Internal Audit Check list

CE Files

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Audit Date		Auditor	ISO

Paper files are becoming obsolete as electronic documentation supersedes them.

All CE Technical files should be in Intraststats Documenttation centre.

All Archive electronic& scanned documents are stored electronically in Paperport

All Archive paper documents are in Paper CE Files.

Any documents missing from Intrastats can be found in Paperport or hard copy files.

Emails can be found in Goldmine and documentation in Intrastats

Question	Y/N	Response/Answer	
Check and list current CE Files in : Intrastats; Does it agree with products being sold requiring CE File Do all Products have a CE File			
Check Cross reference in Intrastats :Family Types Are all the Products present			
Do all files contain the Basic information required Are there any Red areas			
Are MDA guidelines are available for classification information. Library and electronically			
Check that form RG2 has been completed and submitted to MDA for any Class I products			
Check that the files classification information for Canada is in their required format.			
Have there been any product changes since the last Audit			
Have Risk assessments been completed on change			
Have there been any classification changes			
Any new accessories.			
Any label changes			
Any User information changes			
Any sales leaflet changes			
Any Data sheet changes			
Any maintenance or service manual changes			
Any other major changes effecting CE Files			