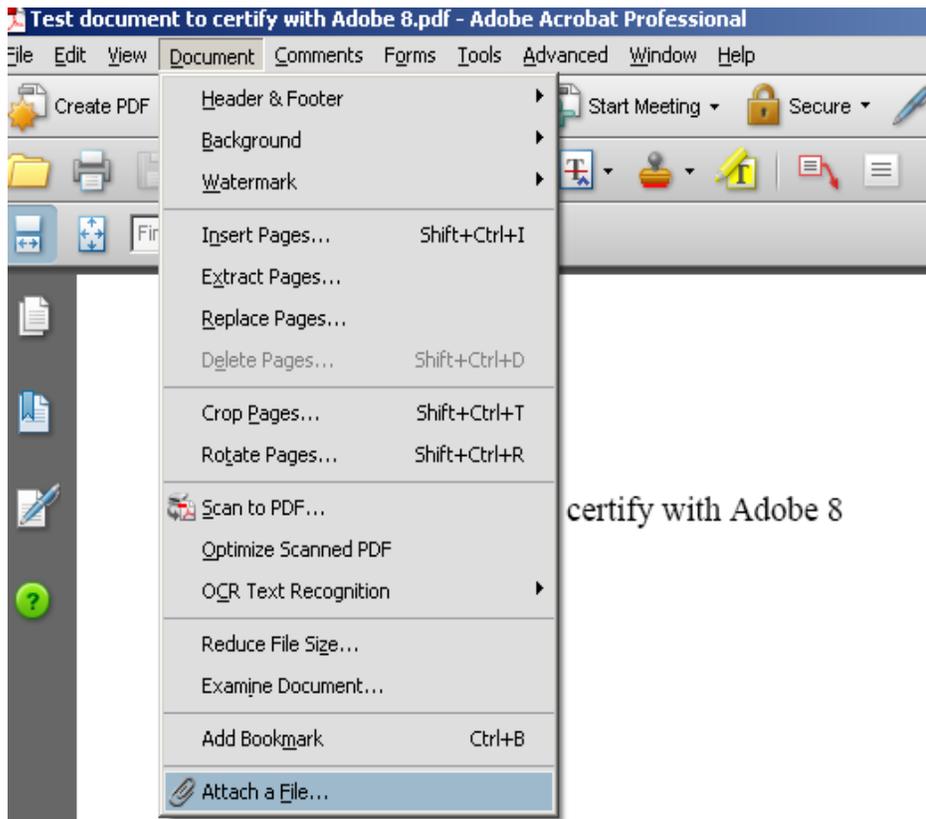


User Guide for CBER's Electronic Signature Process

To Attach a Word Document

Once you have converted the document to PDF, you are ready to electronically stamp the PDF. First, you need to attach the Word version of the document to the PDF.

Attach the Word version of the document to the PDF by selecting *Document* from the toolbar and then *Attach a File*. NOTE: The Word file must be closed before it can be linked to the PDF version.



Browse to the Word file that you created originally, select it and it will show up on the bottom of the PDF screen.



To Use the Electronic Stamp tool

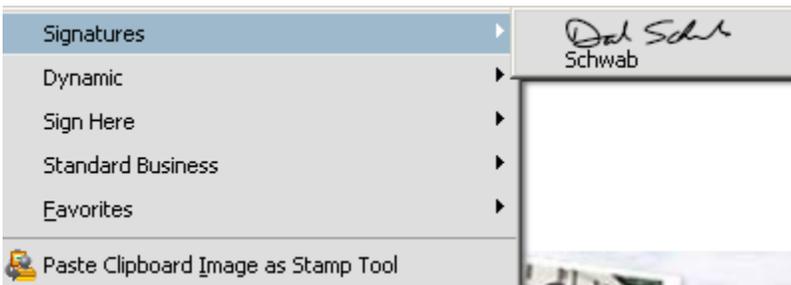
Only the signature authority should use the Adobe Dynamic Stamp Tool for signatures. All others should use the “approved” stamp tool that indicates the person’s name and the date of “approval.”

Locking the signature once you have signed the document:

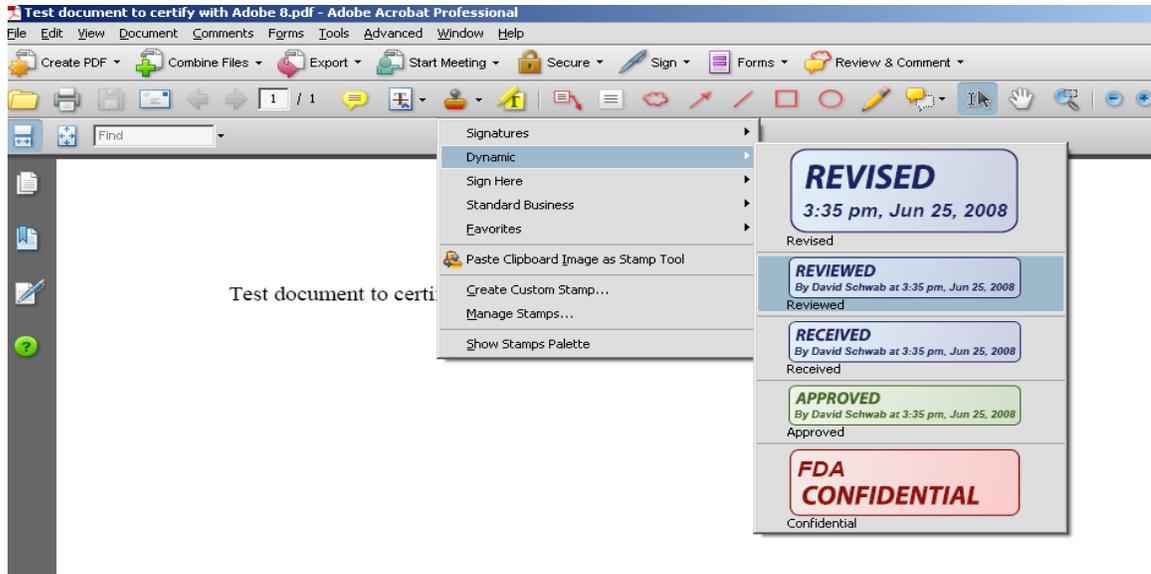
It’s CBER policy to lock the signature to prevent inadvertent deletion.

- After the location and size have been achieved, right click on the signature to produce a list of options. Left click on PROPERTIES to produce the Stamp Properties window.
- Left click on the GENERAL tab. In the bottom-left of the window, click the LOCKED box. The signature is now locked, and only the original user may unlock it. Properties will allow those who wish to view the signature to see what date and time the document was signed. Click CLOSE.

In Adobe, click on the *stamp tool* and choose the category of stamp you wish to use. Use the Signature category if you are putting your electronic signature on a letter or use the Dynamic category to use the Approved stamp.



OR



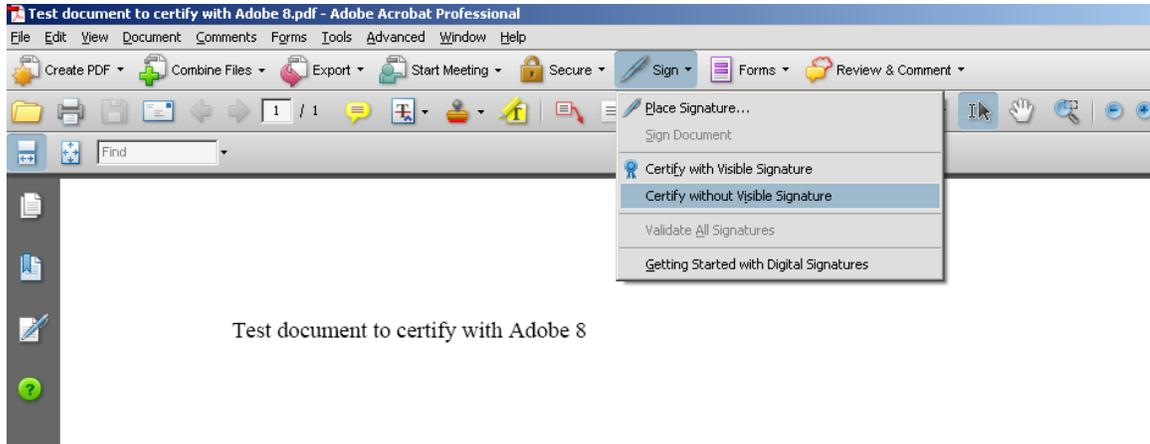
NOTE: If the stamp icon is not viewable, select *View—Toolbars* and make sure that *Comment & Markup* is checked.

To Certify a PDF Document

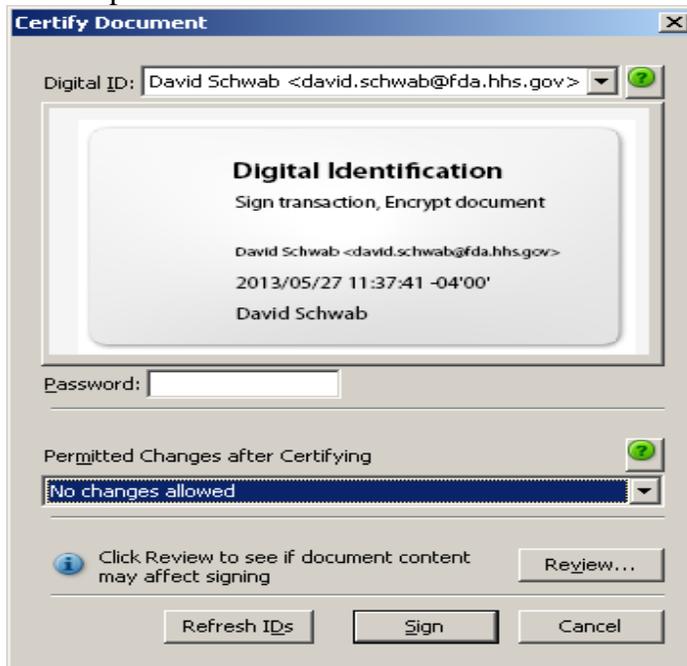
It's CBER policy that any document **MUST** be certified prior to importation into the Electronic Document Room (EDR). All passwords must be removed prior to certification.

Prior to final certification of the PDF document, for marketing submissions, attach the correct WORD version of the document to enable OCTMA's retrieval for redaction and posting purposes. The intent of this step is to have the documents travel together.

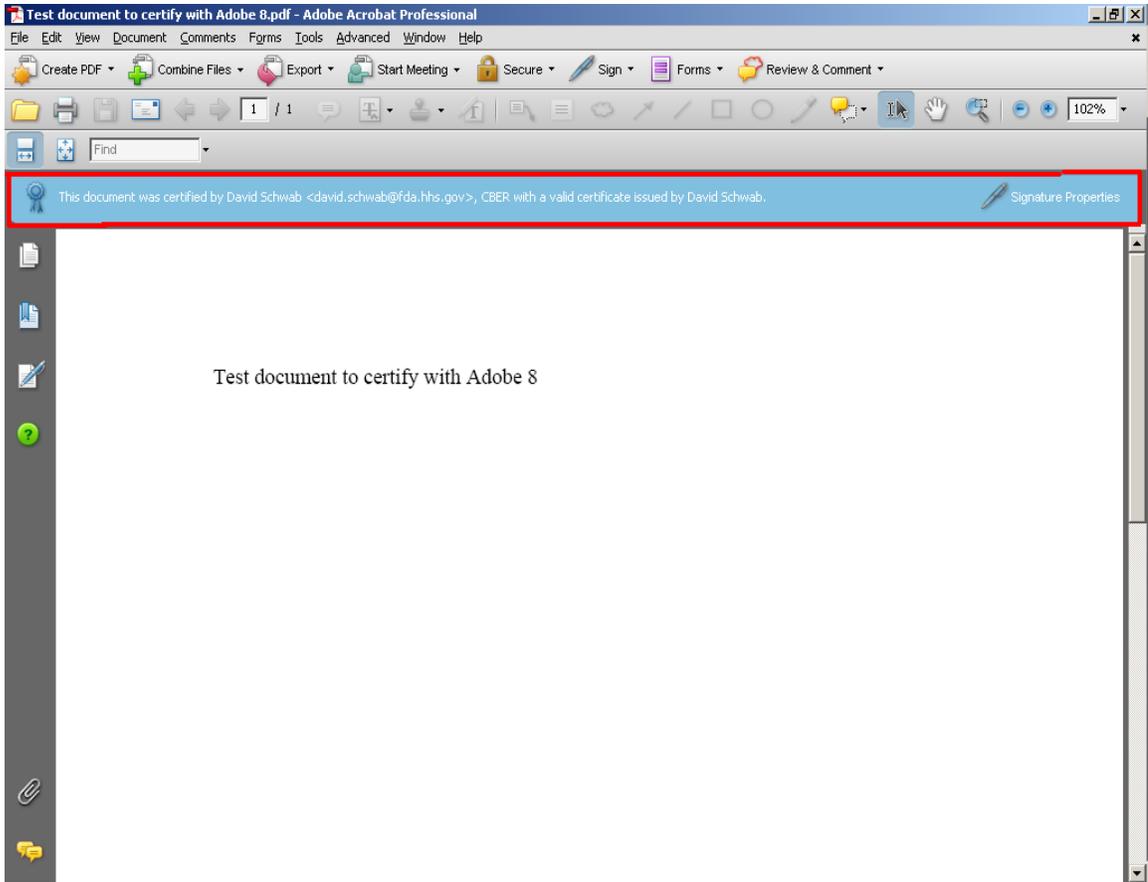
In Adobe, click the drop down arrow next to the Sign option and choose Certify without visible signature.



Enter your password, select *no changes allowed*, and click on *Sign*. You will be prompted for a filename and location to save the newly certified PDF file. Once you specify the filename and the location, click on *Save* and the file will be certified and ready to be imported into the EDR.



You will see a blue bar at the top of your PDF document that reads *This document was certified by (Your Name), CBER with a valid certificate issued by (Your Name)*.

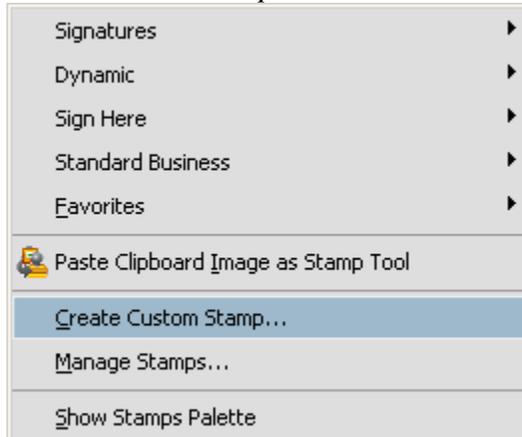


To Create your Electronic Signature Stamp

Your Office contact (Appendix 2) for electronic signatures will make arrangements for the capture of your electronic signature, usually with a representative from OIM. Once the signature is captured, an email will be sent to the user containing the electronic signature file as an attachment.

If you are a signing authority and need to create your electronic signature block, follow these steps:

Click on the arrow next to the Adobe Stamp tool.
Select *Create Custom Stamp*



Click *Browse* to select the location where your PDF signature file is located and click

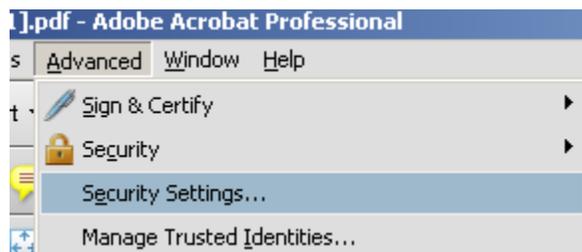


OK.

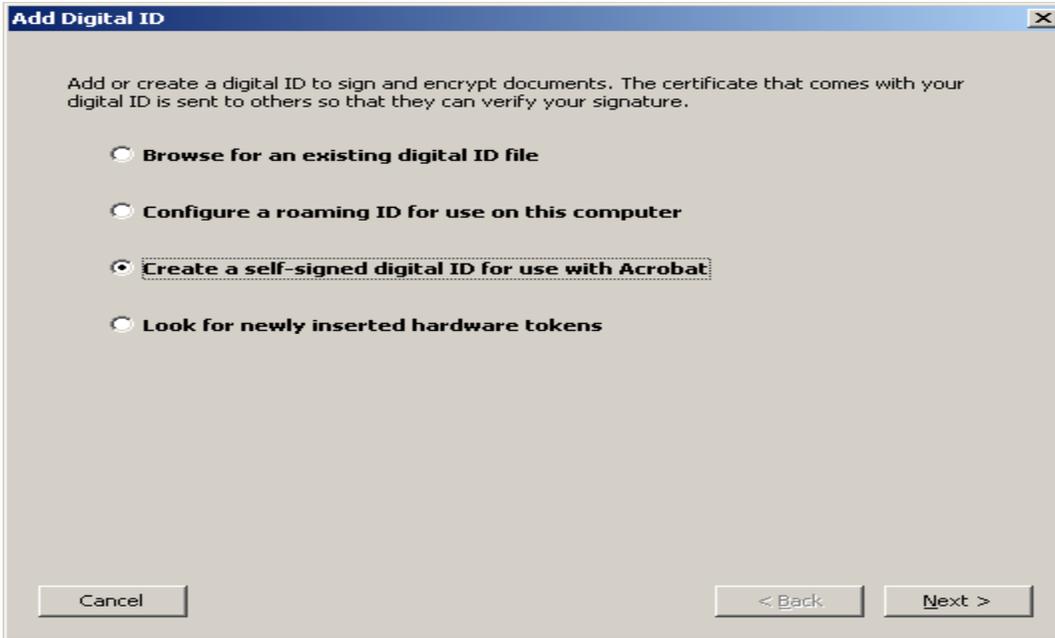
Next, type a Category name you wish to use (i.e. Signatures) and a name for this signature (i.e. your name)

To Create an Adobe Self Signed Secure ID

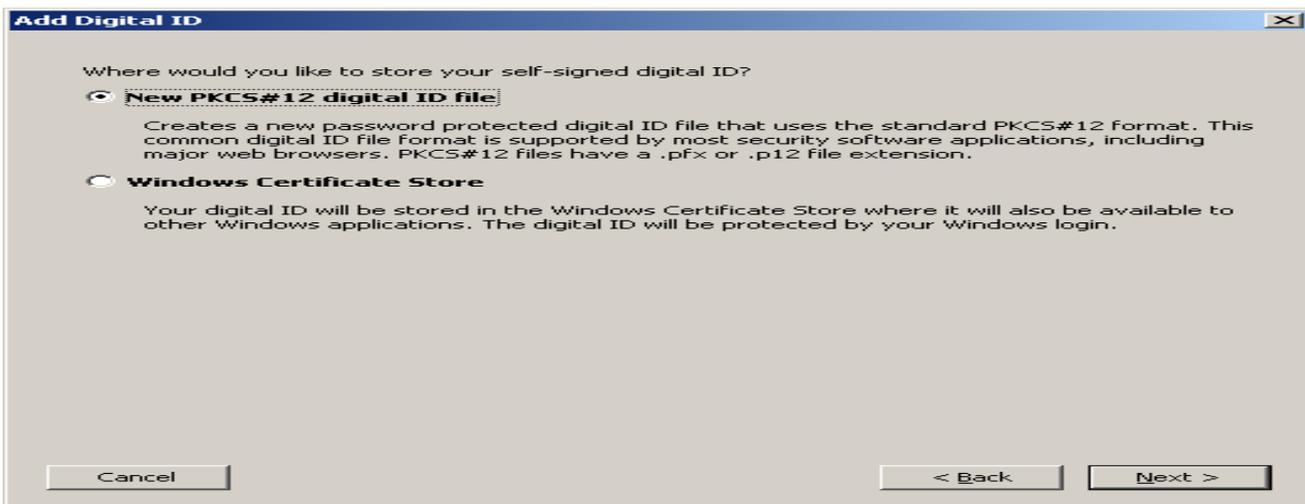
1. Click on *Advanced* and then choose *Security Settings*. Click on *Digital IDs* and if nothing listed, click on *Add ID*.



Next, select *Create a self-signed digital ID for use with Acrobat* and click *Next*.



Select New PKCS#12 digital ID file and click Next.



Fill in your personal information as shown below and click Next.

Add Digital ID

Enter your identity information to be used when generating the self-signed certificate.

Name (e.g. John Smith):

Organizational Unit:

Organization Name:

Email Address:

Country/Region:

Enable Unicode Support

Key Algorithm:

Use digital ID for:

Next, enter a password that you will use whenever you certify a PDF document.

Add Digital ID

Enter a file location and password for your new digital ID file. You will need the password when you use the digital ID to sign or decrypt documents. You should make a note of the file location so that you can copy this file for backup or other purposes. You can later change options for this file using the Security Settings dialog.

File Name:

Password:

Confirm Password:

Click Finish.