
OFFICE OF NEW ANIMAL DRUG EVALUATION REVIEWER'S CHAPTER

CREATING CLEAN ELECTRONIC FILES

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I. PURPOSE


This document:


- Applies to all ONADE-generated documents intended for inclusion in the administrative file, and
- Provides instructions on how to prepare clean electronic files. A clean file is a file that contains no hidden text, comments, or other tracked changes that result from the electronic creation and review of the file.

II. ELECTRONIC FILES

There should always be an electronic file for each document (e.g., review, letter, or memorandum to file) placed in the administrative record. For Submission Tracking and Reporting System (STARS) submissions, clean electronic files are prepared as part of the final action process (see P&P 1243.3030).

A. "Clean" electronic files

An electronic file is "clean" when you have removed all traces of information not intended to be part of the final electronic document. Examples of this trace information include hidden text, comments, and other tracked changes that result from the electronic creation and review of the file. To view comments and tracked changes in Microsoft Word, first display the Review toolbar. Then select "Final Show Markup" button in the toolbar. Tracked changes and comments that have not been removed, will become visible in one or more colors and are usually marked by a vertical black line in the left-hand margin. Tracked changes and comments can be found by selecting the "Next" button () in the Review toolbar. Do not use the Review function in Microsoft Outlook to search for tracked changes because tracked changes are difficult to identify this way.

To view hidden text, select the Show/Hide button () and look for text that only becomes visible when this icon is activated.¹ Previously hidden text will also be marked with dots underneath.

To create a clean electronic file, delete all hidden text, accept or reject visible editorial changes, delete all remaining comments after confirming they have been addressed, turn off track changes, and save the file.

When ONADE Microsoft Word templates (including e-mail templates) are used to create electronic files, they may contain gray shading in the areas where there are form fields. Do not delete the shading, as the document will still be considered "clean."

B. Fonts used in electronic files

- Use 10 point Verdana as the principal font in all documents. However, outputs generated with program-specific fonts or formatting (e.g., SAS) can be included in their original form.
- Use 10 point Symbol font to insert Greek and other characters and symbols.
- Do not embed fonts in a document. To ensure fonts are not embedded, click "File" on the Tools menu of Microsoft Word, click the "Options" tab, click the "Save" tab, uncheck the box "Embed fonts in the file", and finally click "Ok".
- Do not format any part of the document as hidden text.

C. Other file features

- The document language is defaulted to English. When copying and pasting information from another document to the document in which you are working, be sure to right click on your mouse and select "Keep text only" when pasting, to ensure that the document language remains English.
- Use the equation editor in Microsoft Word or the MathType plug-in for statistical equations and similar uses.

¹ To display only hidden text and not all formatting marks, select "File" then "Options". Next, click the "Display" tab, check the "Hidden text" box, and select "OK".

- There is no need to fill in the "Properties" box as it is already prepopulated depending on the Office template that you are using.

III. RESPONSIBILITIES OF ONADE PERSONNEL

All ONADE personnel are responsible for preparing clean electronic file documents for the administrative file. Divisions are responsible for ensuring electronic files are clean before they are finalized out.

If ONADE personnel send electronic files for archiving that are not clean, the file or files in question will remain as is in the archive. They are official records and are part of the administrative files and will not be deleted, replaced, or edited.² If the comments or tracked changes within the file or files in question lead us to believe clarification of the administrative record is in order, ONADE personnel can prepare an amended document and place that in the archive in addition to the document containing track changes.

IV. REFERENCES

CVM Program Policy and Procedures Manual

1243.3030 - Completing Final Action Packages for STARS Submissions

V. VERSION HISTORY

September 4, 2007 – The information in this document was originally contained in ONADE P&P 1243.3030 (November 19, 2003 version). This P&P updates the process to include responsibilities of ONADE staff for creating and sending forward clean electronic files for the administrative file

² ONADE policy is that when ONADE-generated files (both the paper and electronic versions of that file, (be it a consulting review or a primary review) have been processed through STARS they are considered a record and are therefore subject to the Federal Records Act 44 USC 31. Under the provisions of this act, § 3101 (Records management by agency heads; general duties) states that "The head of each Federal agency shall make and preserve records containing adequate and proper documentation of the organization, functions, policies, decisions, procedures, and essential transactions of the agency and designed to furnish the information necessary to protect the legal and financial rights of the Government and of persons directly affected by the agency's activities." This means that even if an electronic record is found to contain edits and comments it is to be preserved as it is. Additionally, 36CFR1222.50 (Records maintenance and storage) also states that each Federal agency shall [...] "Establish and implement procedures for maintaining records and nonrecord materials separately; ensure that record materials generated electronically are clearly identified as records and protected from unauthorized change or deletion for the length of their scheduled retention period."

January 15, 2009 – Added specific information for ONADE Outlook templates. Minor editorial changes.

July 2, 2013 – Document was revised to reflect Microsoft Word 2010 updates, change the font type to Verdana, and make other minor editorial changes.

June 13, 2016 – Updated to current formatting and grammar.