*Contains Nonbinding Recommendations*

# eCopy Program for Medical Device Submissions

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# Guidance for Industry and Food and Drug Administration Staff

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**This document supersedes the guidance of the same title dated April 27, 2020.**

For questions about this document regarding CDRH-regulated devices, contact CDRH's eCopy Program Coordinators at 240-402-3717 or cdrh-eCopyinfo@fda.hhs.gov. For questions about this document regarding CBER-regulated devices, contact CBER's Office of Communication, Outreach, and Development (OCOD), at 800-835-4709 or 240-402-8010, or by email at industry.biologics@fda.hhs.gov.

U.S. FOOD & DRUG ADMINISTRATION

**U.S. Department of Health and Human Services**
**Food and Drug Administration**
**Center for Devices and Radiological Health**
**Center for Biologics Evaluation and Research**

# Preface

## Public Comment

You may submit electronic comments and suggestions at any time for Agency consideration to http://www.regulations.gov. Submit written comments to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852-1740. Identify all comments with the docket number FDA-2018-N-0628. Comments may not be acted upon by the Agency until the document is next revised or updated.

## Additional Copies

### CDRH

Additional copies are available from the Internet. You may also send an email request to CDRH-Guidance@fda.hhs.gov to receive a copy of the guidance. Please include the document number GUI00001797 and complete title of the guidance in the request.

### CBER

Additional copies are available from the Office of Communication, Outreach, and Development (OCOD), Center for Biologics Evaluation and Research (CBER), by calling 800-835-4709 or 240-402-8010, by email, industry.biologics@fda.hhs.gov, or from the Internet at https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances.

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# eCopy Program for Medical Device Submissions

# Guidance for Industry and Food and Drug Administration Staff

***This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff or Office responsible for this guidance as listed on the title page.***

## I. Introduction

Section 745A(b)(3) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), amended by section 207 of the FDA Reauthorization Act of 2017 (FDARA) (Pub. L. 115-521 ), requires that Pre-Submissions and submissions for devices under section 510(k), 513(f)(2)(A), 515(c), 515(d), 515(f), 520(g), 520(m), or 564 of the FD&C Act or section 351 of the Public Health Service Act, and any supplements to such Pre-Submissions or submissions, including appeals of those submissions, be submitted in solely in electronic format specified by the Food and Drug Administration (FDA or the Agency) beginning on such date as specified by FDA in final guidance. The eSTAR Program is the current program for submissions solely in electronic format. For more information on providing regulatory submissions in electronic format, see FDA's guidance "Providing Regulatory Submissions for Medical Devices in Electronic Format — Submissions Under Section 745A(b) of the Federal Food, Drug, and Cosmetic Act."

Until such time that eSTAR is implemented for each specified submission type, Section 745A(b)(1) identifies that Pre-Submissions and submissions for the submission types identified above must be submitted as electronic copies (eCopies).[1] This guidance describes how FDA is implementing the eCopy Program under section 745A(b) of the FD&C Act. The eCopy and eSTAR Programs coupled with the CDRH Portal[2] or Electronic Submissions Gateway Next Generation (ESG NextGen)[3] for CBER submissions are expected to improve efficiency of the review process by allowing for more timely availability of submission content rather than relying solely on delivery, processing, and maintenance of a paper version.

This guidance provides, among other things, the standards for a valid eCopy under section 745A(b)(2)(A) of the FD&C Act. In accordance with section 745A(b), submission types identified in this final guidance must include an eCopy in accordance with the standards

[1] See Section 745A(b)(1) of the FD&C Act.
[2] See FDA's CDRH Portal webpage Send and Track Medical Device Premarket Submissions Online: CDRH Portal
[3] See FDA's webpage Electronic Submissions Gateway Next Generation (ESG NextGen)

provided by this guidance for the submission to be processed and accepted for review by FDA, unless they have been identified as being exempted or waived or meet the criteria for submission solely in electronic format under 745A(b)(3). Submissions under 745A(b)(1) and (2) without an eCopy and eCopy submissions that do not meet the standards provided in this guidance will be placed on format hold until a valid eCopy is submitted to FDA and verified to meet the standards, unless a waiver or exemption has been granted. While the submission is on format hold, the review clock will not begin, and the submission will not be reviewed. Format hold status applies to original submissions, supplements, amendments, and reports.

In section 745A(b), Congress granted explicit statutory authorization to FDA to implement the statutory eCopy requirement by providing standards, criteria for waivers, and exemptions in guidance. Accordingly, to the extent that this document provides such requirements under section 745A(b) of the FD&C Act (i.e., standards, criteria for waivers, and exemptions), indicated by the use of the words *must* or *required*, this document is not subject to the usual restrictions in FDA's good guidance practice (GGP) regulations, such as the requirement that guidance documents do not establish legally enforceable responsibilities. See 21 CFR 10.115(d).

However, this document also provides guidance on FDA's interpretation of the statutory eCopy requirement and the Agency's current thinking on the best means for implementing other aspects of the eCopy Program. Therefore, to the extent that this document includes provisions that are not "standards," "criteria for waivers," or "exemptions" under section 745A(b)(2), this document does not create or confer any rights for or on any person and does not operate to bind FDA or the public but does represent the Agency's current thinking on the topic. The use of the word *should* in such parts of this guidance indicates suggestion or recommendation, but not requirement. An alternative approach can be used if the requirements of the applicable statutes and regulations are satisfied. An alternative approach can be discussed by contacting the FDA staff listed on the guidance title page.

To comply with the GGP regulations ensuring that regulated entities and the public understand guidance documents as nonbinding, FDA guidance documents ordinarily contain standard language explaining the content to be viewed only as recommendations unless specific regulatory or statutory requirements are cited. FDA is not including this standard language in this guidance because it is not an accurate description of all of the effects of this guidance. This guidance contains both binding and nonbinding provisions. Insofar as this guidance provides "standards," "criteria for waivers," and "exemptions" pursuant to section 745A(b) of the FD&C Act, it will have binding effect.

The eCopy Program does not intend to impact (reduce or increase) the type or amount of data that applicants include in submissions for clearance or approval. For the purposes of this guidance applicant includes "submitter", "sponsor" or "holder." Please refer to other FDA device or program-specific guidance documents from CDRH and CBER for the appropriate content to include in submissions.

For additional eCopy Program resources, refer to FDA's webpage entitled, eCopy Medical Device Submissions.

# II. What is an eCopy?

An electronic copy (eCopy) is an electronic version of your medical device submission created and submitted on a compact disc (CD), digital video disc (DVD), flash drive, or via the CDRH Portal or ESG NextGen for CBER submissions. An eCopy is accompanied by a copy of the signed cover letter when mailing in the submission. Other forms submitted within premarket submissions can also be signed with either a wet signature and scanned or a valid digital signature.

# III. For what submission types is an eCopy required?

In accordance with Section 745A(b) of the FD&C Act, an eCopy is required for the following submission types, except those accepted or required through the eSTAR Program[4]:

- Premarket notification submissions (510(k)s) under section 510(k);
- Evaluation of automatic class III designation requests (De Novos) under section 513(f)(2);
- Premarket approval applications (PMAs), including Transitional PMAs under section 515(c), 515(d);
    - This includes all PMA submission types, including, but not limited to, original PMAs, panel-track supplements, 180-day supplements, real-time review supplements, manufacturing site change supplements, 30-Day Notices, 135-Day supplements, and post-approval study supplements and reports, as well as amendments involving changes in the correspondent or ownership and requests for extensions.
- Modular PMAs under 515(c)(4);
- Product development protocols (PDPs) under 515(f);
- Investigational device exemption (IDE) applications under section 520(g);
    - This includes all IDE application types including Original IDEs, IDE reports, IDE supplements and amendments to each of those [see Exemptions below].[5]
- Humanitarian device exemption (HDEs) applications under 520(m);
    - This includes all HDE application types, including, but not limited to, original HDEs, 180-day supplements, manufacturing site change supplements, 30-Day Notices, 135-Day Supplements, and post-approval study supplements and reports, as well as amendments involving changes in the correspondent or ownership and requests for extensions.
- Emergency Use Authorizations (EUAs)[6] under section 564 [see Exemptions below];
- Certain investigational new drug applications (INDs) under section 351 of the Public Health Service (PHS) Act;
    - Applicable only to those INDs required prior to the submission of a biologics license application (BLA) for devices that are regulated by CBER as biological

[4] See FDA's eSTAR Program webpage.
[5] For a description of IDE submission types, see Section 9 of FDA Guidance "FDA Decisions for Investigational Device Exemption Clinical Investigations."
[6] For more information on EUAs, refer to the FDA guidance, "Emergency Use Authorization of Medical Products and Related Authorities."

products. Such INDs are generally those intended for use in screening donated blood for transfusion transmissible diseases.

- Certain BLAs under section 351 of the PHS Act;
    - Applicable only to those devices that are regulated by CBER as biological products whether or not they also require submission of an IND prior to submission of a BLA. Such devices are generally those intended for use in screening donated blood for transfusion transmissible diseases and compatibility testing. This includes Original Applications, Efficacy Supplements, Prior Approval Supplements (PAS), Changes Being Effected in 30 Days (CBE-30), Changes Being Effected (CBE), Labeling Supplements, and Annual Reports; and
- Pre-Submissions
    - While 745A(b) does not require the submission of Q-Submission types other than Pre-Submissions to be made in an electronic format, FDA recommends that all Q-Submissions be submitted in electronic format to facilitate efficient review. Please refer to the Q-Submission Guidance for additional information.

eCopies for all subsequent submissions to an original submission, including amendments (amendments include add-to-files and appeals), supplements, and reports (including annual/periodic and post-approval reports) to the submission types identified above, as well as amendments to supplements and reports, are also required. Please note, Section 745A(b) of the FD&C Act does not apply to Medical Device Reports submitted under 21 CFR Part 803.

Whether it is a single-page submission (i.e., the company cover letter is the only content) or a multi-volume submission, the eCopy requirements apply. Although there is no maximum total submission size restriction, it is recommended that the total package submission not exceed 4 GB to avoid possible delays in the submission process. If you choose to submit through the CDRH Portal, the file size must be under 4 GB; anything larger must be mailed to the CDRH. For electronic submissions to CBER using the ESG NextGen, please refer to FDA's webpage Electronic Submissions Gateway Next Generation (ESG NextGen) for information regarding file size requirements. A submission that is not in electronic format (eCopy or eSTAR, as applicable) will not be received or filed, unless it has been exempted from the electronic submission requirements or the electronic submission requirements have been waived with respect to that submission.

## Exemptions

Above, FDA identified the submission types cited in the statute as being subject to the eCopy requirements. However, the statute also allows for FDA to set forth criteria for exemptions from eCopy requirements. As a general matter, the following types of submissions will be exempt from the requirements under section 745A(b)(1):

- specific types of IDE submissions: expanded access compassionate use requests and reports and emergency use reports,[7] and adverse event reports (all types, e.g., serious, malfunctions); and
- all EUAs.

[7] Refer to CDRH's device advice page entitled "Expanded Access for Medical Devices."

Although these submission types do not require eCopies as per this exemption, FDA encourages submission of eCopies of these submissions, when feasible, in order to facilitate the review process. If submission of an eCopy is not feasible, but there is pertinent electronic information, such as imaging data, to supplement the submission, please contact the lead reviewer to submit this information via Interactive Review. If you choose to submit an eCopy, it must meet the technical standards outlined in Attachment 1.

**Waivers**

FDA believes that, given the widespread availability of software to enable the creation of an acceptable eCopy at little to no cost, all applicants should have the ability to provide an eCopy. Therefore, FDA is not granting waivers for providing an eCopy.

# IV. Are there other submission types not subject to eCopy for which eCopies may be submitted?

Although an eCopy is not required under Section 745A(b) of the FD&C Act, FDA also accepts and encourages you to submit eCopies for:

- Master Access Files (MAFs);
- 513(g) Requests for Information (513(g)s); and
- Clinical Laboratory Improvement Amendments of 1988 (CLIA) categorization requests (CLIA Record; CR) and CLIA Waiver Applications (CW).[8]

eCopies for these three submission types are voluntary; however, if you choose to submit an eCopy, it must meet the technical standards outlined in Attachment 1.

# V. What are the processing steps for an eCopy?

## a. What are the technical standards for an eCopy?

The technical standards for an eCopy are detailed in Attachment 1. An eCopy that does not meet the technical standards in Attachment 1 will not be accepted. If an eCopy is not accepted, the file will be placed on format hold until a valid replacement copy is provided.

## b. What are the recommended methods for creating an eCopy?

*A. Bookmarks and Hyperlinks within PDFs*

Bookmarks and hyperlinks within a single PDF file should be used to assist the reviewers in navigating through the content of the submission. However, while these are not required elements for an eCopy, bookmarks and hyperlinks are essential for the efficient navigation through documents. If you use either bookmarks or hyperlinks, consider the following:

[8] For additional information about CR and CW submissions, see FDA's guidance "Administrative Procedures for CLIA Categorization."

Bookmarks and links references can be created for the heading of a section, subsection, or title of figures and tables within a single PDF file. In general, including a meaningful bookmark to the main table of contents for a submission or item is helpful, and will aid the reviewer in locating information and navigating the submission.

Hyperlinks are used to improve navigation through individual PDF documents and are encouraged. Hyperlinks can be designated by rectangles using thin lines or by blue text or you can use invisible rectangles for hypertext links in a table of contents to avoid obscuring text (note: use of blue text for hyperlinks is the most widely recognized style). Hyperlinks throughout the body of the document to support annotations, related sections, references, appendices, tables, or figures that are not located on the same page are helpful and improve navigation efficiency.

Bookmarks and links are usually most easily created in a word processor by using titles, headers, or styles which can be translated to bookmarks when the file is converted to PDF. Alternatively, bookmarks can be created in the final PDF document either by selecting text and creating a new bookmark to that location with that text as the name, or making a new bookmark and naming it manually.

While it is common to use bookmarks and hyperlinks within a single PDF file, it is also possible to create bookmarks and hyperlinks to other PDF files in your submission. We recommend using bookmarks and hyperlinks to other PDF files when use of those features will assist reviewers navigating through your submission. If you choose to use these features to navigate between different PDF files, then please remember to 1) use relative rather than absolute file paths, 2) use file names that are consistent with the eCopy requirements, and 3) use folder names that are consistent with the eCopy requirements. Please note the requirement to use numeric prefixes in file names, which will allow your files to appear in a meaningful order (rather than alphabetical order based on the first letter of each file name). Changing the file or folder names after you insert the links will break the links. If you use the eSubmitter tool to modify your file or folder names in order to fulfill the eCopy requirements, then any links between PDF files may no longer function.

### *B. Creating a PDF File from the Source Document (Preferred)*

Creating a PDF file from the source document is the preferred method of PDF creation, because this will allow for the automatic creation of searchable text in the PDF. If you have created hyperlinks and bookmarks in your document, we recommend that you test the links after you have created the PDF file to ensure that the links function correctly. When creating a PDF from the source document (e.g., Microsoft Word document), please consider the following:

#### *1. Adobe Plug-Ins*

If you use Adobe plug-ins within PDF files and/or to capture or display data, there is a risk that information may not display correctly because reviewers may not have access to certain plug-ins to review content being displayed by a plug-in.

*2. Fonts*

One of the following fonts should be used in your source document: Times New Roman; Verdana; Arial; Tahoma; or Helvetica. You should avoid using customized fonts and multiple fonts within the same document. We recommend the same font is used throughout the submission.

We recommend the use of a black font color. Blue font may be used for hypertext links. If a font color other than black is used, avoid light colors that do not print well on grayscale printers. It is advised that you test the color reproduction prior to submission by printing sample pages from the document using a grayscale printer. We recommend a font size of 12; however, we will accept smaller fonts.

### *C. Creating a PDF File from a Scanned Document*

The applicant should create all PDF files directly from the source documents whenever feasible rather than creating them by scanning. **PDF documents produced by scanning paper documents are far inferior to those produced directly from the source document, such as a Microsoft Word document, and, thus, should be avoided if at all possible**. Paper documents that include a watermark, such as DRAFT or COPY, are not suitable for scanning as the watermark makes the scanned document difficult or impossible to read. Scanned documents, particularly tables and graphs, are more difficult to read and do not allow the reviewers to copy and paste text for editing.

For any scanned document, we recommend that you perform optical character recognition (OCR) so that the text is searchable. If the text in your document is not searchable, the FDA will use the OCR technology in the eCopy to make it searchable for reviewers. Check to see that the content has been correctly converted by: (1) highlighting an area of text and (2) searching for a word or phrase. If the word or phrase is not returned in the search, then the OCR did not recognize the text. FDA recognizes that use of OCR may not be feasible in some cases for documents with figures and images.

Scanned documents, particularly those with images, photographs, and video recordings tend to be large in file size. Large file sizes may encounter more issues throughout the submission process thus causing delays. Therefore, it is recommended that the total submission package not exceed 4 GB, and attachments not exceed 1 GB. It is recommended that any attached images and videos are compressed in a Microsoft Windows compatible format viewable in native Windows OS applications or the VLC Media Player application (e.g., JPEG, AVC MP4, HEVC MP4). We highly recommend using HEVC video compression for videos. Ultra-High-Definition videos should only be provided if high resolution is necessary to support the review of the device. Take care when determining the proper resolution to display features of interest in images and videos.

FDA recognizes there may be cases in which it is appropriate to have scanned documents added to an eCopy. For example, if you do not digitally sign an Investigator Agreement form required in an IDE submission, then a scanned PDF copy of that signed document would be added to the eCopy.

FDA recommends that you follow these methods to create an eCopy. However, while the methods described in this section are not requirements for eCopy, your eCopy must meet the technical standards in Attachment 1.

### c. Are there special considerations when developing an eCopy for an original submission versus a response to a review hold notification?

There are no special considerations because the eCopy Program does not dictate the content of a document (original, supplement, amendment, or report). Each eCopy is its own entity, and the same technical standards in Attachment 1 apply to each eCopy. This means that volume (if applicable) and PDF numbering start over with each new eCopy rather than continuing from a previously-submitted eCopy. Do not provide previously submitted information in a cumulative fashion. Only include content pertinent to the current submission (e.g., an eCopy for a response to a PMA major deficiency letter only includes the response content, not the original PMA content plus the response content).

### d. Are there any issues to consider when choosing the eCopy media?

While submission through the CDRH Portal or ESG NextGen is the preferred method for eCopy submissions, it is up to each applicant whether to burn your eCopy onto a CD, DVD, or flash drive when mailing a submission to FDA. However, please be aware that certain brands of media, particularly flash drives, come pre-loaded with files that may lead to your eCopy failing the loading process. You should check the media for pre-loaded files and delete them before you copy your eCopy to the media.

NOTE: Should your submission exceed the size of a standard CD, FDA recommends that you use a DVD or flash drive, which has greater storage space, rather than split up your eCopy across multiple CDs.

### e. What if there is another submitting party involved?

In the case that another party (e.g., law firm, consultant) submits a submission on behalf of an applicant, the eCopy must still meet the technical standards in Attachment 1 in order to be successfully processed by FDA. The eCopy requirements are the same regardless of who is submitting the eCopy. While the applicant may or may not include their own company cover letter as part of the eCopy, our technical standards require that the submitting party include a company cover letter.

### f. What if this is a bundled submission?

For bundled submissions, there should be only one version of the company cover letter with a signature and only one eCopy that apply to all submissions in the bundle. There should not be different company cover letters or eCopies associated with each submission in the bundle. The company cover letter should include a list or table of all submissions that are part of the bundle. The list or table should specify the submission number, trade name, and, as applicable, the model number, of each device impacted by the change.

## g. How do you create an eCopy that meets the technical standards?

There is a free eSubmitter-eCopies tool available on FDA's website,[9] which we encourage applicants to use regardless of the Center to which you will be sending your submission. Use of this tool is optional; however, one of the benefits of the tool is that it creates an eCopy in real-time that is consistent with the technical standards described in Attachment 1. The tool guides you through the steps of adding the content and will add any required prefixes to volumes/folders and PDFs.

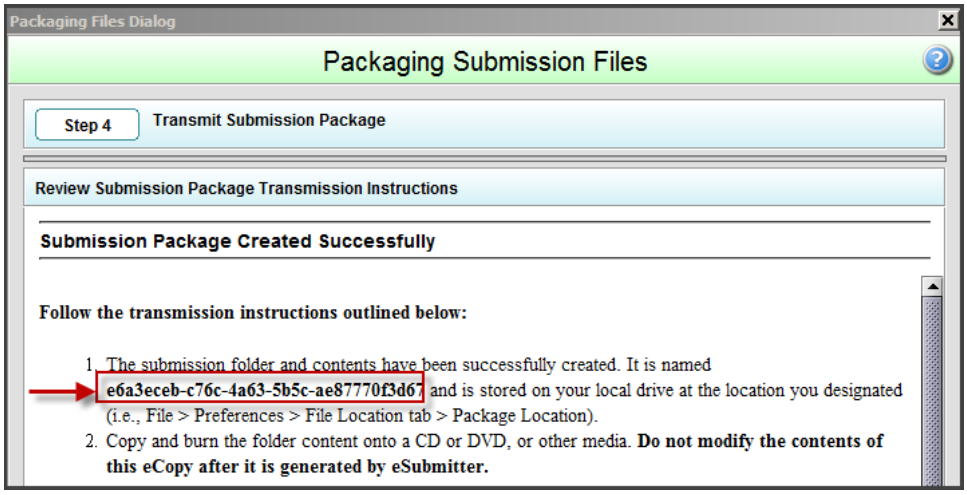
As an additional resource, there is a quick reference guide[10] specific to the eSubmitter-eCopies tool. It is important that you use only this reference guide when using the eSubmitter-eCopies tool and not the generic eSubmitter guides that are available.

> **Tip to Applicants:** If you add any files to your eCopy after using the eSubmitter-eCopies tool, you may create hidden temporary files or other errors that will cause the eCopy to fail the loading process. If a document is open while you are adding it to the submission package and you have modified the document without saving it, then both the document and the hidden cache file of the document will be added to the submission package resulting in a failure when it reaches the FDA for processing. To avoid this from occurring, you must save and close all documents prior to adding the document to the submission package. Use the eCopy Validation Module described in Section V.h below, in order to verify the format of the eCopy.

Please note that the eSubmitter-eCopies tool does not transmit the eCopy through the ESG NextGen or CDRH Portal. Instead, as shown in Figure 1, the eSubmitter-eCopies tool provides the formatted eCopy content for you to download onto your local computer drive. The eCopy content is saved in a folder with a long alpha-numeric name. You need to open up the folder with the long alpha-numeric name that was saved on your local computer drive and burn those contents onto your CD, DVD, or flash drive or submit via the CDRH Portal or ESG NextGen (preferred). Do not add any of the files that the eSubmitter-eCopies tool saves on your local computer drive outside of that folder with the long alpha-numeric name, as those additional files created by the eSubmitter-eCopies tool are for your records only.

[9] See FDA's webpage eSubmitter-eCopies Tool.
[10] Available at https://www.fda.gov/media/84416/download

Figure 1: Snapshot of final packaging screen from eSubmitter-eCopies tool




Should you have any technical questions regarding the eSubmitter-eCopies tool, please contact cdrhesub@cdrh.fda.gov prior to submission of the eCopy to FDA.

## h. How do you know if an eCopy meets the technical standards before you send it to FDA?

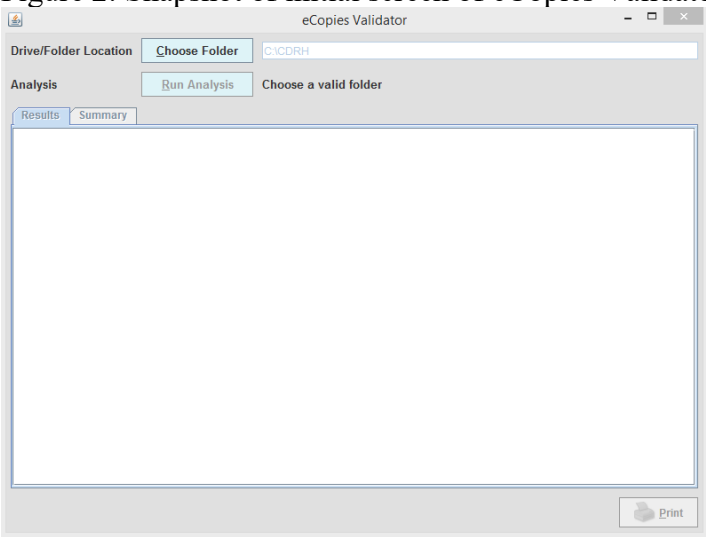
In order to determine if an eCopy meets the technical standards described in Attachment 1 before sending it to FDA, we recommend that applicants verify an eCopy using the free eCopy Validation Module that is now on FDA's website,[11] which we encourage applicants to use regardless of the Center to which you will be sending your submission. This voluntary tool will verify the format of an eCopy and provide information on the error(s) contained in an eCopy.

Figure 2 below shows the initial screen of this tool. You first identify the location of the existing eCopy (e.g., CD, DVD, or flash drive) by clicking Choose Folder. Once you have selected the location of your eCopy, you click Run Analysis. This tool runs through all of the technical standards described in Attachment 1 and either confirms that the eCopy meets the technical requirements or provides the reasons that it does not meet the technical requirements. If you do encounter an error, repackage the submission and use the validator tool to verify the format again, before sending to FDA.

**Tip to Applicants:** It is recommended that you use the eCopy Validation Module to check the final eCopy on the CD, DVD, or flash drive before submitting it to FDA in order to identify any errors or hidden files that may cause an eCopy to fail the eCopy Loader used by FDA.

[11] See FDA's webpage eCopy Medical Device Submissions.

Figure 2: Snapshot of initial screen of eCopies Validator tool




## i. How do you submit an eCopy to FDA?

We recommend submission of the eCopy through the CDRH Portal. However, should you choose to mail the eCopy, you should ensure that the submission includes a signed cover letter and send the media (e.g., CD, DVD, flash drive) to CDRH's or CBER's Document Control Center (DCC). The address for the DCC is available at the website eCopy Medical Device Submissions.

## j. How does FDA process an eCopy?

The determination as to whether or not an eCopy passes the loading process will be made by the appropriate staff at the same time the submission is received by FDA and logged into our database.[12]

If an eCopy passes the loading process, the company cover letter and eCopy contents will be loaded into the appropriate Center's official submission repository.

If an eCopy fails the loading process, we will notify you in writing (email) that your submission is on format hold. The format hold notification will describe the reasons for the eCopy failure and the logistics for submitting a replacement eCopy. It is important that you follow these directions to avoid delays in processing the replacement eCopy. **The submission will be placed and remain on format hold until a valid replacement eCopy is submitted to FDA and verified to meet the technical standards of Attachment 1.**[13]

[12] At CDRH, it is managed by the DCC staff. At CBER, it is managed jointly by the DCC staff and the Regulatory Project Manager (RPM).

[13] Do not confuse a "format hold" with a User Fee hold; a submission may be placed on User Fee hold for failure to pay the User Fee even if a valid eCopy is submitted. In addition, do not confuse a "format hold" with FDA decisions such as Refuse to Accept or Refuse to File. A format hold takes place before a submission is subject to any review process. Once under review, if applicable for that submission type, acceptance and/or filing reviews will be performed. See also Section V.l of this guidance.

## k. What do you provide to FDA in response to a format hold?

As stated above, you will receive a notification that states the specific reason(s) why your eCopy failed the loading process. In response to the format hold notification, you must provide:

- a company cover letter with a signature (preferably with a revised date); and
- a replacement eCopy that meets the technical standards of Attachment 1. Be sure to label the media with the full submission number and identify it as a "replacement eCopy" if mailing to the FDA.

Be sure that you provide a complete eCopy for the submission and not just the corrected files or folders. For eCopies submitted to CBER only, in some cases only those files that could not be uploaded need to be resubmitted. If you have been advised by the CBER RPM that a submission tracking number has been assigned to your submission, the new eCopy and its signed company cover letter should clearly identify the assigned submission tracking number and state that the eCopy is an amendment to that submission.

The company cover letter with a signature is required regardless of whether or not the eCopy failure was related to the company cover letter, because the DCC needs to be able to date stamp the company cover letter to record the receipt date of the replacement eCopy.

Please note that if the only reason your eCopy failed is because of a lack of a signature on your company cover letter, then all you need to provide is a signed paper copy of your revised company cover letter in response to the format hold notification.

## l. How does FDA process a replacement eCopy?

When FDA receives a replacement eCopy, it is processed in the same manner as the initial eCopy. More specifically, a determination is made as to whether or not the replacement eCopy passes the loading process. If it does not, then the submission will be placed on format hold again, and a format hold notification will be issued to you. You should submit a replacement eCopy via the CDRH Portal, ESG NextGen, or to the DCC with a signed copy of your company cover letter. Regardless of how you submit, please clearly identify this submission as a "Replacement eCopy" and include the full document number indicated on your format hold letter.

In your replacement eCopy, please provide the complete content for that specific document (original, supplement, report, or amendment), not just the corrections. Please do not supply just the corrected PDF. For example, if you submitted an eCopy for Amendment 1 to a PMA that includes 10 PDFs, and received a format hold letter for Amendment 1 that identified an invalid naming convention for one of those PDFs, your replacement eCopy for Amendment 1 should include all 10 PDFs with the corrected naming convention for the invalid PDF.

### m. What timeframes need to be considered?

If you are submitting a new submission and receive a format hold notification, you should respond to that format hold notification within 180 days. If FDA does not receive a replacement eCopy within 180 days of the format hold notification, FDA may consider your submission withdrawn and closed in our database.

If you are submitting a response to a review hold notification (e.g., a response to a major deficiency letter for a PMA), you should allow for mail delivery and eCopy processing times in order to ensure that you meet review hold notification deadlines. Use of the CDRH Portal can eliminate mail processing delays. You risk withdrawal and closure of your submission if your response is mailed very close to or at 180 days.

### n. When does review of a submission begin?

Review of a submission will begin only after a valid eCopy has been received and, if applicable, the user fee has been paid. As applicable for the submission type, acceptance or acceptance and filing reviews will then be conducted. Otherwise, the substantive review of the submission will begin.[14]

### o. If you submitted an eCopy for a submission type that did not require an eCopy and you received a format hold letter, what are your options?

If you submitted an eCopy for an IDE expanded access compassionate use request or report or emergency use report, IDE adverse event report, EUA, MAF, 513(g), or CLIA submissions (CRs and CWs), and it did not meet the technical standards in Attachment 1, your submission will be placed on format hold. However, unlike the other submission types that require a valid eCopy, you have the option of responding to that format hold notification with a paper copy in lieu of a replacement eCopy.

## VI. What if your device is regulated by CBER?

CBER will accept an eCopy that includes all elements, including the cover letter, and meets the standards in Attachment 1 through the ESG NextGen[15] or on physical media through CBER's Document Control Center. With the implementation of the statutory requirement, all medical device submission types listed in Section III, as well as all subsequent submissions to an original submission, including amendments, supplements, and reports (reports include annual/periodic and post-approval reports) must be in the form of an eCopy regardless of the Center in FDA in which the submission will be reviewed.

You can submit questions pertaining to the preparation of submissions in electronic format for submission to CBER at ESUBPREP@fda.hhs.gov.

[14] For more information, please see the guidances "FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Goals," and "FDA and Industry Actions on Premarket Approval Applications (PMAs): Effect on FDA Review Clock and Goals."

[15] Refer to FDA's webpage Electronic Submissions Gateway Next Generation (ESG NextGen).

You may also contact CBER at CBER.CDISC@fda.hhs.gov to discuss the potential for submission of data in Clinical Data Interchange Standards Consortium (CDISC) format.[16]

[16] See FDA's webpage Study Data for Submission to CDER and CBER.

# Attachment 1 – Technical Standards for eCopies

Below are the standards that are written into the FDA eCopy software coding. If an eCopy does not meet all of the required standards identified in Sections A through D below, then the eCopy will not pass FDA's eCopy loading process.

The following section is a simple summary of the process for creating an eCopy. It is critical that you read and understand all of the technical standards addressed in Attachment 1.

**The basic steps for developing an eCopy are as follows:**

1. Determine the content of your document (original, supplement, amendment, or report). This is not dictated by the eCopy Program.

2. Create your company cover letter following the specific requirements in Section A. Make sure your company cover letter includes a signature.

3. Based on the content, determine whether you want to have a volume-based or non-volume-based structure for your eCopy. This determination is made independently for each eCopy and is not dependent on the format chosen for any previous document. See Section B below.

   If you chose a volume-based submission, then add your volumes to the eCopy following the naming convention in Section B below.

4. Create your PDFs and add them to the eCopy. PDFs are the main file type, if not the only file type, that comprises your eCopy. Please note that PDFs should be created by converting the files from the original (native) format (e.g., Microsoft Word) using Adobe Acrobat whenever possible, rather than creating them as scanned versions of the printed files, which are far inferior in quality.

   For the naming convention for PDFs, follow the specifics in Section C, Part 1. Do not name a PDF using the volume/folder naming convention as the two differ from each other.

   PDFs can only be added to the root level of the eCopy or under a volume/folder as shown in Figures 3 through 12 below. The "root level" of an eCopy is defined as the main level that you see when you open a CD, DVD, or flash drive. If you have a volume-based submission, then your PDFs must be named with the prefix count starting with "001_" in each volume (001_, 002_, etc.) as shown in Figure 10 and Figure 11 below.

   You may have a single PDF that comprises your eCopy if it meets all of the standards in Section C, including the naming convention. The single PDF must have a "001_" prefix. Please note that the file size limit, in particular, must be taken into consideration if you are contemplating using a single PDF; see Section C, Part 4 below for details.

Aside from naming convention, do not forget the other PDF standards that you need to meet: (1) Adobe Acrobat or similar; (2) no embedded attachments; (3) no security settings; and (4) 50MB or smaller in size.

5. If you need to add non-PDFs to your eCopy, follow the instructions in Section D. Non-PDF files are added by zipping them and placing the zip file(s) under a "MISC FILES" or "STATISTICAL DATA" folder. Do not place any PDFs in either of these two folders. Please note that it is preferable that statistical data be provided in a structured format readable by common statistical analysis software packages.

6. If submitting via mail, prepare your package for submission. The package includes: (1) your eCopy burned to a CD, DVD, or flash drive, ensuring the media includes a copy of your signed company cover letter as described in Section A below.

7. The eCopy package can be mailed to the DCC or electronically sent using the CDRH Portal or ESG NextGen.

## A. Company Cover Letter Requirements

The company cover letter for the eCopy Program must include a signature on behalf of the company to meet standards. Do not confuse a company cover letter with Form FDA 3514 (CDRH Premarket Review Submission Cover Sheet).[17] A company cover letter is the document that is on your letterhead and includes information such as the purpose of your submission, contact information (including phone number and email address[18]), along with your signature. When describing the purpose of your submission, please use characteristics such as the submission type (e.g., PMA, Pre-Submission), stage of review (i.e., original, amendment, supplement, or report), and any other key words or information that will assist in FDA's processing of the submission. It is especially important to include the submission tracking number if one has already been assigned and provided to you.

Please also note that it is FDA's preference that responses to deficiencies identified during submission review not be incorporated into the company cover letter for ease of processing on both the part of the applicant and FDA. Instead, please incorporate your responses into the main body of your submission.

## B. Volume or Non-Volume Structure Requirements

The structure of an eCopy is highly dependent on the overall size of the submission and can be organized as a volume-based or non-volume-based submission as described below. Although there is no maximum total submission size restriction, it is recommended that the total package submission not exceed 4 GB to avoid possible delays in the submission process.

[17] Available at https://www.fda.gov/media/72421/download

[18] For additional information about email communications with CBER, see SOPP 8119: Use of Email for Regulatory Communications, available at https://www.fda.gov/media/108992/download

### 1. *Non-Volume-Based eCopy*

A non-volume based eCopy is generally recommended for small submissions. This eCopy structure includes one or more PDFs at the root level. **See Section C for required PDF file technical standards, particularly the required PDF naming convention.** Examples of non-volume-based eCopies are shown in Figures 3 through 9 below.[19]

Figure 3: Pre-Submission for which all content was was placed in a single PDF

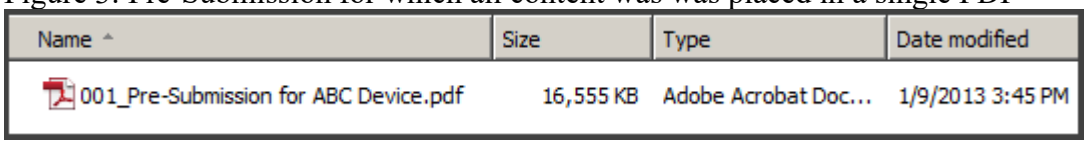



Figure 4: PMA annual report for which all content was was placed in a single PDF

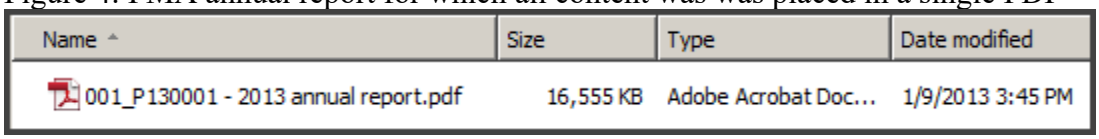
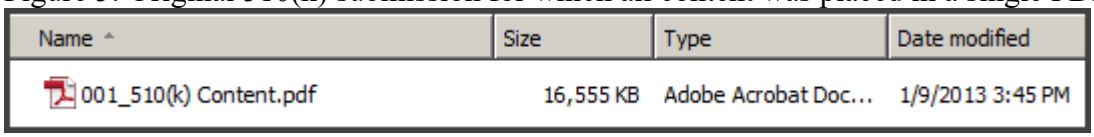
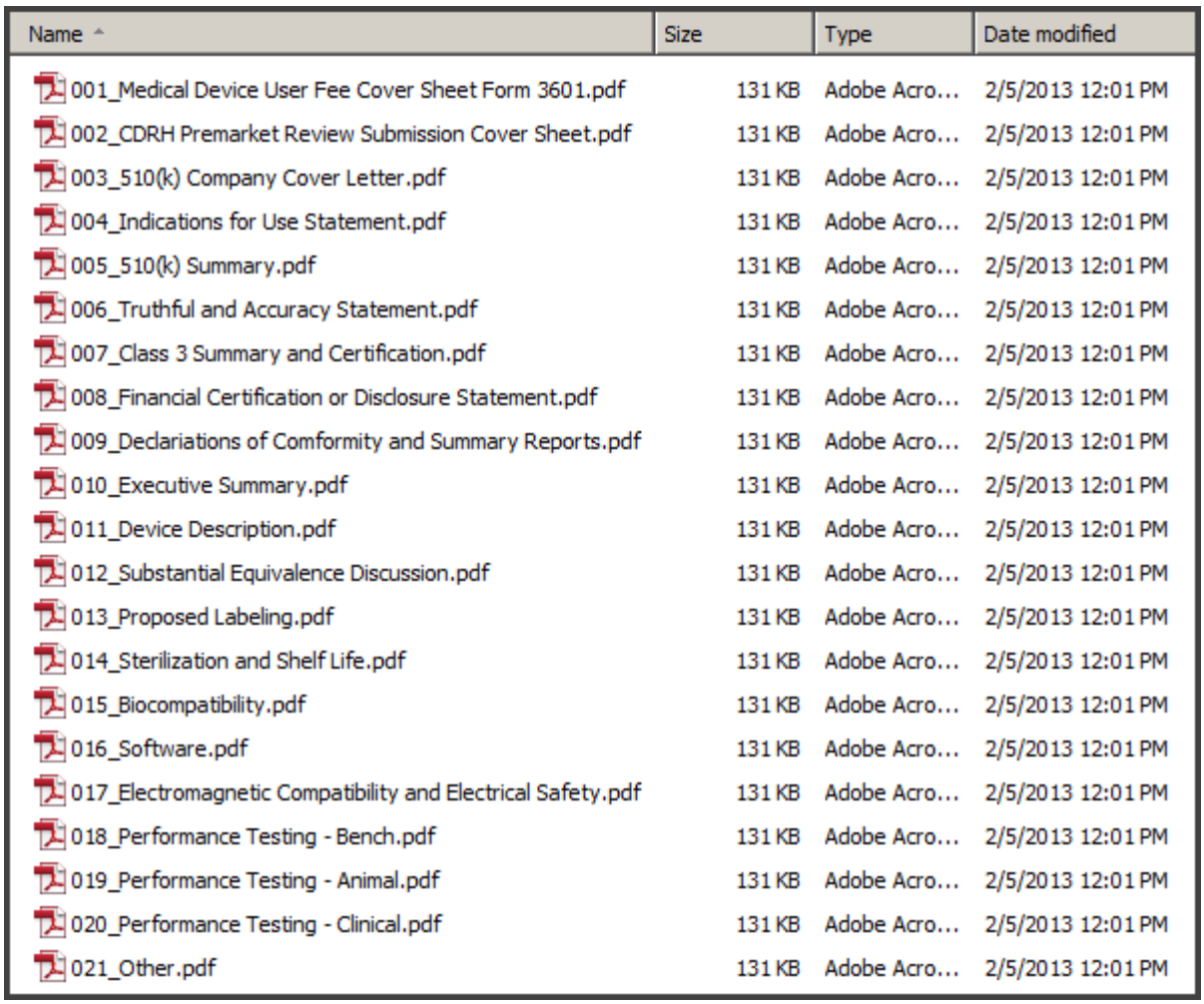



Figure 5: Original 510(k) submission for which all content was placed in a single PDF



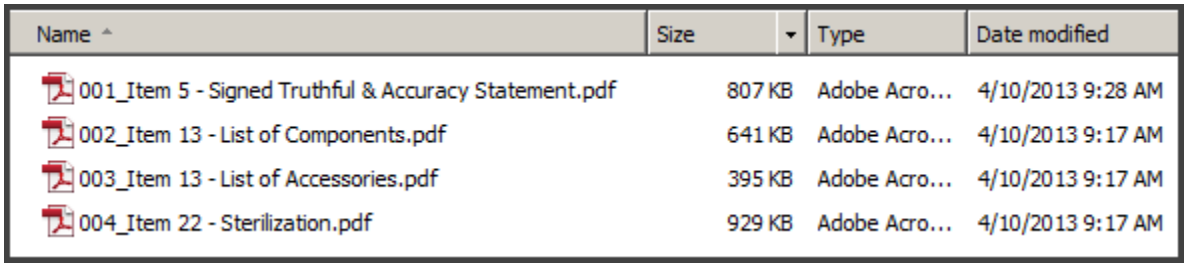

[19] Note that these figures are solely illustrative examples for the structure and naming conventions of non-volume-based eCopies. Some submission types in these examples require the use of eSTAR and an eCopy of these submission types will not be accepted.

Figure 6: Original 510(k) submission for which the content was added as individual PDF files



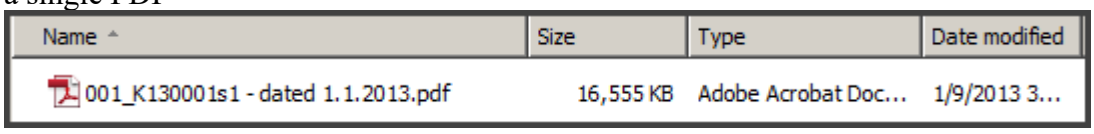
| Name | Size | Type | Date modified |
|---|---|---|---|
| 001_Medical Device User Fee Cover Sheet Form 3601.pdf | 131 KB | Adobe Acro... | 2/5/2013 12:01 PM |
| 002_CDRH Premarket Review Submission Cover Sheet.pdf | 131 KB | Adobe Acro... | 2/5/2013 12:01 PM |
| 003_510(k) Company Cover Letter.pdf | 131 KB | Adobe Acro... | 2/5/2013 12:01 PM |
| 004_Indications for Use Statement.pdf | 131 KB | Adobe Acro... | 2/5/2013 12:01 PM |
| 005_510(k) Summary.pdf | 131 KB | Adobe Acro... | 2/5/2013 12:01 PM |
| 006_Truthful and Accuracy Statement.pdf | 131 KB | Adobe Acro... | 2/5/2013 12:01 PM |
| 007_Class 3 Summary and Certification.pdf | 131 KB | Adobe Acro... | 2/5/2013 12:01 PM |
| 008_Financial Certification or Disclosure Statement.pdf | 131 KB | Adobe Acro... | 2/5/2013 12:01 PM |
| 009_Declariations of Comformity and Summary Reports.pdf | 131 KB | Adobe Acro... | 2/5/2013 12:01 PM |
| 010_Executive Summary.pdf | 131 KB | Adobe Acro... | 2/5/2013 12:01 PM |
| 011_Device Description.pdf | 131 KB | Adobe Acro... | 2/5/2013 12:01 PM |
| 012_Substantial Equivalence Discussion.pdf | 131 KB | Adobe Acro... | 2/5/2013 12:01 PM |
| 013_Proposed Labeling.pdf | 131 KB | Adobe Acro... | 2/5/2013 12:01 PM |
| 014_Sterilization and Shelf Life.pdf | 131 KB | Adobe Acro... | 2/5/2013 12:01 PM |
| 015_Biocompatibility.pdf | 131 KB | Adobe Acro... | 2/5/2013 12:01 PM |
| 016_Software.pdf | 131 KB | Adobe Acro... | 2/5/2013 12:01 PM |
| 017_Electromagnetic Compatibility and Electrical Safety.pdf | 131 KB | Adobe Acro... | 2/5/2013 12:01 PM |
| 018_Performance Testing - Bench.pdf | 131 KB | Adobe Acro... | 2/5/2013 12:01 PM |
| 019_Performance Testing - Animal.pdf | 131 KB | Adobe Acro... | 2/5/2013 12:01 PM |
| 020_Performance Testing - Clinical.pdf | 131 KB | Adobe Acro... | 2/5/2013 12:01 PM |
| 021_Other.pdf | 131 KB | Adobe Acro... | 2/5/2013 12:01 PM |

Figure 7: Response to 510(k) hold letter for which each item being responded to was added as an individual PDF file



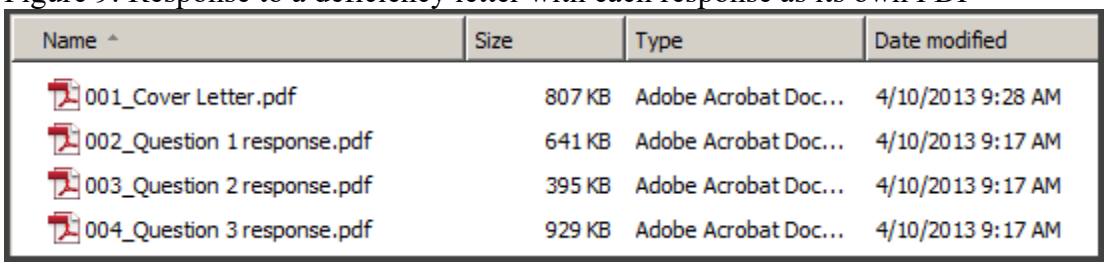
| Name | Size | Type | Date modified |
|---|---|---|---|
| 001_Item 5 - Signed Truthful & Accuracy Statement.pdf | 807 KB | Adobe Acro... | 4/10/2013 9:28 AM |
| 002_Item 13 - List of Components.pdf | 641 KB | Adobe Acro... | 4/10/2013 9:17 AM |
| 003_Item 13 - List of Accessories.pdf | 395 KB | Adobe Acro... | 4/10/2013 9:17 AM |
| 004_Item 22 - Sterilization.pdf | 929 KB | Adobe Acro... | 4/10/2013 9:17 AM |

Figure 8: Response to a 510(k) deficiency letter for which for which all content was placed in a single PDF



| Name | Size | Type | Date modified |
|---|---|---|---|
| 001_K130001s1 - dated 1.1.2013.pdf | 16,555 KB | Adobe Acrobat Doc... | 1/9/2013 3... |

Figure 9: Response to a deficiency letter with each response as its own PDF



| Name | Size | Type | Date modified |
|---|---|---|---|
| 001_Cover Letter.pdf | 807 KB | Adobe Acrobat Doc... | 4/10/2013 9:28 AM |
| 002_Question 1 response.pdf | 641 KB | Adobe Acrobat Doc... | 4/10/2013 9:17 AM |
| 003_Question 2 response.pdf | 395 KB | Adobe Acrobat Doc... | 4/10/2013 9:17 AM |
| 004_Question 3 response.pdf | 929 KB | Adobe Acrobat Doc... | 4/10/2013 9:17 AM |

### 2. *Volume-Based eCopy*

A volume-based eCopy is generally recommended for large or complex submissions in order to facilitate the review of the submission. This eCopy structure includes volumes (i.e., folders) at the root level. Each volume, in turn, includes one or more PDF files. No other file types but PDFs can be placed in these volumes.

A naming convention for the volumes is required in order to assure that the system can create a sort order of the folders. Without this sort order, the volumes will load in alphabetical order and, thus, be out of order.

**Each volume must have the following naming convention:**

- **VOL_xxx_Descriptive Name** (e.g., VOL_001_Mechanical Testing); or
- **VOL_xxx** (e.g., VOL_001).

**The volume numbering must have a non-repeating, consecutive prefix. The first volume has the prefix of VOL_001. The second volume has a prefix of VOL_002, etc. If this volume naming convention is not followed, the eCopy will fail the loading process.**

The Descriptive Name part of the name of the volumes is optional. However, if a Descriptive Name is used for a volume, it should be descriptive of its content and meaningful to the reviewer. The Descriptive Name can be up to 125 characters and can have spaces, dashes (not elongated dashes), underscores, and periods. For additional naming guidance refer to Section C, Part 1 below.

**No Subfolders:** Under this eCopy structure, you must avoid placing any subfolders under a volume or the eCopy will fail the loading process. Even if you have non-PDF documents that are associated with a particular volume, you cannot embed the “MISC FILES” or “STATISTICAL DATA” folder within one of these volumes or it will fail the eCopy loading.

**NOTE:** A slight variation of a volume-based eCopy structure includes both volumes and at least one PDF file at the root level. This structure commonly occurs when an applicant adds a PDF of the company cover letter at the root level with all other PDFs organized under multiple volumes. See Figure 12 as one example.

Examples of volume-based eCopies are shown in Figures 10 through 12 below.

Figure 10: Original PMA with the PDF content of VOL_001 and VOL_002 shown

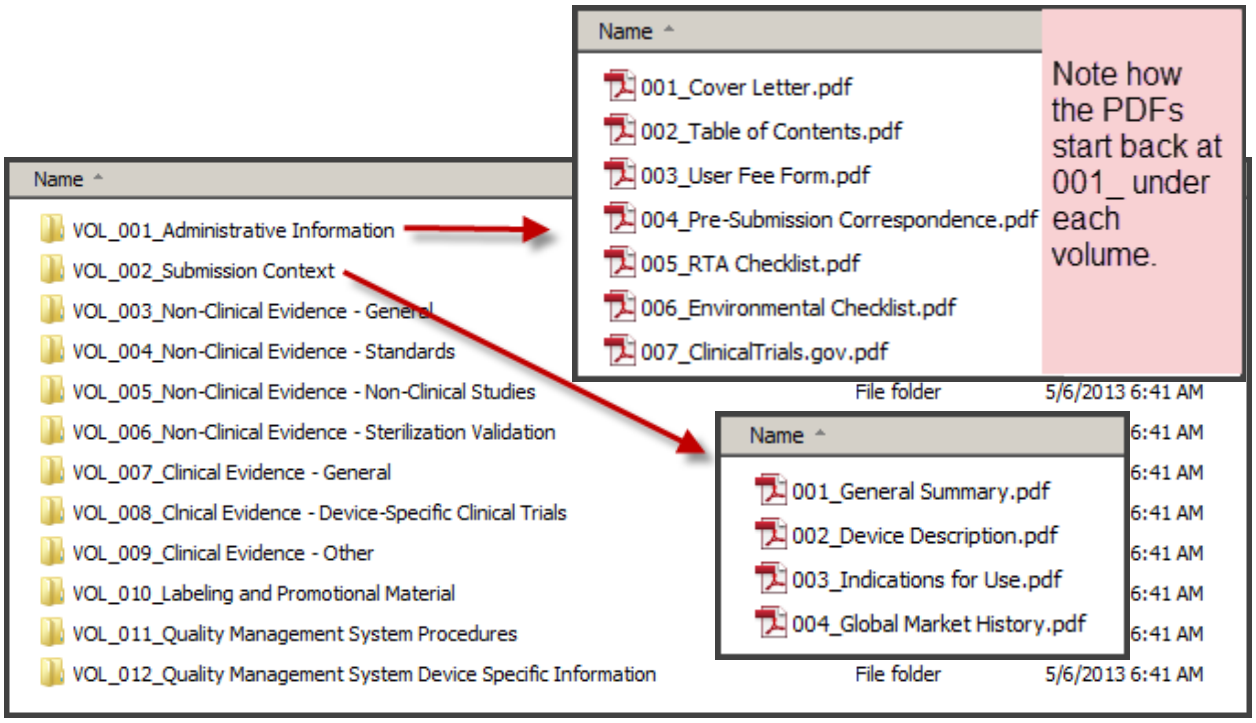



Figure 11: Original IDE with the PDF content of VOL_002 and VOL_003 shown

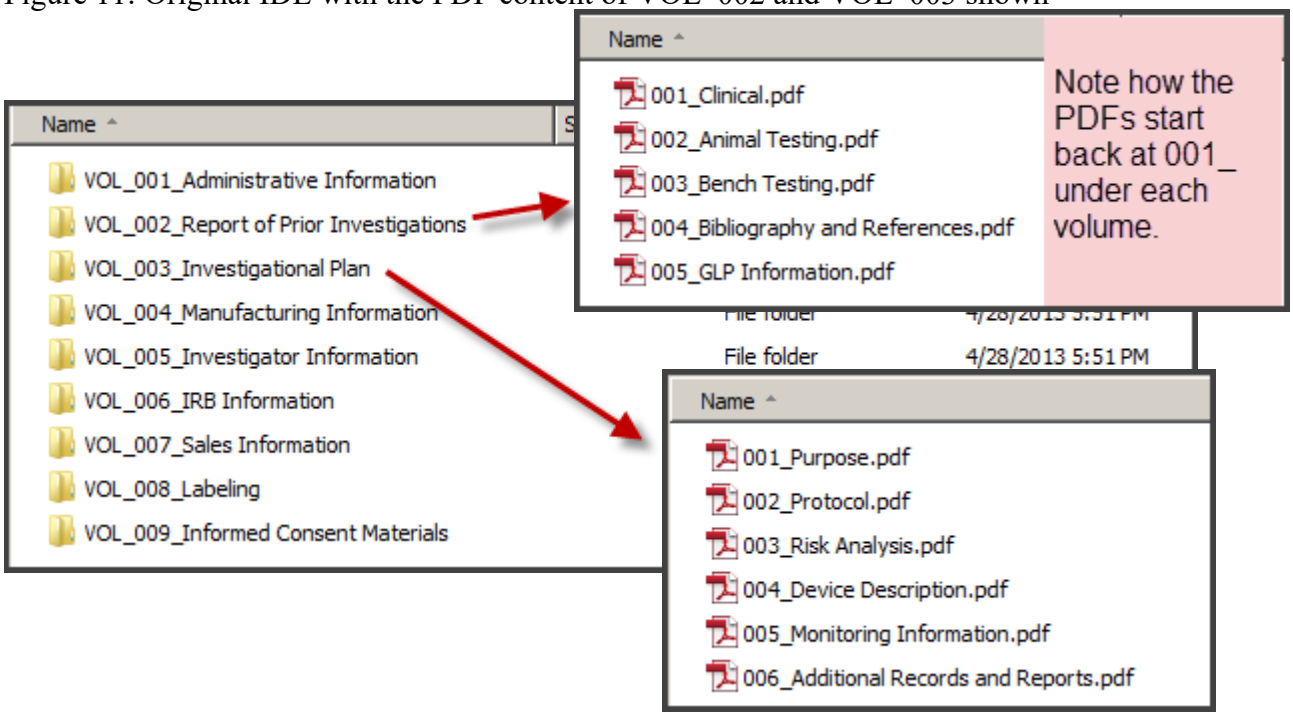
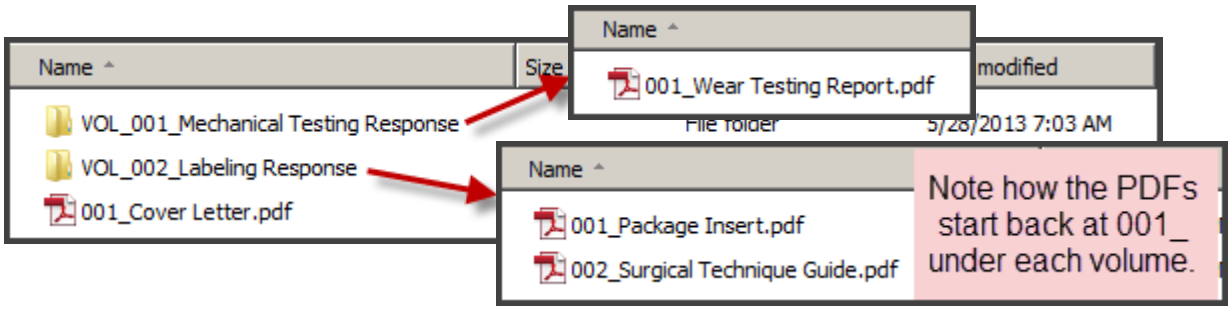


Figure 12: Response to hold notification for which the responses were grouped by topic




## C. PDF File Requirements

Whether you choose a volume-based or non-volume-based eCopy structure, PDF is the primary file format used for an eCopy. (See Section D for how to add non-PDF files to an eCopy.) **Below are the requirements for PDF files. If you do not follow them, your eCopy will fail the loading process.**

**NOTE:** You may choose to have a single PDF that comprises the entire submission, as long as all PDF file requirements below are met. However, it is important to note that, as described in Section C, Part 4 below, no individual PDF file may exceed 50MB. Also keep in mind that large files take longer to open and search than do small files. A very large file can also be difficult for reviewers to work with, unless there are bookmarks or hyperlinks. See Section C, Part 4 below for details.

### *1. Specific PDF File Naming Convention*

Regardless of which eCopy structure is used, a naming convention is required in order to assure that the loading system can create a sort order of PDF files that matches the order of files to be read by review staff. Without this sort order, the files will load in alphabetical order and, thus, be out of order.

**You must use the following naming convention for all PDF files, whether part of a volume-based or non-volume-based eCopy:**

- **xxx_Descriptive Name**

**The PDF file name has a non-repeating, consecutive 3-digit number prefix followed by an underscore (_). The first PDF has the prefix of 001_, the second PDF has a prefix of 002_, etc.** Keep in mind that if you have a volume-based submission, you need to start over with the numbering of the PDFs at 001_, 002_, etc. within each volume, as shown in Figure 10 and Figure 11 above. **If this PDF file naming convention is not followed, the eCopy will fail the loading process.**

**eCopies that are comprised of only a single PDF need to have the 3-digit prefix of 001_.**

The Descriptive Name part of the file name should be descriptive of its content and meaningful to the reviewers. The Descriptive Name can be up to 125 characters and can have

spaces, dashes (not elongated dashes), underscores, and periods. **However, the Descriptive Name must <u>not</u> contain any of the following special characters or non-English letters or it will fail the loading process**:

- tilde (~)
- asterisk (*);
- elongated dash (–);
- apostrophe (’);
- single quotation mark (‘);
- double quotation marks (“);
- colon (:);
- pound sign (#);
- vertical bar (|);
- forward slash (/);
- backward slash (\);
- greater than sign (>);
- less than sign (<);
- question mark (?); and
- various other symbols (e.g., →,*,β,α,∞,±,™).

Examples of the PDF file names are throughout the figures in Attachment 1.

**<u>NOTE</u>:** There is no correlation between the 3-digit file name prefix and the content or section location of the PDF file (e.g., a Section 10 response does not need a “010_” prefix). The 3-digit prefix is only used by the loading software to load the PDFs in the correct order; otherwise, the system would load the PDF files alphabetically. Depending on the Center involved, the review staff may or may not even see the 3-digit prefix after it is loaded into the official repository.

This is why it is important that you have meaningful Descriptive Names for your PDF files so that it is clear to review staff what the content of the file involves. You can use the Descriptive Name to also refer to Section or Tab numbers or review deficiency items. Descriptive Names will facilitate the review process by allowing the reviewer to easily navigate through the information. Examples of the varying Descriptive Names for the PDF files are throughout the figures in Attachment 1.

### *2. No Embedded Attachments or Attributes*

Our previous version of the eCopy software rejected PDF files with embedded attachments and attributes. We found that the rejected PDF files were due to embedded attachments or attributes that the applicant did not intentionally embed and of which they were unaware. Accordingly, in order to streamline the eCopy processing, we have updated our software to not reject PDFs with embedded attachments or attributes. **However, do <u>not</u> intentionally embed attachments to PDF files because those embedded attachments are not compatible with our official repository, which can result in this information being missed during the review (e.g., we cannot search for content in an embedded attachment in a PDF; the attachment is removed when a PDF is downloaded from the official repository).**

**<u>NOTE</u>**: Do not confuse embedded attachments or attributes with hyperlinks or bookmarks, as these are very different. Hyperlinks and bookmarks are not only permitted, but are also encouraged, because they facilitate navigation of the submission by the reviewer; they are described in Section V.b above.

### 3. *No PDFs that Require a Password to Open*

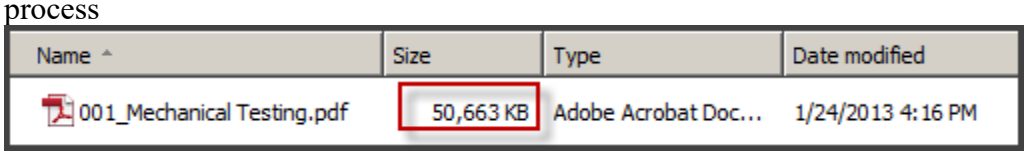
PDF files that contain protection allowing a user to open the submission but protect it from modification can be accepted and processed. However, we discourage submitting PDF files with any type of security setting, because this affects our ability to redact Confidential Commercial Information efficiently. Furthermore, PDFs with password protection cannot be accepted or loaded into our system, so any submission with a password will be placed on format hold.

### 4. *PDF File Size Limited to 50MB or Below*

While there is no limitation on the total size of an eCopy, each PDF file must be limited to 50MB or smaller.

Be careful to look at the file size after you have added it to your eCopy media (CD, DVD, or flash drive), as shown in Figure 13. The file size shown here is what the loading software will use to determine if the size technical standard has been met. Do not use the size limit in the file properties or the size limit that appears when you hover the cursor over a PDF file, as both of these sizes will be smaller and will mislead you as to whether or not the PDF size technical standard has been met.

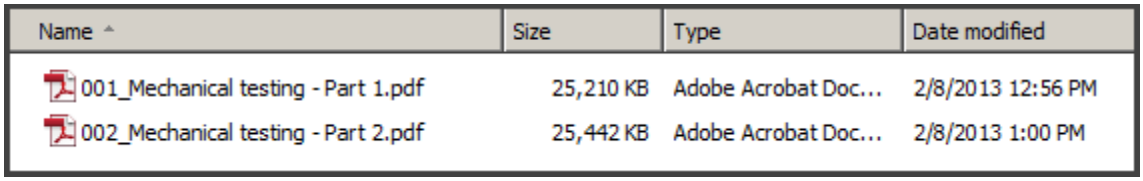
Figure 13: PDF that has exceeded the 50MB size limit and will fail the eCopy loading process



| Name | Size | Type | Date modified |
|---|---|---|---|
| 001_Mechanical Testing.pdf | 50,663 KB | Adobe Acrobat Doc... | 1/24/2013 4:16 PM |

If a file size is greater than 50MB, then you must split the contents into multiple files. We recommend that you name the files in a way that clearly reflects that it was originally a single file that was split into multiple files. One suggested way of accomplishing this is by naming the files as Parts 1 and 2 as shown in Figure 14 below.

Figure 14: Example of how you can split and label a PDF greater than 50MB into multiple files



| Name | Size | Type | Date modified |
|---|---|---|---|
| 001_Mechanical testing - Part 1.pdf | 25,210 KB | Adobe Acrobat Doc... | 2/8/2013 12:56 PM |
| 002_Mechanical testing - Part 2.pdf | 25,442 KB | Adobe Acrobat Doc... | 2/8/2013 1:00 PM |

## D. Requirements for How to Add Non-PDF Files via "STATISTICAL DATA" and "MISC FILES" Folders

Section B describes how both a volume-based and non-volume-based eCopy includes PDF files. However, in addition to PDF files, an eCopy may also include non-PDF files, if applicable for a particular submission.

The three required steps for adding non-PDF files to an eCopy are as follows:

- Add a "STATISTICAL DATA" or "MISC FILES" folder to the root level of the eCopy. These folders must be spelled precisely, but they are not case sensitive.

- Zip all non-PDF content into one or more zip file(s). In order to avoid loading errors, we recommend that the naming convention for a zip file(s) or any of the content that you add to the zip file(s) avoid use of special characters or non-English letters as identified in C.1., above. There is no size limit for a zip file.

- Statistical data, videos, and medical images (e.g., CT, MRI, or X-rays in DICOM format) are typically large files. This, in turn, will lead to excessively large submission sizes. Although there is not a size limit for the zip files discussed in this section, FDA strongly recommends that you take any appropriate and feasible steps to reduce the file sizes. For example, videos can be compressed to much smaller sizes than that of the original recording. It is important to recognize that very large file sizes take much longer to load and may present viewing issues with the FDA review staff. Whenever possible, make the non-PDFs that you zip into reasonably small file sizes. If you have multiple large non-PDFs, split them into separate zip files.

- Add the zip file(s) to the "STATISTICAL DATA" or "MISC FILES" folder.

**If you do not follow these requirements, the eCopy will fail the loading process.**

**NOTE**: Depending on the type of non-PDF files that you want to add to your eCopy, you may determine that it is appropriate to have both the "STATISTICAL DATA" and "MISC FILES" folders in your eCopy. Figure 16 below illustrates this.

Below describes the type of appropriate information as part of a "STATISTICAL DATA" or "MISC FILES" folder.

### *1. "STATISTICAL DATA" folder*

The "STATISTICAL DATA" folder is used to add types of statistical information, including metadata, data line listings and program codes, to the eCopy in their native formats, such as, but not limited to: SAS; XPORT; XML; SGML; S-Plus; R files; ASCII; Molfiles; and Excel. Metadata includes data dictionaries and terminologies, formats, annotated case report forms, statistical analysis details, and any other information that contributes to understanding and using the data. There are no restrictions on the format used; however, file formats that include variable labels and dictionary information (such as SAS XPORT) are encouraged.[20]

**Do not forget to zip the content before placing it within the STATISTICAL DATA folder.**

### *2. "MISC FILES" folder*

[20] For further information, see the final guidance, "Providing Regulatory Submissions in Electronic Format – Standardized Study Data."

The "MISC FILES" folder is used to add types of files that that cannot be submitted (or should not be submitted) in PDF format and are not statistical in nature (e.g., videos, medical imaging in DICOM format, machine readable software source code). These miscellaneous files may be included in the eCopy under the MISC FILES folder in their native formats, such as, but not limited to: .gif; .tif; .jpg; .avi; .mpeg; .wmv; and .txt. There are no restrictions on the native format.

In addition, for the purposes of streamlining the review process, FDA encourages you to also include, under the MISC FILES folder, Microsoft Word versions of certain documents or pieces of information that were also provided in the main body of the eCopy as PDFs. In other words, include the PDF version in the main body of the eCopy as part of the volume-based or non-volume-based eCopy structure and include a Microsoft Word version in the MISC FILES folder to assist the reviewer. **Do not include Microsoft Word versions in lieu of the PDF versions.** Documents such as those listed below are commonly requested via Interactive Review to enable FDA feedback to the applicant and/or completion of the review. Inclusion of these documents within the MISC FILES folder in an eCopy can help to minimize potential delays during the substantive review of the submission. Suggested documents include, as applicable:

- Labeling for any submission, preferably with each piece (e.g., physician labeling, patient labeling, operators manual) as a separate file;
- Summary of Safety and Effectiveness Data (SSED) for PMAs; and
- Summary of Safety and Probable Benefit (SSPB) for HDEs.

In order to avoid loading errors, we recommend that the naming convention for any files you add to the zip files for the MISC FILES folder avoid use of special characters or non-English letters as identified in C.1., above. However, for Microsoft Word documents included in the MISC FILES folder, it is recommended that you use a naming convention similar to the PDF equivalent files so that reviewers can easily make the correlation.

**Do not forget to zip the content before placing it within the MISC FILES folder.**

Figure 15 provides an example of non-volume-based eCopy with a MISC FILES. Figure 16 provides an example of a volume-based eCopy that includes both the STATISTICAL DATA and MISC FILES folders. Both figures show the zip file(s) directly under the folder.[21]

[21] Note that these figures are solely illustrative examples for the structure and naming conventions of non-volume-based eCopies containing MISC FILES and/or STATISTICAL DATA folders. Some submission types in these examples require the use of eSTAR and an eCopy of these submission types will not be accepted.

Figure 15: Example of a non-volume-based submission with a “MISC FILES” folder

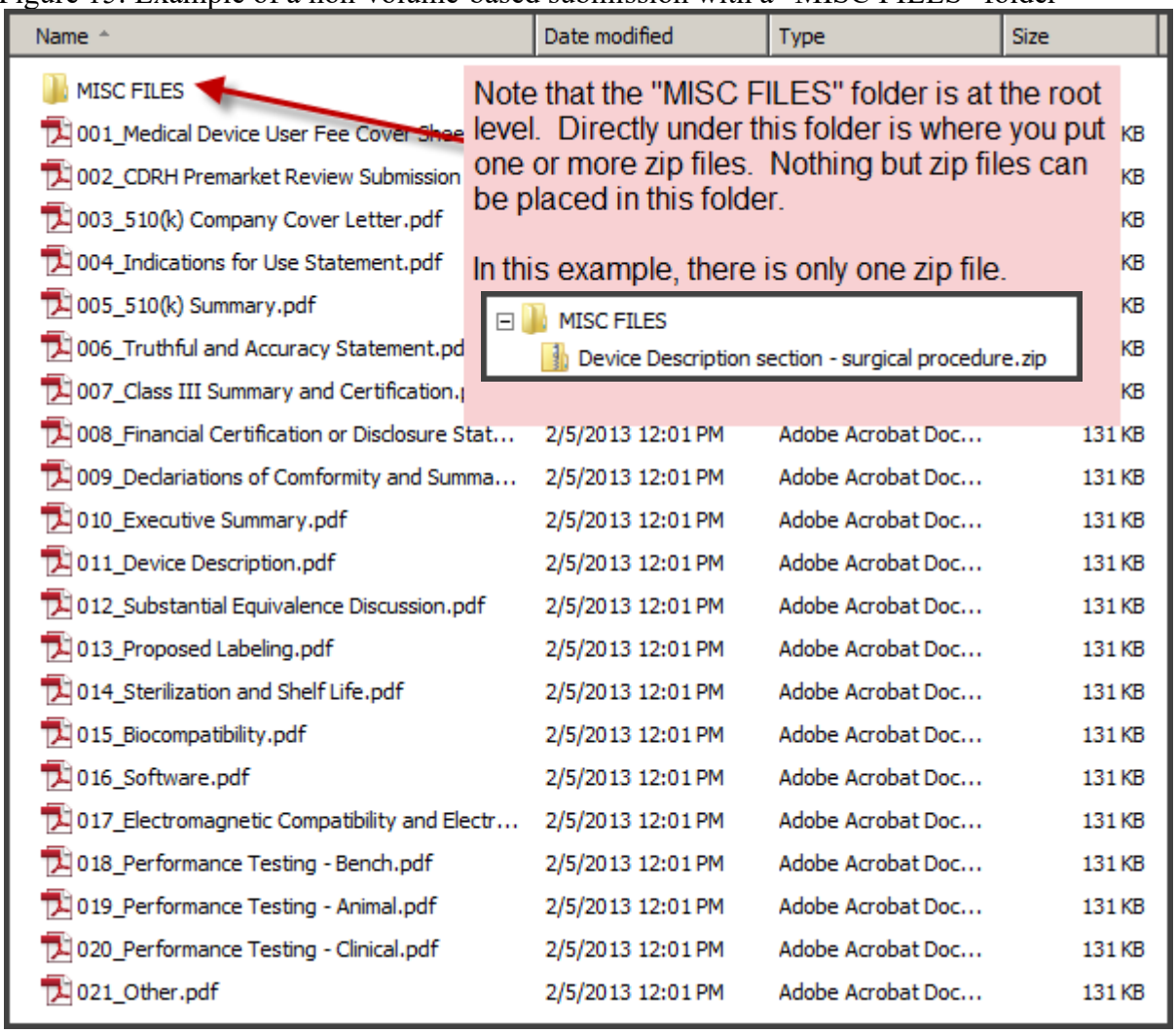
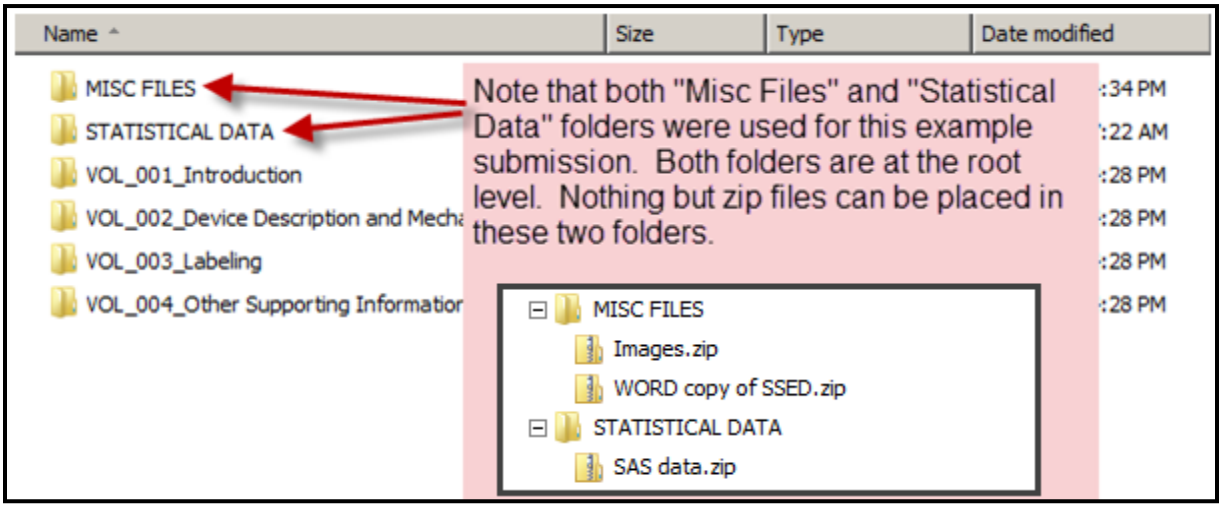



Figure 16: Example of a volume-based submission with “MISC FILES” and “STATISTICAL DATA” folders



| Guidance History* | Date | Description |
|---|---|---|
| Revisions to Final Guidance | December 2025 | Revisions issued under Level 2 guidance procedures (21 CFR 10.115(g)(4)). Clarified the intersection of the eCopy Program with the eSTAR Program and the availability of the CDRH Portal or ESG NextGen, as well as minor updates to reflect modern technical standards. |
| Revisions to Final Guidance | April 2020 | Revisions issued under Level 2 guidance procedures (21 CFR 10.115(g)(4)). Minor update to clarify that EUAs can be submitted via email as described in the "Emergency Use Authorization of Medical Products and Related Authorities" guidance. |

*This table was implemented beginning December 2025 and previous guidance history may not be captured in totality.