public officers properly discharge their official duties). Regulatory notes are useful to refute assertions by defendants, witnesses, or others. Regulatory notes also aid in defending lawsuits against FDA agents. This has been an issue of significance in several regulatory cases in the federal sector.

2.1.4 – Quality Characteristics of Regulatory Notes

2.1.4.1 – General Considerations

See IOM 2.4 for English language requirement. Regulatory notes should be accurate, objective, factual, and free of personal feelings or conclusions. Regulatory notes should be made at the time of the event they represent. Regulatory notes are original, contemporaneous, sequential recordings of an activity, and may be handwritten in ink or electronically. (See IOM 2.1.5 for information on what to do under rare circumstances when regulatory notes cannot be taken contemporaneously such as when entering a restricted environment.)

When using electronic notes, you should exercise good judgment when deciding if a change is contemporaneous, or if a change should be initialed and dated. For example, changes or backspacing to correct information as it is being written ordinarily would not need initialing and dating if the changes were made contemporaneously with the activity being documented. However, if you are returning to the information to change it after it was initially recorded, you should initial and date the change. (See IOM 2.1.4.3.1 for information on how to document corrections in your regulatory notes.)

2.1.4.2 – Entries

Regulatory notes should contain sufficient detail to refresh your memory regarding field activities, such as inspections, investigations, consumer complaints, and sample collections. They should include descriptions of your activities during the operation and your findings, such as objectionable conditions observed, or details of a sample collection. If a checklist is used during an inspection, don't repeat that information in your regulatory notes and attach it to your EIR. The checklist should be handled as part of the notes. Also see IOM 5.7.1. Likewise, when relevant information is contained on an FDA form, or in an exhibit collected during an inspection, that information need not be repeated in your notes. The act of issuing the form, collection of the exhibit, your review of the record, etc., should be recorded in your regulatory notes.

Regulatory notes should contain the substance of all significant discussions with people contacted during the activity, (for example, discussions of individual responsibility and refusals). When entering a direct quote in your regulatory notes, such as a statement against self-interest, it is important that the exact words be used to preserve the original intent of the individual and subject. Every quote of significance appearing in the final report should be in your regulatory notes since it is part of the source documents, which will support any regulatory or administrative action.

2.1.4.3 – Format

You may choose to take your regulatory notes as handwritten notes (bound journal), electronic, or as a combination of the two. Follow your management's direction. Regulatory notes, whether written or electronic, are subject to audit at any time; must be available for review; and must, on demand, be surrendered to your supervisor or other authorized personnel. Advancing technology may increase the preservation options available. Division policy should be followed regarding the preservation of all regulatory notes.

2.1.4.3.1 – Handwritten Hardcopy Regulatory Notes

When taking handwritten regulatory notes, use a bound notebook. Bound notebooks provide continuity and integrity and prevent lost or misplaced pages. Loose-leaf and spiral bindings allow easy removal of pages, an invitation to vigorous and heated cross-examination on the witness stand. (See IOM 2.1.5 for information on situations where taking regulatory notes in your bound notebook may not be feasible.)

Do not erase, edit, or rewrite original notes. Do not leave excessive space between diary entries. Any additions, deletions, or corrections to handwritten regulatory notes should be identified by strike-through for deletions, brackets [] for additions, and by initialing and dating your changes.

The bound notebook in which your handwritten regulatory notes are kept should be identified with your name, telephone number, and address to facilitate their return if lost. To assist in the return of lost regulatory notes, include the following information in the bound notebooks inside cover, or as a placard affixed to the back cover:

This book is the property of the U.S. Government.
If found, place in mailbox.
POSTMASTER: Postage guaranteed
Please return to: [Enter your FDA office mailing address here]

2.1.4.3.2 – Electronic Regulatory Notes (ERN)

You have the option of taking regulatory notes electronically as long as you can identify and attest that the electronic notes were taken by you, and you can ensure document integrity. ERN can be taken in eNSpect (preferred method), or outside of eNSpect, in software such as Microsoft OneNote or Word. You should contact your supervisor if you have questions on which software to use.

2.1.4.3.2.1 – ERN Taken in eNSpect

eNSpect provides the capability to record and store electronic notes. This is OII's preferred method for taking regulatory notes electronically. See eNspect-Home Site for the complete *User Guide and Frequently Asked* Questions section for additional information.

2.1.4.3.2.2 – ERN Taken Outside of eNSpect

If using software/programs other than eNSpect, any additions, deletions, or corrections to regulatory notes should be identified by using strikethrough font for deletions, brackets [] for additions, and by initialing and dating your changes. See to IOM 2.1.4.1 – General Considerations. Notes should be stored in a method where they are preserved in a manner that ensures data integrity and are retrievable if needed, for example, uploaded into eNSpect or saved on electronic storage media. Adhere to agency directives and procedures to safeguard and file electronic notes. Regulatory notes taken outside of eNSpect can be printed. If printed, you should be able to attest to the fact that the notes are accurate, complete, and were taken contemporaneously. This includes electronically signing the ERN file before printing or applying handwritten initials and date to each printed page. If this procedure is used, the original electronic storage media, can be identified with the firm name, dates, and investigator's initials; placed in an FDA-525 envelope or equivalent; and then sealed with an Official Seal, FDA-415a. NOTE: See IOM 5.6.6.2.3 - Exhibits, for guidance on the identification and storage of electronic data. Regulatory notes are not exhibits to the EIR (See IOM 2.1.6 for Retention of Regulatory Notes).

2.1.4.3.3 – Switching between Handwritten and Electronic Regulatory Notes

At your management's discretion, you can switch between taking regulatory notes electronically and in your handwritten journal. However, it is important to document when switching between the two forms because your regulatory notes are meant to be recorded contemporaneously. When switching between the two formats during a single operation, make a note in both formats that you will be taking notes using the other format and why (e.g., "Entering production room floor to observe sanitation – notes to be taken via bound journal/handwritten. Will switch back to eNSpect ERN upon return to conference room."). Be sure to include the date and time at which you are switching. Repeat the same process each time you switch between formats. This practice ensures that there is no unaccounted-for gap in your regulatory notes for the same operation (e.g., inspection, investigation).

2.1.5 – Recording Regulatory Notes in Restricted Environments

In rare circumstances, you may be unable to take regulatory notes using your notebook or electronic note-taking device because doing so might introduce contamination from your notebook into the environment (e.g., pharmaceutical clean rooms, egg-laying hen houses) or from the environment into your notebook (e.g., environmental sampling of manure pits during egg inspections, drug manufacturing areas where high-potency, cytotoxic, or β-lactam drugs are exposed). Additionally, if you use an

electronic notetaking device, you may be unable to use it in environments that present an explosion hazard.

You should attempt to take contemporaneous notes in the most reasonable manner possible. Make a note in your official regulatory notes that you will be taking notes using another method and the reason (e.g., "Entering cleanroom to observe sterile operations – notes to be taken on sterile cleanroom paper provided by firm to prevent contamination"). If taking notes on unbound sheets of paper, please refer to supervisory guidance.

If you are unable to take notes in any manner, you should record your recollection of the events and/or observations in your regulatory notebook as soon as you are able to. Include the reason you could not contemporaneously take notes in your regulatory notebook and the time between the event and/or observations and the notes.

After the inspection, preserve the notes according to your division policy and in consultation with supervisor guidance.

2.1.6 – Retention of Regulatory Notes

Identify your regulatory notes with your name and the inclusive dates they cover before they are turned over for storage (does not apply to ERN taken within eNSpect). Follow your division policy regarding the maintenance of regulatory notes.

Based on your division policy, regulatory notes may be kept by you, filed with the final report, or kept by the division in a separate, designated file.

If you leave the FDA, or are transferred from your division, identify any regulatory notes in your possession and turn them into the division you are leaving. Divisions are to retain regulatory notes as official records as outlined in the FDA Staff Manual Guide (see SMG 3291.1).

Regulatory notes prepared by center personnel during a field inspection/investigation are official records. Center personnel are to follow their center's policy regarding the retention of regulatory notes. In general, all regulatory notes should be maintained in the district or center where the original report is filed.

2.2 - Records Management

A record as defined by the National Archives and Records Administration (NARA), the Federal agency that oversees all records management rules and regulations, "includes all recorded information, regardless of form or characteristics, made or received by a Federal agency under Federal law or in connection with the transaction of public business and preserved or appropriate for preservation by that agency or its legitimate successor as evidence of the organization, functions, policies, decisions, procedures, operations, or other activities of the United States Government or because of the informational value of data in them." (44 U.S.C. 3301). Records must be retained until they are ready for disposition (instructions for managing records when not needed for agency business) and at what point they can be destroyed or transferred in accordance with their Record Schedule.

2.2.1 – Types of Records

Different types of records require distinct maintenance and handling based on their record schedule and the type of record. This section describes the main records disposition categories.

2.2.1.1 – Permanent Records

Records that contain historically significant materials, provide evidence of agency accomplishments, or document important events in national history, and as a result will be preserved by NARA.

2.2.1.2 – Temporary Records

Records with a temporary disposition that will eventually be destroyed or deleted when all relevant business needs have expired.

2.2.1.3 – Intermediary Records

Records of an intermediary nature, meaning that they are created or used in the process of creating a subsequent record. To qualify as an intermediary record, the record must also not be required to meet legal or fiscal obligations, or to initiate, sustain, evaluate, or provide evidence of decision-making.

2.2.1.4 – Transitory Records

Records required only for a short time (generally less than 180 days) and are not required to meet legal or fiscal obligations, or to initiate, sustain, evaluate, or provide evidence of decision-making.

2.2.2 – Records Retention

Per current FDA policy, records must be maintained for the duration of their retention period in accordance with their corresponding record schedule in the format that they are received. For example, paper and electronic records received from firms must be maintained in accordance with their retention periods even if they are scanned and/or uploaded into eNSpect. The official record is the original paper or electronic record received from the firm.

All records must be maintained for a certain amount of time and in a certain manner. See corresponding section of the IOM for specific information about how to handle many of the most common record types. Contact your supervisor or compliance office overseeing the case for additional guidance about specific record retention policies including record schedules, maintenance, destruction, transfer, and storage.

Due to government-wide mandates to transition away from paper records, all records should be collected, created, stored, and distributed electronically to the fullest extent possible. Electronic records should not be printed for storage--electronic record management solutions should be pursued instead. Some situations, such as issuing FDA Forms (i.e., FDA-482, FDA-483, FDA-484) or Firm Correspondence (FMD-145), may require the creation of a physical record.

2.2.3 – Additional Information about Records Management

Additional records management information can be found in the links below:

- Records Definitions: https://www.archives.gov/files/records-mgmt/rm-glossary-of-terms.pdf
- Transitory and Intermediary Record Guidance: https://www.archives.gov/files/records-mgmt/grs/grs05-2.pdf
- OII Records SharePoint: Records Management - Home (sharepoint.com)
- FDA Records Control Schedules: https://www.archives.gov/records-mgmt/rcs/schedules/index.html?dir=/departments/department-of-health-and-human-services/rg-0088

- OII Standard National File Plan: http://qmis.fda.gov:80/mc/index.cfm?initialRequest=http%3A%2F%2Fqmis.fda.gov%3A80%2Fmc%2Fmain%2Findex.cfm%3Fevent%3DshowFile%26ID%3DDMTEXEDZ3JEVRILSFG%26static%3Dfalse

2.2.4 - Specific Records Investigators Handle and Create

Examples of records you will likely handle in your career as a CSO can be found in this section.

2.2.4.1 - Regulatory Notes

See IOM 2.1.

2.2.4.2 - Administrative Notes

See IOM 2.1.2.

2.2.4.3 - E-mail

E-mails are official government records and are required to be retained appropriately. Most FDA employee emails are saved within outlook for seven years after employees depart the agency. This policy coincides with the HHS email policy and NARA GRS 6.1 record retention requirement for emails.

If any emails in your possession are associated with cases or are under legal hold, they may require longer than a seven-year retention. In such cases, an alternate electronic repository may be required to store the corresponding emails. For additional information or guidance, communicate with your supervisor or the compliance office overseeing the case.

Capstone employee emails are saved permanently then transferred to NARA; however, this only applies to a small number of senior leaders.

See additional email policies:

- HHS Email Policy: https://intranet.hhs.gov/policy/records-management
- NARA Email Record Schedule: https://www.archives.gov/files/records-mgmt/grs/grs06-1.pdf
- NARA file formats for permanent electronic records: https://www.archives.gov/records-mgmt/policy/transfer-guidance-tables.html
- Information about Capstone employee emails: https://www.archives.gov/records-mgmt/email-management/capstone-training-and-resources.html

2.2.4.4 - Collection Reports and Lab Analytical Packages

Collection reports include documents collected from a firm and documents created by the FDA regarding the collection of a product, environmental, or documentary sample. Collection reports should remain intact and be stored at the home division of the firm where the sample was collected or the office from which any regulatory action would be executed.

Local division procedures should be followed for storing collection reports; however, in most cases physical collection reports of product and environmental samples should be stored separately from physical inspection records, while documentary samples should be stored with corresponding inspection records.

Lab analytical packages demonstrate laboratory results from a sample collection, and if physical records exist, they should be stored with their corresponding collection report at the home division

of the firm where the sample was collected, or the office from which any regulatory action would be executed.

All efforts should be made to maintain Collection Reports and Lab Analytical Packages electronically such as in Compliance Management Systems (CMS).

2.2.4.5 - Memoranda

Memoranda may include investigational or administrative subject matter and should be retained according to their content. Investigational memoranda should be stored at the home division of the firm visited or referenced in the memorandum and may include investigations, tracebacks, consumer complaints, Reportable Food Registry Responses, Out-Of-Business, etc.

Administrative memoranda should be stored appropriately and may include topics such as Exceeding Travel Allowance, Internal Decision Memos, Other than Coach Class Travel accommodations, etc. All efforts should be made to maintain memoranda electronically, such as in CMS, eNSpect, or Enterprise Content Management System (ECMS).

2.2.4.6 - Recall Audit Check Reports

The results of recall audit checks are reported on FDA Form 3177, "Recall Audit Check Report." See IOM Exhibit 7-2. Divisions have the option of completing the form FDA 3177 electronically or as a hard copy. The preferred method is electronically.

The form FDA 3177 will be routed through your supervisor to the recall coordinator at the division monitoring the recall, who will store the official signed form in the recall file. (See IOM 7.4.1.4)

2.2.4.7 - Consumer Complaints

Per SOP-000544, all consumer complaint records are stored electronically in CMS consumer complaint files. Hard copy files and documents provided by the complainant are stored in the division firm files.

If documents, records, or photographs are received from the complainant, the documentation is scanned into CMS and the hard copy documents are sent to the complainant receiving org for filing.

2.2.4.8 - Correspondence

Correspondence typically includes electronic or physical mail among FDA employees, or between FDA employees and the public or regulated industry.

If the correspondence is received from regulated industry in response to an FDA Form 483 or regulatory meeting, or is related to an inspection or investigation activity, then the correspondence should be filed in the Establishment File or Compliance File related to the activity. Physical correspondence should be stored in the home division of the associated firm. Electronic correspondence should be stored in the appropriate electronic repository per OII or program policy.

Firm management should be requested to provide their inspection or investigation responses via program division email boxes as per program policy. Correspondence that is not associated with an inspection or investigation activity should be filed per OII local, or program policy. All efforts should be made to maintain correspondence electronically such as in CMS, eNSpect, ECMS, RES (Recall Enterprise System), or other electronic repository.

2.2.4.9 - Attachments

Documents attached to the EIR not provided by the firm during the inspection and referred to in the EIR, may be referred to under the attachment heading.

See IOM 5.7.4 for additional information.

2.2.4.10 - Exhibits

Exhibits are materials collected from the firm after the FDA Form 482 Notice of Inspection or FDA Form 482d Request for FSVP Records is issued and before the FDA Forms 483, 483a, or 4056 are issued or the inspection is closed out.

See IOM 5.7.3 for additional information on records obtained.

2.2.4.11 - Additional Documents Collected during Inspection

Materials not used in an EIR do not need to be kept under an official file plan.

Hard copy documents collected from the firm that are not needed as exhibits should be destroyed in accordance with your program division or office policy. If the inspection is ongoing, you may return such documents to the firm.

Electronic documents obtained on storage media containing exhibits should be handled per IOM 5.6.6.2. Documents not used in the EIR should not be deleted from storage media.

2.2.4.12 - Photographs

The photographs included and described in the EIR are considered the official exhibit and are maintained in the eNSpect system. See IOM 5.6.7 for additional information on preserving photographic evidence.

2.2.5 - Litigation Holds or Injunctions

There are circumstances where the FDA must maintain records beyond the Records Management requirements. These circumstances are generally related to legal cases pending with the agency. You may receive a notice that there is a litigation hold or injunction regarding destruction of records. This includes deletion of e-mails related to a particular matter. Read these notices carefully if you receive one.

2.2.5.1 – Litigation Holds

Litigation holds are holds placed on records. The request to hold records comes from the FDA OCC to ensure that records associated with an ongoing legal action are not destroyed. Records under litigation hold cannot be deleted or destroyed while the legal hold is active. If you are notified directly of a litigation hold on records in your possession, you should preserve those records until you are notified that the litigation hold is no longer active. For the purposes of supporting the preservation of OII records under litigation hold, there is a consolidated list of known litigation holds and added it to the OII Records Management SharePoint Site. (See link below for this list and additional guidance.)

2.2.5.2 – Injunctions

Injunctions are legal actions with potentially extensive or indefinite time periods until completion or lifting of the injunction, especially in the case of permanent injunctions. Records that lead to the development of an injunction cannot be destroyed prior to the end of the injunction, and therefore, must be preserved in a similar manner as litigation holds. For the purposes of supporting the

preservation of OII records under injunction, there is a consolidated list of known injunctions on the OII Records Management SharePoint Site. (See link below for this list and additional guidance.)

2.2.5.3 – Additional Information

The litigation holds and injunctions lists linked below may not include all existing litigation holds or injunctions. If you are aware of any additional litigation holds or injunctions, you must preserve all associated records, regardless of their inclusion on these lists.

OII Records Management SharePoint Site with litigation hold and injunction lists and additional relevant guidance can be found at OII Records Management.

2.3 – Information Disclosure

Sharing of information, regardless of the manner, must comply with FOIA, other applicable laws such as the Privacy Act and FDA procedures. Do not disclose any non-public information (NPI) (written or verbal) obtained during FDA official duties, unless you are authorized to do so by Division of Information Disclosure Policy (DIDP). Do not release any originals or copies of reports, memos, regulatory notes, forms (e.g., FDA-483, 484, 464, etc.), confidential or trade secret information obtained by a firm, or similar investigational documents to anyone outside the agency without express concurrence and appropriate authorization of division or headquarters management, the Office of the Chief Counsel (OCC), or information disclosure personnel. Unauthorized disclosure of confidential commercial or financial information, trade secrets, or personal privacy information could be a civil or criminal violation and may carry legal or other consequences for the disclosing official.

NPI includes information exempt from public disclosure under FOIA (see also FDA regulations under (21 CFR Part 20 Subpart D - Exemptions), as well as any other information prohibited from public disclosure under federal law or regulation, including the Privacy Act and the Trade Secrets Act (See other CFR disclosure references for an inexhaustive list). Examples of non-public information include confidential commercial information, trade secret information, pre-decisional FDA communications, investigative information, enforcement information, and personal privacy information. Confidential information in particular includes commercial or financial information "customarily kept private, or at least closely held," by the submitter. Submitted confidential information that FDA determines is exempt from public disclosure will be held in confidence by FDA unless required or authorized by regulation, statute, or court order.

Disclosure of non-public information must follow FDA regulations:

- 21 CFR 20.85 – other federal government departments or agencies
- 21 CFR 20.88 – state/local
- 21 CFR 20.89 – foreign
- 21 CFR Part 20 – Freedom of Information Act (FOIA)
- 21 CFR Part 21 – Privacy Act
- Other disclosure procedures found on the Division of Information Disclosure page

If non-public information is inadvertently disclosed, follow ORA's Addressing Inadvertent Disclosures SOP. Any information disclosure questions should be directed to DID at FDAinfoshare@fda.hhs.gov.

2.3.1 – Subpoena

If you are served a subpoena (commanding your appearance in court) or a subpoena duces tecum, (commanding the production of any record or testimony, or the giving of information relating to official FDA matters), immediately advise your supervisor and Division of Information Disclosure (DID) at FDAinfoshare@fda.hhs.gov. A testimony specialist will instruct you about the proper procedures and actions, so you are able to comply with the subpoena. (See 21 CFR 20.1, 20.2 and the Regulatory Procedures Manual (RPM) chapter 10-11, "Testimony; Production of Records; Certification of Records.")

2.3.2 – Requests by the Public

See IOM 2.3.4 regarding information requested by the public under FOIA. For procedures for sharing non-public information with federal, state, local, or foreign government officials, see IOM 2.3.3.

If a complainant requests sample results, see IOM 8.1.3. For procedures on the release of EIRs to the establishment inspected, see Field Management Directive (FMD)-145. For procedures on the disclosure of analytical results to establishments pursuant to Section 704(d) of the FD&C Act [21 U.S.C. 374 (d)], see IOM 4.6.2.59.

2.3.3 – Sharing non-public information with other government officials

If you receive requests for non-public information from officials of other federal agencies or from state or local officials, contact your designated state liaison or DID at FDAinfoshare@fda.hhs.gov. If you receive requests for non-public information from foreign officials contact International Federal Engagement at "oraopdiintlandfederalgroup@fda.hhs.gov.

Follow the current guidance:

- SMG 2830.3 Sharing Non-Public Information with Foreign Government Officials
- SMG 1410.65 Disclosure of Trade Secret Information to Foreign Governments
- SMG 1410.66 Delegation of Authority for Disclosure of Non-Public Information to Foreign Government Officials or Receipt of Non-Public Information from Foreign Government Officials
- MAN-000006 Regulatory Procedures Manual Chapter 3: Commissioning and Information Sharing (Specifically Section 3-6-4 Sharing Non-Public Information with Federal Government Officials and Section 3-6-3 Sharing Non-Public Information with State and Local Government Officials)

FDA's practice regarding requests for non-public information (NPI) from state government officials and agencies is governed by 21 CFR 20.88. All exchanges of confidential commercial or financial information with all state government officials must be authorized through DID and made pursuant to a written confidentiality agreement with the government official or officials seeking to access the non-public information.

Requests for NPI from foreign regulatory authorities are governed by 21 CFR 20.89. These confidentiality agreements are established and managed by the Office of Global Policy and Strategy and can be found on the confidentiality agreement webpage.

Requests for non-public information from other federal government departments and agencies are governed by 21 CFR 20.85. All exchanges of non-public information with federal government officials outside of DHHS must be authorized through DIDP pursuant to a written confidentiality arrangement with the government official.

For any questions regarding the sharing of non-public information with a state, local, or federal entity, please contact DID at FDAinfoshare@fda.hhs.gov.

2.3.4 – Freedom of Information Act (FOIA)

The Public Information section of the Administrative Procedures Act, 5 U.S.C 552, more commonly known as the FOIA, adopts a general rule that, except where specifically exempt, all documents in government files shall be made available to the public. The regulations exempt certain information, such as personal privacy, deliberative process, open investigatory, as well as a company's trade secrets or confidential commercial or financial information.

You can find information about disclosure and confidentiality of information related to FDA records and documents in 21 CFR Parts 20 and 21, 21 CFR 71.15, 170.102, 312.130, 314.430, 514.11, 514.12, 601.50, 814.9, and within other documents and statutes as detailed on the Division of Information Disclosure page. In addition to the FOIA, other acts such as the , PHS Act, and 18 U.S.C. 1905 also contain information relating to the confidentiality of information in government files. Note that special care should also be taken to protect the identity of confidential sources, see IOM 5.4.1.8.

All OII staff must adhere to FDA's laws and procedures regarding the maintenance of confidentiality of non-public information.

2.3.4.1 – Requests for Documents

If you receive requests for information, you may direct the requester to the FDA Electronic Reading Room (https://www.fda.gov/regulatory-information/freedom-information/electronic-reading-room). If answers cannot be found, the requester may be directed to submit a FOIA request at https://www.fda.gov/regulatory-information/freedom-information/how-make-foia-request. If your office receives a request, forward an electronic copy of the request to the director of https://www.fda.gov/regulatory-information/freedom-information/whom-contact-about-foia

2.3.5 – Internal FDA Documents

FDA records that are intended for internal use only may contain information protected from disclosure to the public by a FOIA exemption. Examples include work plans, internal decision memos, internal federal agency emails, and attorney-client communication. Do not disclose such records without consultation from an information disclosure expert in DID. If you receive requests for internal documents, or for parts of them, see IOM 2.3.

2.4 – English Language Requirement

Records or Federal Records are defined in 44 U.S.C. 3301 as including "all recorded information, regardless of form or characteristics, made or received by a Federal agency under Federal law …" which includes regulatory notes, memoranda, inspection reports, emails, and official government forms e.g. SF-71, FDA-482-FDA-483, etc. made or received by an agency of the United States Government under Federal law or in connection with the transaction of public business and preserved or appropriate for preservation by that agency or its legitimate successor as evidence of the organization, functions, policies, decisions, procedures, operations or other activities of the Government or because of the informational value of the data in them (44 U.S.C. 3301). (See also § 1222.10 of this part for an explanation of this definition).

All official FDA documents generated during your routine duties shall be completed in English. This requirement is necessary to facilitate efficiency in the workplace. For instance, many of your work products used in support of FDA's regulatory process are subject to review and auditing by your supervisor, utilized by your co-workers, and others, including the public, in that they are releasable

under the Freedom of Information Act (FOIA). The agency does not have the resources to assure the accurate and timely English translation of documents written in a non- English language in order to facilitate their use in the conduct of official business. English is generally considered to be the common language of the U.S.; therefore, it is necessary to standardize the language utilized in the production of official FDA documents.

Additionally, FDA imposes English only requirements on the public for information submitted to the agency. For example, 21 Code of Federal Regulations section 803.13(a) (English Reporting Requirement) states that all reports required in this part which are submitted in writing or electronic equivalent shall be submitted to FDA in English.

2.5 – Full Name Requirement

Full name means the person's first name, middle initial, last name, and any appropriate suffixes (e.g., Jr. Sr.). If an establishment inspection report is associated with the operation, the fact that there is no middle initial should be explained in the Individual Responsibility and Persons Interviewed section of the report (see IOM 5.6.3).