## **Document VOP 24 Needs, Risks and Expectations of External Parties Revision ID31060**

Suggested Upload Document Name: Risk Assesment For Updating Document ID31060 Completed by Derek Lamb 22 Sep 2022

## Reason for Risk Assesment

added objective of the vop only really applies to VST 9001, but useful for viamed 13485

Document VOP 24 Needs, Risks and Expectations of External Parties Revision ID31060 Is linked to the Following Standards and processes

Assesment Question ID31060

Update Risk on Update Affect

Notes On Risk / Benefits statement i required

31060Q0 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

Risk Fregency Does Update due to Update Affect? 1.Improbable 🗸 No V Risk Likly Due to Update 1.Negligible

Action Required: No Action Required

Notes On Risk / Benefits statement i required

31060Q1 VST Ltd ISO9001:2015 Section: 4.1

Understanding the organization and its context

The organization shall determine external and internal issues that are relevant to its

and its strategic direction and that affect its ability to achieve the intended result(s) of its quality

management system.

The organization shall monitor and review information about these external and internal

NOTE 1 Issues can include positive and negative factors or conditions for consideration. NOTE 2 Understanding the external context can be facilitated by considering issues arising from legal,

technological, competitive, market, cultural, social and economic environments, whether international, national,

regional or local.

NOTE 3 Understanding the internal context can be facilitated by considering issues related to values, culture,

knowledge and performance of the organization.

Does Risk Fregency Update due to Update Affect? 1.Improbable > Yes V Risk Likly Due to Update 1.Negligible Action Required: No Action Required

Notes On Risk / Benefits statement i required only added objective and some internal references does not affect the processes section 4.1

VST Ltd ISO9001:2015 Section: 4.2 3106002

Understanding the needs and expectations of interested parties

Due to their effect or potential effect on the organization sability to consistently provide products and

services that meet customer and applicable statutory and regulatory requirements, the organization

shall determine:

- a) the interested parties that are relevant to the quality management system;
- b) the requirements of these interested parties that are relevant to the quality management

The organization shall monitor and review information about these interested parties and their

relevant requirements.

Does Risk Fregency Update due to Update Affect? 1.Improbable > No V Risk Likly Due to Update 1.Negligible

No Action

Required

Action Required:

Notes On Risk / Benefits statement i

31060Q3 VST Ltd ISO9001:2015 Section: 6.1

When planning for the quality management system, the organization shall consider the

referred to in 4.1 and the requirements referred to in 4.2 and determine the risks and opportunities that

need to be addressed to:

- c) prevent, or reduce, undesired effects;

Does Risk Fredency Update due to Update Affect? 1.Improbable > No V Risk Likly Due to Update

1.Negligible

No Action

Required

Action Required:

required

Notes On Risk / Benefits statement i

a) give assurance that the quality management system can achieve its intended result(s);

- b) enhance desirable effects;
- d) achieve improvement.

Does Risk Frequency Update due to Update Affect? 1.Improbable > No V Risk Likly Due to Update

> 1.Negligible Action Required:

Notes On Risk / Benefits statement i required

31060Q4 <sup>Q</sup>ProcessProcess 9

Distribution Of Faxes Distribute recieved faxs Current Known Risk lost faxes

Current Likly 1 Current Frequency 1

22/09/2022, 12:39

Required 31060Q5 <sup>Q</sup>ProcessProcess 11 Risk Fregency Notes On Risk / Benefits statement i Update due to Update required Distribution Of Mail Affect? 1.Improbable > Distibuting incoming post to correct person Current Known Risk Royal Mail fail to deliver post No ✔ Risk Likly Due to Update Current Likly 3 Current Frequency 1 3.Serious Action Required: No Action Required 31060Q6 <sup>Q</sup>ProcessProcess 14 Does Risk Freqency Notes On Risk / Benefits statement i Update due to Update Fax Paper Affect? 1.Improbable > Ensuring that fax reports have been generated for both sent and received faxes and ensuring there is paper in the fax machine No ➤ Risk Likly Due Current Known Risk Phone lines go down to Update The paper tray is empty 1.Negligible Current Likly 1 Current Frequency 1 Action Required: No Action Required 31060Q7 <sup>Q</sup>ProcessProcess 15 Does Risk Freqency Notes On Risk / Benefits statement i Update due to Update required Filing and Archiving Paperwork to be filed in the correct order Affect? 1.Improbable > No 🗸 Risk Likly Due Current Known Risk Paperwork is filed incorrectly Current Likly 1 Current Frequency 1 to Update 1.Negligible Action Required: No Action Required <sup>Q</sup>ProcessProcess 21 Risk Freqency Notes On Risk / Benefits statement i 31060Q8 Does Office Sales Projects Update due to Update Ensuring office job list is being updated and completed Affect? 1.Improbable > No ✔ Risk Likly Due Current Known Risk Office is short staffed or over worked Current Likly 2 Current Frequency 1 to Update 2.Minor Action Required: No Action Required 3106009 ProcessProcess 36 Risk Fregency Notes On Risk / Benefits statement i Does **Emailing Of Invoices** Update due to Update required Invoices are emailed to customers Affect? 1.Improbable ✓ No V Risk Likly Due Current Known Risk Computer or network failure to Update Current Likly 2 Current Frequency 1 2.Minor Action Required: No Action Required 31060Q10 QProcessProcess 5859 Risk Fregency Notes On Risk / Benefits statement i Does Update due to Update Review Un-shipped Parcels required Affect? 1.Improbable ✓ audit and snap shot - this is an audit of a part of goods out, listing of the parcels that are sat waiting on a customer response No V Risk Likly Due to Update Current Known Risk Customer forgets to come back to us and parcels stay ready for shipping. 2.Minor As the package is already pick pack and ready to leave the building all computer traces Action Required: will show as shipped. No Action Current Likly 2 Current Frequency 1 Required 31060Q11 QProcessProcess 5871 Risk Fregency Notes On Risk / Benefits statement i Does Update due to Update reauired Check Sale Or Returns Review the Sale or Return list in intrastats. Ensure it is up to date. Affect? 1.Improbable > ➤ Risk Likly Due Current Known Risk That goods could be sent to a customer or goods returned but the list to Update is not updated 2.Minor Current Likly 2 Current Frequency 1 Action Required: No Action Required 31060Q12 ProcessProcess 5872 Risk Fregency Notes On Risk / Benefits statement i Does Update due to Update required Check Sale Or Returns Export Affect? 1.Improbable ✓ Review the Sale or Return list in intrastats. Ensure it is up to date. No **∨** Risk Likly Due Current Known Risk That goods could be sent to a customer or goods returned but the list to Update is not updated Current Likly 2 Current Frequency 1 2 Minor Action Required: No Action Required

1.Negligible Action Required: No Action Required Does Risk Frequecy 31060Q38 QProcessProcess 7699 Notes On Risk / Benefits statement i Shred Sensitive Paperwork In JL Office Update due to Update required Affect? 1.Improbable > Shredding of sensitive information No ✔ Risk Likly Due Current Known Risk Broken shredder to Update Current Likly 1 Current Frequency 1 1.Negligible Action Required: No Action Required 31060Q39 ProcessProcess 7709 Does Risk Frequency Notes On Risk / Benefits statement i Update due to Update required Delivered not Invoiced Affect? 2.Remote Ensure invoices are generated for shipped orders Current Known Risk Computer/network breakdown No V Risk Likly Due to Update delivery is missed and remains un invoiced. Current Likly 2 Current Frequency 2 2.Minor Action Required: No Action Required 31060Q40 ProcessProcess 7712 Does Risk Frequency Notes On Risk / Benefits statement i Update due to Update **Review Inward Payments** required Review the payments received to ensure proformas can be shipped Affect? 1.Improbable > No ✔ Risk Likly Due Current Known Risk Computer network breakdown to Update Current Likly 3 Current Frequency 1 3.Serious Action Required: No Action Required 31060Q41 QProcessProcess 7735 Does Risk Fregency Notes On Risk / Benefits statement i Ensure SOR's Are Followed Up Update due to Update required Ensure samples and Sale or Return items are followed up after 4 weeks for feedback and Affect? 1.Improbable > No ✔ Risk Likly Due the item(s) is returned as appropriate Current Known Risk Computer/network breakdown to Update Current Likly 2 Current Frequency 1 2.Minor Action Required: No Action Required 31060Q42 QProcessProcess 7740 Does Risk Frequecy Notes On Risk / Benefits statement i Update due to Update Weights Per Region Needed To Submit EC Sales List reauired Affect? 1.Improbable > Filling in HMRC data requires Weights and dimensions per region in the EC No ✔ Risk Likly Due This process ensures all the data is in place for the report to Update Current Known Risk Fines for late submission 1.Negligible Current Likly 1 Current Frequency 1 Action Required: No Action Required 31060Q43 ProcessProcess 7748 Does Risk Frequency Notes On Risk / Benefits statement i Update due to Update required Check Repair Orders Affect? 2.Remote Check the orders against the customer paperwork, that we have generated, for the repair No ✔ Risk Likly Due we have received in. to Update Current Known Risk That details will be incorrect and it will affect the customer. That mistakes may be missed. 2.Minor Current Likly 2 Current Frequency 2 Action Required: No Action Required 31060Q44 ProcessProcess 7749 Risk Freqency Notes On Risk / Benefits statement i Check Repair Quotes Update due to Update required Affect? 2.Remote Check the quotes that we send out for the repairs we have received in. No 🗸 Risk Likly Due Current Known Risk That mistakes may be missed. That details will be incorrect and it will affect the customer. to Update Current Likly 2 Current Frequency 2 2.Minor Action Required: No Action Required 31060Q45 ProcessProcess 7752 Does Risk Freqency Notes On Risk / Benefits statement i Update due to Update required SRS Folder Ensure all outstanding repairs are being dealt with Affect? 1.Improbable >

Current Known Risk repairs get stuck in the system

Current Likly 2 Current Frequency 1

No ✔ Risk Likly Due

to Update

Action Required: No Action Required 31060Q46 QProcessProcess 7758 Does Risk Frequecy Notes On Risk / Benefits statement i Check For GHX Orders Update due to Update required Check the emails for orders from GHX Affect? 1.Improbable > No V Risk Likly Due Current Known Risk Computer/network breakdown to Update Current Likly 2 Current Frequency 1 2.Minor Action Required: No Action Required 31060Q47 QProcessProcess 7760 Does Risk Frequency Notes On Risk / Benefits statement i Update due to Update required Send Service Offers Affect? 1.Improbable > Send letters to existing customers to remind them that a service is due on their equipment Current Known Risk Computer/network breakdown No V Risk Likly Due to Update Current Likly 1 Current Frequency 1 1.Negligible Action Required: No Action Required 31060Q48 QProcessProcess 7761 Does Risk Frequecy Notes On Risk / Benefits statement i Update due to Update Send VST Delivery Notifications required **Emailing Notifications of shipments** Affect? 1.Improbable > No ✔ Risk Likly Due Current Known Risk Limited risks, and if the email fails to get delivered the customer will to Update still receive their shipment. Current Likly 2 Current Frequency 1 2.Minor Action Required: No Action Required 31060Q49 \( \text{ProcessProcess 7783} \) Does Risk Fregency Notes On Risk / Benefits statement i PDF VST Invoices And Purchase Orders Update due to Update required Process of PDF ing Invoices into the system for easy of use in the future and the Emailing Affect? 1.Improbable > No ✔ Risk Likly Due of Invoices to customers to Update NOW DONE AUTOMATICALLY 2.Minor Current Known Risk Incorrect name given to Invoice when saving the PDF. Action Required: customer gets incorrect invoice. No Action Current Likly 2 Current Frequency 1 Required 31060Q50 QProcessProcess 7792 Does Risk Frequency Notes On Risk / Benefits statement i Update due to Update required Shipped Order Success Report Affect? 1.Improbable > A report is generated from figures in Intrastats to display how many orders have been No × Risk Likly Due shipped without errors Current Known Risk Computer/network breakdown to Update Current Likly 2 Current Frequency 1 2.Minor Action Required: No Action Required 31060Q51 ProcessProcess 7795 Does Risk Frequency Notes On Risk / Benefits statement i Update due to Update required Answering UK Web Questions Affect? 1.Improbable ~ Answering any questions that are asked via the website from within Intrastats Current Known Risk Computer/network breakdown No ✔ Risk Likly Due to Update Current Likly 1 Current Frequency 1 1.Negligible Action Required: No Action Required 31060Q52 ProcessProcess 7837 Does Risk Frequency Notes On Risk / Benefits statement i Review External Parties Influencing The QMS VST / Viamed Update due to Update required Affect? 1.Improbable > related to this isse but does To Review the External Parties Influencing The QMS VST / Viamed Checked the Scopes and Risks, Yes 🗸 Risk Likly Due affect it Review the Underlining Processes and Tasks to Update Current Known Risk External party has un-reviewed expectations 1.Negligible Current Likly 1 Current Frequency 1 Action Required: No Action Required 31060Q53 ProcessProcess 7953 Risk Freqency Notes On Risk / Benefits statement i Vandagraph Delivery Notifications Update due to Update required Affect? 1.Improbable > To Send Vandagraph Delivery notifications Current Known Risk task not carried out No **∨** Risk Likly Due Current Likly 1 Current Frequency 1 to Update

			1.Negligible   Action Required: No Action Required	
	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	Update Affect?	Risk Freqency due to Update  1.Improbable  Risk Likly Due to Update  1.Negligible  Action Required: No Action Required	Notes On Risk / Benefits statement i required
31060Q55	Final Notes		•	
	No ISO Procedures or Process are negativly affected by updating this document with the new document	nt 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 assessment button