

FDA Electronic Submissions Gateway (ESG)

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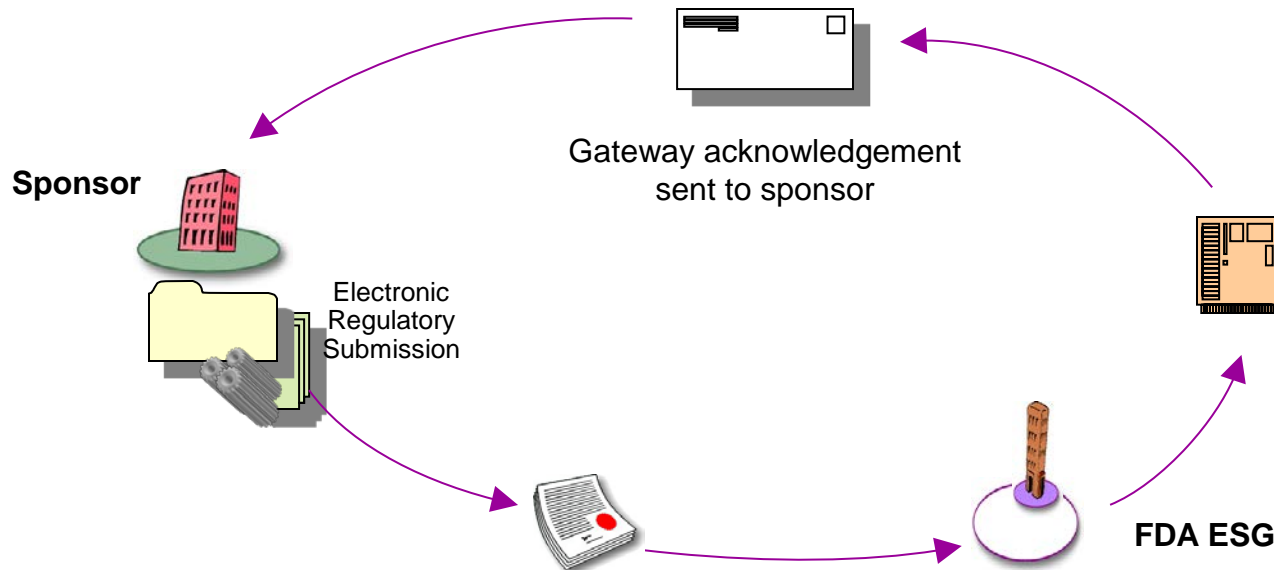
Talking Points

1. **What is the Gateway?**
2. **Receiving Units**
3. **Submission Transaction Processing**
4. **Submission Options**
5. **WebTrader**
6. **Web Trader Hosted Solution/Demo**
7. **Statistics**
8. **Gateway Accounts and Cost**
9. **Health Canada**
10. **Future Plans**
11. **ROI**
12. **Submission Processing Time**
13. **Advice**
14. **Registration Process**
15. **Outages**
16. **Salutation**
17. **Appendix – PKI Certificates**

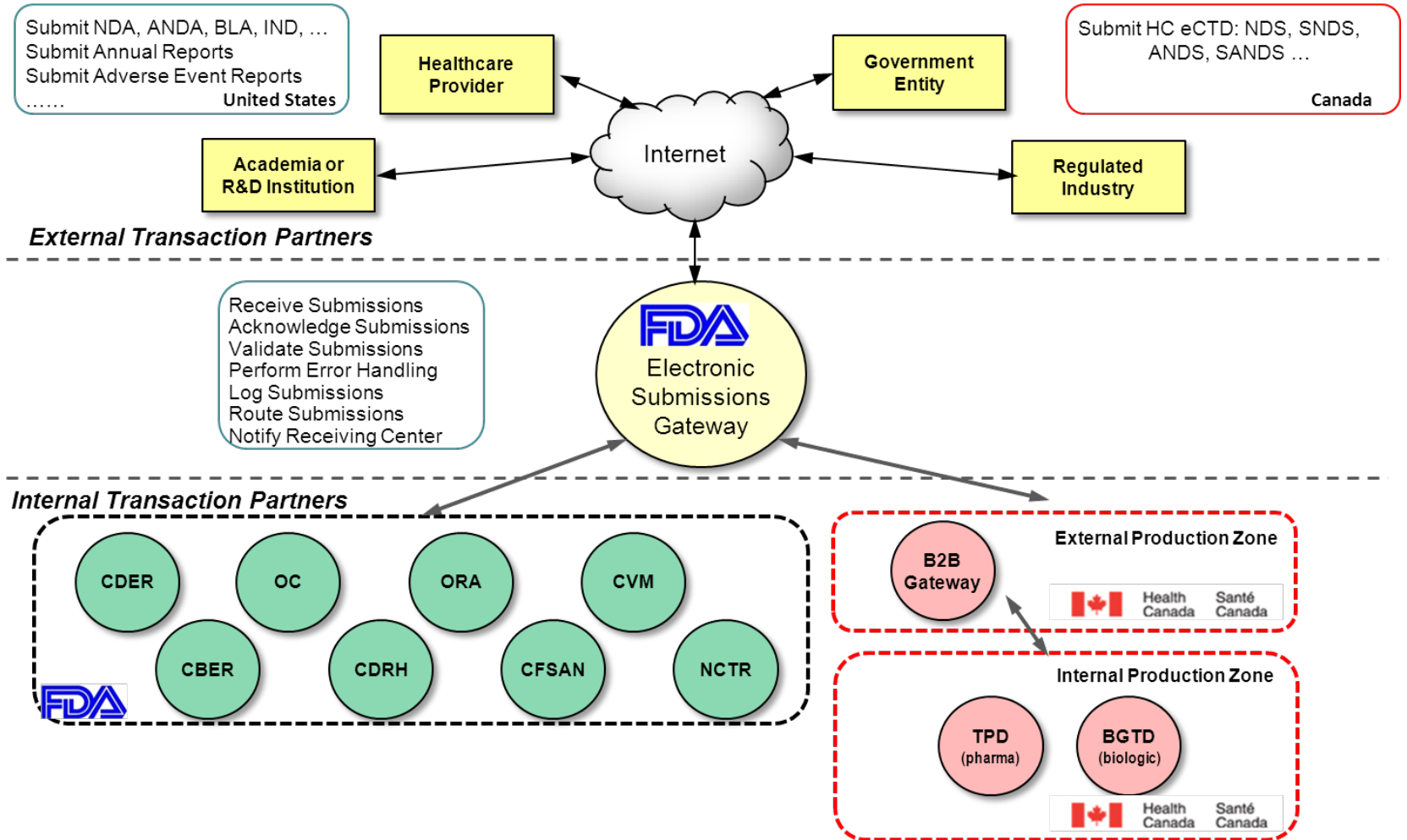
What is the Gateway?

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.



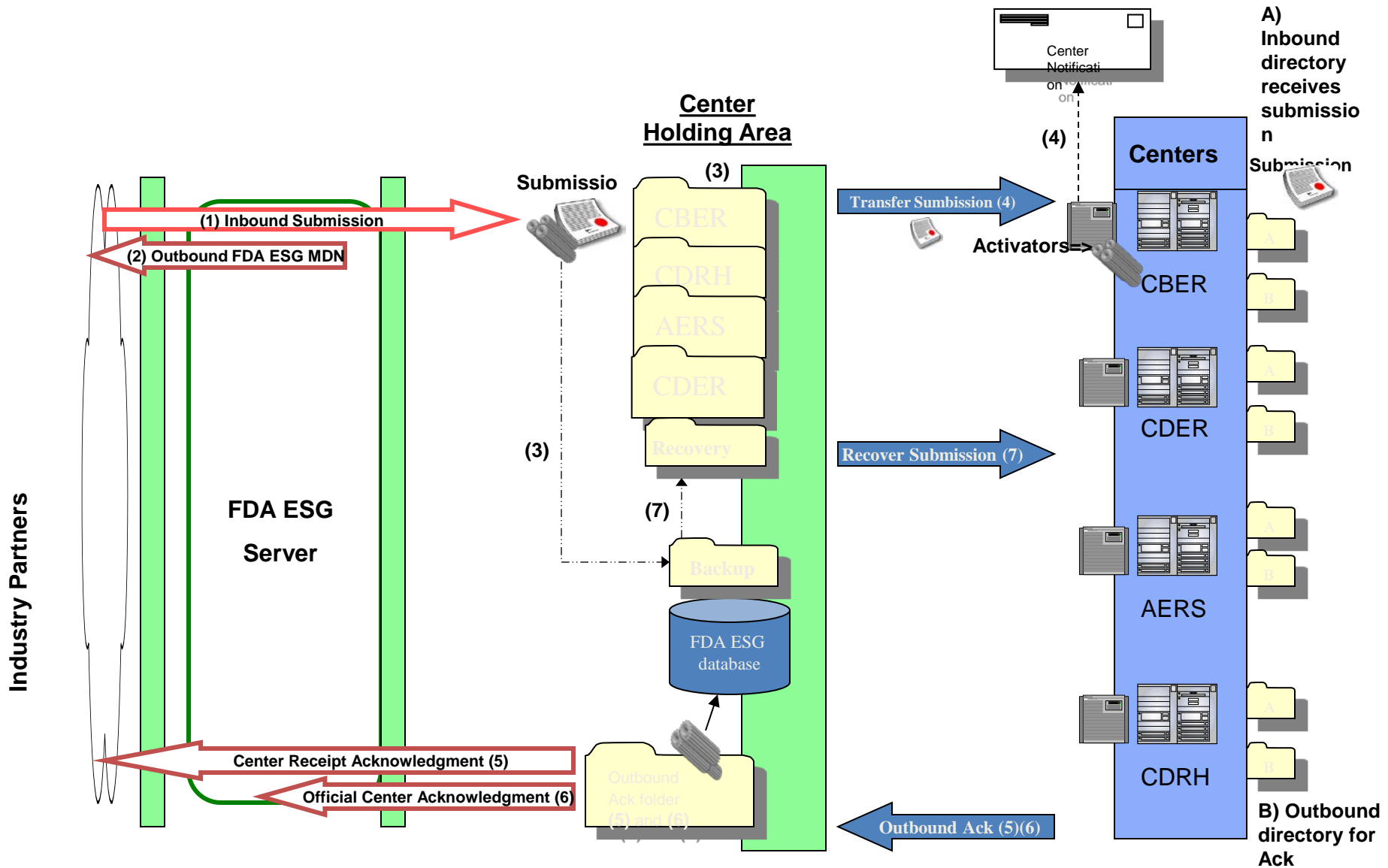
FDA ESG Gateway



Participating Centers/OPDIVs

- AERS
- CDER
- CBER
- CDRH
- CVM
- OC
- CTP
- MWP
- CFSAN
- Health Canada

Processing of an Inbound Submission



Processing of an Inbound Submission

1. FDA ESG receives an inbound submission.
2. FDA ESG sends a Message Delivery Notification (MDN) to the submitter (Message 1).
 - Receipt of an MDN confirms that the submission was successfully received by the FDA ESG.
3. The inbound submission is processed, submission is unpackaged and deposited in the Center Holding Area.
 - A copy of the submission is stored for 10 days in the Backup directory.
4. The submission is automatically transferred to the Center.
 - The official receipt timestamp is applied to the submission.
 - An email is sent notifying the Center that a submission has arrived.
5. A Center Receipt Acknowledgement is automatically generated and sent to the submitter via the FDA ESG (Message 2).
 - This Acknowledgement contains the official receipt timestamp.
6. The Center validates and processes the submission.
 - Depending on the submission, an Official Center Acknowledgement may be sent (Message 3).
 - If errors occur during validation and loading, they will be noted in the Official Center Acknowledgement.
7. If necessary, the Backup copy of the submission may be recovered by the Center.

Multi-file or Directory Based Submission

- FDA ESG Web Interface Submissions
 - The FDA ESG Web Interface utilizes the tarring and gzip functions for file/directory consolidation when transmitting multi-file submissions.
 - Because this process is done automatically during the signing of the file, no intervention is required.
- Gateway-to-Gateway (B2B) Submissions
 - Partners are required to both tar and gzip (compress) multi-file submissions.
 - For best optimization when processing and transmitting large multi-file submission files, first "tar" the files and then compress them using gzip.
 - To fulfill this requirement
 - The current AS2 solution will/should have a tar and zip utility prescribed. There are Operating System-specific utilities available for performing the tar operation.
 - If the application does not have tar/gzip capabilities, a utility must be acquired. Please refer to the User Guide on the FDA ESG website for recommended utilities.

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
- Single submission/manual

- **FDA ESG Web Trader Hosted Solution**

- **Citrix Access to ESG infrastructure**
- **User Account's Established**
- **No Thin Client Requirements**

- **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
- Automated Process/Batches

What is the Web Trader

- Web Trader is a requirement from the original FDA ESG RFP (request for proposals)
- The intention of this function was to even the playing field between big PhRMA companies and the rest 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, if you are an account holder
- It is part of the Axway COTS product suite utilized by the FDA.
- The Web Trader requires that specific versions of JRE and JCE be available on your desktop in order to ensure that the software product functions properly.
- The Web Trader applet copies and packages your submission on your desktop in a secure fashion, transmits the submission in a fully encrypted message to the FDA and then remove any traces of it's presence from your PC.
- This paradigm alleviates the burden of system validation and the associated cost of 21 CFR 11 compliance

Web Trader Challenges

- Setup is difficult and requires IT support
 - Many small companies do not have IT staff
- Not cost effective for infrequent users
 - High level of user frustration evident from help desk emails
- ESG requirements constrain desktop technologies for users
 - ESG Web Trader requires JRE 1.7.x (55) and Internet Explorer versions 7 - 11.

What is the Proposed Solution?

- The proposed WebTrader Hosted solution is a Citrix based solution.



Benefits of WebTrader Hosted solution

- Improved user experience
- No setup required on the user desktop
- No constraints on desktop technology
- Less help desk support
- **What are the drawbacks of Web Trader Hosted Solution?**
- Introduces an additional login (for access to Citrix)
- Can't be used for large submissions (>1 GB)

Web Trader Hosted Solution

- **Demo Credentials**

- **WTHS**

- **WTHS Test URL:**

<https://esghosted.test.fda.gov/Citrix/XenApp/auth/login.aspx>

FDA ESG Submission Statistics (Inbound)

	2006 - 2014									
	2006	2007	2008	2009	2010	2011	2012	2013	2014	Totals
AERS	55,156	159,562	252,614	300,672	472,142	557,917	717,345	876,475	389,053	3,780,936
CDER	1,639	11,175	24,797	45,510	69,739	93,503	107,681	124,232	43,588	521,864
CBER	294	1,504	2,557	4,483	5,588	6,397	6,927	8,412	2,987	39,149
CDRH	1,575	1,527	4,619	21,296	119,087	280,312	462,316	666,927	263,120	1,820,779
CVM		288	843	859	945	17,932	35,429	40,241	11,078	107,615
OC			188	16,275	48,232	55,676	64,285	65,430	21,935	272,021
CTP				5	223	348	642	1,237	133	2,588
MWP					1,138	2,530	2,499	737	237	7,141
ACA							62	207	159	428
GDUFA							2,771	2,926	432	6,129
CFSAN							458	3,564	65	4,087
HC								324	1,268	1,592
Totals	58,664	174,056	285,618	389,100	717,094	1,014,615	1,400,415	1,790,712	734,055	6,564,329

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 \$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, which is available as freeware
 - 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.**

Health Canada

Regulatory Cooperation Council (RCC)

- The A4 initiative, the Common Electronic Submissions Gateway (CESG), was one of four initiatives sanctioned by the Food and Drug Administration (FDA) under the RCC umbrella
- Structured Quarterly Reports
- Office of Management and Budget (OMB) monitored
- Political Imperative
 - Provided motivation
 - OMB
 - Presidential endorsement
 - The Carrot or the Stick

The Journey

- The Beginning
 - June 17, 2011, email query from Craig Anderson
 - June 21, 2011, DIA Annual; Chicago
 - Bob Yetter (FDA) and Mike Ward (HC)
 - Meet with Mike Ward and discussed building a Gateway for Health Canada
 - Mike Ward put me in contact with Vikesh Srivastava
 - First conversation with Vikesh Srivastava – June 28, 2011
 - Called colleagues at the PhRMA ERS WG and asked what this build would mean to regulated Industry – June 28, 2011
 - July 6, 2013, first CBER high level internal meeting to discuss necessary items/hurdles to make this initiative a success.
 - August 10, 2011, Agency discussion and presentation (Mac Lumpkin)

The Journey

- August 10, 2011, Proposed Gateway Submission Process
- August 17, 2011, version 1.0 of proposed Concepts of Operations (CONOPS) Document
- September 21, 2011, Finalized Concept of Operations
- September 28, 2011, Started Discussions of Technical Proof of Concept for Health Canada implementation
- October 5, 2011, Final CONOPS Document.
- November 16, 2011, Discussion regarding Regulatory Cooperation Council (RCC)
- December 7, 2011, Officially adopted as the A4 initiative of the RCC
- December 12, 2011, Starting funding mechanism discussions
- January 31, 2012, RCC Stakeholder Presentation – Presented Indicative Work Plan A4 initiative to Public Stakeholders

The Journey

- February 1, 2012, Settled on the Cooperation Research and Development Agreement (CRADA) as funding mechanism
- February 1, 2012, Dano Murphy and Charles Kemp agree to shepherd the CRADA process
- February 6, 2012, Started ESG Contract Modification process for Health Canada implementation.
- September 28, 2012, Signed new FDA ESG support contract
- December 8, 2012, ESG Axway software upgrade to 5.9.6
- December 12, 2012, ESG Contract Modification signed
- January 2, 2013, Commissioner approves CRADA
- January 4, 2013, Center Director of Center for Biologics Evaluation and Research signs the CRADA

The Journey

- January 10, 2013, Director General for Resource Management and Operations Directorate and Therapeutic Product Directorate sign the CRADA
- February 22, 2013, Funds are obligated and the Implementation Whole-heartedly commences
- August 3, 2013, Axway software upgrade version 5.10.1
- September 27, 2013 FDA ESG new infrastructure delivered
- October 21, 2013, H.C. crossed the finish line to their new beginnings
- November 6, 2013, Health Canada begins on-boarding industry trading partners
- January 31, 2014, CESG is publically available

Concept of Operations (ConOps)

- August 17, 2011 – October 5, 2011
- Twelve versions of the document
- Full scope of the development effort detailed
- Rules of Engagement
 - Operational Constraints
 - Security Considerations
 - Proposed System Description (High Level)
 - Organizational Impacts
 - Use Cases
 - Performance Characteristic (30 gigabyte limit)
- Electronic Signature Policy
- September 21, 2011 started Technical Proof of Concept Tests
- Changed the FDA system design as a result of some of the issues encountered during the Proof of Concept testing

Funding

- Finding a suitable vehicle that would allow for the transfer of funds to support the CESG build was unusually difficult.
- Discussions focused on the vehicle for funding for two months. Frustrations were exceedingly high as there were no good vehicles to accomplish this task - that is if you were not connected to DOD and the Canadian military.
- With no good options in sight and a desperate need to be able to transfer funds across the US border into the US Government the discussion focused on the Cooperative Research and Development Agreement (CRADA) vehicle and we decided to utilize it.
- Beginning of the process to the final signed CRADA document – February 1, 2012 to January 10, 2013
- Dano Murphy - CBER's expert in this area. Dano functioned as CBER's lead and worked with Health Canada's Legal representatives on developing the CRADA and shepherding it through the maze of legal processes. Dano and Charles Kemp are the unspoken heroes of this initiative.

Implementation

- Began in earnest on February 22, 2013
- Leveraged the ConOps that the results from the Technical Proof of Concept to bring the system enhancement forward.
- Added infrastructure to the FDA ESG across the Production and Pre-Production Environments.
 - Two Application servers
 - One Production
 - One Pre-Production
 - Two Database servers
 - One Production
 - One Pre-Production
 - Additional Networks accounts and permissions
 - Added Health Canada in our paradigm as if it were a Center at the FDA.
- Enables regulated Industry to utilize one x.509 version 3 class 1 certificate for regulatory submissions to two distinct Regulatory Authorities.

Security



- Mission Critical System
- Federal Information Security Management Act (FISMA) Moderate rating.
- Re-Evaluating the System Security Posture
- Authority to Operate (ATO) in place
- Signed Interim Security Agreement (ISA) between Health Canada and the Food and Drug Administration (FDA)
- We have addressed our POA&M items (Plan of Action and Milestones)
- The FDA Electronic Submissions Gateway (ESG) receives guidance compliant submissions from our regulated Industry that are certified to be virus free. To date we have not been unavailable due to a virus attack.
- FDA CBER electronic submissions infrastructure has never been unavailable due to a virus attack.

Security



- The FDA ESG, also known as the Common Electronic Submissions Gateway (CESG), does not keep copies of submissions targeted for receipt by Health Canada for any duration of time.
- The FDA ESG does keep copies of the submissions targeted for the FDA in our Storage Area Network for 10 working days before they are deleted.

Delivery

- FDA infrastructure delivered and fully configured – September 14, 2013.
- HC infrastructure delivered and configured – September 24, 2013
- Health Canada has limited on boarding after the September 27, 2013, Production delivery.
- After January 31, 2014, full and open Production System enrollment for Health Canada
- **Twenty-six months from Concept to Delivery**

ESG Future Plans - October 28, 2013

- New Submission Types – Health Canada
- Web Trader Login Capacity testing – accomplished for version 5.10.1,
 - Currently 250 concurrent users in 5 minutes
 - Expand to 500 – 1,000 concurrent users in % minutes in 2018
- Stood the Web Trader Hosted Facility/Solution
 - Finished Security Assessment
 - Completed Industry Testing
 - Production June 1, 2014
- Starting Interactions with Veterans Administrations
 - Delayed

ESG Future Plans - October 28, 2013

- Increase Software Support model
 - From Standard Support model
 - To Mission Critical Support
- Technical Refresh Plan
 - New Test Environment with Internet Connectivity
 - Second Cluster for Pre-Production Environment
 - Second Cluster Production Environment
 - Goal is to make the ESG/CESG a high availability system with 99.9% up time.
- New Governance Board
- **Software?**

ESG Future Plans - October 28, 2013

- Discussed New Software Purchase
 - Two-way communications
 - Tetra-byte submission transport
 - API's
 - Improved Submission Processing
 - CFT
 - New Submission Tools
 - Sentinel
 - Secure Transport
- Stabilize and prepare for the new Regulatory Mandates
- Disaster Recovery Site for the Agency is currently being studied

Business Justification

FDA Electronic Submission Gateway - ROI

Below are a few of the benefits realized following the implementation of the FDA ESG:

- Improves costs, resource requirements, and time efficiencies for both Sponsors and the Agency
- Facilitated moving product teams to a fully electronic submission process
- Obviated need to burn CDs/DVDs or create tapes
- Reduced hardware/software, costs, and resources associated with media creation
- Eliminated QC of submission associated with creating media
- Eliminated courier and FedEx fees associated with Regulatory submissions
- Eliminated paper output
- Reduced costs associated to processing, tracking, and archiving paper

FDA Electronic Submission Gateway – ROI (cont.)

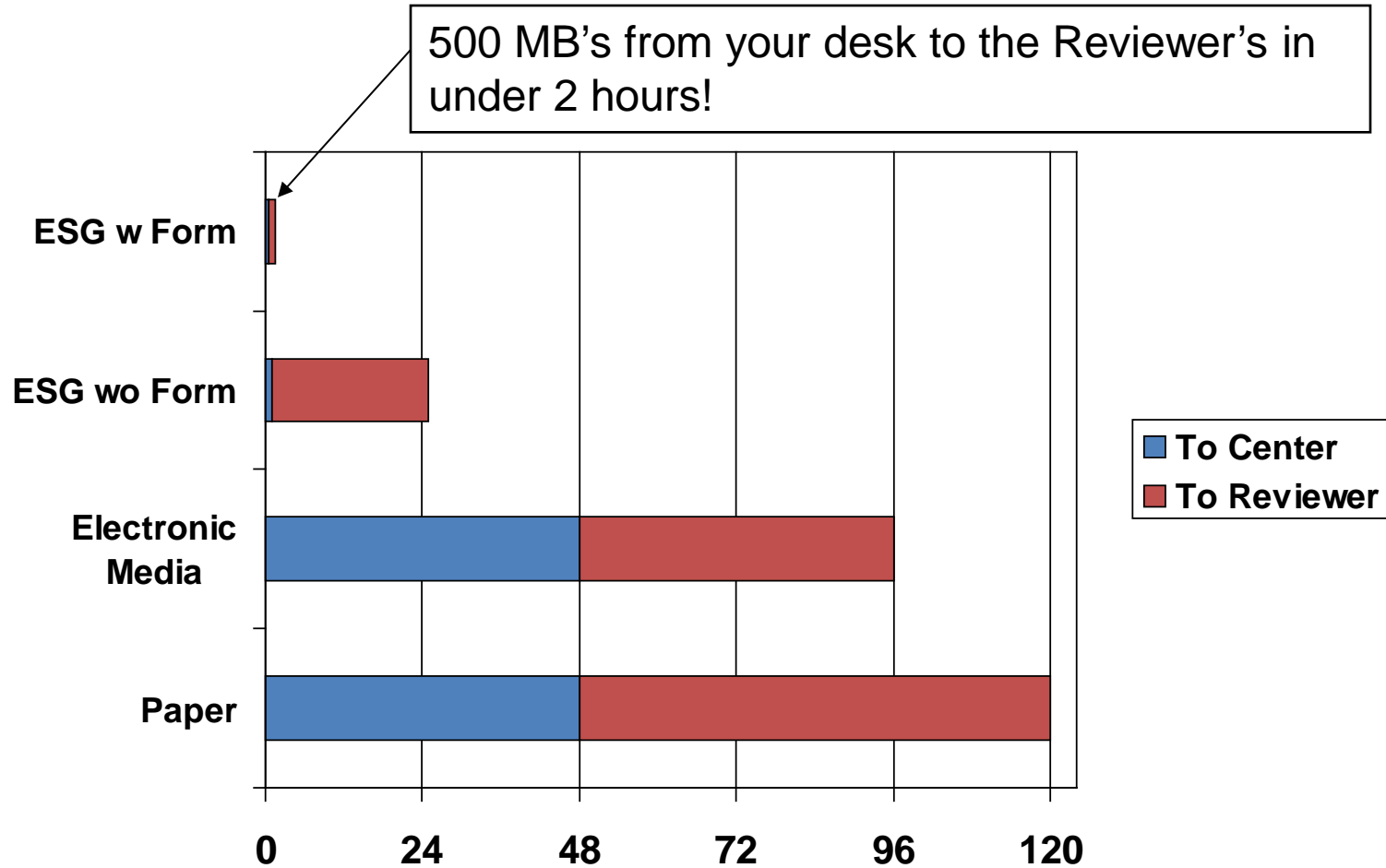
- Reduced costs associated with maintenance of 3 DocuTech printers
- Eliminated need for DocuTech printers (within 1st year of implementation)
- Facilitated redeployment and reduction of resources required to process paper or media-based submissions
- Provided a more efficient and secure transfer of electronic submissions
- Enabled implementation of SAFE Digital Signatures which facilitated additional benefits/gains
- Facilitates earlier receipt of the submission by the Agency and access to the submission by the Reviewer

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

Processing Times for Submissions by Format



Digital Signatures

- FDA does not require submission of a paper copy for electronic submissions submitted via the FDA ESG.
- FDA forms (e.g., 1571, 356h) and documents require a signature. Accepted signature methods by FDA are:
 - **Scanned signatures**
 - **Digital signatures**
 - **Flattened digital signatures. A flattened digital signature must include (see example):**
 - **the printed name of the signer**
 - **the date and time when the signature was executed**
 - **the reason for signature**
- Please utilize the .pdf self sign signature on the FDA fill-able forms.
- The Agency does not check electronic/digital signatures unless there is a directed inspection involving the submission transmission.

Advice/Issue

- If your certificate is not accepted by the FDA registration module or if you have to replace an existing certificate.
 - Enclose the .cer or .p7b file in a .zip file and send as an email attachment to ESGHELPDESK@fda.hhs.gov
 - Or change the .cer or .p7b extension to .txt and send as an email attachment to ESGHELPDESK@fda.hhs.gov (please specify the original extension of the file)
- In short – email the Helpdesk.

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>

ESG Outages

- The ESG is a 99.5% uptime system 24/7/365
- Let's Talk About Computer System Reality
 - Things fail in spite of your best contingency plans
 - No one can account for Acts of GOD
 - What is an Act of GOD
 - Weather (hurricanes, tornadoes, blizzards)
 - Earthquakes
 - Equipment Failures occur even when proper maintenance and redundancies have been built into a system and they are tested.
 - We had two Acts of GOD during the week of August 22, 2010
 - Earthquake, 5.9 on Richter Scale August 23rd
 - Hurricane, Irene August 27th
- Ok, so you have become dependant upon the ESG and you are wondering what you should do in the case of an outage?
- **First thing – do not panic**

ESG Outages (cont.)

- Since May 6, 2006 the ESG has been hard down less than twelve times (90% of those instances occurred before 2009)
- Outages range from three up to 48 hours
- The ESG has suffered from an occasional performance issue.
- Performance issues are infrequent.

- What is the process once a system wide outage or incident has been confirmed?
 - We send notification to all stakeholders via our Listserv
 - Post the system outage on the FDA Industry Systems (FIS) webpage
 - ESG System Status link is on the ESG webpage and system interface

ESG Outages (cont.)

- Regulated Industry aka account holders will be notified once the system is functional or if it has been determined that it will take more than 48 hours to bring the system back up.
- More than 48 hours have never elapsed on any outage before we brought the system up back up.
- Typical outage is six to twelve hours.
- Ok – I know you are wondering what is the most affective manner to proceed with your submissions in the case of an outage?

ESG Outages (cont.)

- Recommendations

- Follow email for our updates
- At 24 hours burn a copy of your submission to media and wait 24 more hours before considering sending the media based submission
- Notice will be sent if the ESG will down for more that 48 hours.

- Realities

- It takes 3-5 business days to process media based submissions at the FDA.
- We do not want to overload our document rooms with a glut of media due to an outage of less than 48 hours
- Even delaying the transmission of a submission 24 to 48 hours will still place the submission in the reviewers hands faster than sending it to the FDA on media via courier.
- Call the review division and discuss options

Electronic Submissions Gateway

Thank you

Appendix

Supplemental Information - Installing Certificates

After you make the choice from the above list follow the on screen instructions to complete the purchase. CA will send you an email with PIN number and a link to a website where you can import/install the certificate. Accept all defaults and say “yes” to all pop-ups, your certificate will be installed in your browser. Note, if you are using WebTrader, you do not have to install the certificate on the same machine that you will be using. Once the certificate is installed in the browser you can export the public and private keys out and use them where ever you want. B2B system users will need to install the certificates in their system. Configuring the certificates may defer from sponsor to sponsor depending on what gateway software being used.

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.**

Supplemental Information - Purchasing Certificates

- If you are trying to use an outsourced certificate, the following are the companies that sell the X.509 certificates (Displayed in alphabetical order). Click on the link to go to website where you can purchase the certificate.
 - Geotrust:
http://www.geotrust.com/products/client_certificates/my_credential.asp
 - GlobalSign:
http://www.globalsign.net/digital_certificate/personalsign/index.cfm If you select this, buy PersonalSign2 Pro™ Certificate with one year validity
 - Verisign: <http://www.verisign.com/products-services/security-services/pki/pki-application/email-digital-id/index.html>

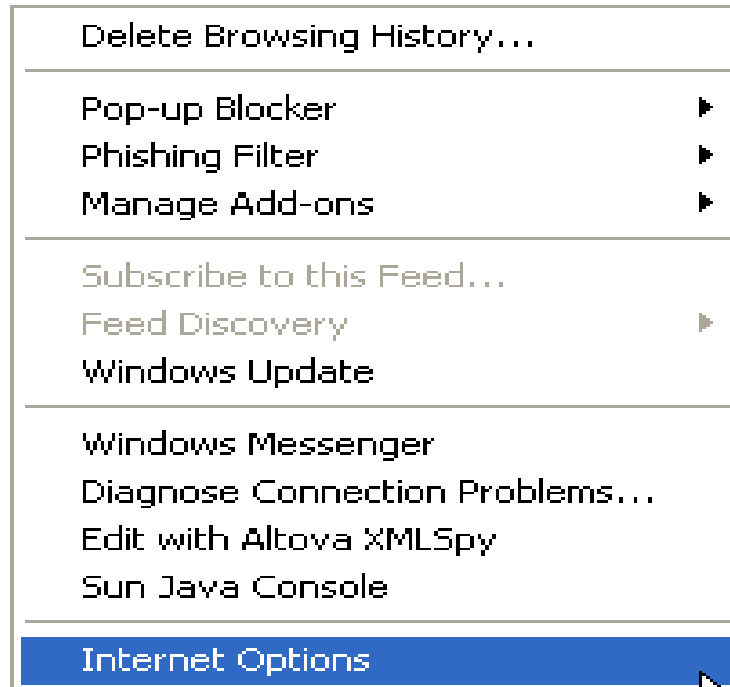
Purchasing and Installing Your Digital Certificate (cont.)

- 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



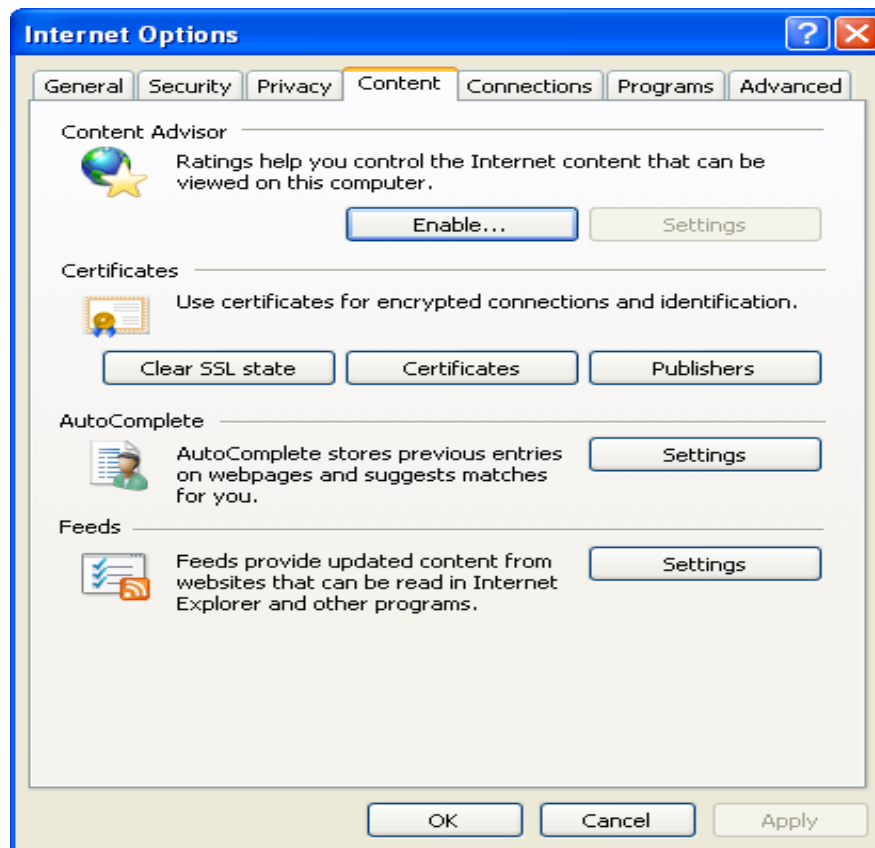
Purchasing and Installing Your Digital Certificate (cont.)

- **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

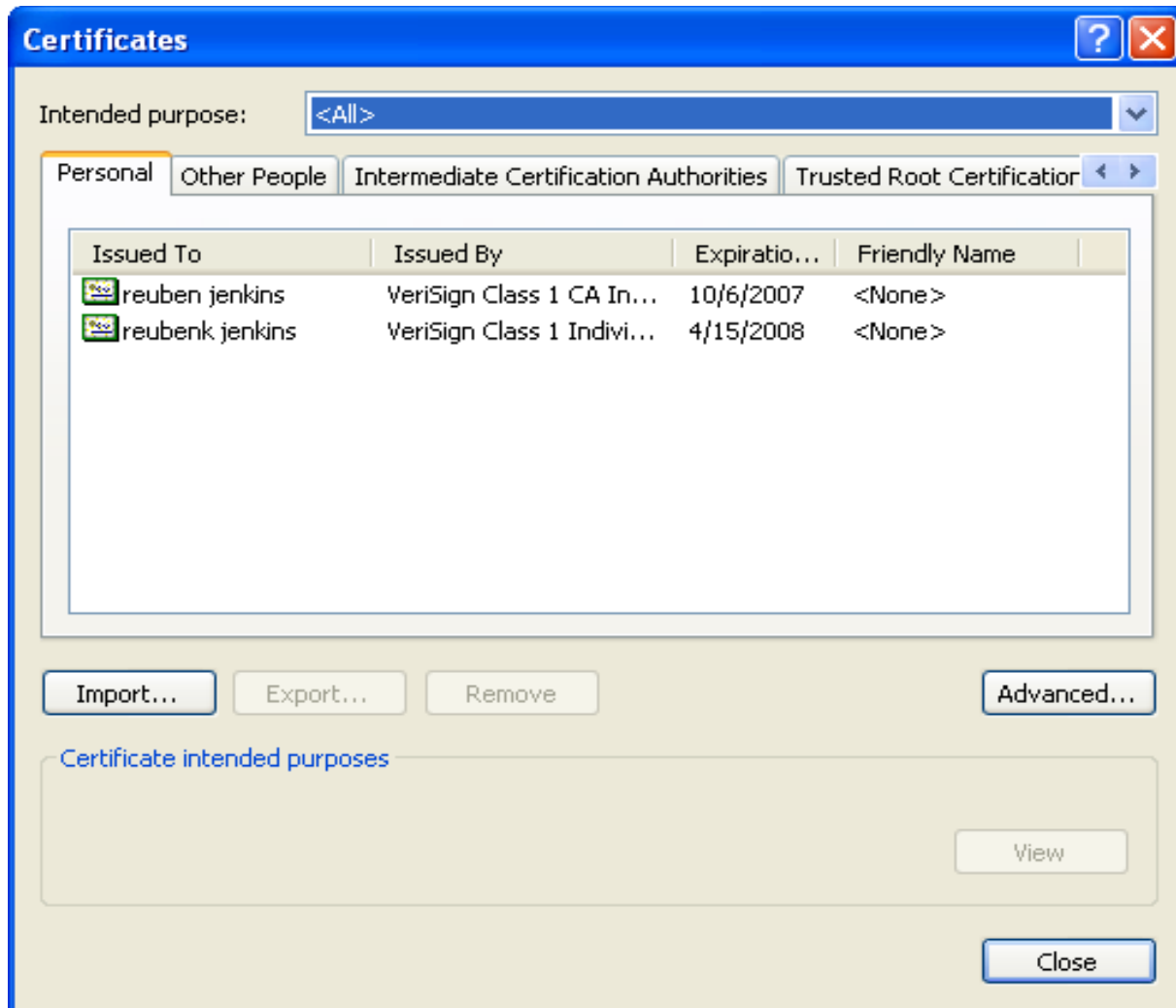


Purchasing and Installing Your Digital Certificate (cont.)

- **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).**

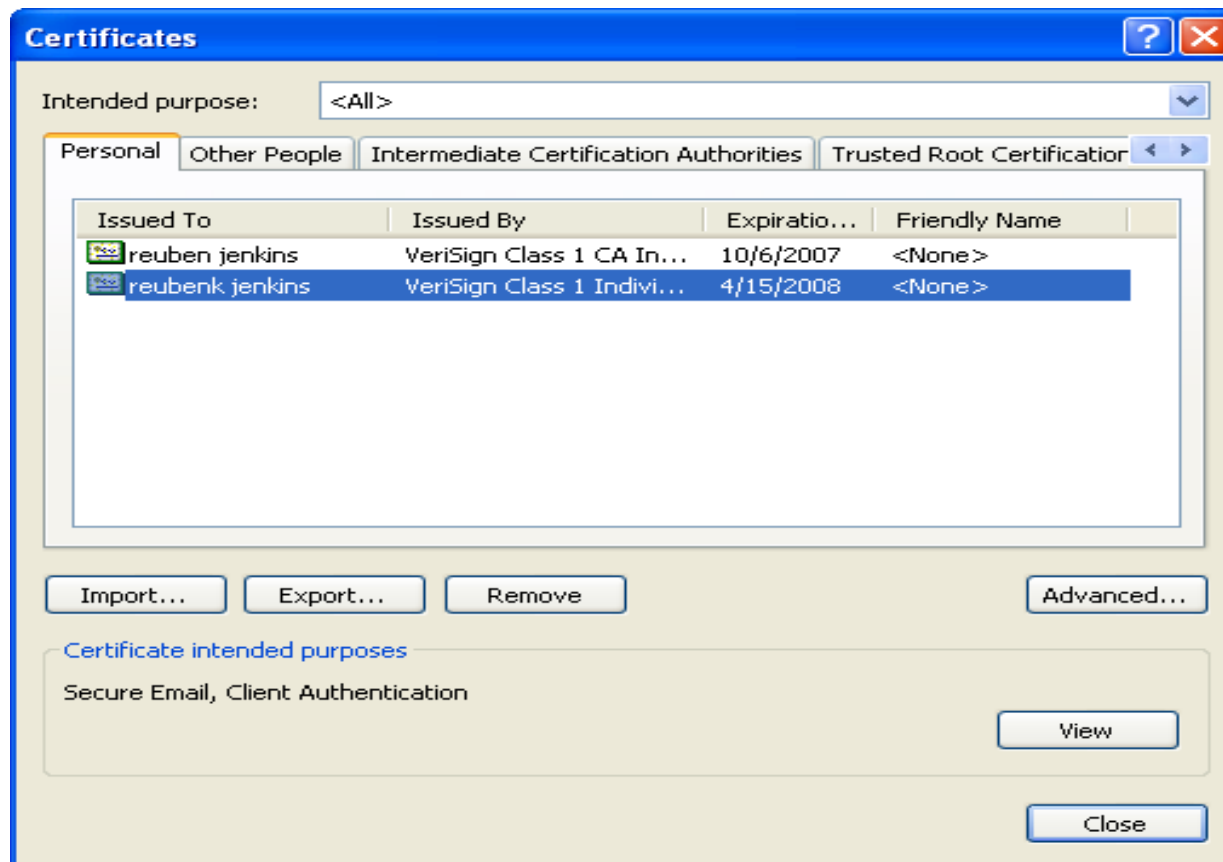
If the digital cert (.cer) is not in this location, please contact your vendor to identify the digital cert (.cer) location. To complete the ESG registration process you must know the location of your digital cert (.cer).

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.



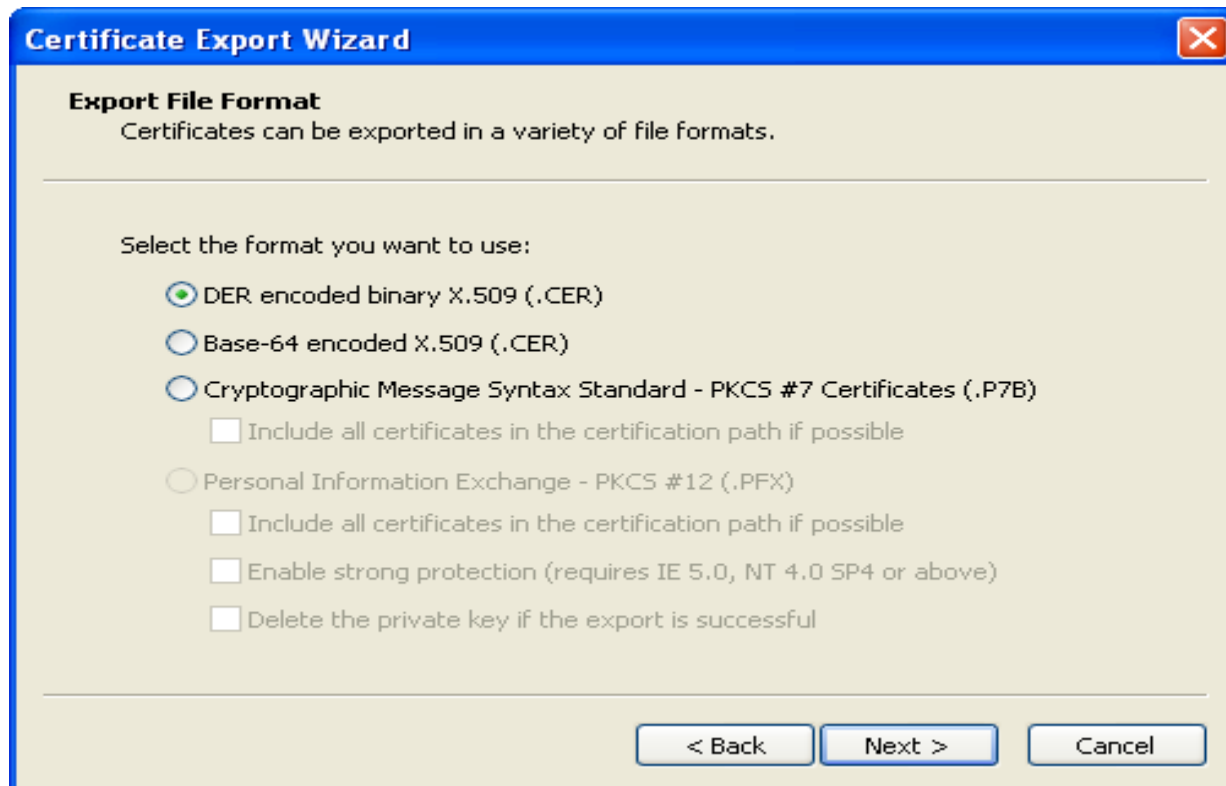
Exporting Your digital Cert (.CER) for ESG Test Account Registration (cont.)

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



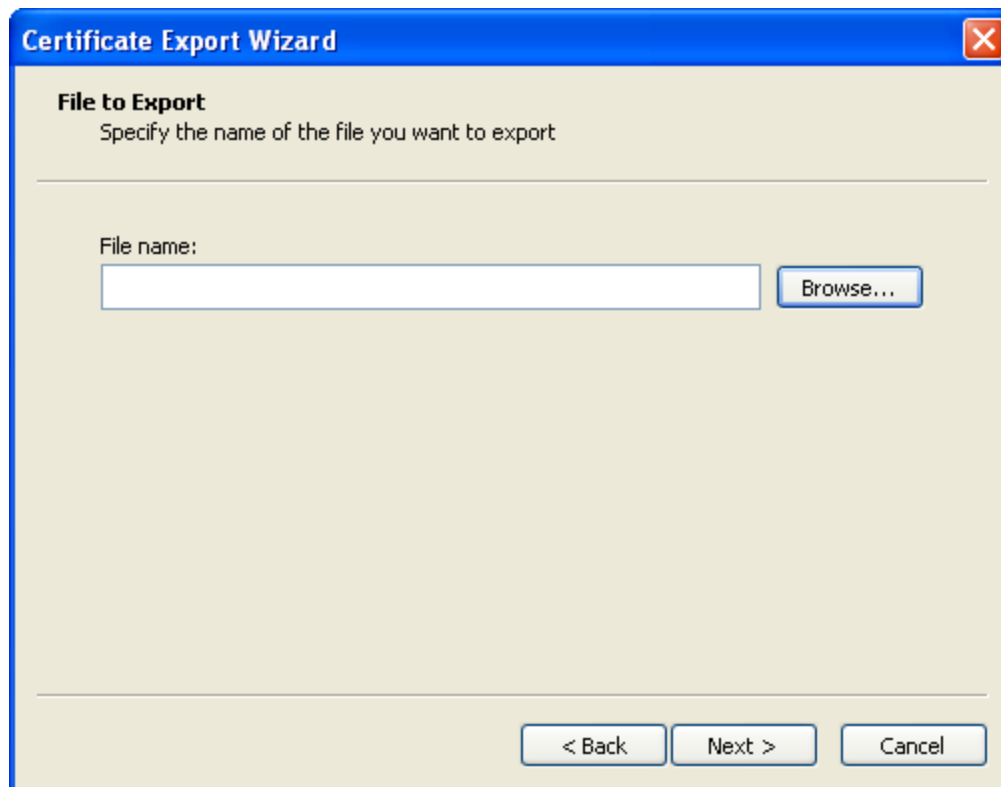
Exporting Your digital Cert (.CER) for ESG Test Account Registration (cont.)

- 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.)

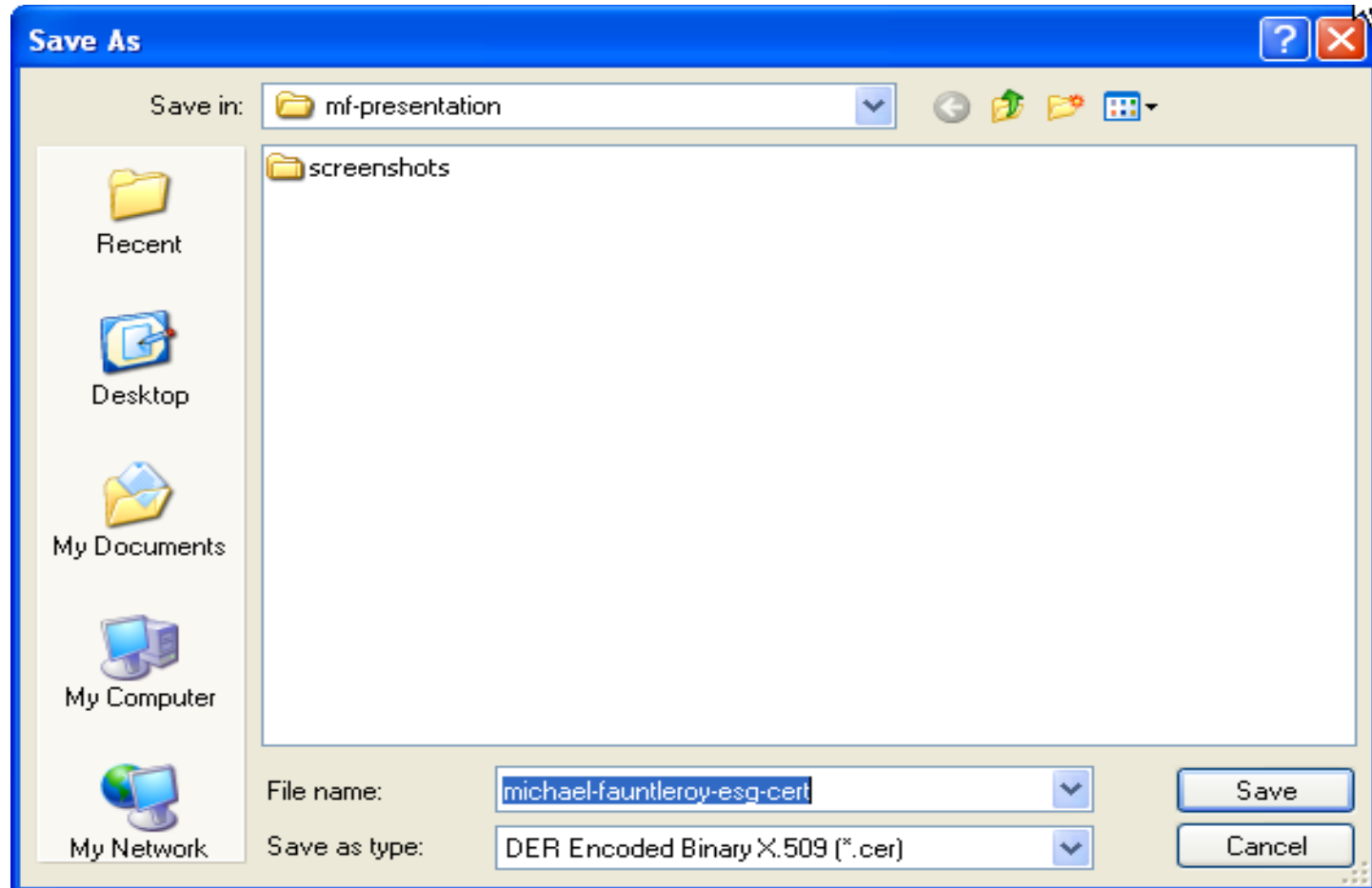
- The Certificate Export Wizard – File to Export Window will launch.



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

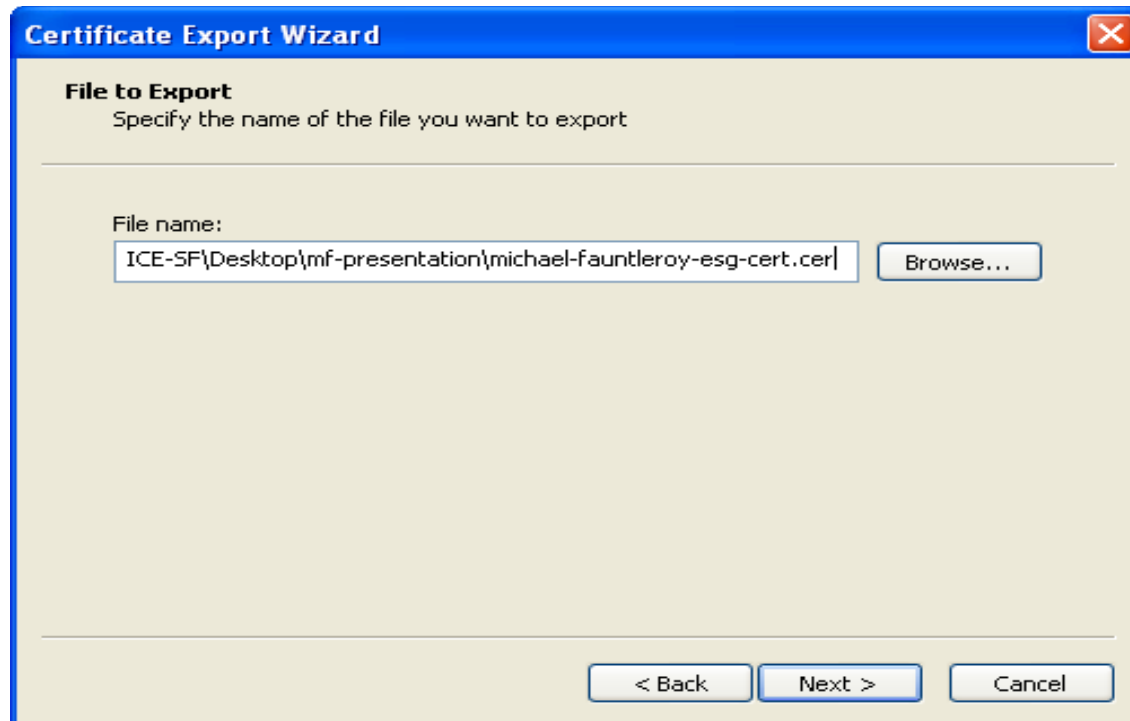
- **Choose Browse. The Save As Window will launch. Navigate to the location where you want to store the exported digital cert (.cer).**
- **Create a name for the digital cert (.cer). We recommend something that will remind you that the digital cert (.cer) supports the ESG. Choose Save**

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.



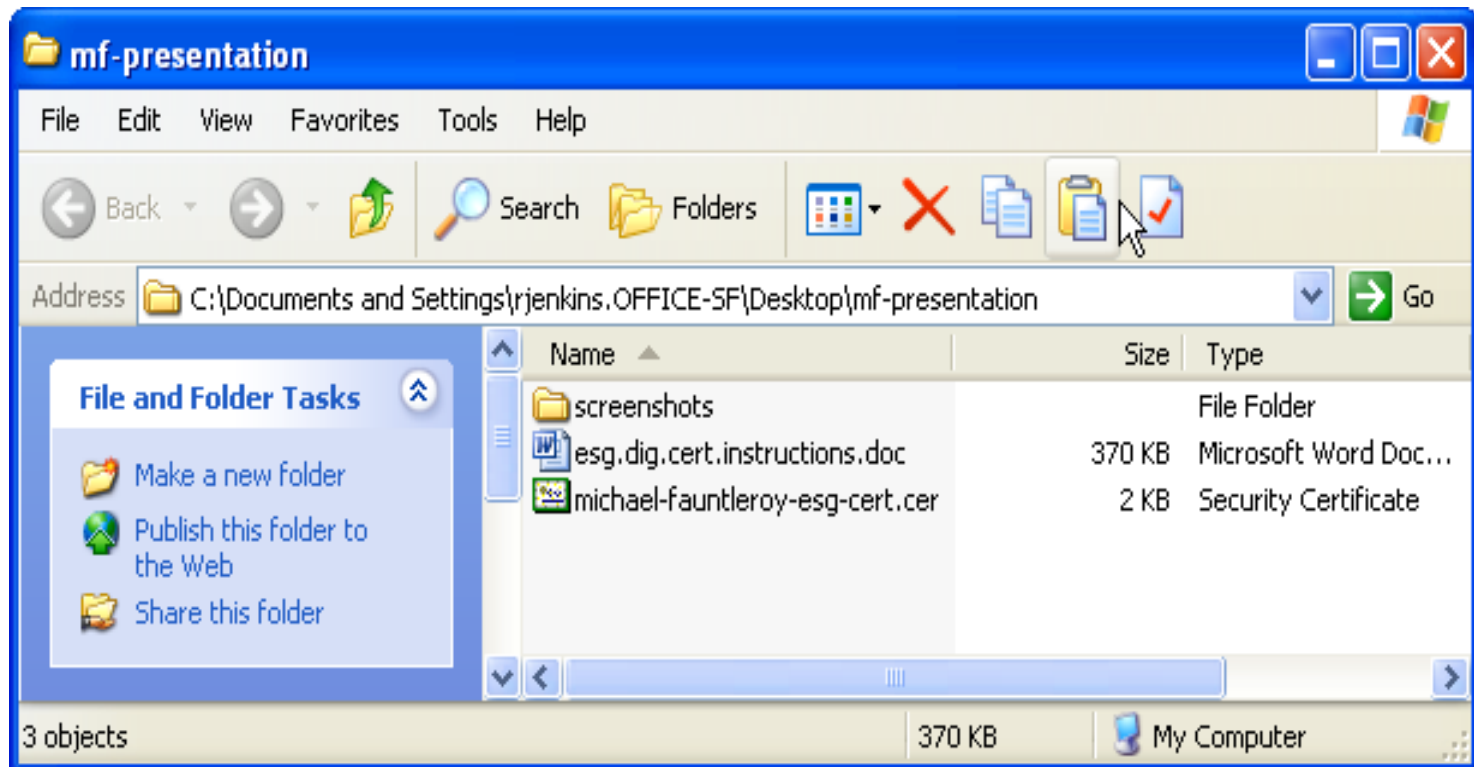
Exporting Your digital Cert (.CER) for ESG Test Account Registration (cont.)

- 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

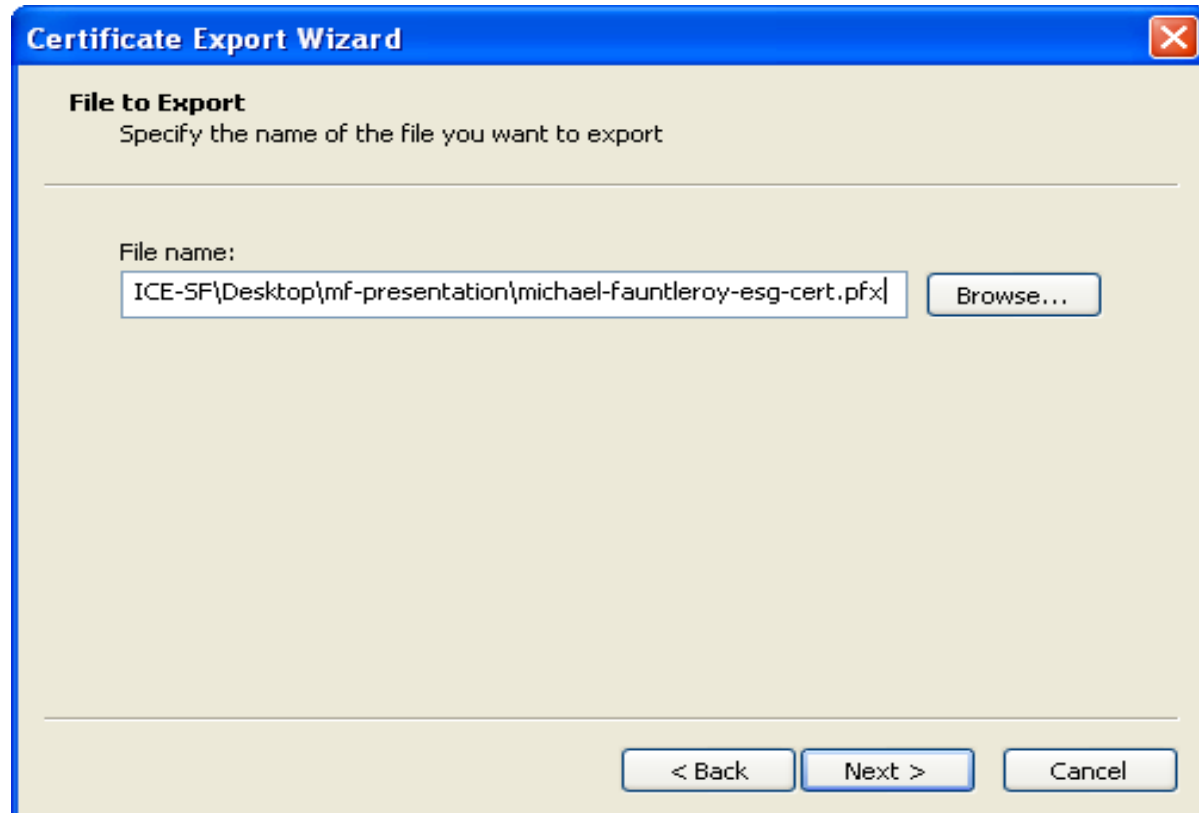
- The Certificate Export Wizard – Password Window will launch. Enter and confirm Password. Choose Next. (Remember this password! The ESG will ask for it when you transmit files!)



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." Below this is a horizontal line and the instruction "Type and confirm a password." 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 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.



Additional Information

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

