

Document VOP 27 Software Validation Revision ID31064

Suggested Upload Document Name: **Risk Assesment For Updating Document ID31064**

Completed by [Derek Lamb](#) 10 Jun 2022

Reason for Risk Assesment

new vop dealing with software validations
removed the initial list of tasks in the holding document

Document VOP 27 Software Validation Revision ID31064 Is linked to the Following Standards and processes

Risk Assesment Question ID31064	Does Update Risk Affect	Risk Frequency due to Update	Notes On Risk / Benefits statement if required	Further Action Required on Issue
31064Q0 Does this Update warrant updating Any External Parties due to any Terms and Conditional Agreements E.G. Notified Body or is the update a Significate change to any ISO Certifications	Does Update Affect? No ▾	Risk Frequency due to Update 1.Improbable ▾ Risk Likly Due to Update 1.Negligible ▾ Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
31064Q1 Viamed Ltd ISO13485:2016 Section: 4.1.6 Quality management system For each quality management system process, the organization shall: The organization shall document procedures for the validation of the application of computer software used in the quality management system. Such software applications shall be validated prior to initial use and, as appropriate, after changes to such software or its application. The specific approach and activities associated with software validation and revalidation shall be proportionate to the risk associated with the use of the software. Records of such activities shall be maintained (see 4.2.5).	Does Update Affect? No ▾	Risk Frequency due to Update 1.Improbable ▾ Risk Likly Due to Update 1.Negligible ▾ Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
31064Q2 Viamed Ltd ISO13485:2016 Section: 7.5.6	Does	Risk Frequency	Notes On Risk / Benefits statement if	Further Action Required

Validation of processes for production and service provision
 The organization shall validate any processes for production and service provision where the resulting output cannot be or is not verified by subsequent monitoring or measurement and, as a consequence, deficiencies become apparent only after the product is in use or the service has been delivered.
 Validation shall demonstrate the ability of these processes to achieve planned results consistently.
 The organization shall document procedures for validation of processes including:

- a) defined criteria for review and approval of the processes;
- b) equipment qualification and qualification of personnel;
- c) use of specific methods, procedures and acceptance criteria;
- d) as appropriate, statistical techniques with rationale for sample sizes
- e) requirements for records (see 4.2.5);
- f) revalidation, including criteria for revalidation;
- g) approval of changes to the processes.

The organization shall document procedures for the validation of the application of computer software used in production and service provision. Such software applications shall be validated prior to initial use and, as appropriate, after changes to such software or its application. The specific approach and activities associated with software validation and revalidation shall be proportionate to the risk associated with the use of the software including the effect on the ability of the product to conform to specifications.
 Records of the results and conclusion of validation and necessary actions from the validation shall be maintained (see 4.2.4 and 4.2.5).

Update due to Update Affect?	1.Improbable ▼	required	on Issue
No ▼	Risk Likly Due to Update		
	1.Negligible ▼		
	Action Required: No Action Required		

31064Q3 VST Ltd ISO9001:2015 Section: 8.5.1
 Control of production and service provision
 The organization shall implement production and service provision under controlled conditions.
 Controlled conditions shall include, as applicable:

- a) the availability of documented information that defines:
 - 1) the characteristics of the products to be produced, the services to be provided, or the activities to be performed;
 - 2) the results to be achieved;
- b) the availability and use of suitable monitoring and measuring resources;
- c) the implementation of monitoring and measurement activities at appropriate

Does Update Affect?	Risk Frequency due to Update	Notes On Risk / Benefits statement if required	Further Action Required on Issue
No ▼	1.Improbable ▼		
	Risk Likly Due to Update		
	1.Negligible ▼		
	Action Required: No Action Required		

stages to verify that criteria for control of processes or outputs, and acceptance criteria for products and services, have been met;




d) the use of suitable infrastructure and environment for the operation of processes;

e) the appointment of competent persons, including any required qualification;

f) the validation, and periodic revalidation, of the ability to achieve planned results of the processes for production and service provision, where the resulting output cannot be verified by subsequent monitoring or measurement;

g) the implementation of actions to prevent human error;

h) the implementation of release, delivery and post-delivery activities

<p>31064Q4  Process7851 Software Validation Scan Un-QA Product To Order To test intrastats does not allow picking of unprocessed products to live customer orders</p>	<p>Does Risk Frequency Update due to Update Affect? 1.Improbable ▾ No ▾ Risk Likly Due to Update 1.Negligible ▾ Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required Likelihood is Improbable as this process tests the actual system of preventing UN-QA stock getting past QA.
This process itself is to reduce the risk of UN-QA product getting past goods out</p>	<p>Further Action Required on Issue</p> <input data-bbox="1848 622 2150 657" type="text"/>
<p>31064Q5  Process7852 Software Validation Expired Stock To attempt to Scan a product that has gone past its expire date.</p>	<p>Does Risk Frequency Update due to Update Affect? 1.Improbable ▾ No ▾ Risk Likly Due to Update 1.Negligible ▾ Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p>	<p>Further Action Required on Issue</p> <input data-bbox="1848 984 2150 1019" type="text"/>
<p>31064Q6  Process7853 Software Validation Non Sell Able Shelf Warehouse shelves can be tagged as sellable stock / unsellable stock. Either for quarantine purposes or holding items for other customer orders. Test that Order picking cannot pick unsellable stock locations to an Order</p>	<p>Does Risk Frequency Update due to Update Affect? 3.Occasional ▾ No ▾ Risk Likly Due to Update 1.Negligible ▾</p>	<p>Notes On Risk / Benefits statement if required</p>	<p>Further Action Required on Issue</p> <input data-bbox="1848 1347 2150 1382" type="text"/>

Action
Required:
No Action
Required

31064Q7 Process7854 Software Validation In Production List Software Validation of the production lists. By confirming no extra production jobs are stuck in the system, and all listed production jobs are found. the production tracking is validated	Does Update Affect? <input type="button" value="No"/> Risk Frequency due to Update <input type="button" value="2.Remote"/> Risk Likly Due to Update <input type="button" value="2.Minor"/> Action Required: No Action Required	Notes On Risk / Benefits statement if required <input type="text"/>	Further Action Required on Issue <input type="text"/>
31064Q8 Process7855 Software Validation - Production Lists Software Validation - Production Lists Review the current active production lists in intrastats to the actual in progress production lists	Does Update Affect? <input type="button" value="No"/> Risk Frequency due to Update <input type="button" value="2.Remote"/> Risk Likly Due to Update <input type="button" value="2.Minor"/> Action Required: No Action Required	Notes On Risk / Benefits statement if required <input type="text"/>	Further Action Required on Issue <input type="text"/>
31064Q9 Process7856 Software Validation Unchecked Orders To check order picking cannot pick against an unchecked order	Does Update Affect? <input type="button" value="No"/> Risk Frequency due to Update <input type="button" value="2.Remote"/> Risk Likly Due to Update <input type="button" value="2.Minor"/> Action Required: No Action Required	Notes On Risk / Benefits statement if required <input type="text"/>	Further Action Required on Issue <input type="text"/>
31064Q10 Process7857 Software Validation Stock Tracking Check To confirm Software Validation Stock Tracking Check, is functioning as expected	Does Update Affect? <input type="button" value="No"/> Risk Frequency due to Update <input type="button" value="1.Improbable"/> Risk Likly Due to Update	Notes On Risk / Benefits statement if required <input type="text"/>	Further Action Required on Issue <input type="text"/>

2.Minor

Action
Required:
No Action
Required

31064Q11 [Process7858](#)
Software Validation Attempt To QA Some Stock
Test the QA System that Staff not trained for QA are unable to QA a Product.

Does
Update
Affect?
No

Risk Frequency
due to Update
3.Occasional
Risk Likly Due
to Update
1.Negligible
Action
Required:
No Action
Required

Notes On Risk / Benefits statement if
required

Further Action Required
on Issue

31064Q12 [Process7861](#)
Software Validation Of Training Documents Forced Reading
Software Validating Of Training Documents via Forced Required Reading

Does
Update
Affect?
No

Risk Frequency
due to Update
2.Remote
Risk Likly Due
to Update
1.Negligible
Action
Required:
No Action
Required

Notes On Risk / Benefits statement if
required

Further Action Required
on Issue

31064Q13 [Process7850](#)
Software Validation Scan Incorrect Product
Test the Goods out process disabling picking of items not relating to an order

Does
Update
Affect?
No

Risk Frequency
due to Update
1.Improbable
Risk Likly Due
to Update
1.Negligible
Action
Required:
No Action
Required

Notes On Risk / Benefits statement if
required

Further Action Required
on Issue

31064Q14 [Process7865](#)
Software Validation Conflicting Audits
Software Validiation of the system:
To check all process(s) tasks and audits are not clashed with the same person

Does
Update
Affect?
No

Risk Frequency
due to Update
1.Improbable
Risk Likly Due

Notes On Risk / Benefits statement if
required

Further Action Required
on Issue

doing the Task as the Audit.

to Update
1.Negligible ▾
Action
Required:
No Action
Required

31064Q15 Process7870 Software Validation Non Conformance Product Risk Feedback Loop Scope to check the automatic system of tagging product non conformance and other issues to the post market surveillance review report.	Does Update Affect? <input type="checkbox"/> No ▾ Risk Frequency due to Update <input type="checkbox"/> 1.Improbable ▾ Risk Likly Due to Update <input type="checkbox"/> 1.Negligible ▾ Action Required: No Action Required	Notes On Risk / Benefits statement if required <div style="border: 1px solid black; height: 100%; width: 100%;"></div>	Further Action Required on Issue <div style="border: 1px solid black; height: 20px; width: 100%;"></div>
31064Q16 Process7875 Software Validation Document Control To test document control is working as intended.	Does Update Affect? <input type="checkbox"/> No ▾ Risk Frequency due to Update <input type="checkbox"/> 1.Improbable ▾ Risk Likly Due to Update <input type="checkbox"/> 1.Negligible ▾ Action Required: No Action Required	Notes On Risk / Benefits statement if required <div style="border: 1px solid black; height: 100%; width: 100%;"></div>	Further Action Required on Issue <div style="border: 1px solid black; height: 20px; width: 100%;"></div>
31064Q17 Process7880 Software Validation Out Of Date Documents To confirm the out of documents computer software functions as expected flagging out of date items on to the list	Does Update Affect? <input type="checkbox"/> No ▾ Risk Frequency due to Update <input type="checkbox"/> 1.Improbable ▾ Risk Likly Due to Update <input type="checkbox"/> 1.Negligible ▾ Action Required: No Action Required	Notes On Risk / Benefits statement if required <div style="border: 1px solid black; height: 100%; width: 100%;"></div>	Further Action Required on Issue <div style="border: 1px solid black; height: 20px; width: 100%;"></div>
31064Q18 Process7881 Software Validation - Live Orders To compare Opera Live Orders to Intrastats Back order Active List	Does Update <input type="checkbox"/> Risk Frequency due to Update <input type="checkbox"/> 1.Improbable ▾	Notes On Risk / Benefits statement if required	Further Action Required on Issue <div style="border: 1px solid black; height: 20px; width: 100%;"></div>

NO LONGER REQUIRED
Opera is now out of the system

Affect? Risk Likly Due
 to Update

Action
Required:
No Action
Required

31064Q19 Process52
Software Verification Clear Down Backup Emails
Keeps a month or so backup emails

Does Update Affect?	Risk Frequency due to Update	Notes On Risk / Benefits statement if required	Further Action Required on Issue
<input type="button" value="No"/>	<input type="button" value="1.Improbable"/> Risk Likly Due to Update <input type="button" value="2.Minor"/> Action Required: No Action Required		

31064Q20 Process7879
Software Validation Scheduled Tasks And Audits
To check the Scheduled Tasks and Audits is working as Intended.
To also Check the Out of Date documents is working as Intended.

Does Update Affect?	Risk Frequency due to Update	Notes On Risk / Benefits statement if required	Further Action Required on Issue
<input type="button" value="No"/>	<input type="button" value="1.Improbable"/> Risk Likly Due to Update <input type="button" value="1.Negligible"/> Action Required: No Action Required		

31064Q21 Process8013
Software Validation Test Email System
Ensure Email system working as intended

Does Update Affect?	Risk Frequency due to Update	Notes On Risk / Benefits statement if required	Further Action Required on Issue
<input type="button" value="No"/>	<input type="button" value="1.Improbable"/> Risk Likly Due to Update <input type="button" value="1.Negligible"/> Action Required: No Action Required		

31064Q22 ProcessProcess 7048
Control of monitoring and measuring devices

Does Update	Risk Frequency due to Update	Notes On Risk / Benefits statement if required	Further Action Required on Issue

Control of monitoring and measuring devices
Current Known Risk that equipment will be missed
Current Likly 1 Current Frequency 2

Affect? 2.Remote
No Risk Likly Due to Update
1.Negligible
Action Required:
No Action Required

31064Q23 Process 7679
Check Stock Requirements Supplier Teledyne
To check that we have stock in for customer proformas and orders. Or review if any stock needs to be ordered.
Current Known Risk That a customer is told we have stock and then we are unable to ship.
Current Likly 2 Current Frequency 1

Does Update Risk Frequency due to Update
Affect? 1.Improbable
No Risk Likly Due to Update
2.Minor
Action Required:
No Action Required

Notes On Risk / Benefits statement if required

31064Q24 Process 7680
Check Stock Requirements Supplier Envitec
To check that we have stock in for customer proformas and orders. Or review if any stock needs to be ordered.
Current Known Risk That a customer is told we have stock and then we are unable to ship.
Current Likly 2 Current Frequency 1

Does Update Risk Frequency due to Update
Affect? 1.Improbable
No Risk Likly Due to Update
2.Minor
Action Required:
No Action Required

Notes On Risk / Benefits statement if required

31064Q25 Process 7681
Check Stock Requirements Supplier Posey
To check that we have stock in for customer proformas and orders. Or review if any stock needs to be ordered.
Current Known Risk That a customer is told we have stock and then we are unable to ship.
Current Likly 2 Current Frequency 1

Does Update Risk Frequency due to Update
Affect? 1.Improbable
No Risk Likly Due to Update
2.Minor
Action Required:
No Action Required

Notes On Risk / Benefits statement if required

31064Q26 Process 7682

Does Risk Frequency Notes On Risk / Benefits statement if Further Action Required

Check Stock Requirements Supplier Blueprint

To check that we have stock in for customer proformas and orders. Or review if any stock needs to be ordered.

Current Known Risk That a customer is told we have stock and then we are unable to ship.

Current Likly 2 Current Frequency 1

Update due to Update required

Affect? 1.Improbable

No

Risk Likly Due to Update

2.Minor

Action

Required:

No Action

Required

on Issue

31064Q27 Process 7736

Production Start Job List

When a new production is needed we the production job to the list of procedures.

Check to make sure that every new job has a procedure linked to it.

Current Known Risk That a job will be carried out without a procedure.

Current Likly 2 Current Frequency 2

Does Update due to Update

Affect? 2.Remote

No

Risk Likly Due to Update

2.Minor

Action

Required:

No Action

Required

Notes On Risk / Benefits statement if required

Further Action Required on Issue

31064Q28 Process 7737

Production In Production List

Review the Production List, check and list those items that were started more than 30 days ago have not been through QA.

Audit is carried out and production is reviewed and chased at this point.

Current Known Risk Production jobs is finished but not been QA, may get lost in the system

Current Likly 2 Current Frequency 2

Does Update due to Update

Affect? 2.Remote

No

Risk Likly Due to Update

2.Minor

Action

Required:

No Action

Required

Notes On Risk / Benefits statement if required

Further Action Required on Issue

31064Q29 Process 7849

Review Product Failures New Codes

Review the Customer Returns and Review Product Failures New Codes

Current Known Risk Product failures / returns do not get reviewed and a new Risk may occur

Current Likly 1 Current Frequency 3

Does Update due to Update

Affect? 3.Occasional

No

Risk Likly Due to Update

1.Negligible

Action

Required:

No Action

Required

Notes On Risk / Benefits statement if required

Further Action Required on Issue

<p>31064Q30 Process 7850 Software Validation Scan Incorrect Product Test the Goods out process disabling picking of items not relating to an order Current Known Risk system allows incorrect items to be picked to customer orders Current Likly 1 Current Frequency 1</p>	<p>Does Update Affect? <input type="checkbox"/> No <input type="checkbox"/> Yes Risk Frequency due to Update <input type="text" value="1.Improbable"/> Risk Likly Due to Update <input type="text" value="1.Negligible"/> Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required <input type="text"/></p>	<p>Further Action Required on Issue <input type="text"/></p>
<p>31064Q31 Process 7851 Software Validation Scan Un-QA Product To Order To test intrastats does not allow picking of unprocessed products to live customer orders Current Known Risk Unprocessed product gets out into the field, resulting in recalls Current Likly 1 Current Frequency 1</p>	<p>Does Update Affect? <input type="checkbox"/> No <input type="checkbox"/> Yes Risk Frequency due to Update <input type="text" value="1.Improbable"/> Risk Likly Due to Update <input type="text" value="1.Negligible"/> Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required Likelihood is Improbable as this process tests the actual system of preventing UN-QA stock getting past QA.
This process itself is to reduce the risk of UN-QA product getting past goods out</p>	<p>Further Action Required on Issue <input type="text"/></p>
<p>31064Q32 Process 7852 Software Validation Expired Stock To attempt to Scan a product that has gone past its expire date. Current Known Risk Expired product leaves the building and unusable products get to customers Current Likly 1 Current Frequency 1</p>	<p>Does Update Affect? <input type="checkbox"/> No <input type="checkbox"/> Yes Risk Frequency due to Update <input type="text" value="1.Improbable"/> Risk Likly Due to Update <input type="text" value="1.Negligible"/> Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required <input type="text"/></p>	<p>Further Action Required on Issue <input type="text"/></p>
<p>31064Q33 Process 7853 Software Validation Non Sell Able Shelf Warehouse shelves can be tagged as sellable stock / unsellable stock. Either for quarantine purposes or holding items for other customer orders. Test that Order picking cannot pick unsellable stock locations to an Order Current Known Risk quarantine stock leaves the building to a customer order, or stock on hold for a customer gets shipped to another customer. Current Likly 1 Current Frequency 3</p>	<p>Does Update Affect? <input type="checkbox"/> No <input type="checkbox"/> Yes Risk Frequency due to Update <input type="text" value="3.Occasional"/> Risk Likly Due to Update <input type="text" value="1.Negligible"/> Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required <input type="text"/></p>	<p>Further Action Required on Issue <input type="text"/></p>

<p>31064Q34 Process 7854 Software Validation In Production List Software Validation of the production lists.</p> <p>By confirming no extra production jobs are stuck in the system, and all listed production jobs are found. the production tracking is validated Current Known Risk Software tracking of production jobs fails. Current Likly 2 Current Frequency 2</p>	<p>Does Risk Frequency Update due to Update Affect? 2.Remote No Risk Likly Due to Update 2.Minor Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p> <div style="border: 1px solid gray; height: 100px;"></div>	<p>Further Action Required on Issue</p> <div style="border: 1px solid gray; height: 30px;"></div>
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<p>31064Q35 Process 7855 Software Validation - Production Lists Software Validation - Production Lists Review the current active production lists in intrastats to the actual in progress production lists Current Known Risk Software inaccuracys in production Current Likly 2 Current Frequency 2</p>	<p>Does Risk Frequency Update due to Update Affect? 2.Remote No Risk Likly Due to Update 2.Minor Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p> <div style="border: 1px solid gray; height: 100px;"></div>	<p>Further Action Required on Issue</p> <div style="border: 1px solid gray; height: 30px;"></div>
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<p>31064Q36 Process 7856 Software Validation Unchecked Orders To check order picking cannot pick against an unchecked order Current Known Risk Customer recieves incorrect items due to order not being checked. Current Likly 2 Current Frequency 2</p>	<p>Does Risk Frequency Update due to Update Affect? 2.Remote No Risk Likly Due to Update 2.Minor Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p> <div style="border: 1px solid gray; height: 100px;"></div>	<p>Further Action Required on Issue</p> <div style="border: 1px solid gray; height: 30px;"></div>
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<p>31064Q37 Process 7857 Software Validation Stock Tracking Check To confirm Software Validation Stock Tracking Check, is functioning as expected Current Known Risk Stock gets mislaid in the warehouse Current Likly 2 Current Frequency 1</p>	<p>Does Risk Frequency Update due to Update Affect? 1.Improbable No Risk Likly Due to Update 2.Minor Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p> <div style="border: 1px solid gray; height: 100px;"></div>	<p>Further Action Required on Issue</p> <div style="border: 1px solid gray; height: 30px;"></div>
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<p>31064Q38 ProcessProcess 7858 Software Validation Attempt To QA Some Stock Test the QA System that Staff not trained for QA are unable to QA a Product. Current Known Risk Untrained staff QA/Processing Product Current Likly 1 Current Frequency 3</p>	<p>Does Risk Frequency Update due to Update Affect? 3.Occasional <input type="button" value="v"/> <input type="button" value="No"/> Risk Likly Due to Update 1.Negligible <input type="button" value="v"/> Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p> <div style="border: 1px solid gray; height: 100px;"></div>	<p>Further Action Required on Issue</p> <div style="border: 1px solid gray; height: 20px;"></div>
<p>31064Q39 ProcessProcess 7861 Software Validation Of Training Documents Forced Reading Software Validating Of Training Documents via Forced Required Reading Current Known Risk required reading not read. Current Likly 1 Current Frequency 2</p>	<p>Does Risk Frequency Update due to Update Affect? 2.Remote <input type="button" value="v"/> <input type="button" value="No"/> Risk Likly Due to Update 1.Negligible <input type="button" value="v"/> Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p> <div style="border: 1px solid gray; height: 100px;"></div>	<p>Further Action Required on Issue</p> <div style="border: 1px solid gray; height: 20px;"></div>
<p>31064Q40 ProcessProcess 7865 Software Validation Conflicting Audits Software Validiation of the system: To check all process(s) tasks and audits are not clashed with the same person doing the Task as the Audit.</p> <p>Current Known Risk non Automatic Current Likly 1 Current Frequency 1</p>	<p>Does Risk Frequency Update due to Update Affect? 1.Improbable <input type="button" value="v"/> <input type="button" value="No"/> Risk Likly Due to Update 1.Negligible <input type="button" value="v"/> Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p> <div style="border: 1px solid gray; height: 100px;"></div>	<p>Further Action Required on Issue</p> <div style="border: 1px solid gray; height: 20px;"></div>
<p>31064Q41 ProcessProcess 7870 Software Validation Non Conformance Product Risk Feedback Loop Scope to check the automatic system of tagging product non conformance and other issues to the post market surveillane review report. Current Known Risk issues not carried out Current Likly 1 Current Frequency 1</p>	<p>Does Risk Frequency Update due to Update Affect? 1.Improbable <input type="button" value="v"/> <input type="button" value="No"/> Risk Likly Due to Update 1.Negligible <input type="button" value="v"/> Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p> <div style="border: 1px solid gray; height: 100px;"></div>	<p>Further Action Required on Issue</p> <div style="border: 1px solid gray; height: 20px;"></div>

<p>31064Q42 ProcessProcess 7875 Software Validation Document Control To test document control is working as intended. Current Known Risk If not carried out, document index is unvalidated Current Likly 1 Current Frequency 1</p>	<p>Does Update Affect? <input type="checkbox"/> No <input checked="" type="checkbox"/> Yes Risk Frequency due to Update <input type="checkbox"/> 1.Improbable <input checked="" type="checkbox"/> 1.Negligible Risk Likly Due to Update <input type="checkbox"/> 1.Improbable <input checked="" type="checkbox"/> 1.Negligible Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p> <div style="border: 1px solid gray; height: 100px;"></div>	<p>Further Action Required on Issue</p> <div style="border: 1px solid gray; height: 20px;"></div>
<p>31064Q43 ProcessProcess 7879 Software Validation Scheduled Tasks And Audits To check the Scheduled Tasks and Audits is working as Intended. To also Check the Out of Date documents is working as Intended. Current Known Risk Tasks and Audit Rolling Issues Key to ISO requirements. risk of losing standards Current Likly 1 Current Frequency 1</p>	<p>Does Update Affect? <input type="checkbox"/> No <input checked="" type="checkbox"/> Yes Risk Frequency due to Update <input type="checkbox"/> 1.Improbable <input checked="" type="checkbox"/> 1.Negligible Risk Likly Due to Update <input type="checkbox"/> 1.Improbable <input checked="" type="checkbox"/> 1.Negligible Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p> <div style="border: 1px solid gray; height: 100px;"></div>	<p>Further Action Required on Issue</p> <div style="border: 1px solid gray; height: 20px;"></div>
<p>31064Q44 ProcessProcess 7880 Software Validation Out Of Date Documents To confirm the out of documents computer software functions as expected flagging out of date items on to the list Current Known Risk Old document in the system Current Likly 1 Current Frequency 1</p>	<p>Does Update Affect? <input type="checkbox"/> No <input checked="" type="checkbox"/> Yes Risk Frequency due to Update <input type="checkbox"/> 1.Improbable <input checked="" type="checkbox"/> 1.Negligible Risk Likly Due to Update <input type="checkbox"/> 1.Improbable <input checked="" type="checkbox"/> 1.Negligible Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p> <div style="border: 1px solid gray; height: 100px;"></div>	<p>Further Action Required on Issue</p> <div style="border: 1px solid gray; height: 20px;"></div>
<p>31064Q45 ProcessProcess 7881 Software Validation - Live Orders To compare Opera Live Orders to Intrastats Back order Active List NO LONGER REQUIRED Opera is now out of the system Current Known Risk no risks, confirmation back orders is working as inteneded Current Likly 1 Current Frequency 1</p>	<p>Does Update Affect? <input type="checkbox"/> No <input checked="" type="checkbox"/> Yes Risk Frequency due to Update <input type="checkbox"/> 1.Improbable <input checked="" type="checkbox"/> 1.Negligible Risk Likly Due to Update <input type="checkbox"/> 1.Improbable <input checked="" type="checkbox"/> 1.Negligible Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p> <div style="border: 1px solid gray; height: 100px;"></div>	<p>Further Action Required on Issue</p> <div style="border: 1px solid gray; height: 20px;"></div>

31064Q46 Does Generic CE File Attached to All Technical file #2
Of type 5 require any Notificaions and/or Risk assesment updates due to this
update

Does Risk Frequency
Update due to Update
Affect? 1.Improbable ▼
No ▼ Risk Likly Due
to Update
1.Negligible ▼
Action
Required:
No Action
Required

Notes On Risk / Benefits statement if
required

Further Action Required
on Issue

31064Q47 Final Notes

No ISO Procedures or Process
are negativly affected by updating this document with the new document proposed

SAVE FORM Only saves your progress in filling in above Questions - No feed back to pressing save form button

Once Form Complete Print Page to PDF (Landscape mode prefereable), go back to document upload page and upload to risk assesment button