

FDA Electronic Submissions Gateway (ESG)

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Talking Points

What is the Gateway?

FDA ESG - Submission Options

WebTrader

Gateway Cost

ROI for your investment

Registration

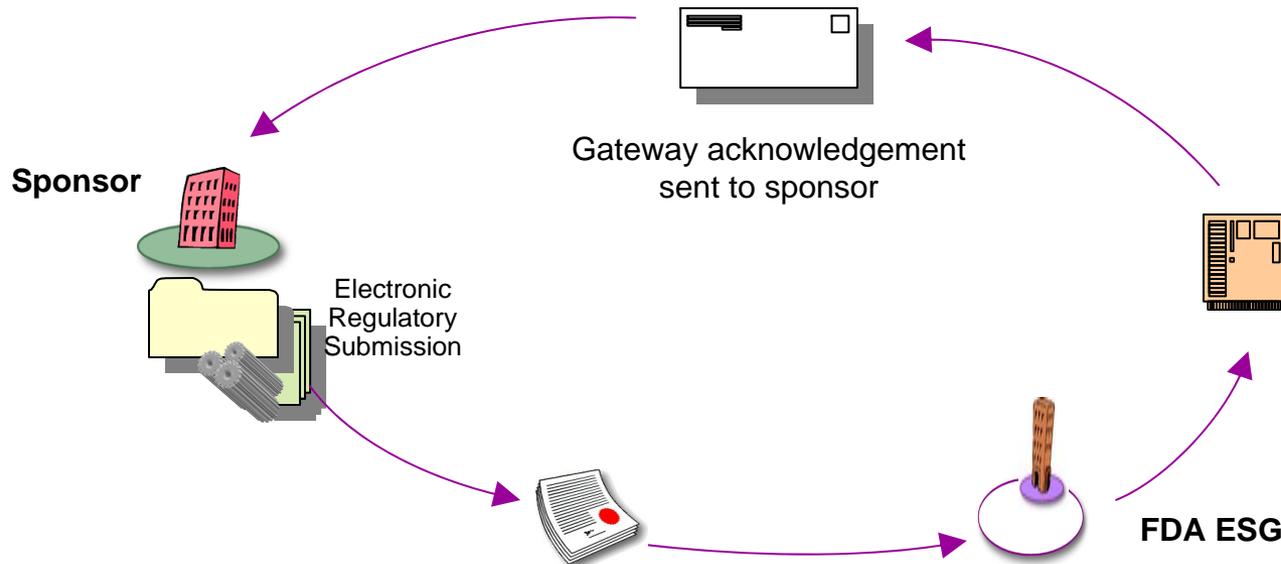
Common WebTrader Problems

SPL

What is the Gateway?

An agency-wide solution and central transmission point for accepting secure electronic regulatory submissions over the Internet.

The FDA ESG is a conduit, or "highway", that automatically routes submissions to the proper FDA Center of Office. It does not open or review these submissions.



FDA ESG – Submission Options

- **FDA ESG Web Interface (WebTrader)**

- Sends submissions via Hyper Text Transfer Protocol Secure (HTTPS) through a web browser per Applicability Statement 2 (AS2) standards
- Low cost option
- Uses Java applet

- **Gateway to Gateway (AS2)**

- Applicability Statement 2 (AS2) Gateway-to-Gateway
 - Electronic submission protocol that uses HTTPS for communications
- Attribute/Header and routing ID information will be used to route submission
- Requires an AS2 compliant gateway software

What is the Web Trader

- Web Trader is a requirement from the original FDA ESG RFP (request for proposals)
- The intention was to even the playing field between big PhRMA companies and the request of the Drug and Biologic Industry in the area of electronic submissions.
- The Web Trader is an applet that is download onto your PC when you log on the FDA ESG webpage using your x.509 version 3 class I digital certificate.
- The Web Trader requires a specific versions of JRE and JCE to function
- It is part of the Axway software product suite utilized by the FDA.
- The Web Trader requires that specific versions of JRE and JCE by available on your desktop in order to ensure that the software product can function properly.
- The purpose of the Web Trader applet is to copy and package your submission in a secure fashion, transmit the submission in a fully encrypted message and then remove any traces of it's presence on your PC.
- This simple act removes the requirement for system validation and those associated cost as part of the 21 CFR 11 compliance

What is the Web Trader

- Account holders will need to load required JAVA and Browser on their desktop and setup their proxy/firewall to communicate with ESG.
- ESG requirements constrain desktop technologies for users
 - ESG requires JRE 1.5.x and Internet Explorer 6, 7, 8 or Firefox 2.0.x. Often, users have other application that are not compatible with JRE 1.5.x
- Must obtain a digital certificate in order to utilize the FDA ESG.
- The digital certificate (x.509 version 3 class 1) should be 1-3 years in duration

Gateway Cost (for WebTrader option)

- The FDA does not charge for the use of ESG.
- **The only costs incurred should relate to the following:**
 - purchase of an x.509 version 3 class I PKI certificate with duration of 1-3 years, typically \$20-\$30
 - desired network infrastructure improvement (ESG tested using various internet connection bandwidths from a T1 to OC3 line)
 - ESG WebTrader applet does not require installation of software other than JAVA, available for free
 - cost of desktop support

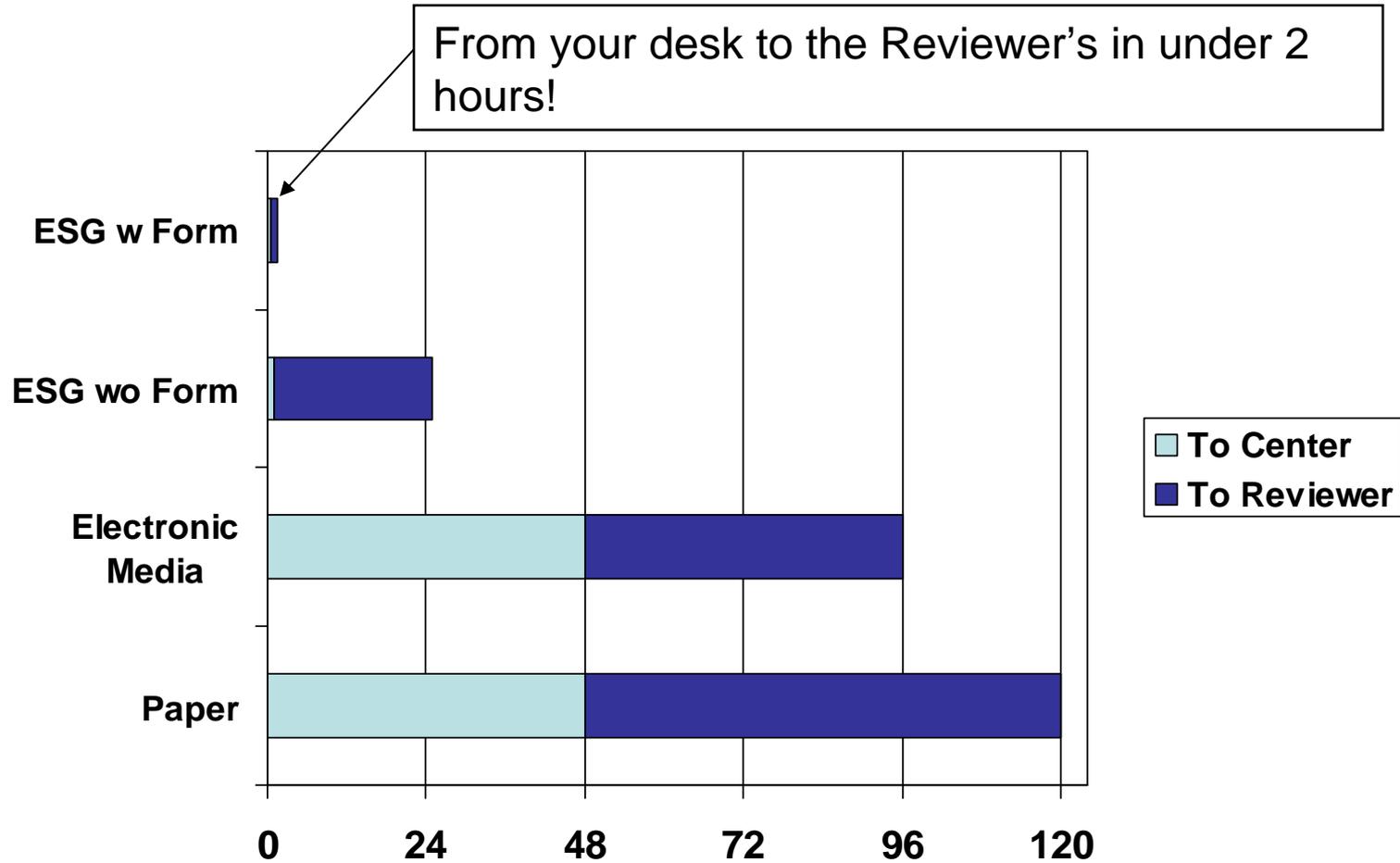
Multiple WebTrader Accounts

- **A company can have multiple WebTrader accounts.**
 - FDA recommends companies to have multiple WebTrader accounts if they have large amounts of submissions
 - company's naming conventions for multiple accounts is company name followed by user initials or designated number
 - e.g., Sun PhRMA – SRP
 - e.g., Sun PhRMA – 001
- **Testing of multiple accounts:**
 - each account must send guidance-compliant test submission
 - only one load test required if the accounts are located in same physical location, or if on the same physical network as the company's previous accounts

Shared Accounts

- **Certificates are not to be shared.**
 - they are associated with individual accounts
- **WebTrader accounts are not to be shared.**
 - certificates associated with accounts to determine the origin of a submission
 - PKI certificate utilizes public/private key exchange for encrypting and decrypting as the submission signature
 - FDA must be able to establish origin of a submission to supply electronic information for FDA review
 - use of a PKI certificate and account name determines origin of the regulatory submission
- **The determination of origin is the key factor.**

Processing Times for Submissions by Format



FDA ESG – ROI

Comparative Costs Projections Based on 1500 Submissions

Operating Costs

Item	<u>Traditional Media</u>			<u>ESG</u>		
	Unit Cost	Quantity	Total Cost	Unit Cost	Quantity	Total Cost
Shipping	\$8.25	1500	\$12,375.00	N/A		
Credentials (digital certificates)	N/A			\$20.00	20	\$400.00
Resources:						
Hours	\$63.89	1500	\$95,835.00	\$63.89	104	\$6,644.00
Quarter Hours	N/A			\$15.97	1500	\$23,955.00
Materials:						
CDROM	\$0.15	1490	\$223.00	N/A		
DLT	\$50.00	10	\$500.00	N/A		
Binders (Cover Letters)	\$1.50	1500	\$2,250.00	N/A		
Total Cost			\$111,183.00			\$30,999.00

Digital Signatures

- **FDA does not require paper copies of submission if sent using FDA ESG.**
- **FDA forms (e.g., 1571, 356h) and documents require signatures:**
 - scanned signatures
 - digital signatures
 - flattened digital signatures, which must include these:
 - printed name of the signer
 - date and time of signature
 - reason for signature
- **Please use PDF self-sign signature form.**
- **FDA does not check electronic/digital signatures unless directed to inspect transmission.**

Digital Signatures (cont.)

- maintain certificates associated with the self-sign signature in the event of a directed inspection
- Agency cannot assign greater importance to electronic signatures than to paper signatures; not all paper-based signatures checked
- PKI x.509 version 3 class I certificate used by ESG allows Agency to determine origin of submission
- Agency's General Council articulated the ability to determine origin of submission as standard in order to implement electronic submission transmission
- PKI x.509 version 3 class I certificate determines origin of submission using public/private key exchange

FDA ESG Process – Before You Register

- **Understanding Submission Guidelines**
 - FDA Centers have specific guidelines for preparing electronic submissions
 - ESG website provides links to center-specific submission guidelines
- **Submission Types**
 - FDA Center(s) will only accept specific types of submissions
 - see Submission Types by Center on the ESG website for each Center's acceptance requirements

FDA ESG Process – Before You Register (cont.)

- **Submit a Letter of Non-Repudiation Agreement**
 - allows FDA to receive electronically-signed submissions (compliant to 21 Code of Federal Regulations [CFR] Part 11.100)
 - send copy to Office of Regional Operations (ORO) and ESG Project Manager
 - sample letters located on FDA ESG website
- **Obtain a Digital Certificate**
 - FDA ESG uses digital certificates to secure transaction and communications
 - an electronic document that conforms to International Telecommunications Union’s X.509 specifications
 - FDA accepts X.509 .v3 certificates, must be valid for 1-3 years
 - use the public key when registering (.p7b or .cer extension)
 - use the private key to sign the submissions (.p12 or .pfx extension)
 - ESG website has information on how to obtain digital certificate
- **Determine Submission Method**
 - web-based (WebTrader)
 - Gateway-to-Gateway (B2B) submissions using industry standards for the transport protocol (AS2)
 - separate registration will be required for each option selected

WebTrader Checklist - <http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/ucm114831.htm>

Most Frequently Occurring Errors – WebTrader Registrations

- **correct JRE (Java Runtime Environment) or JCE (Java Cryptography Extension) not installed**
- **firewall rules not set to allow communications over port 3080**
 - **firewall port 3080 must be open for WebTrader applet to send submissions to FDA**
 - **WebTrader User Interface communications done through port 443**
- **certificate fails on import**
 - **send the certificate to esgreg@gnsi.com**

Common WebTrader Problems

When registering for an account, I get an error stating that: The Company Name is already in use.

The “Company Name” is actually an account name and must be unique throughout the entire ESG test (or production) system. Other companies have mitigated this by appending a unique identifier to the company name, like the WebTrader user’s initials.

When trying to log in, I get the error: Enter a valid user ID and password.

The username and password combination that you entered was not a valid combination for any account. Make sure you are using the correct username and password, and note that both are case-sensitive.

When trying to log in, I get an error: Your user account has been locked out by the system.

The username that you entered does not currently have an enabled account. This could be because the account has not yet been approved, or that there have been too many consecutively failing login attempts.

Common WebTrader Problems (cont.)

I just registered for an account, but when I try to log in, I get an error: **Your user account has been disabled.**

After you register, we need to approve your account before you are able to log in.

After logging in, I see a red box with: **“Error downloading unlimited strength Java Cryptography Extensions (JCE)”**.

The error means that the unlimited strength Java Cryptography Extensions (JCE) are not correctly installed. For more information on the JCE install, please see:

http://www.accessdata.fda.gov/esg/userguide/webhelp/Java_Runtime_Edition.htm

When signing a submission, I received an error: **Could not retrieve private key.**

This error means that either the file you picked to use as a signing certificate was not an actual private key file, or that you incorrectly entered the unlocking pass phrase.

The FDA does not (and can not) know the pass phrase for your certificate.

Common WebTrader Problems (cont.)

I see the following error in the receipt: Message signed with certificate that is not configured on the sender.

When sending a submission, it is signed using a private key (a .pfx file). The FDA ESG must have the public key (a .cer or .p7b file) from the same certificate on file in your account to verify the signature.

Send the public key to esgreg@gnsi.com along with the name of your account.

Do I have to send all the tests to get a production account?

Every test account has to send an FDA-compliant submission to the appropriate center to receive a production account. Other tests vary, as specified at:

<http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/ucm114831.htm>

I sent a request for technical support to esgprep@fda.hhs.gov and did not receive a response within four hours.

The correct e-mail address for all technical support for the ESG is esgreg@gnsi.com.

Common WebTrader Problems (cont.)

Can my company have another account in production now that the first has been approved?

Every production account has to have a matching test account, and the test account must have submitted the appropriate tests and been approved individually for production. Please see:

<http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/ucm114831.htm>

Can I use the same cert for both my Test account and my Production account?

Yes, you can. We encourage this as both can then be updated at the same time when the certificate expires.

Can I register for a second account?

Each user can have only one active account, allowing for as many submissions as you would like. If you need to retire an existing account, you could then register for a new account.

How many people can share one account?

Accounts in the ESG cannot be shared. Each individual must have their own account. There is no limit to the number of accounts that one company may have.

Common WebTrader Problems (cont.)

Have you received my test submissions?

In the WebTrader inbox, there will be a link to the receipt and acknowledgement if the ESG server and the FDA center server (respectively) have received the submission. If there are no errors in the text of these files, then the submission has been received successfully.

This also applies to production submissions.

I sent in my submission, and I have a receipt, but I do not have an acknowledgement.

Receipts and acknowledgements can contain error messages. If there is an error message in the receipt, then no acknowledgement will ever be sent, because there was no attempt to deliver the submission to the center server.

I haven't received my e-mail ACKs.

The ESG does not send any acknowledgements by e-mail. Acknowledgements are only received through the WebTrader interface.

SPL Support

- FDA ESG provides links from it's webpage to the SPL webpage/information for the convenience of its potential account holders
- The FDA ESG helpdesk found at esgreg@gnsi.com is not the appropriate group to handle queries regarding account holders SPL message
- The FDA ESG helpdesk forwards your concerns to the SPL group in an attempt to facilitate obtaining an answer to your query
- The FDA ESG is not equipped to address questions on electronic submissions content. Those queries are sent to the OPDIV in question.
- We will remind that OPDIV in question a an account holder presents a question that has not been responded to in a two week period per our policy

ESG Resources and Contacts

- **Website:** <http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/default.htm>
 - Registration Information
 - System Requirements
 - User Guide and Tutorials
 - Digital Signatures and Certificates
 - System Status and Help Desk
 - Links to submission guidelines
- **Email for preparation/Registration/Policy:** esgprep@fda.gov
 - For questions and assistance in setting up test and production accounts
- **Email for technical issues:** esgreg@gnsi.com
 - This email is for system and submission related issues
- **FDA project manager: Michael Fauntleroy**
 - Email: michael.fauntleroy@fda.hhs.gov
 - Phone: 301-827-5132
 - Address: Office of the Director (HFM-25)
Center for Biologics Evaluation and Research
Food and Drug Administration
11400 Rockville Pike, Room 4119
Rockville, MD 20857

Electronic Submissions Gateway

Thank you

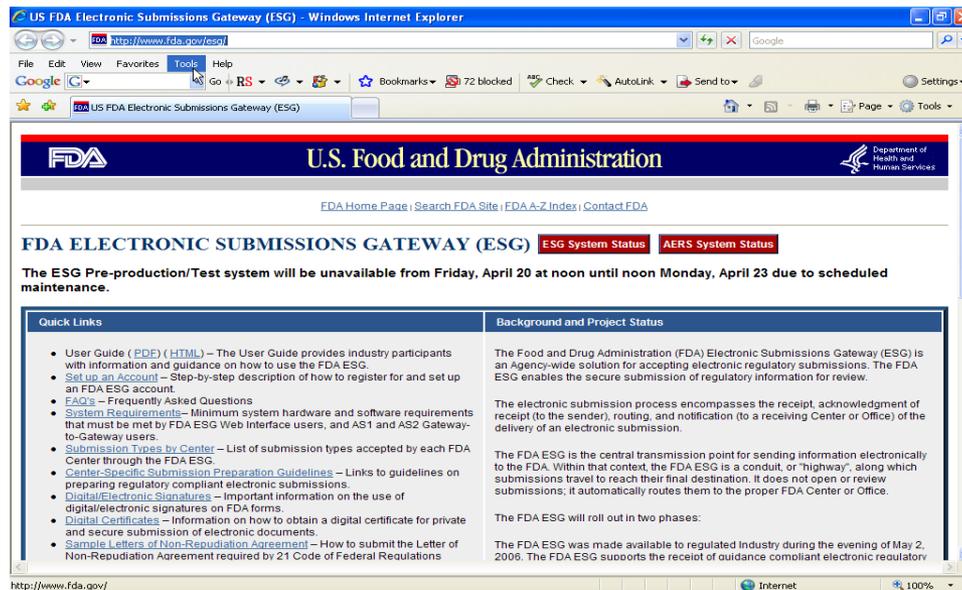
Appendix

Purchasing and Installing Your Digital Certificate

- **Identify company personnel who are designated to send electronic submissions through the Electronic Secure Gateway (ESG).**
- **Identify the computers they will use to send electronic submissions. Digital certs are computer specific.**
- **Purchase your x509 digital cert (.cer) from a vendor of choice. Online purchase is the fastest method.**
- **Once purchased, you should receive an email with the URL to the secure vendor site and your digital ID.**
- **Ensure that you login from the computer you intend to use to send submissions through the ESG.**

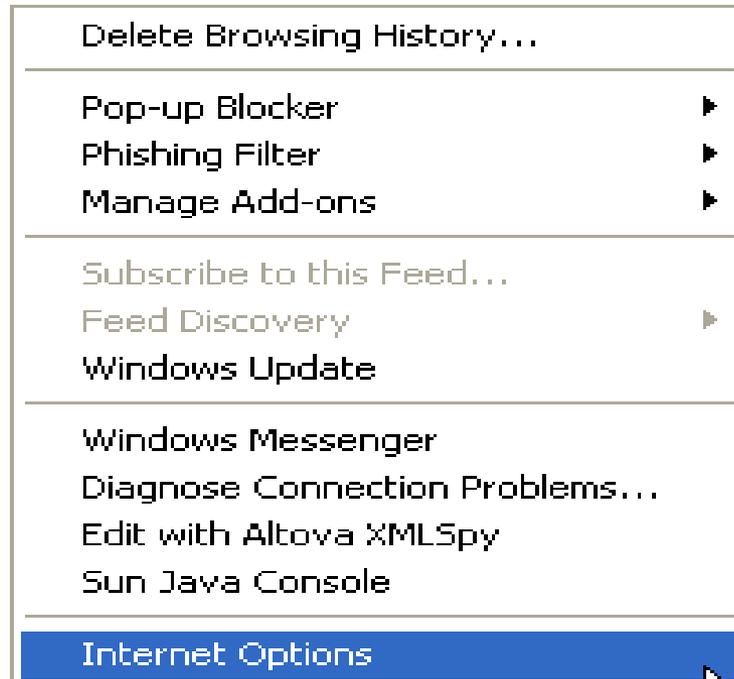
Purchasing and Installing Your Digital Certificate (cont.)

- Login to the vendor site, input your digital ID, and the site will install the digital cert (.cer). This is usually done using some sort of install wizard. Choose the default options during each step.
- Open Internet Explorer. Choose Tools



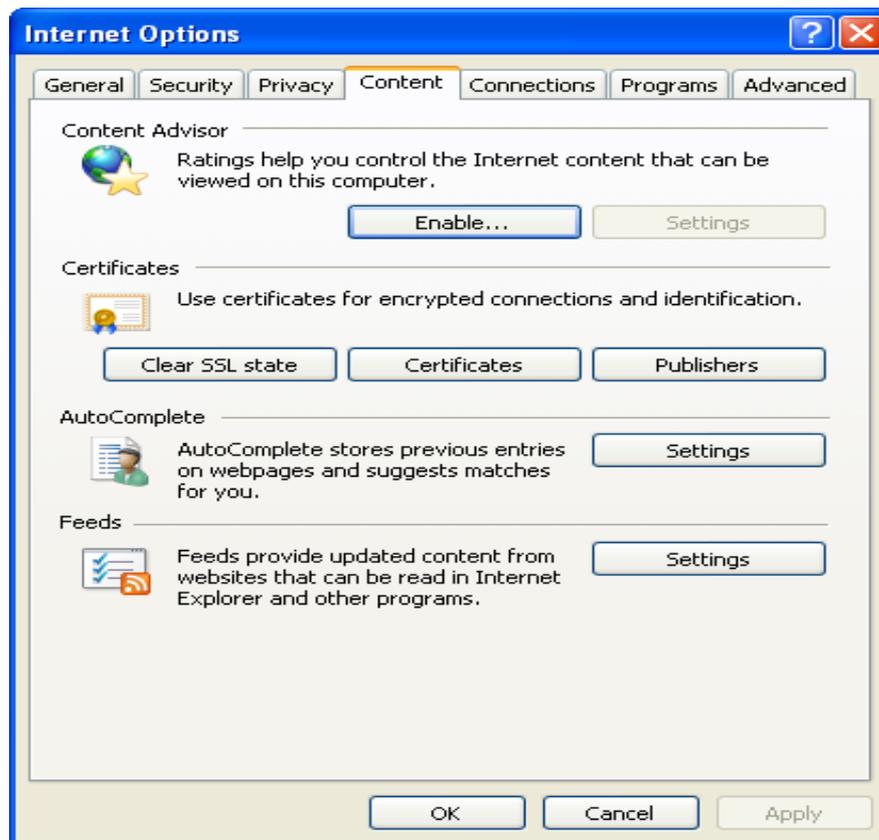
Purchasing and Installing Your Digital Certificate (cont.)

- **Choose Internet Options. The Internet Options Window will launch.**
- **Choose Internet Options**



Purchasing and Installing Your Digital Certificate (cont.)

- Choose the Content Tab and the Certificates Button
- Choose the Content Tab and the Certificates Button

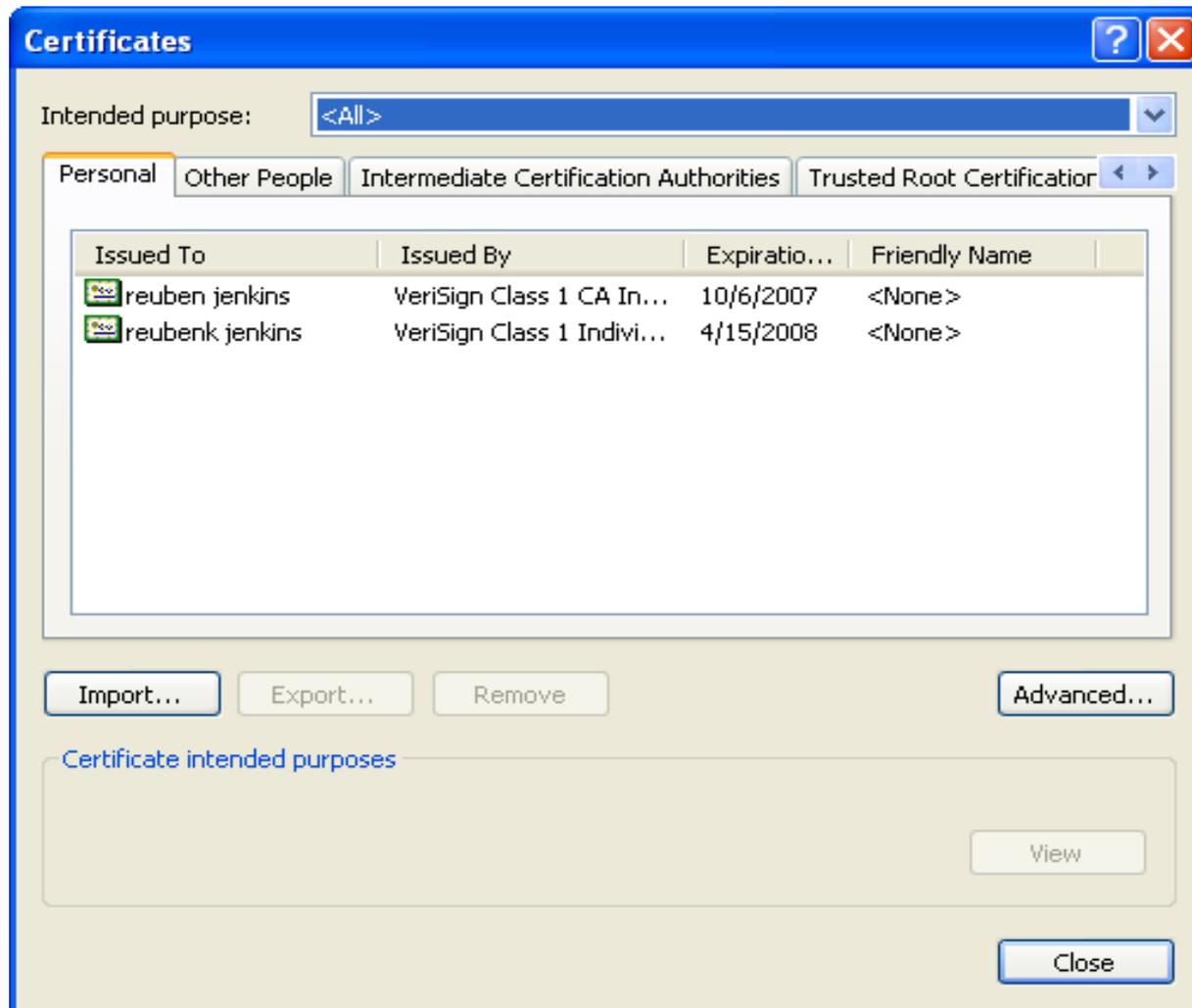


Purchasing and Installing Your Digital Certificate (cont.)

- **You will be directed to the Internet Explorer Certificates Window. The Personal tab is the default option. This is the location where the installation process should store your digital cert (.cer).**

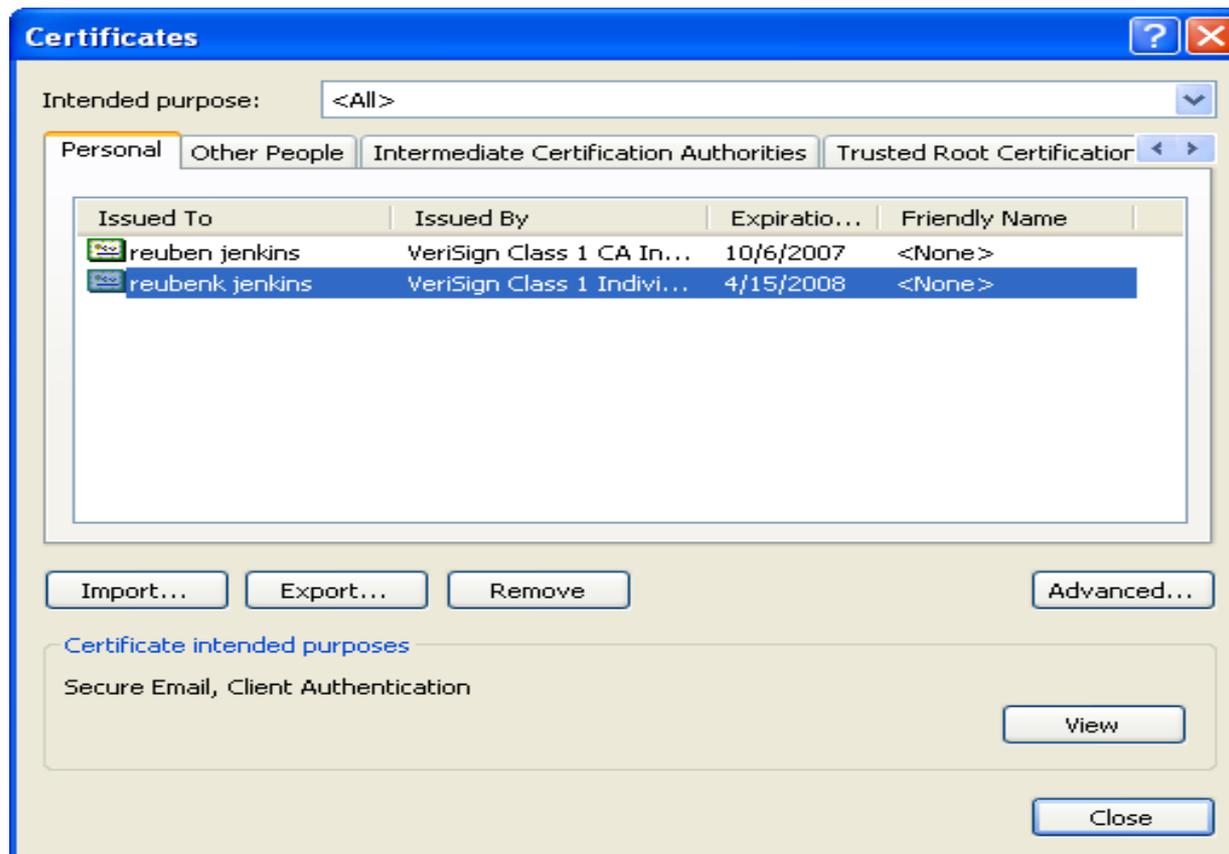
If the digital cert (.cer) is not in this location, please contact your vendor to identify the digital cert (.cer) location. To complete the ESG registration process you must know the location of your digital cert (.cer).

Purchasing and Installing Your Digital Certificate (cont.)



Exporting Your digital Cert (.CER) for ESG Test Account Registration (cont.)

- Highlight the digital cert (.cer) and the Export Button will become available.



Exporting Your digital Cert (.CER) for ESG Test Account Registration (cont.)

- Choose the Export button and the Certificate Export Wizard Window will launch. Choose Next.



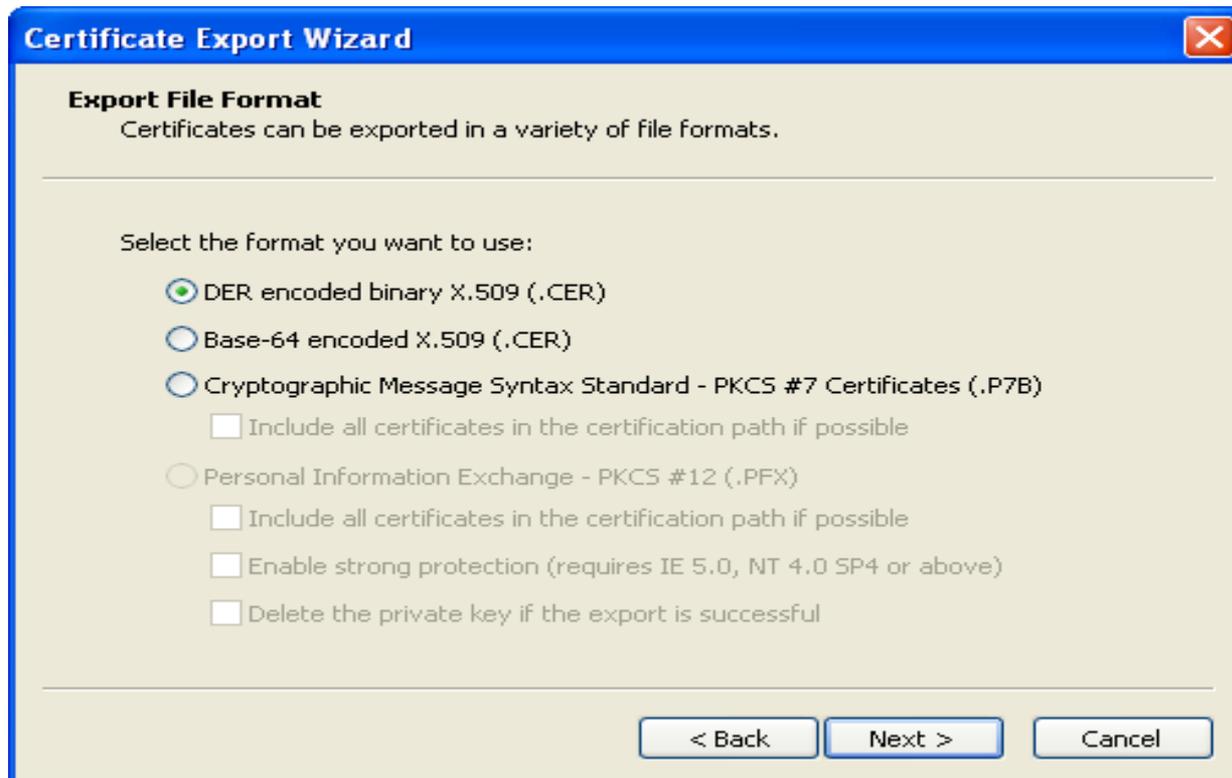
Exporting Your digital Cert (.CER) for ESG Test Account Registration (cont.)

- The Certificate Export Wizard – Export Private Key Window will launch. Choose the default option. Choose Next.



Exporting Your digital Cert (.CER) for ESG Test Account Registration (cont.)

- The Certificate Export Wizard – Export File Format Window will launch. Choose the default option. Choose Next.



Exporting Your digital Cert (.CER) for ESG Test Account Registration (cont.)

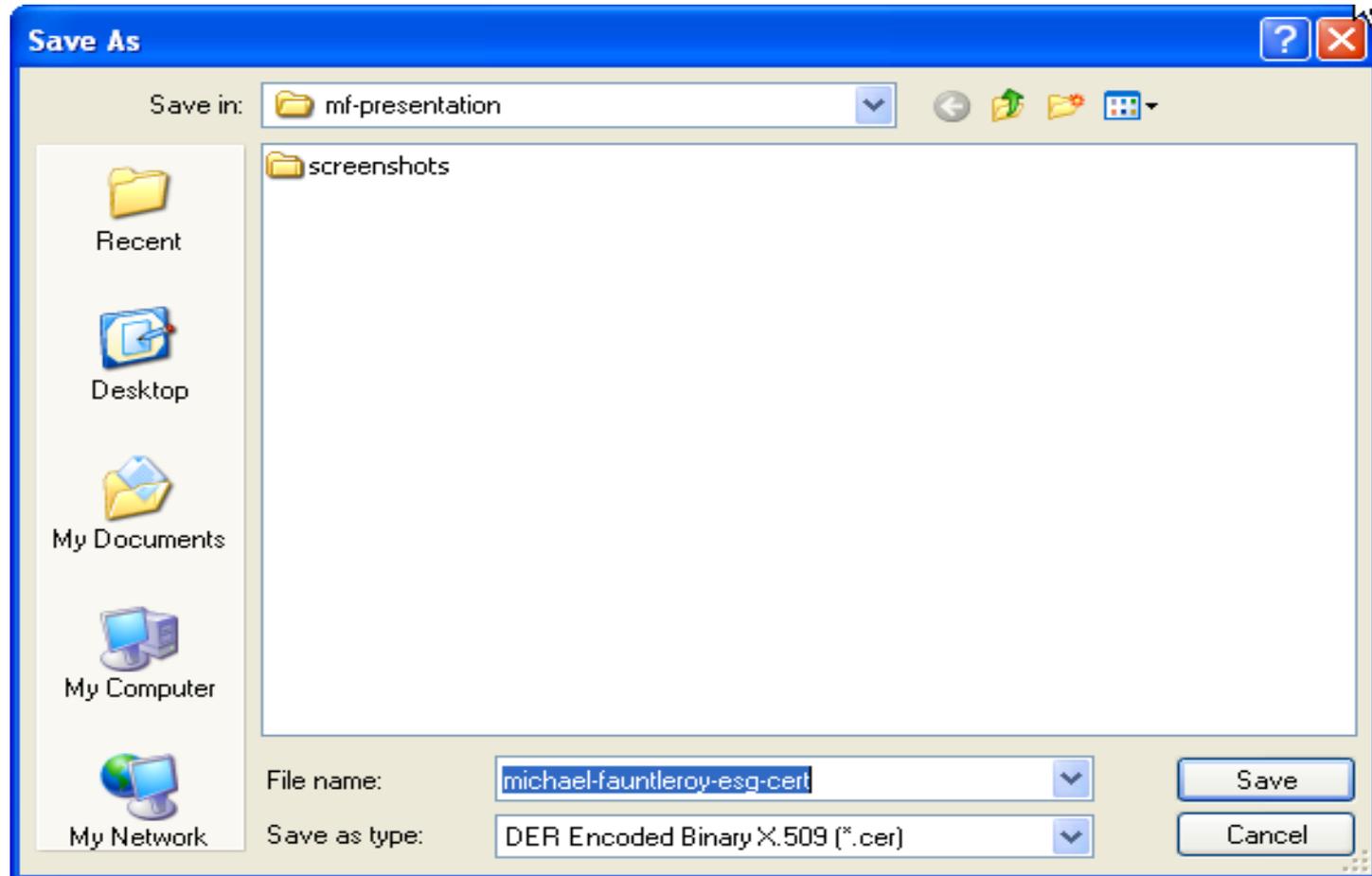
- The Certificate Export Wizard – File to Export Window will launch.



Exporting Your digital Cert (.CER) for ESG Test Account Registration (cont.)

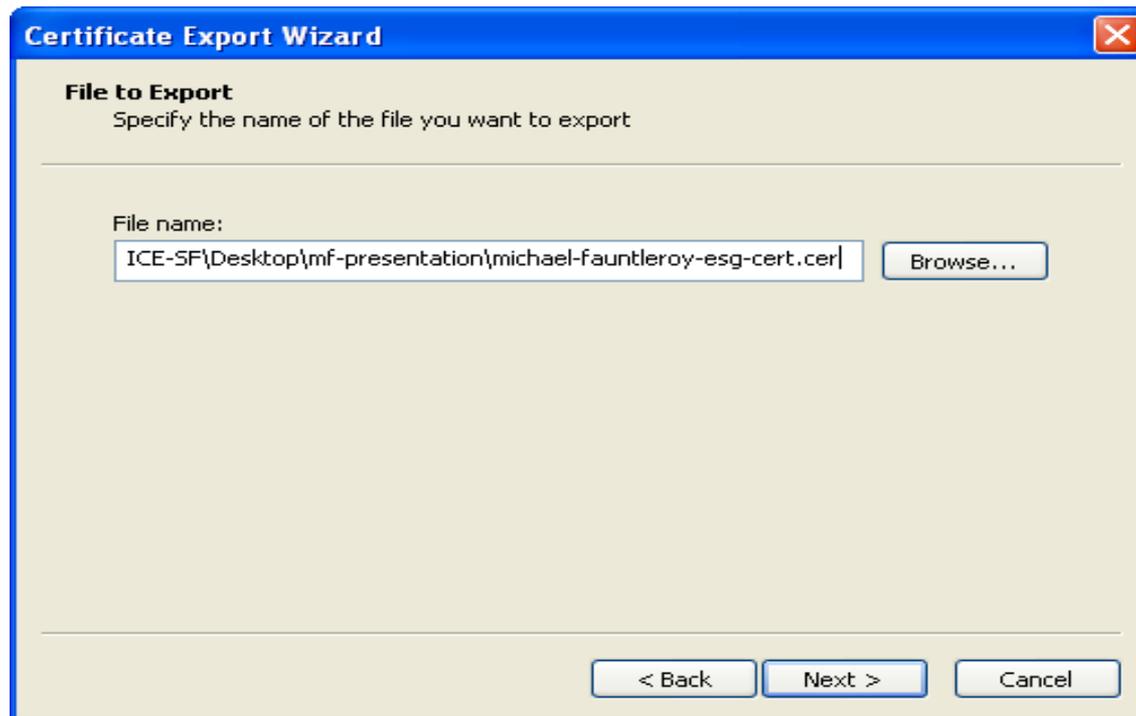
- **Choose Browse. The Save As Window will launch. Navigate to the location where you want to store the exported digital cert (.cer).**
- **Create a name for the digital cert (.cer). We recommend something that will remind you that the digital cert (.cer) supports the ESG. Choose Save**

Exporting Your digital Cert (.CER) for ESG Test Account Registration (cont.)



Exporting Your digital Cert (.CER) for ESG Test Account Registration (cont.)

- The Certificate Export Wizard will return you to the Certificate Export Wizard – File to Export window. The storage path for your digital cert (.cer) will be inserted in the File Name area. Choose Next.



Exporting Your digital Cert (.CER) for ESG Test Account Registration (cont.)

- The Certificate Export Window – Completing the Certificate Export Wizard Window will launch. Choose Finish.



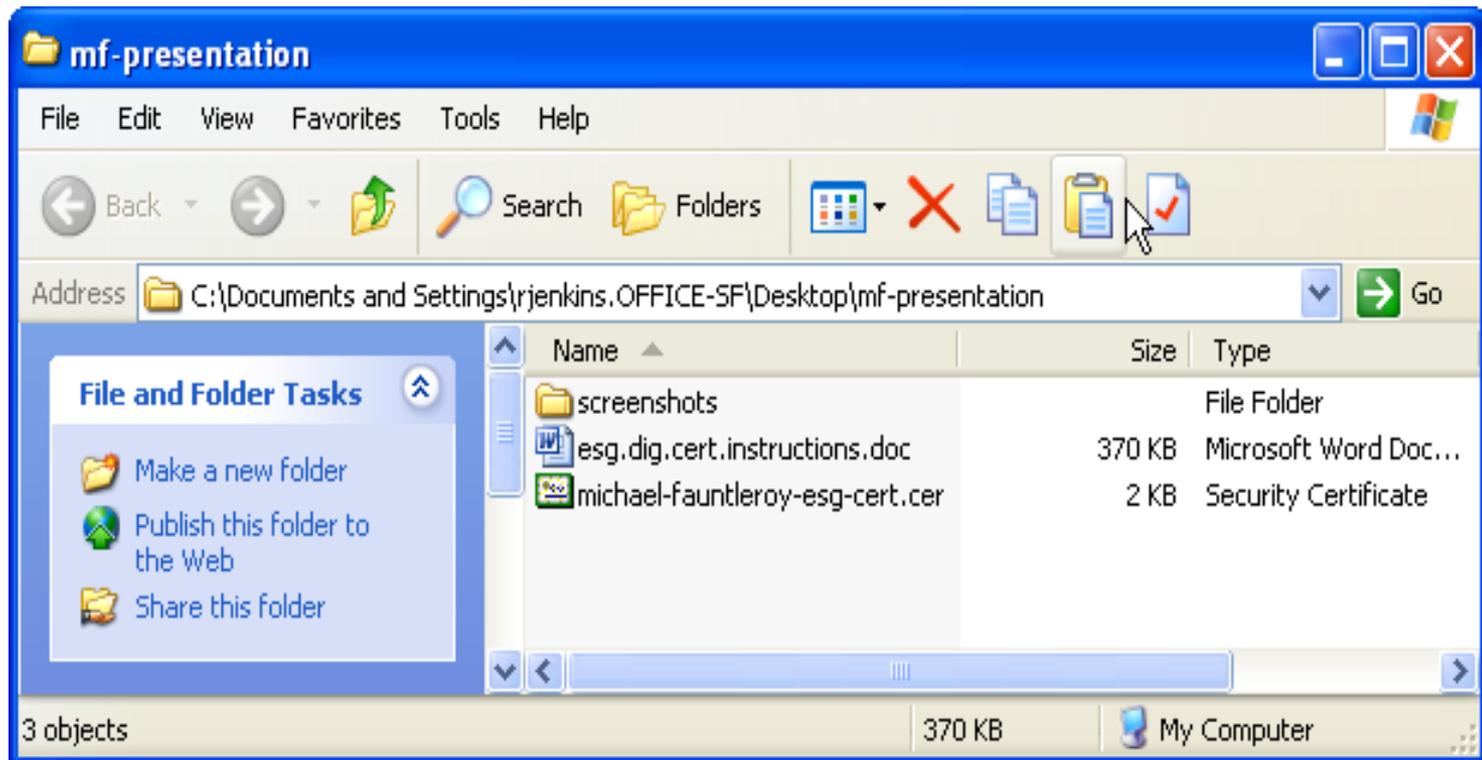
Exporting Your digital Cert (.CER) for ESG Test Account Registration (cont.)

- If the export was successful, the Certificate Export Wizard will display the message below after you choose Finish.



Exporting Your digital Cert (.CER) for ESG Test Account Registration (cont.)

- Navigate to the digital cert (.cer) storage location to verify a successful export.



Additional Information

- Once you have established your test account and the ESG personnel have verified, approved, and accepted your digital cert (.cer), you will need to create a .pfx file format version of your digital cert (cer).
- During the submission transmission process, the ESG will prompt you for the .pfx version of your digital cert and a password. Once the password is verified, your digital cert (.pfx) will attach itself to each and every file you transmit through the ESG.

Additional Information

- **Converting your digital cert from a .cer to a .pfx file for file/submission transfer through the ESG.**
- Follow steps in slides 9 and 10.
- **The Certificate Export Wizard – Export Private Key Window will launch. Choose the “Yes, export the private key” option. Choose Next.**

Additional Information



Certificate Export Wizard [Close]

Export File Format
Certificates can be exported in a variety of file formats.

Select the format you want to use:

- DER encoded binary X.509 (.CER)
- Base-64 encoded X.509 (.CER)
- Cryptographic Message Syntax Standard - PKCS #7 Certificates (.P7B)
 - Include all certificates in the certification path if possible
- Personal Information Exchange - PKCS #12 (.PFX)
 - Include all certificates in the certification path if possible
 - Enable strong protection (requires IE 5.0, NT 4.0 SP4 or above)
 - Delete the private key if the export is successful

< Back Next > Cancel

Additional Information

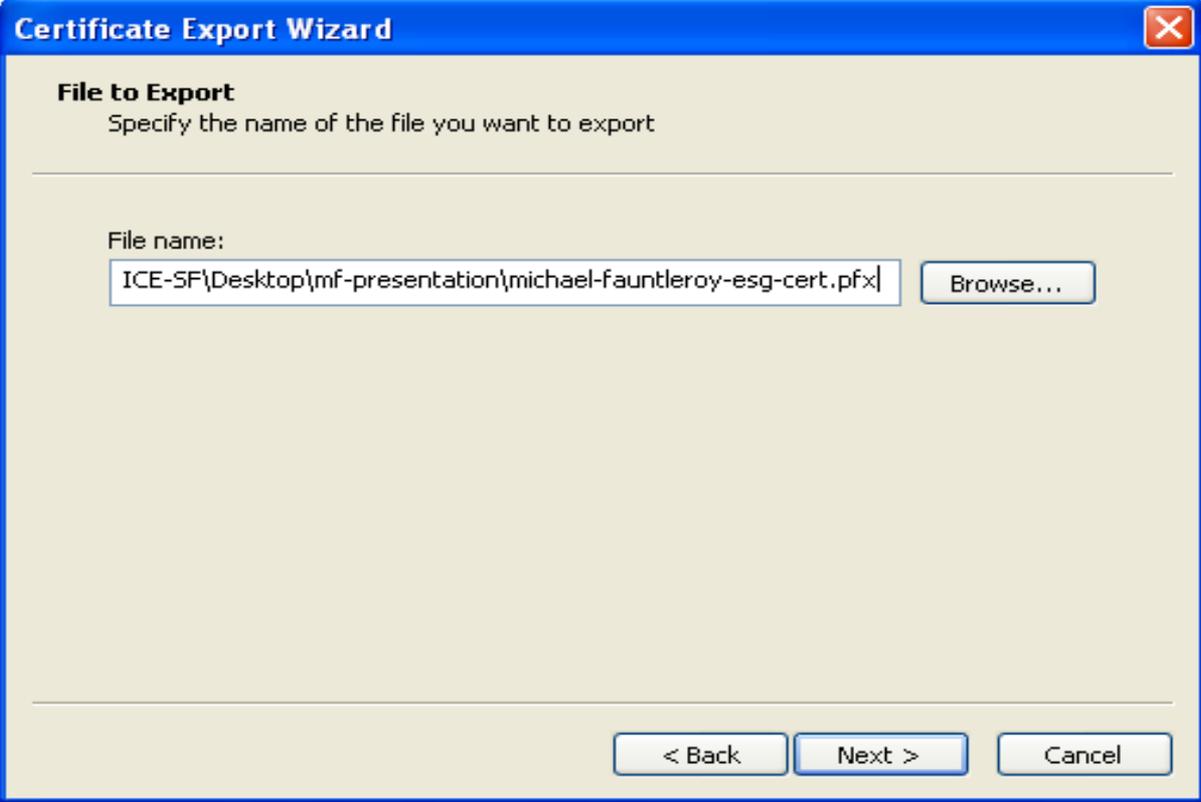
- The Certificate Export Wizard – Password Window will launch. Enter and confirm Password. Choose Next. (Remember this password! The ESG will ask for it when you transmit files!)



The screenshot shows a Windows-style dialog box titled "Certificate Export Wizard" with a close button in the top right corner. The main heading is "Password" and the text below it reads: "To maintain security, you must protect the private key by using a password." A horizontal line separates this from the instruction "Type and confirm a password." Below this, there are two text input fields. The first is labeled "Password:" and contains seven asterisks. The second is labeled "Confirm password:" and also contains seven asterisks. At the bottom of the dialog, there are three buttons: "< Back", "Next >", and "Cancel".

Additional Information

- You must browse to determine a storage location for the digital cert (.pfx) and name the file appropriately. Choose Next.



The image shows a Windows dialog box titled "Certificate Export Wizard". The window has a blue title bar with a close button in the top right corner. The main area is light beige and contains the following text and controls:

- File to Export**
Specify the name of the file you want to export
- A horizontal line separates the title from the input area.
- File name:**
A text input field containing the path: `ICE-SF\Desktop\mf-presentation\michael-fauntleroy-esg-cert.pfx`
- A "Browse..." button to the right of the text input field.
- A horizontal line at the bottom of the main area.
- At the bottom of the dialog, three buttons: "< Back", "Next >", and "Cancel".

Additional Information

- The digital cert (.pfx) will be exported. Navigate to the digital cert (.pfx) storage location to verify a successful export.

