
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 all traces of information that are not intended to be part of the final electronic document are removed. 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, you will first need to display the Reviewing toolbar. Then select “Final Showing Markup” in the “Display for Review” 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. You can also find tracked changes and comments by selecting the “Next” button () in the Reviewing toolbar.

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

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

When you use ONADE templates to create electronic files, they will contain gray shading in the areas where there are form fields. You do not need to delete the shading; the document will still be considered “clean.”

B. Fonts used in electronic files

1. Use 12 point Times New Roman 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.
2. Use 12 point Symbol font to insert Greek and other characters and symbols.
3. Embed all fonts used in a document to prevent the possibility of font substitution when viewing the document.² Font substitution could result in an unreadable document or, more likely, a misinterpretation of the document, e.g., an “m” is substituted for the Greek character mu (μ). To embed the document’s fonts, click “Options” on the Tools menu of Microsoft Word, click the “Save” tab, select the “Embed TrueType fonts” check box, deselect (if necessary) the two sub-menu items related to embedding only characters

¹ To display only hidden text and not all formatting marks, select “Tools” then “Options”. Next, click the “View” tab and select “Hidden text” under “Formatting Marks” and select “Ok”.

² Font embedding enables fonts used in the creation of a document to travel with that document, ensuring that a user sees the pages exactly as the author intended.

used or not embedding common system fonts, and finally “Save” the document.

4. Do not format any part of the document as hidden text.

C. Other file features

1. The document language should be set to English. To choose the language for the entire document in Microsoft Word, select “Edit” then “Select all”. Next, go to “Tools” then “Language” then “Set Language” and select “English (U.S.)”. Make sure the “Do not check spelling or grammar” is not checked, and then click “Ok”.
2. Use the equation editor in Microsoft Word or the MathType plug-in for statistical equations and similar uses.
3. Fill in Title field in file properties by selecting “File” then “Properties,” and then the “Summary” tab. Use the principal submission identifier number as the title (e.g., A-123456-E-1234-OT (A1)). You may also fill in additional fields if specified in your division, team, or staff operating procedures.

III. RESPONSIBILITIES OF ONADE PERSONNEL

All ONADE personnel are responsible for preparing clean electronic file documents for the administrative file. Supervisors are responsible for ensuring that 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 our archive. They are official records and are part of our administrative files and will not be deleted, replaced, or edited.³ If the

³ ONADE policy is that once an ONADE-generated file has been processed through STARS (be it a consulting review or a primary review) it is final and is a record. This means that when a ONADE-generated file (both the paper and electronic versions of that file) 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

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 that we will add to the archive in addition to the document being amended.

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

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".

Responsible Office: Office Of New Animal Drug Evaluation

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