LORENZ eValidator 5.3.0

(Incluye Nuevas Reglas de Validación Septiembre 2013)

Nees New Validation Criteria v.4.0

Ectd New Validation Criteria v.5.0

1. DESCARGA E INSTALACIÓN

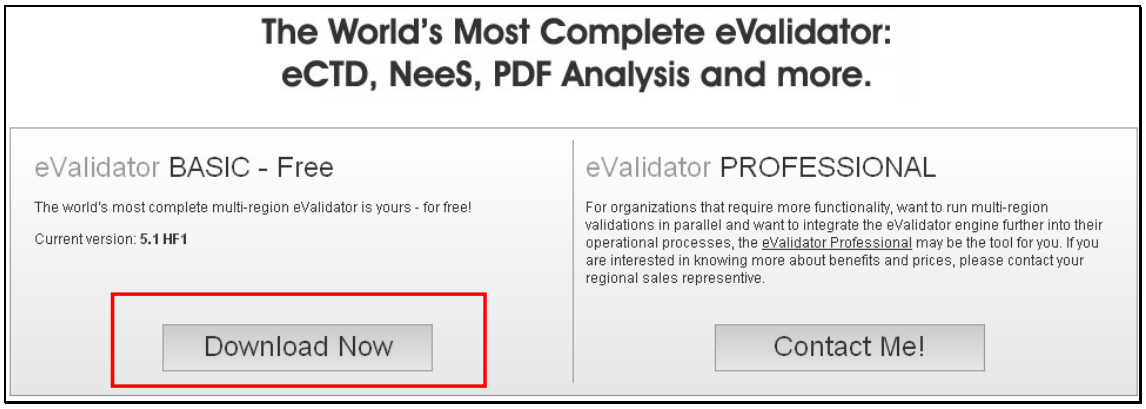
Descarga desde:

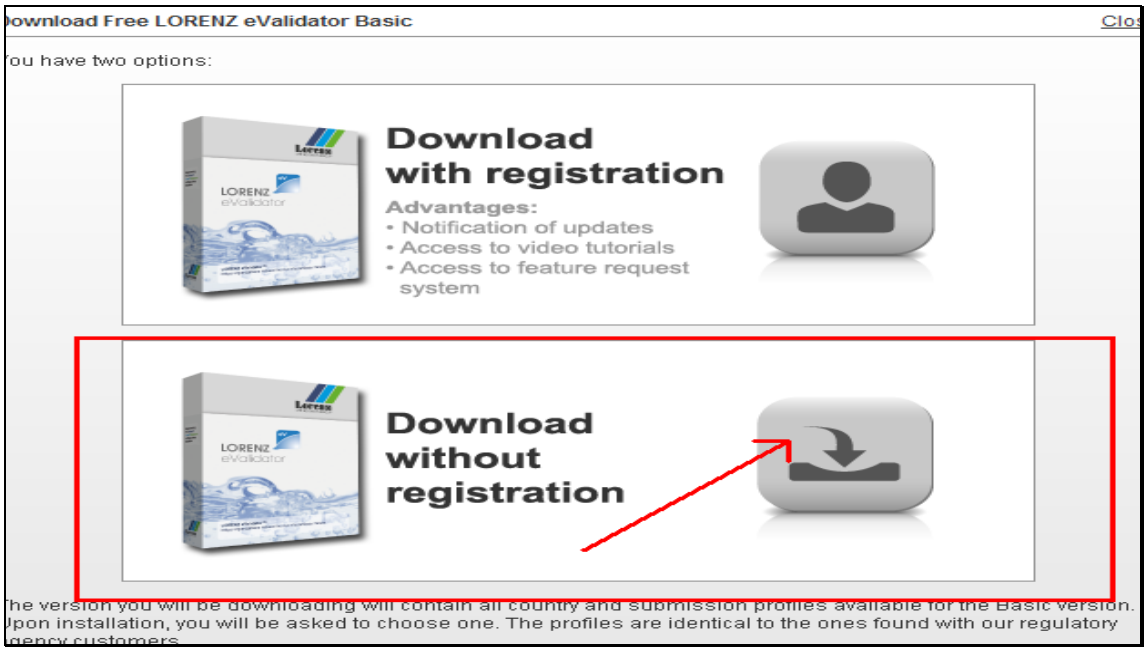
Directamente pinchando en el enlace de la AEMPS

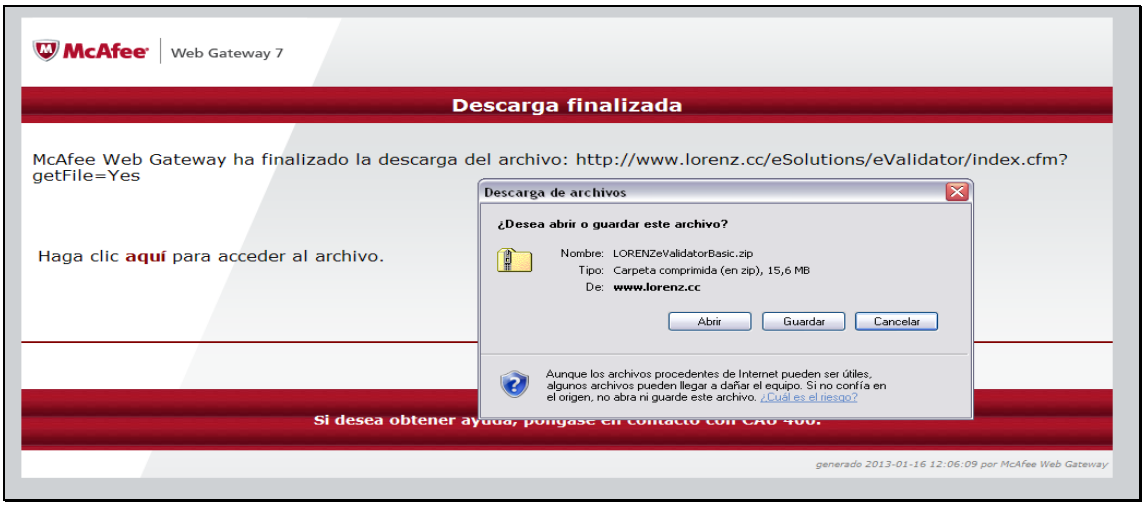
http://www.lorenz.cc/eSolutions/eValidator/index.cfm?getFile=Yes

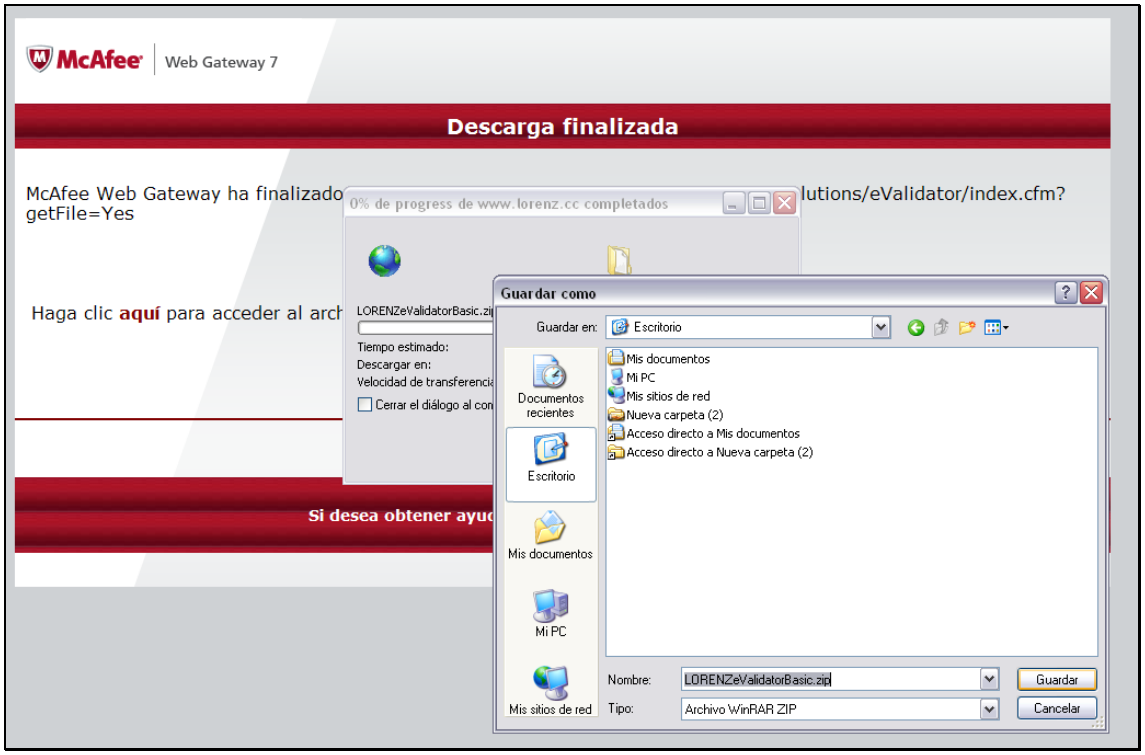
o desde la pagina de Lorenz

http://www.lorenz.cc/eSolutions/eValidator/

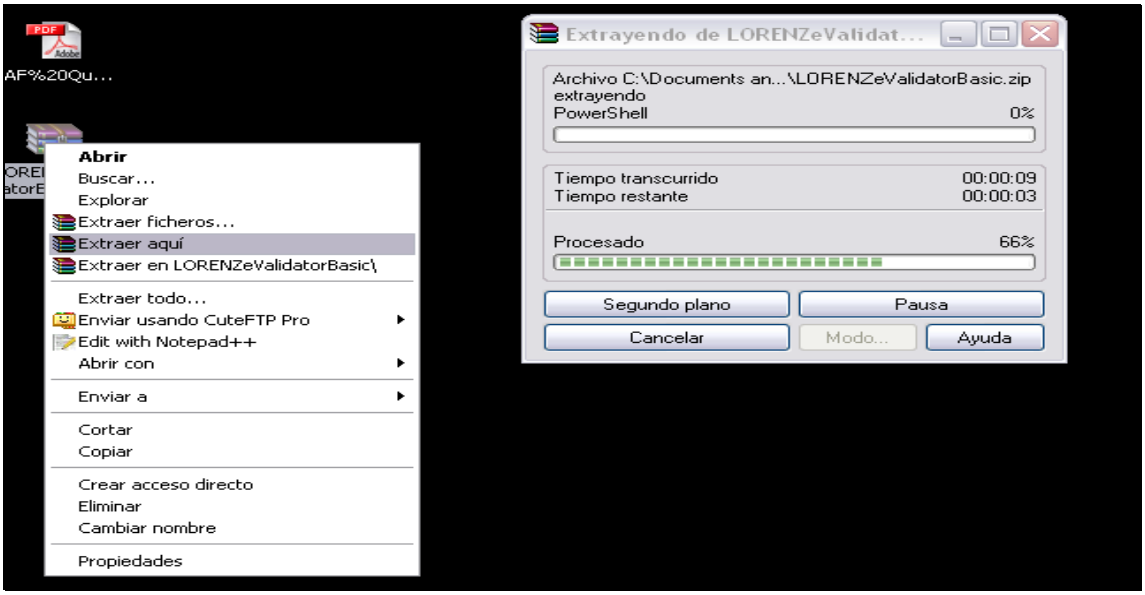




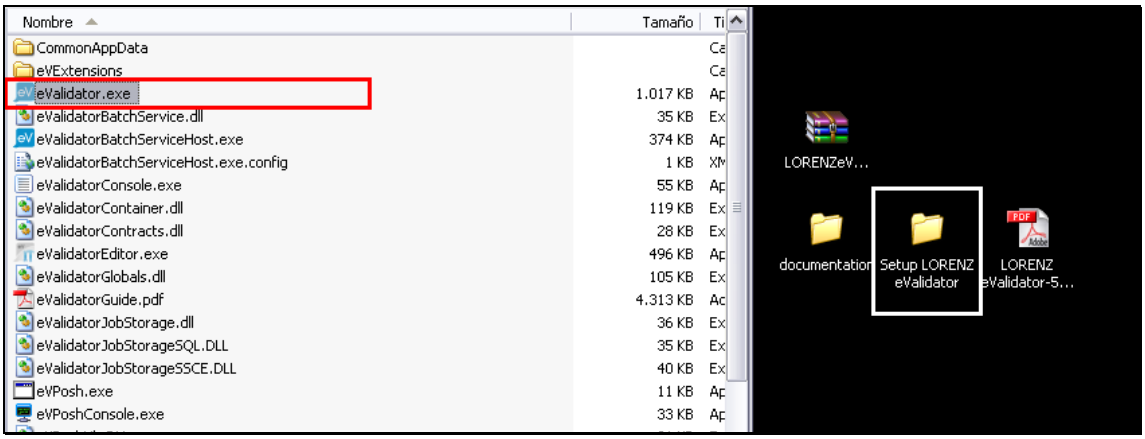




Guardamos el archivo en el PC y lo descomprimimos:



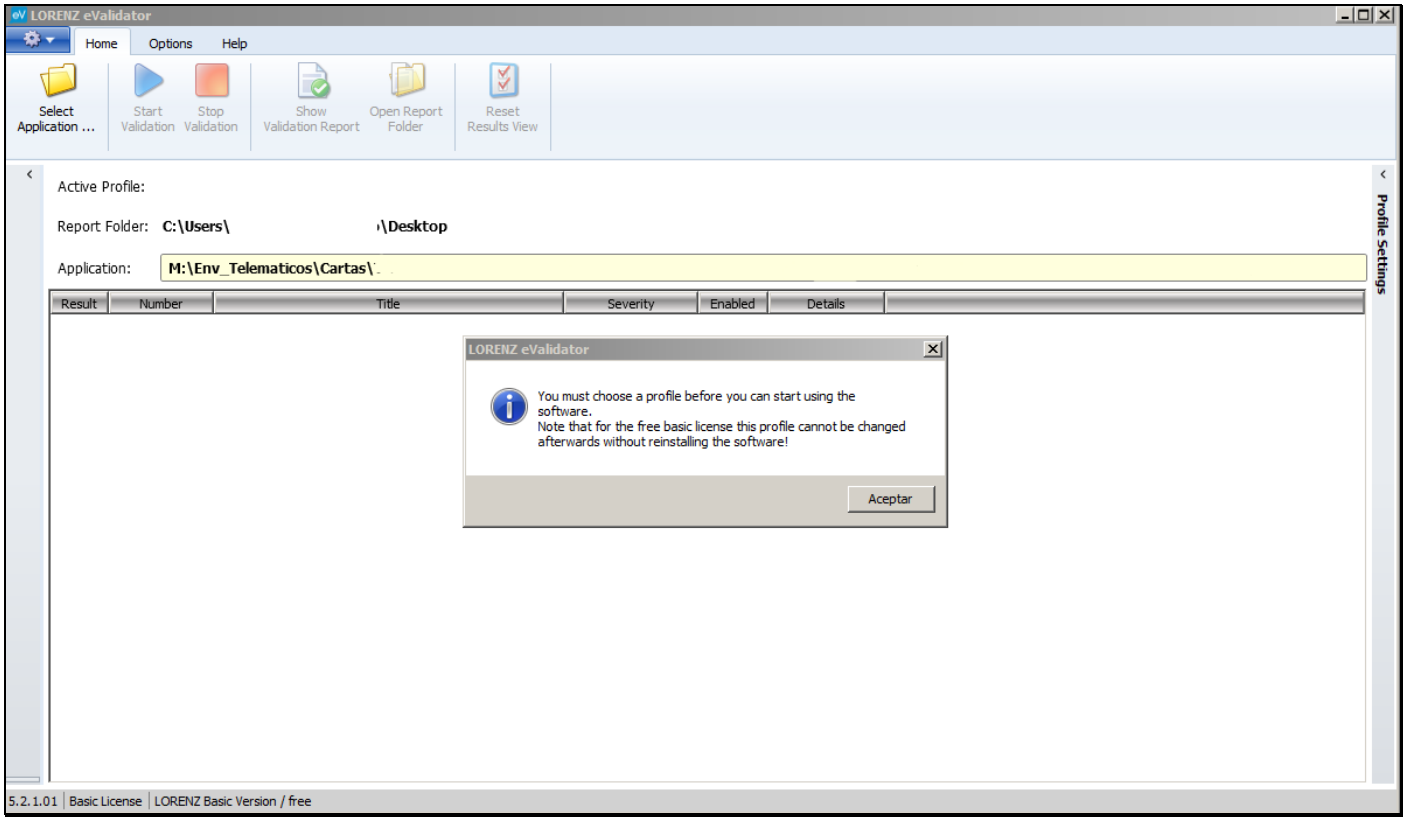
Tendremos tres carpetas, tras descomprimir el archivo. Localizamos en una de ellas ” Setup LORENZ eValidator” el ejecutable “eValidator.exe”



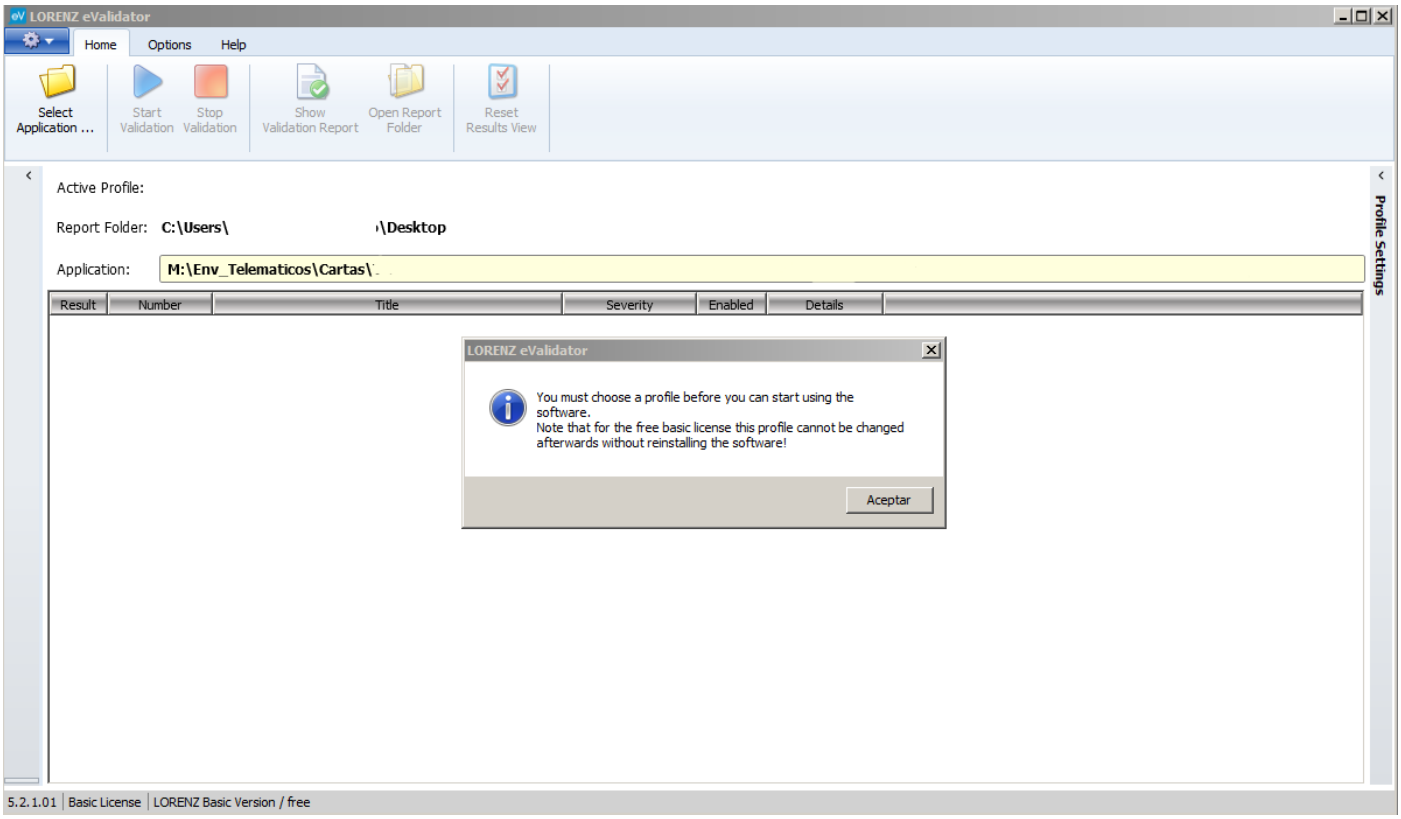
Iremos aceptando las diferentes pantallas que vayan apareciendo (Siguiente/Next) hasta finalizar

2. USO DEL VALIDADOR

La primera vez que lo ejecutemos, nos pedirá indicar el perfil a utilizar. En esta versión gratuita será necesario reinstalar el programa para modificar el perfil seleccionado.

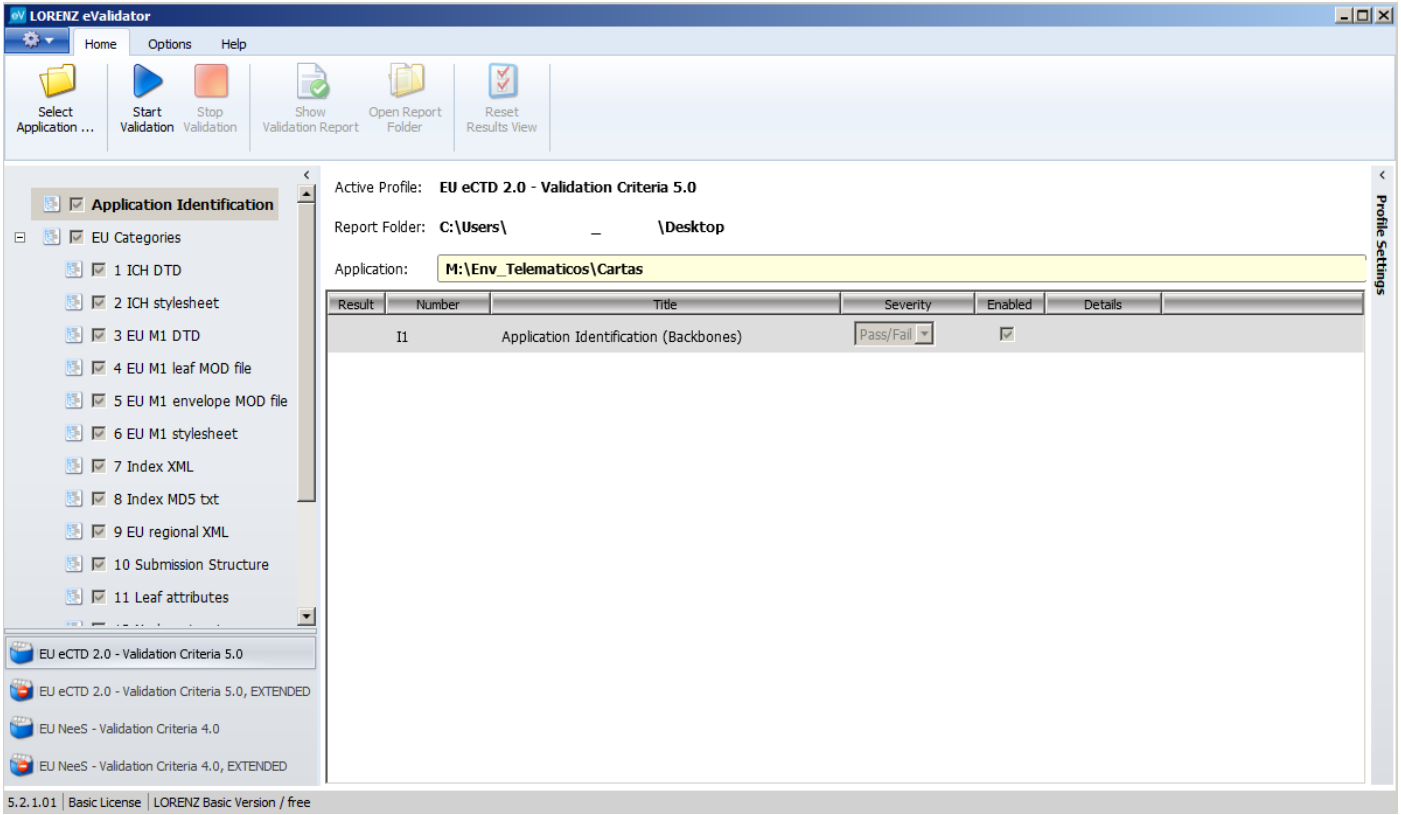


En nuestro caso seleccionaremos el perfil EU con las últimas reglas de validación aprobadas

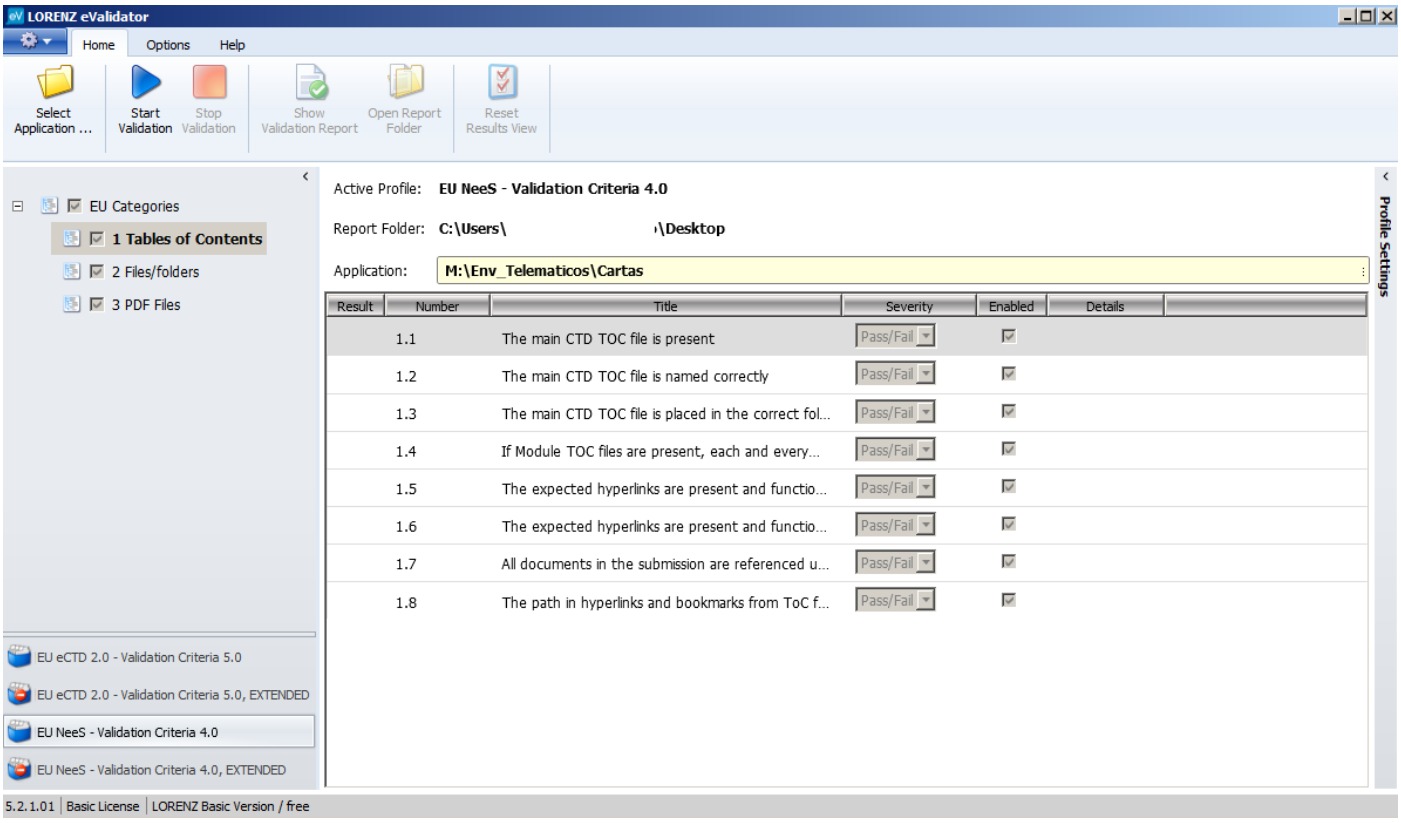


En función del formato de la secuencia a validar, seleccionaremos entre las opciones

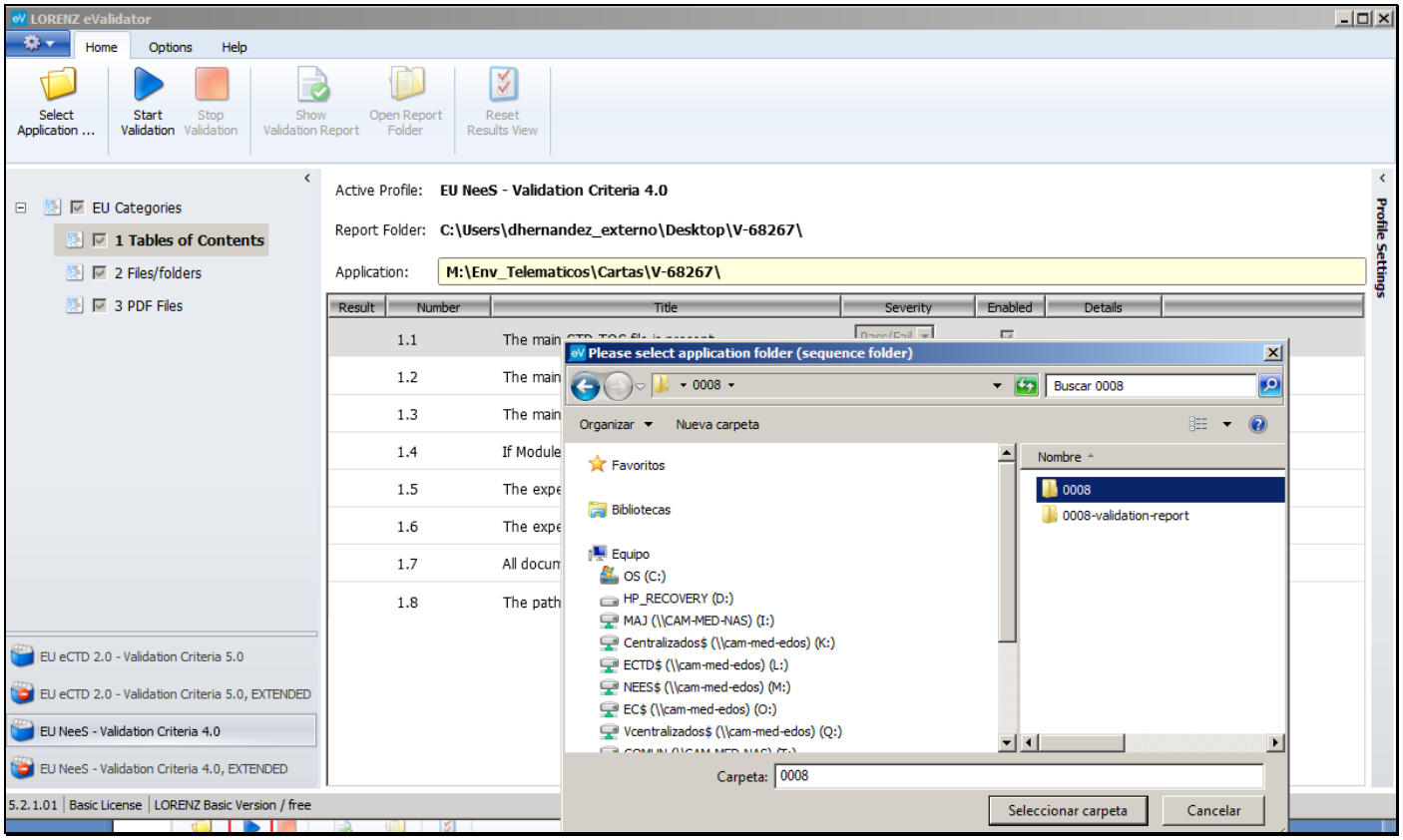
En el caso de eCTD :



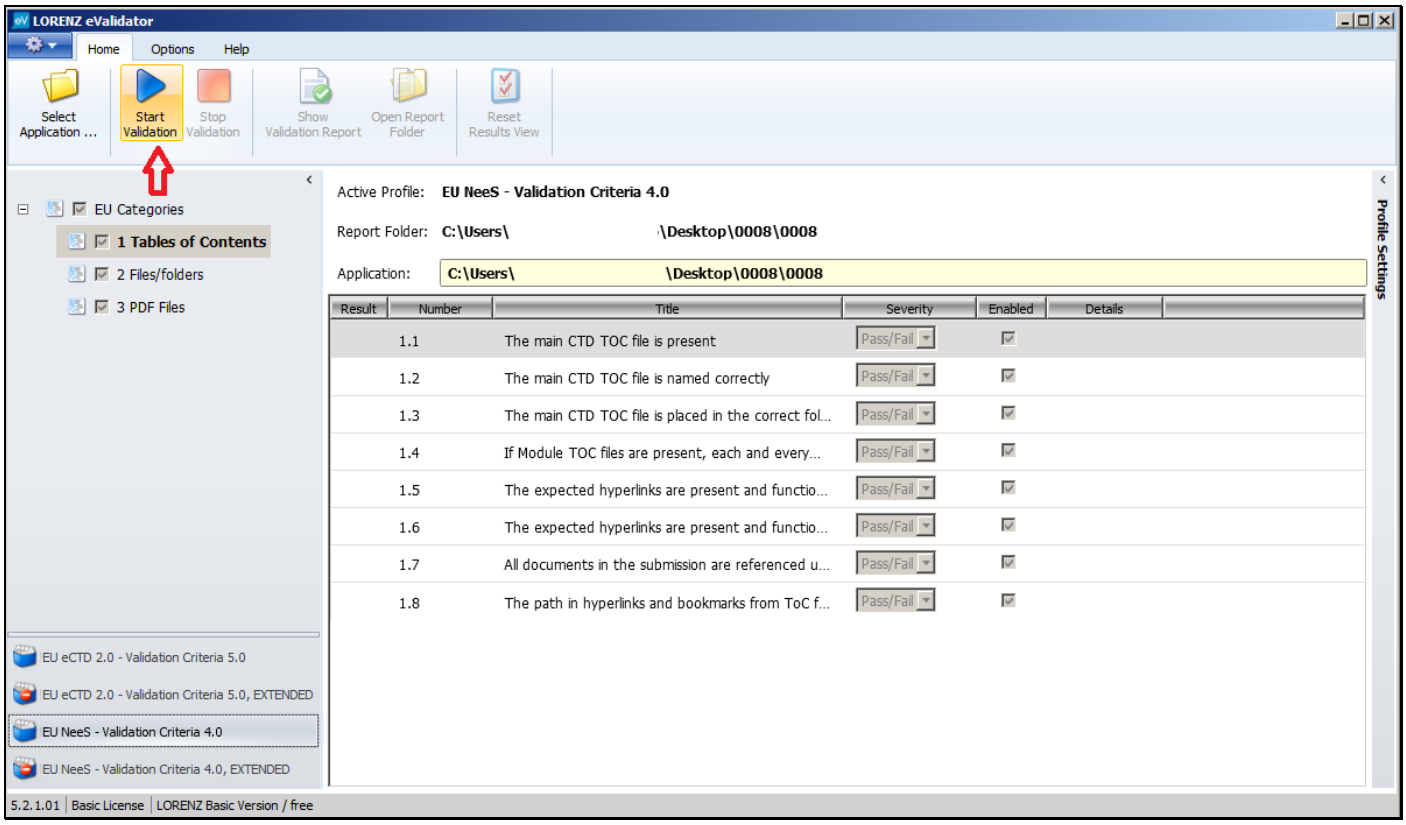
En el caso de formato Nees :



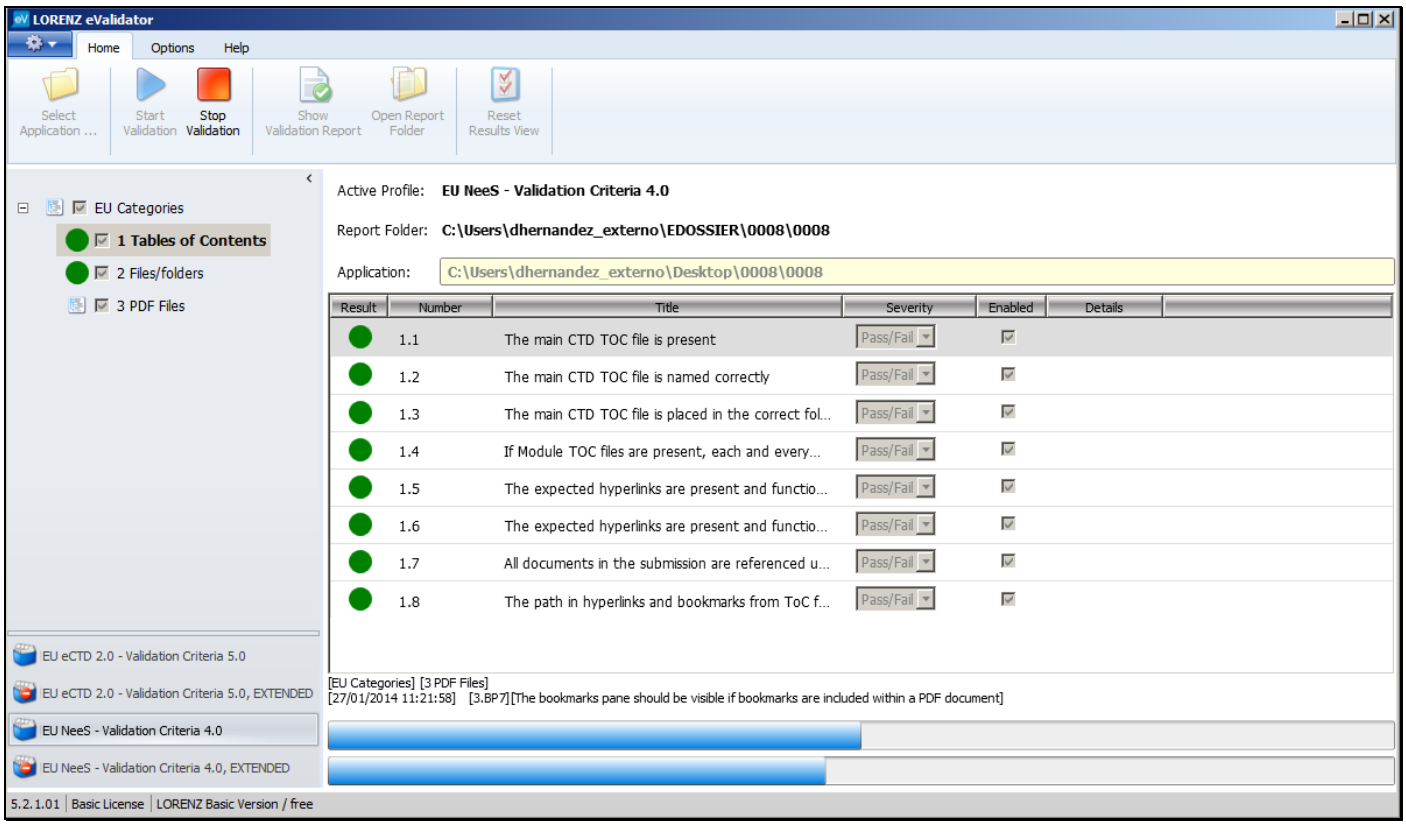
Seleccionamos la ubicación de la secuencia a validar desde “Select Application”

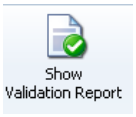


➢ **Iniciamos la validación desde "Start Validation"**

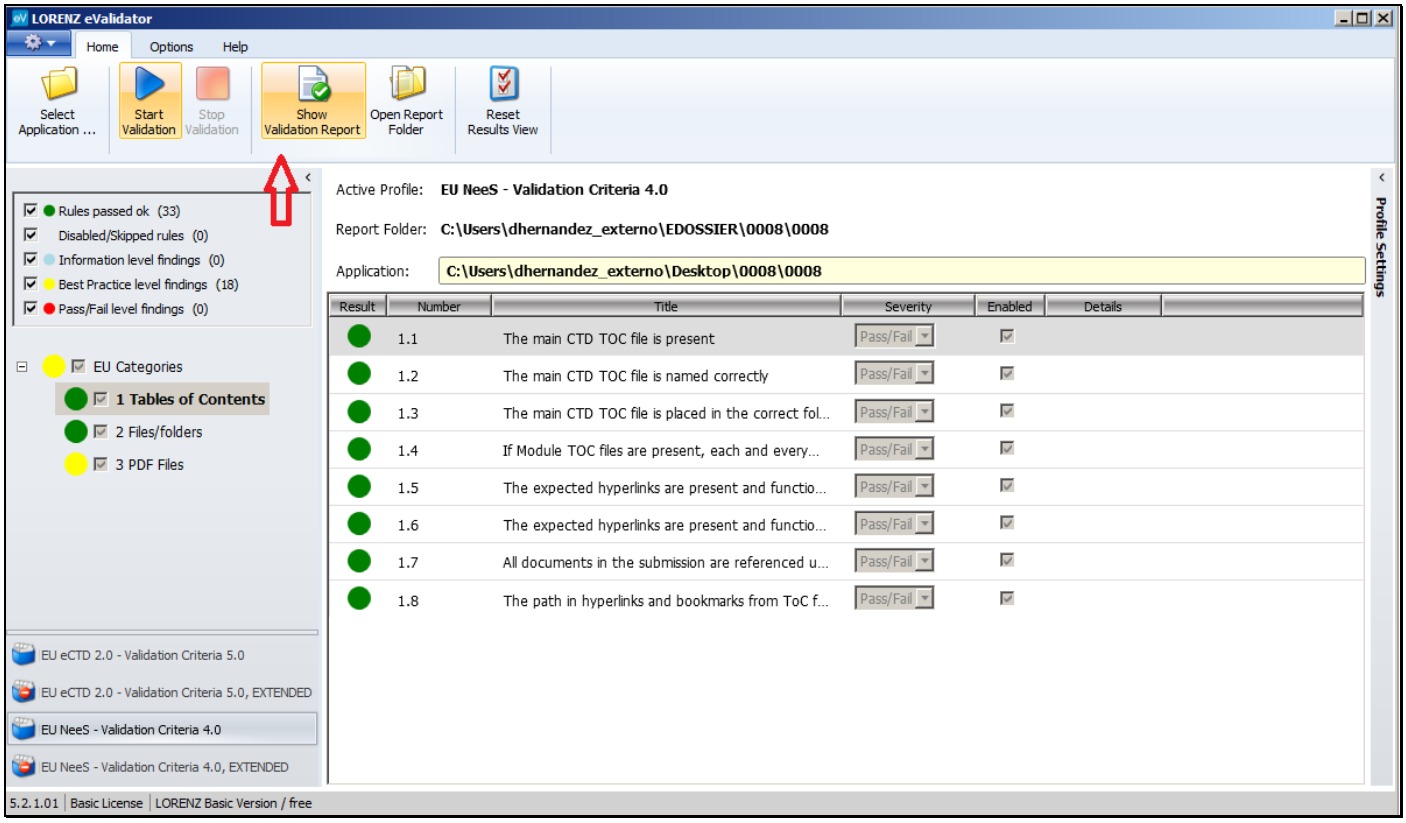


Comenzará entonces la validación, mostrándose barra de progreso en la parte inferior

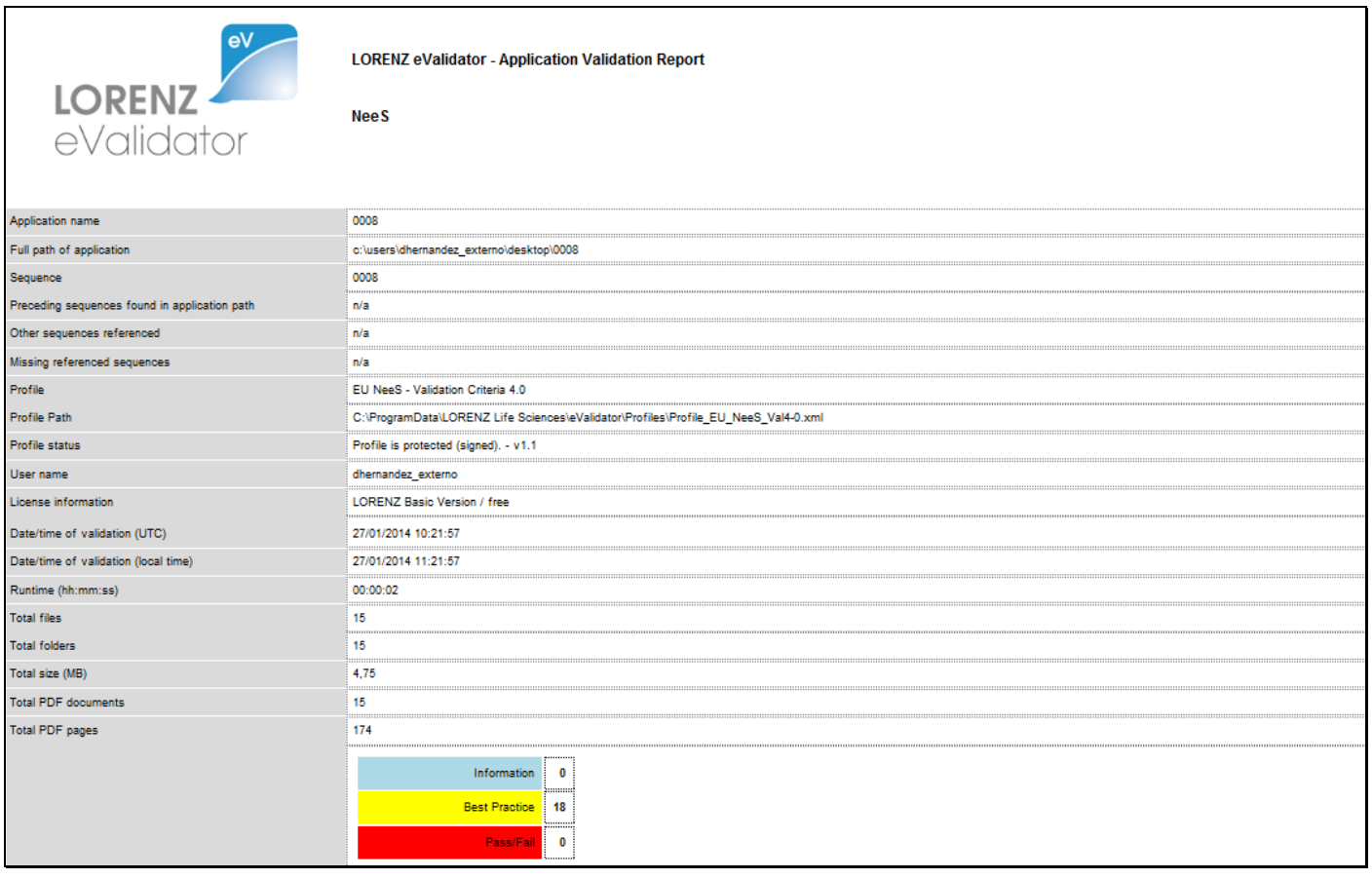




- **Una vez finalizado, accederemos al informe de validación mediante “Show Validation Report”**



Se abrirá una ventana en el navegador con el informe donde se muestran los errores encontrados cuya importancia ira en función del código de color siendo el rojo motivo de rechazo, amarillo buenas prácticas y azul información a destacar.



LORENZ eValidator - Application Validation Report

NeeS

Application name	0008
Full path of application	c:\users\dhernandez_externo\desktop\0008
Sequence	0008
Preceding sequences found in application path	n/a
Other sequences referenced	n/a
Missing referenced sequences	n/a
Profile	EU NeeS - Validation Criteria 4.0
Profile Path	C:\ProgramData\LORENZ Life Sciences\eValidator\Profiles\Profile_EU_NeeS_Val4-0.xml
Profile status	Profile is protected (signed). - v1.1
User name	dhernandez_externo
License information	LORENZ Basic Version / free
Date/time of validation (UTC)	27/01/2014 10:21:57
Date/time of validation (local time)	27/01/2014 11:21:57
Runtime (hh:mm:ss)	00:00:02
Total files	15
Total folders	15
Total size (MB)	4,75
Total PDF documents	15
Total PDF pages	174

EU Categories		
EU Categories / 1 Tables of Contents		
1.1	OK	The main CTD TOC file is present
1.2	OK	The main CTD TOC file is named correctly
1.3	OK	The main CTD TOC file is placed in the correct folder
1.4	OK	If Module TOC files are present, each and every module folder (/m1, /m2, etc.) contains the correctly named Module TOC file
1.5	OK	The expected hyperlinks are present and functioning in the main CTD TOC file.
1.6	OK	The expected hyperlinks are present and functioning in the Module TOC files, if present.
1.7	OK	All documents in the submission are referenced using a hyperlink in a TOC, either the main ctd-toc.pdf or in a module-specific TOC, as appropriate.
1.8	OK	The path in hyperlinks and bookmarks from ToC files should never contain the four digit NeeS folder.
EU Categories / 2 Files/folders		
2.1	OK	The files provided in the folders for Module 1 are in acceptable formats
2.2	OK	The files provided in the folders for Module 2-5 are in acceptable formats