InfinityQS ProFicient 5 Deployment Work Instruction

Purpose

The purpose of this document is to describe the verification details required to complete the deployment of an InfinityQS Proficient 5 project and associated data into the IQS Production system for the Galway Site.

This does not include Hardware or Workstation setup which should be handled through the Global Process Change Analysis SOP, 90440692.

Applicable Documents

See the table below for documents referenced in this procedure:

Document Name	Document Number
IQS ProFicient Admin WI	90646153
InfinityQS ProFicient Project Creation Work Instruction	90646157
IQS Proficient Project Deployment SCS	92654001
Corp WI - Process Change	90440692
IQS Specification and Control Limit File template	90999064
Global ERES WI	90632768
Global ESQ SOP	97045433

Equipment & Materials

See the table below for equipment and materials referenced in this procedure:

Description	Part Number
N/A	N/A

Definitions

The following terms are used in this procedure:

Term	Definition
IQS	InfinityQS
Author	ME, QE or designated Project developer who has been trained in InfinityQS ProFicient Project Deployment WI, 90646161 and InfinityQS ProFicient Project Creation, 90646157
Proficient	Proficient 5 (Corporate)
NRM	Normalized Rank Mean
Sigma	Standard Deviation
Windchill	BSIL Quality Document Management System

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90646161 AI
Page 1 of 16

| Term	Definition
SPC	Statistical Process Control
DMS	IQS Data Management System
DCS	IQS Data Collection Service
Windchill Controlled Objects	IQS Objects whose configuration is documented and controlled in Windchill i.e. projects used for quality purposes.
Non-Windchill Controlled Objects	IQS Objects whose configuration may or may not be documented and is not controlled in Windchill i.e. projects used for engineering or non-quality related reasons.

Project Modelling

This section describes the development process for a new project configuration.

The overall project development work flow between the requesting department and IQS Admin is as shown below:

IQS – Project Development Process
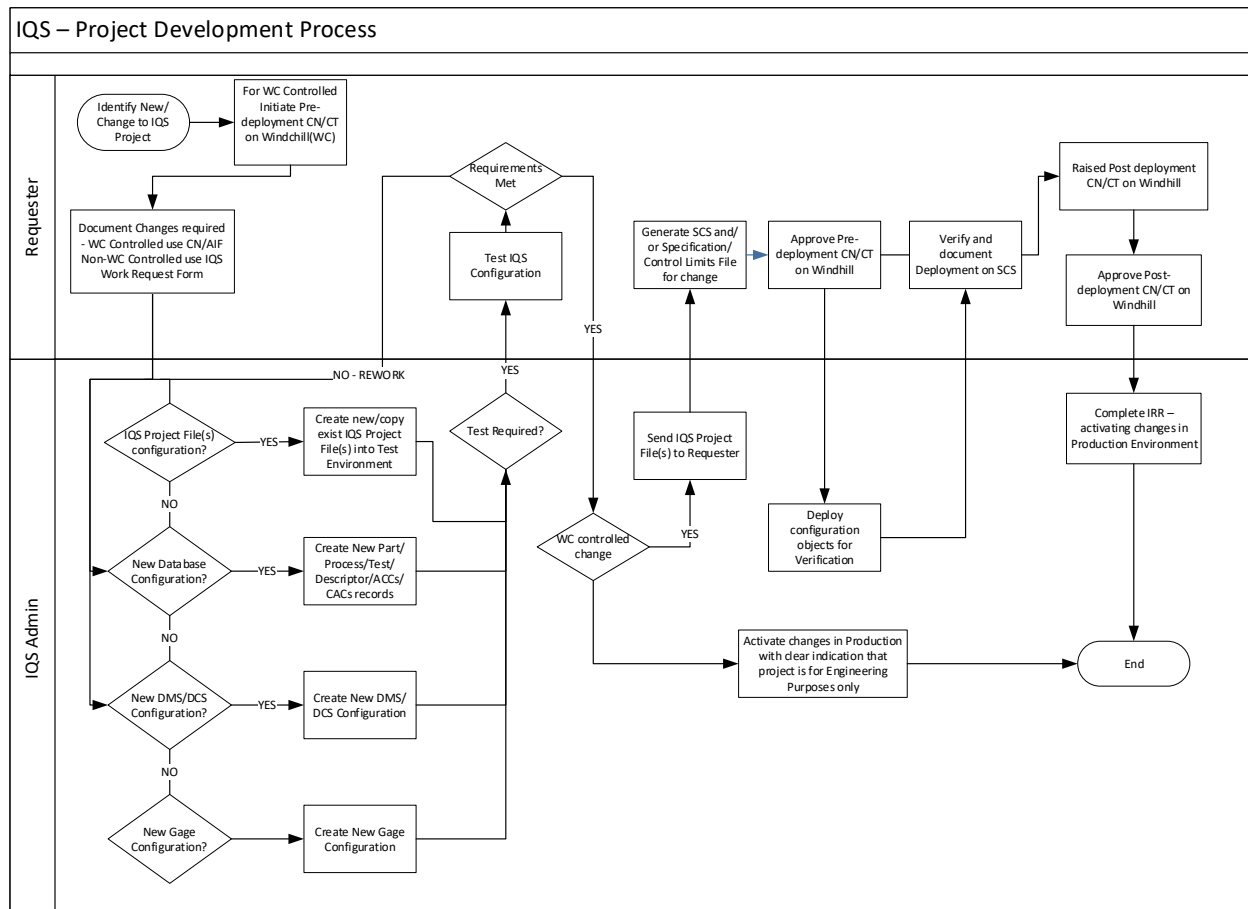
Deploying a new Windchill Controlled project

This section describes how to Approve and Deploy a new project configuration.

The overall project creation work flow for Windchill Controlled IQS Objects is as shown below:
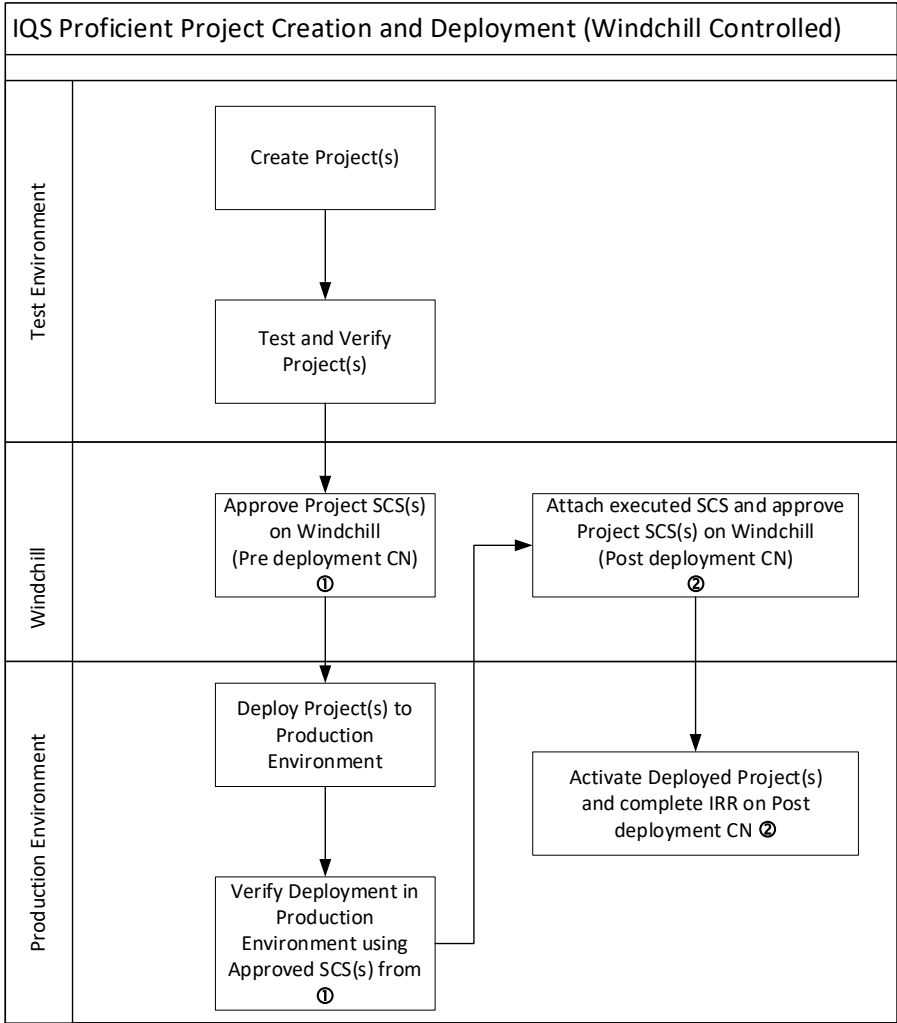
A Project is created on the Test Environment on the IQS Server using the InfinityQS ProFicient Project Creation Work Instruction, 90646157.

Projects used to make quality decisions must be verified using an approved SCS and the documented verification approved on Windchill prior to deployment to production.

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E.D: 16/Jan/2025
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90646161 AI
Page 3 of 16

	Step	Action
Create Project	1.	The Project or Project Component should be created as per InfinityQS ProFicient Project Creation WI, 90646157.
	2.	The Project or Project component should be created, tested and verified in the IQS Test Environment.
	3.	Once the project has been verified and is ready for submission to Windchill the IQS SCS document should be initiated.
	4.	A Proficient Project SCS document should be completed for each Windchill Controlled Project and a unique identifier created for each Project SCS document on Windchill. Document type for the SCS on Windchill should be 'E&AS Software Design.
		The IQS Administrator that will be implementing the change onto the production environment will functionally approve for the Software Developer role. The Administrator/ Software Developer role is to ensure that the data provided in the SCS is correct. After implementation and execution of the SCS on the Production Environment, the Administrator/Software Developer role is to verify that the data provided in the SCS is correctly implemented on the production environment. Additional approvers may also be added, to verify the process specific database data "ie specifications, control limits" in the change number is correct.
		The role of Software Quality (SQE) for the IQS Project SCS documents approval may be fulfilled by a Quality Engineer who has completed the following training:
		•Classroom Course PL-8953 "Software Validation Training for Minor Upgrades - Infinity QS Proficient Project Creation Work Instruction 90646157 - Infinity QS Proficient 5 Project Deployment Work Instruction 90646161.
		(The IQS Project SCS is a configuration file only, which details how the previously installed and validated IQS Application will be used. As such, the content of the SCS and the configurations therein are specific to each unique implementation of the software in the value stream/functional area and the process it is deployed in and the functional expertise in such instances resides with the Core team in the area.)
	5.	Non-Windchill Controlled Projects do not require a SCS to deploy to production but must be clearly marked as for Engineering Purposes only or not to be used for Quality Decisions. Refer to IQS SharePoint for IQS Work Request Form for requesting new/updates to Non-Windchill Controlled Projects.

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E.D: 16/Jan/2025
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90646161 AI
Page 4 of 16

	Step	Action
IQS Projects with Measurement Gages connected:	1.	Due to their connection to IQS, certain Measurement Gages are classified as "Data Generators" per Global ERES WI 90632768. Per Global ESQ SOP 97045433, Class D equipment qualification deliverables are therefore required. However, on consideration of Intended Use, it may be evident that calibration defines and verifies the functions and capabilities of these systems. The equipment is connected directly to IQS (e.g. via Com Port /USB/Cable Communications format) and verification of data transfer requirements from these devices to IQS is documented per this IQS Deployment WI 90646161. All ERES requirements are managed through the validated IQS system. Additional documentation for these measurement gages may therefore be deemed not required. As all system capability and functionality is documented as described above, no additional risk is introduced by the omission of Class D ESQ deliverables in these cases.

	Step	Action
Deployment SCS and InfinityQS SCS	1.	The Proficient Project SCS is to be filled in for each project with all necessary files attached, and approved on Windchill.
	2.	All files attached to the Proficient Project SCS should be listed in Table 1. Software Attachments.
	3.	The project file name, size in bytes and the date/time stamp are recorded in Table 3 InfinityQS Project files. This data is verified once the project file is copied to the Production Server during the execution of the checklist.
	4.	Section 4.1 to 4.9 details the contents of the project file. This is to be filled in the ME/QE requesting the change. This completed document is then submitted for approved on Windchill as an SCS document type.
	5.	If applicable the DMS and DCS configuration settings are recorded in section 4.6.2 which will include screenshots of the setup.

Infinity QS Project Deployment Work Flow

Infinity QS Project Deployment

Database Configuration	IQS Project Data Entry Configuration	Chart Definition/User Interface	Specification and Control Limits	Alarm Rules and Process Event Detail	Gauge Set-Up and/or External Data Source Details
Part Details	Verify Part Group and Parts linkage	Chart Category	Specification and Control Limits File		Verify Gauge Configuration setup for IQS Gauge Server (if required)
Process Details	Verify Process Group and Process linkage	Header Set-Up	Use Specification Import Utility to import specs	Set Alarm Rules for each Test	Special Data Acquisition Driver (Buffer File / Query Analyser) (If required)
Test Details	Verify Test Group and Test Linkage	Report Set-Up	Verify Imported Specifications		
Descriptor Details (Shift, Job, User-Defined)	Verify Test Calculations (If required)	Graph Set-Up	Manually set Control Limits as per detail in Specification and Control Limits File (Cannot be Imported using utility)	Set Process Event triggers	Verify DMS/DCS Configuration (if required)
Assignable Cause and Corrective Action Details	Verify Descriptor Detail linkage (if required)	Data Selection (Verify against Chart text File)			
	Verify Basic and Advanced Options	Toolbar Button Configuration			
Verified Against SCS	**Verified Against SCS/ DEC.txt file**	**Verified Against SCS/ Chart.txt file**	**Verified Against Specification Limits File**	**Verified Against SCS**	**Verified Against SCS**

(Left margin labels: Phase, Verification Method)

Colour Code of where Data is Saved:

Database Level	Project Level	Gauge Server	DMS/DCS Utility	Data Acquisition Driver

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90646161 AI
Page 6 of 16

Proficient Project SCS Verification

Step	Deployment Section as per Workflow	Deployment Question	Proficient Project SCS Action
1.	Database Configuration	Is there any Update to the database configuration?	• Record Database Details "FILE=DRV=…." and "DSN=…" *DSN should be pointed from Development Database to the Production Database.*
2.	Database Configuration	Are there new or updated Parts to be deployed?	Fill in Part details in Database details section of the check list. • Part Location/Hierarchy • Part Group • Part Number All of the above is verified against the SCS and/or Part.txt file for Upload if available.
3.	Database Configuration	Are there new or updated Processes to be deployed?	Fill in Process details in Database details section of the check list. • Process Hierarchy • Associated Process Group All of the above is verified against the SCS
4.	Database Configuration	Are there new or updated Tests to be deployed?	Fill in Test details in Database details section of the check list. • Associated Test Group • Associated Part(s) • Define Data type to be collected: Variable/Defects/Defectives All of the above is verified against the SCS
5.	Database Configuration	Are there new or updated Descriptor requirements to be deployed?	Fill in Descriptor requirements details in Database details section of the check list. • Define if Shift numbers are to be associated with the Project • Associate Shift(s) • Define if Serial Numbers are to be associated with the Project • Define any User-Defined Descriptor(s) to be associated with the Project All of the above is verified against the SCS

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E.D: 16/Jan/2025

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90646161 AI
Page 7 of 16

Step	Deployment Section as per Workflow	Deployment Question	Proficient Project SCS Action
6.	Database Configuration	Are there new or updated Assignable Causes or Corrective Actions to be deployed?	Fill in Assignable Cause and/or Corrective Action details in the Database details section of the in check list. • Define Assignable Cause Group • Define Assignable Causes • Define Corrective Action Group • Define Corrective Actions All of the above is verified against the SCS
7.	IQS Project Data Entry Configuration	Are there new or updated DEC(s) to be deployed?	Fill in Project details in check list. Define DEC (if required) • Define Subgroup including Sample Size. • Associated Part(s) • Associated Process(es) • Associated Test(s) • Define Calculations. • Define DEC Optional Items (Descriptors) • Define Enabled Basic Options • Define Enabled Advanced Options • Define Alternative sampling plan All of these can be verified against DEC.txt file imbedded in the SCS. The information in this DEC.txt file is copied directly from the DEC on the project file. Project Toolbar Route: Data Entry, Configuration, View, Copy **Any new or updated DEC requires the Attachment of an updated Project File**
8.	Chart Definition/User Interface	Are there new or updated Charts/User Interfaces to be deployed?	Define Chart(s) (if required) • Select Chart Category(ies) • Define Chart Parameters based on Category. • State if a template is being used to define Chart. • Define Data Selection time window • Define Maximum Number of returned Items (if required) • Define Selection limits (if required) • Define charted Subgroups based on Flag selection

Step	Deployment Section as per Workflow	Deployment Question	Proficient Project SCS Action
			All of the above can be verified against Chart.txt file imbedded in the SCS. The information in this Chart.txt file is copied directly from the Data Selection option on the chart within the project file. Project Toolbar Route: Chart, Configuration, Data Selection, Copy • Define Header Set-Up • Define Report Set-Up • Define Graph Set-Up • Define Processing Options All of the above is verified against the SCS Define User interface Configuration • Define Button configuration • Associated Text, Image and Command line. • Define Button Menu options. • Display Mode **Note:** New Button Images .jpg files can be saved in this location \\anvcacxawp00002 O:\TOOLBAR. All of the above is verified against the SCS **Any new or updated Charts/User Interface requires the Attachment of an updated Project File**
9.	Specification and Control Limits	Are there new or updated Specification Limits to be deployed?	Fill in Specification Limit details in check list. • Associated Part • Associated Test • Associated Process (if required) • Define Specification limits Source documentation • Define Specification limits • Define Reasonable limits (if required) • Define Warning limits (if required) The above detail may be put into the IQS Specification and Control Limits File using template 90999064 and saved in Windchill. This must be

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E.D: 16/Jan/2025
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90646161 AI
Page 9 of 16

Step	Deployment Section as per Workflow	Deployment Question	Proficient Project SCS Action
			approved in Windchill prior to transfer using the IQS Specification Import Utility. The verification of the specification importation must be signed on the template coversheet. This template coversheet must be scanned and attached to a new revision of the Specification and Control limits file. **Note:** Control Limits are imported using the Import Database Structure Utility. Any updates to the Specification and Control limits file require that the verification cover page be resigned, scanned and attached in Windchill to the new revision.
10.	Specification and Control Limits	Are there new or updated Control Limits to be deployed?	Fill in Control Limit details in check list. • Define if control limits are to be calculated from the collected data or to be set. • Identify which SPC rules are to be implemented. If control limits are to be set: • Define Control Limits • Define Calculated Process Mean • Define Calculate Process Standard Deviation (Sigma) The above detail can be put into the IQS Specification and Control Limits File using template 90999064 and saved in Windchill. Control Limits can be verified against the Specification and Control Limits file. • Record effective date for Control Limits This is recorded on the SCS document **Note:** Control Limits are imported using the Import Database Structure Utility.
11.	Alarm Rules and Process Event Detail	Are there a new or updated Alarm	Fill in Alarm Notification rule details in check list. • Process Name • Test Name

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E.D: 16/Jan/2025
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90646161 AI
Page 10 of 16

Step	Deployment Section as per Workflow	Deployment Question	Proficient Project SCS Action
		Notification Rules to be deployed?	• Chart Type • Processing • Notification Rule(s) All of the above is verified against the SCS
12.	Alarm Rules and Process Event Detail	Are there a new or updated Process Events to be deployed?	Fill in Process Event details in check list. Define Process Event Triggers. • Add Screenshot of Required Event triggers (Toolbar Route: Preference-Project-Special) Define Process Event response procedure (if required) All of the above is verified against the SCS Any new or updated Process Event Detail requires the Attachment of a new Project File
13.	Gauge Set-Up and/or external data Source Details	Is there a new or updated Gage to be deployed?	Fill in Gage details and Gage connection details to the Gage server in check list. • Define Gage data transfer settings • Define Gage connection type Define Gage server Configuration: • Define Gage Interface • Define Initialization Strings • Define Delay prior to sending Initialization String • Define Communication Source • Define Baud Rate • Define Parity • Define Data Bits • Define Stop Bits • Define Flow control • Define Buffer size. Define Gage server Device Settings: • Define Gage Interface • Define Interface Format • Define data type (ASCII/Binary) • Define Resolution (bits) • Define Full scale value • Define Decimal separator

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E.D: 16/Jan/2025
IQS ProFicient Project Deployment WI
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90646161 AI
Page 11 of 16

Step	Deployment Section as per Workflow	Deployment Question	Proficient Project SCS Action
			• Define Multiplexer Channel number • Define Defect/Defective code • Define Literal (NRM, Max, Min…) • Define Reading Number • Define Measurement Value(s) • Define Measurement Value Calculation(s) • Define Record Description • Define Channel Number • Define Gage Identifier • Define Gage Serial Number • Define Gage, Gain value, Zero Value and Precision • Define Gage polling settings Attach PC COM port to Server Mapping File. All of the above is verified against the SCS
	Gauge Set-Up and/or external data Source Details	Are there a new or updated External Data sources to be deployed?	Fill in External Data sources details in check list. • Define External Data source type • Define DMS DataStore Setup • Define OLEDB connection details • Define Infinity Service Account Access to external DB • Define SQL code for data extraction • Define Data Collection Service Setup Synchronization • Define Part/Process/Test/descriptor alignment details Attach Data Extraction file if available. All of the above is verified against the SCS
14.	Gauge Set-Up and/or external data Source Details	Is there a new or updated DMS Grid Data Configuration to be deployed	Note: The DMS Grid Data Provider is validated for use for the following parts only: Taxus Element, Ion, Promus Element, Promus Element Plus, Promus Premier, Carotid, Synergy, Omega, Mustang, Charger and Gladiator. Verify DMS Configuration Details against the SCS.

Released
E.D: 16/Jan/2025
IQS ProFicient Project Deployment WI
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90646161 AI
Page 12 of 16

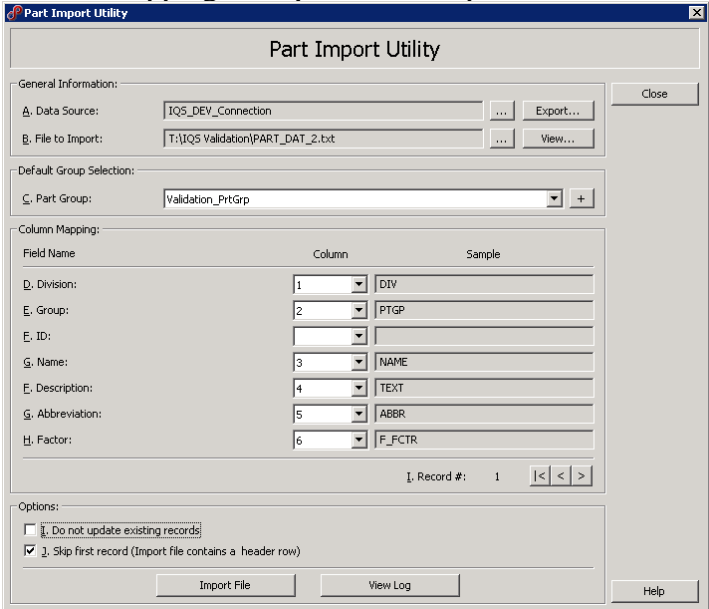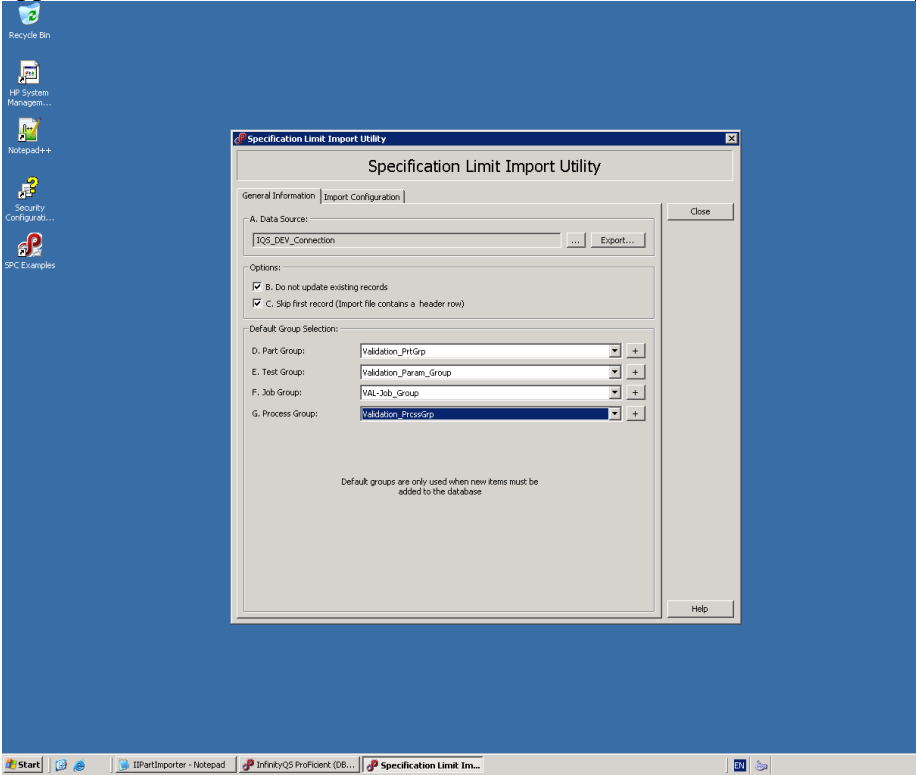| Step	Deployment Section as per Workflow	Deployment Question	Proficient Project SCS Action
			Attach DMS configuration file
15.	Gauge Set-Up and/or external data Source Details	Is there a new or updated DCS Configuration to be deployed	Note: The DCS is validated for use for the following parts only: Taxus Element, Ion, Promus Element, Promus Element Plus, Promus Premier, Carotid, Synergy, Omega, Mustang, Charger and Gladiator. Verify DCS Configuration Details against the SCS. Attach DCS configuration file

Known Changes when Deployed to Production Environment	Database link change:	If transferring a project file that is connected to the validation database, then **Validation DSN: iqsv** Must be changed to **Production DSN: iqsp**
	Toolbar Links	Toolbar project paths in the command line which are linked to the test environment must be changed to the path on the production environment.
	Chart User Defined Descriptors	Any user defined descriptors linked to the charts in the validation database will lose this link when transferred to production database. The link must be re-established in the production environment.
	File Size and Time / Date Stamp	Once deployment to production server is complete, the new file size and time /date stamp must be recorded on the SCS document. Attach the new project .zip file to the deployed revision of the SCS.

	Step	Action
Importing Part/ Specification Details:	1.	A Specification and Control Limits File may be completed using template 90999064 and approved in Windchill prior to Importing Specifications. This must be approved in Windchill prior to transfer using the IQS Specification Import Utility.

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E.D: 16/Jan/2025
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90646161 AI
Page 13 of 16

Step	Action
	The Specification and Control Limits File is an Excel file which must be saved as a tab delimited .txt file prior to importation using the utility. The verification of the specification importation must be signed on the template coversheet. This template coversheet must be scanned and attached to a new revision of the Specification and Control limits file. This .txt file can then be imported into the Proficient Database using the Part import Utility or Specification import Utility as applicable. Note: Control Limits are imported using the Import Database Structure Utility and verified via the SCS deployment process. Where importing of specification/ part files is being completed, there is no requirement to complete 100% verification of part/ specification details for • PTA Products Mustang, Gladiator and Charger only. • SDC Products; Balloons and Top Assembly; PROMUS PLUS, PROMUS OUS, Promus PREMIER, TAXUS Element, ION & SYNERGY.
2.	**Part Importing:** Using the Part Import Utility, the administrator completes column mapping as required with input from the SCS author. The following are options which can be selected: <table><tr><td>Option</td><td></td></tr><tr><td>Do not update existing records</td><td>If no changes are required to existing parts</td></tr></table>

Released   IQS ProFicient Project Deployment WI   90646161 AI

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Step	Action	
	Skip first record	If this contains description of content eg Target, USL, LSL
	Select import file.	
3.	**Specification Importing:** Using the Specification Import Utility, the administrator completes column mapping as required with input from the SCS author. Part Group, Test Group, Job Group and Process Group are selected as applicable. The following are options which can be selected: | Option	
---	---
Do not update existing records	If no changes are required to existing parts
Skip first record	If this contains description of content eg Target, USL, LSL | Select import file.	
4.	**Control Limit Importing:** Using the Import Database Structure Utility, the IQS administrator imports the control limits as required with input from the SCS author.	

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E.D: 16/Jan/2025

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90646161 AI
Page 15 of 16

Step	Action
5.	When completing file import, the administrator must confirm that the mapping/import has been completed correctly by checking one of the part/ specification /control limit details on the .txt file attached with part/ spec details on production database.

Configuration Files Approval

Step	Action
1.	Upon approval of the Proficient Project SCS document on Windchill the System Admin copies the new project file to the Production server if required and/or recreates the new or updated Project file component on the Production server.
2.	The details of the Project file (if copied from Windchill) are verified by the InfinityQS Proficient System Admin.
3.	The approved Proficient Project SCS document is printed from Windchill and as each section is implemented on the Production Server by the System Admin this is witnessed and verified by the Project author/updater.
4.	The completed, witnessed and verified Checklist SCS is scanned and attached to the approved Proficient Project SCS document on Windchill, the revision number is incremented and the document is re-approved.
5.	The new configuration files are then released to production.

Record Keeping

Windchill
For Windchill controlled IQS objects records are stored as SCS Documents, Specification and Control Limit Files and associated CN/CTs.

Step	Action
N/A	N/A