**OFFICE OF NEW ANIMAL DRUG EVALUATION REVIEWER'S CHAPTER**

## CREATING CLEAN ELECTRONIC FILES

## I.    PURPOSE

This document describes how to prepare clean electronic files. Clean files contain no hidden text, comments, or other tracked changes that result from the electronic creation and review of the file. Clean files are prepared for all Office of New Animal Drug Evaluation (ONADE)-generated documents included in an administrative 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, including hidden text, comments, and other tracked changes that result from the electronic creation and review of the file. When ONADE templates (Word and email templates) are used to create electronic files, they may contain gray shading in the form fields. Do not delete the shading, as the document will still be considered clean.

To view comments and tracked changes in Word, click to the Review toolbar and click the Final Show Markup button. Tracked changes and comments that were not removed will become visible in one or more colors and are marked by a vertical black line in the left-hand margin. Tracked changes and comments can be found by clicking the Next button (  ). Do not use the Review function in Outlook 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.

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[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.

### B. Fonts Used in Electronic Files

- Use 11-point Arial font in all documents. However, outputs generated with program-specific fonts/formatting (e.g., SAS) can be included in their original form. Ensure the font is 11-point Arial font when inserting Greek letters and other characters and symbols.

- To insert a symbol, select the Insert ribbon in Word and click the Symbol dropdown. In our documents, the standard format for the trademark (™), copyright (©), and registered trademark (®) symbols is superscript. When inserting the registered trademark or copyright symbol, this must be superscripted manually for the correct format.

- Do not embed fonts in a document. To ensure fonts are not embedded, click File on the Tools menu of 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 into your current document, right click the 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.

- There is no need to fill in the Properties box; it is 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 finaled out. If ONADE personnel send electronic files for archiving that are not clean, then the file(s) in question 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

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2 ONADE policy is that when ONADE-generated files (paper and electronic versions; consulting and primary reviews) are processed through STARS, they are considered records and are subject to Federal Records Act 44 USC 31. § 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." As such, if an electronic record is found to contain edits and comments, then it is to be preserved as-is. 36CFR1222.50 (Records maintenance and storage) 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."

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 – ONADE Reviewer's Chapter

1243.3030 - Completing Final Action Packages for Submission Tracking and Reporting System (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

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.

March 4, 2020 – Updated to current format. No substantive changes were made to the content.

January 26, 2021 – Updated section II B to clarify information about inserting and formatting symbols within our documents.

July 22, 2022 – Quality systems review for minor formatting updates.

March 29, 2023 - Updated the information on standards to reflect the office switch to Arial 11 point font as our standard font. To bring all office quality system documentation into compliance with the FDA Visual Identity Program approved fonts, ONADE has adopted Arial 11 point font. The font of this document was changed from Verdana 10 point font to Arial 11 point font.