## Document VM3COP10.02 Product Recall locate products out in the Field **Revision ID23643**

Suggested Upload Document Name: Risk Assesment For Updating Document ID23643

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the quality management system shall be controlled. Records are a special type of document and shall be controlled according to the requirements given in

	Risk Assesment	21					
	locating existing sold S an be recall immediatly	Stock ha	as been improve	d			
Method Imp	provement, does not affec	t the I	ISO System				
Document	VM3COP10.02 Product Rec	call loca	te products out in	n the Field Revis	ion ID2364	3 Is linked to the Following Standards a	and processes
Risk Assesment ID23643		Does Update Affect	Fraguency	Severity Likly	Risk Rating	Notes On Risk / Benefits statement if required	Further Action Required on Issue
23643Q0	Does this Update warrant updating Any External Parties due to any Terms and Conditional Agreements E.G. Notified Body	No 🗸	1.Improbable <b>∨</b>	1.Negligible	No Action Required		
23643Q1	Viamed Ltd ISO13485:2016 Section: 4.2.4 Control of documents Documentation requirements Documents required by	Yes 🗸	1.Improbable ➤	1.Negligible	Needs Setting	Method of tracing stock out in the field has been improved, Does not break the ISO SYSTEM	

## 4.2.5.

A documented procedure shall define the controls needed to:

- a) review and approve documents for adequacy prior to issue;
- b) review, update as necessary and re-approve documents;
- c) ensure that the current revision status of and changes to documents are identified;
- d) ensure that relevant versions of applicable documents are available at points of use;
- e) ensure that documents remain legible and readily identifiable;
- f) ensure that documents of external origin, determined by the organization to be necessary for the planning and operation of the quality management system, are identified and their distribution controlled; g) prevent deterioration or loss of documents; b) prevent the unintended
- h) prevent the unintended use of obsolete documents and apply suitable identification to them. The organization shall ensure that changes to

documents are reviewed and approved either by the original approving function or another designated function that has access to pertinent background information upon which to base its decisions. The organization shall define the period for which at least one copy of obsolete documents shall be retained. This period shall ensure that documents to which medical devices have been manufactured and tested are available for at least the lifetime of the medical device as defined by the organization, but not less than the retention period of any resulting record (see 4.2.5), or as specified by applicable

23643Q2 Viamed Ltd ISO13485:2016 Section: 7.2.3

Communication
The organization shall
plan and document
arrangements for
communicating with
customers in relation
to:

- a) product information;
- b) enquiries, contracts or

Yes ▼ 1.Improbable ▼ 1.Negligible ▼ Needs Setting

Method of tracing stock out in the field has been improved, Does not break the ISO SYSTEM

order handling, including amendments; c) customer feedback, including complaints; d) advisory notices. The organization shall communicate with regulatory authorities in accordance with applicable regulatory requirements.

23643Q3 Viamed Ltd ISO13485:2016 Section:

8.3.1 General

The organization shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. The organization shall document a procedure to define the controls and related responsibilities and authorities for the identification, documentation, segregation, evaluation, and disposition of nonconforming product. The evaluation of nonconformity shall include a determination of the need for an investigation and notification of any

Yes ▼ 1.Improbable ▼ 1.Negligible ▼ Needs Setting

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external party responsible for the nonconformity. Records of the nature of the nonconformities and any subsequent action taken, including the evaluation, any investigation and the rationale for decisions shall be maintained (see 4.2.5) 23643Q4 VST Ltd ISO9001:2015 Section: 5.1.2 Customer focus 5.1.2 Customer focus Top management shall demonstrate leadership and commitment with respect to customer focus by ensuring that: a) customer and applicable statutory and regulatory requirements are Needs 1.Improbable ➤ 1.Negligible determined, understood Yes 🕶 Setting and consistently met; b) the risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed: c) the focus on enhancing customer satisfaction is maintained.

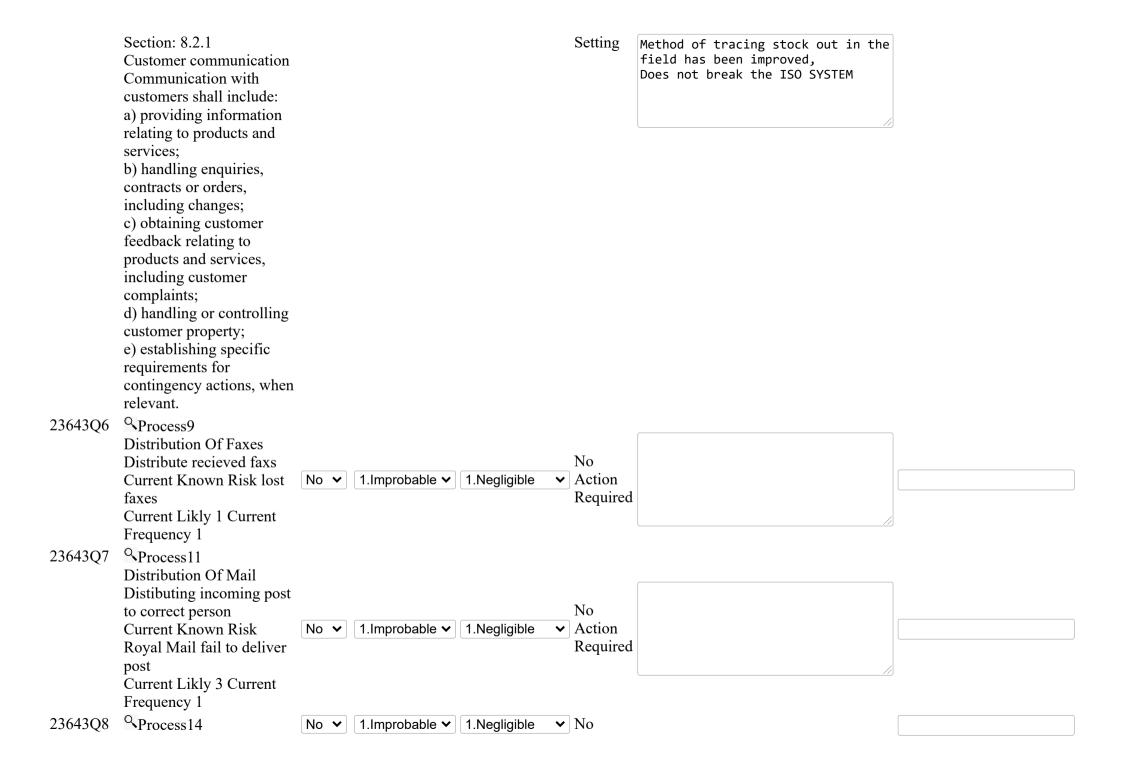
Method of tracing stock out in the field has been improved, Does not break the ISO SYSTEM

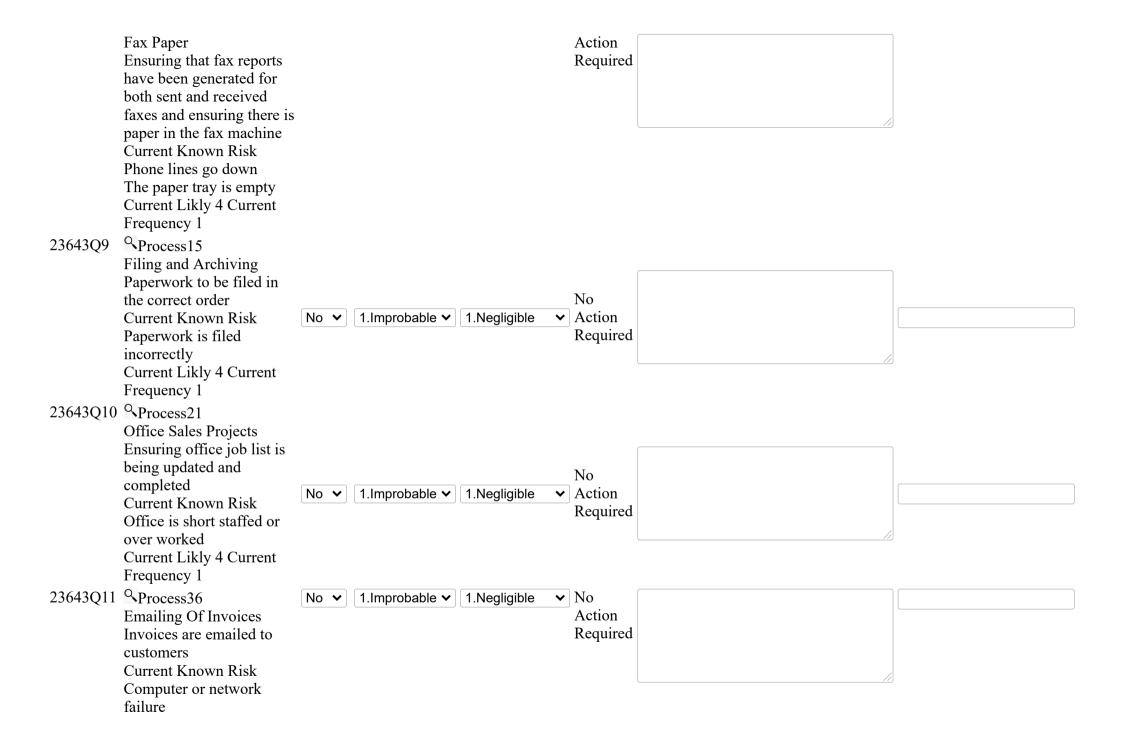
23643Q5 VST Ltd ISO9001:2015

Yes 🕶

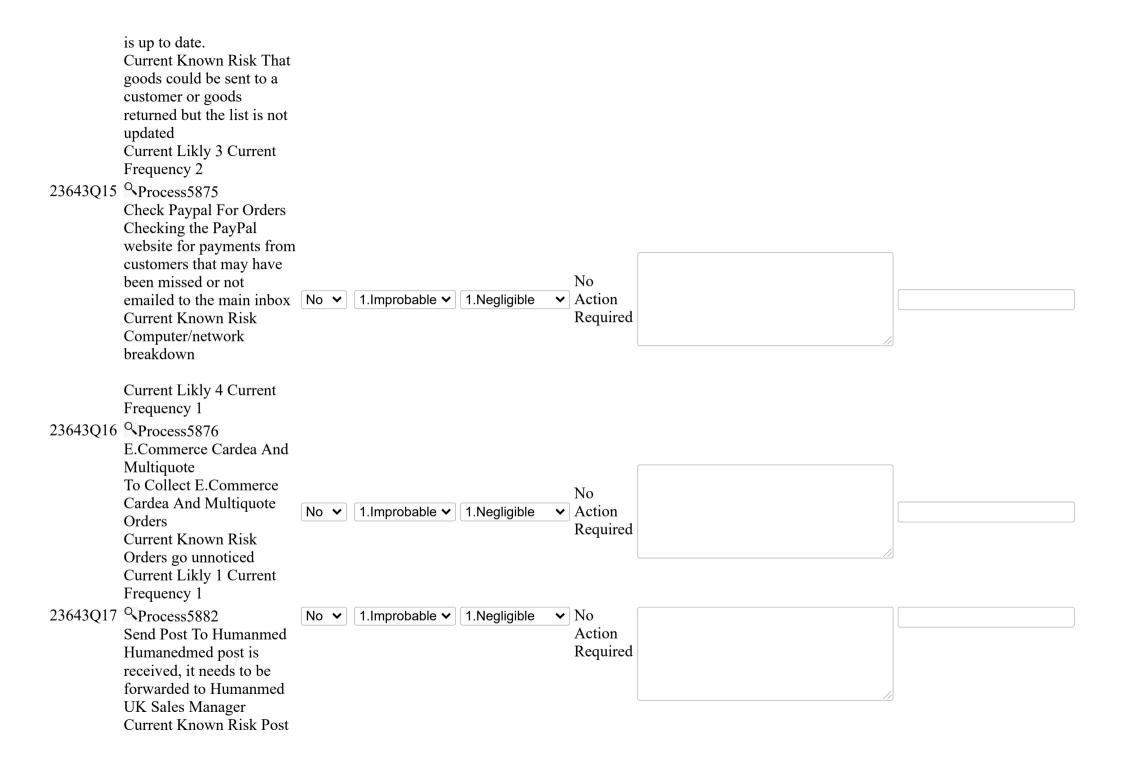
1.Improbable ➤ 1.Negligible

gligible V Needs

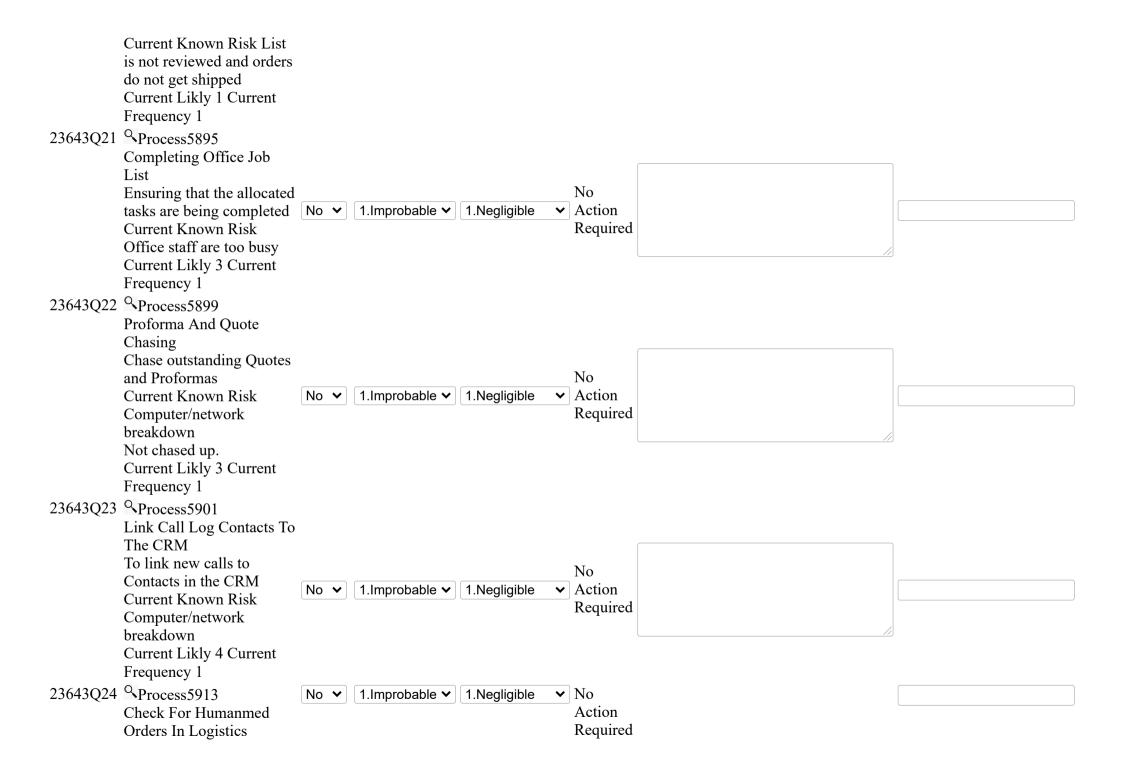


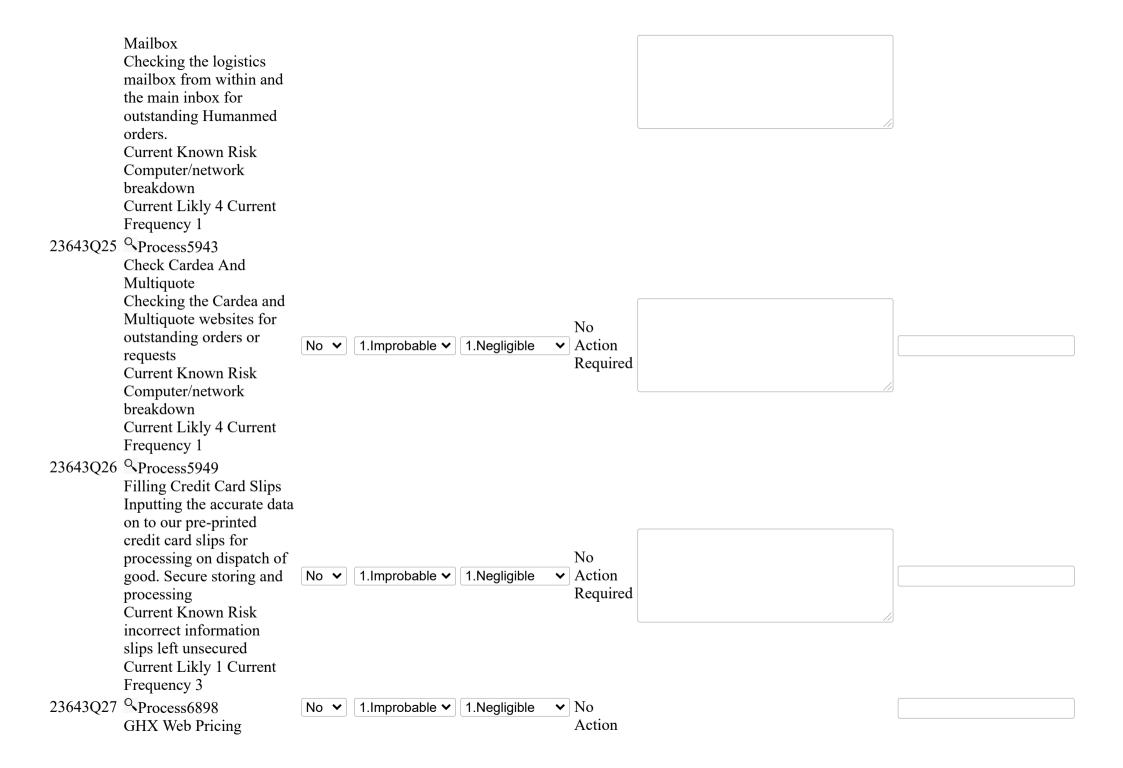


Current Likly 4 Current Frequency 1 23643O12 Process5859 Review Un-shipped Parcels audit and snap shot - this is an audit of a part of goods out, listing of the parcels that are sat waiting on a customer response No Current Known Risk **∨** Action Customer forgets to come No 🗸 Required back to us and parcels stay ready for shipping. As the package is already pick pack and ready to leave the building all computer traces will show as shipped. Current Likly 4 Current Frequency 1 23643Q13 QProcess5871 Check Sale Or Returns Review the Sale or Return list in intrastats. Ensure it is up to date. No Current Known Risk That **∨** Action 1.Improbable ∨ 1.Negligible goods could be sent to a Required customer or goods returned but the list is not updated Current Likly 3 Current Frequency 2 23643Q14 QProcess5872 1.Improbable ➤ 1.Negligible **∨** No No **∨** Action Check Sale Or Returns Required **Export** Review the Sale or Return list in intrastats. Ensure it

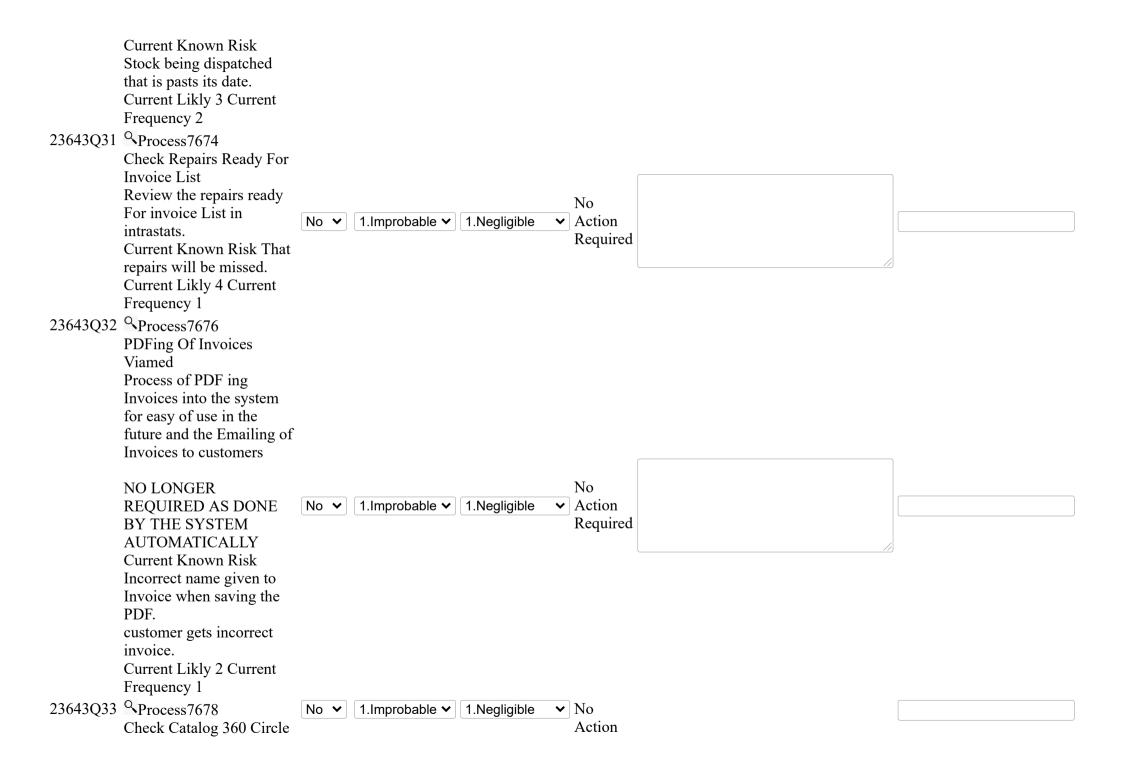


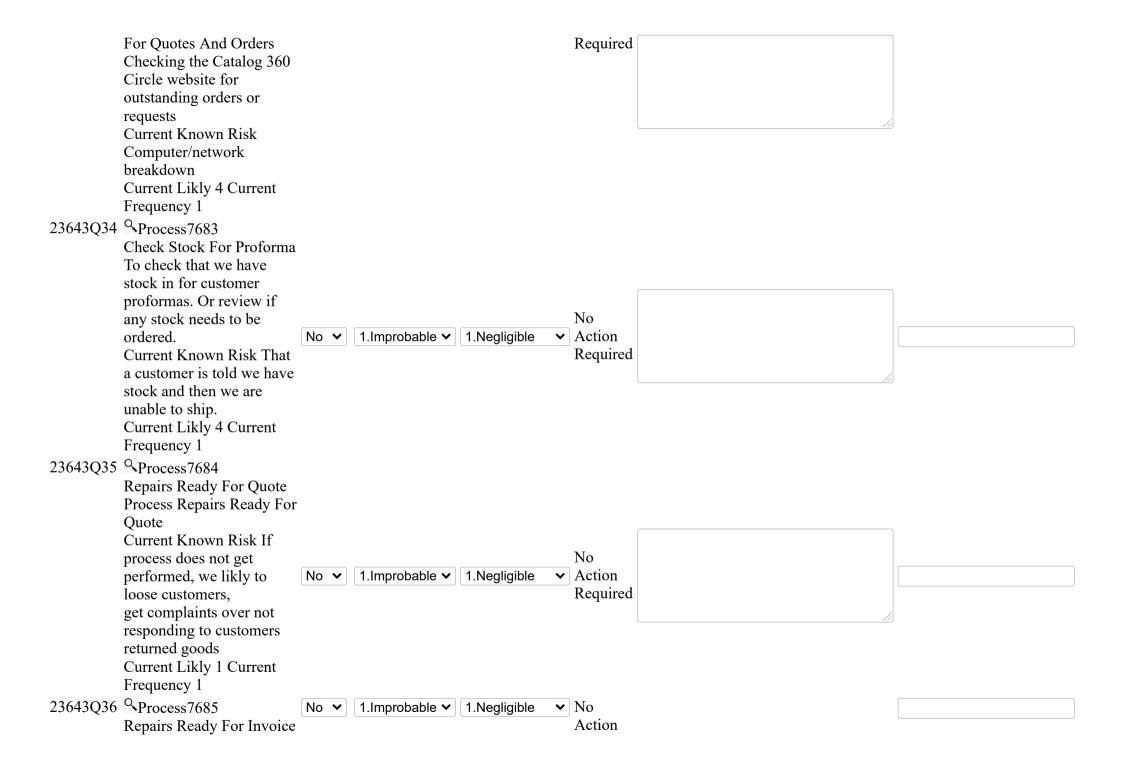
23643Q18	is not sent Current Likly 4 Current Frequency 1 Process5892 Checking EBay And Amazon For Orders And Messages Checking the eBay and Amazon accounts for orders that have not been emailed to the main inbox and checking to see if there are messages or questions. Current Known Risk Computer/network breakdown	No ✔ 1.Improbable ✔ 1.Negligible	No ➤ Action Required	
23643Q19	Current Likly 2 Current Frequency 2  Process5893 Answering Website Questions Answering any questions that are asked via the website from within Intrastats Current Known Risk Computer/network breakdown	No ✔ 1.Improbable ✔ 1.Negligible	No ✓ Action Required	
23643Q20	Current Likly 1 Current Frequency 1  Process5894 Checking Of Active List Check the Active Back orders ensure no orders get missed	No ✔ 1.Improbable ✔ 1.Negligible	No Action Required	



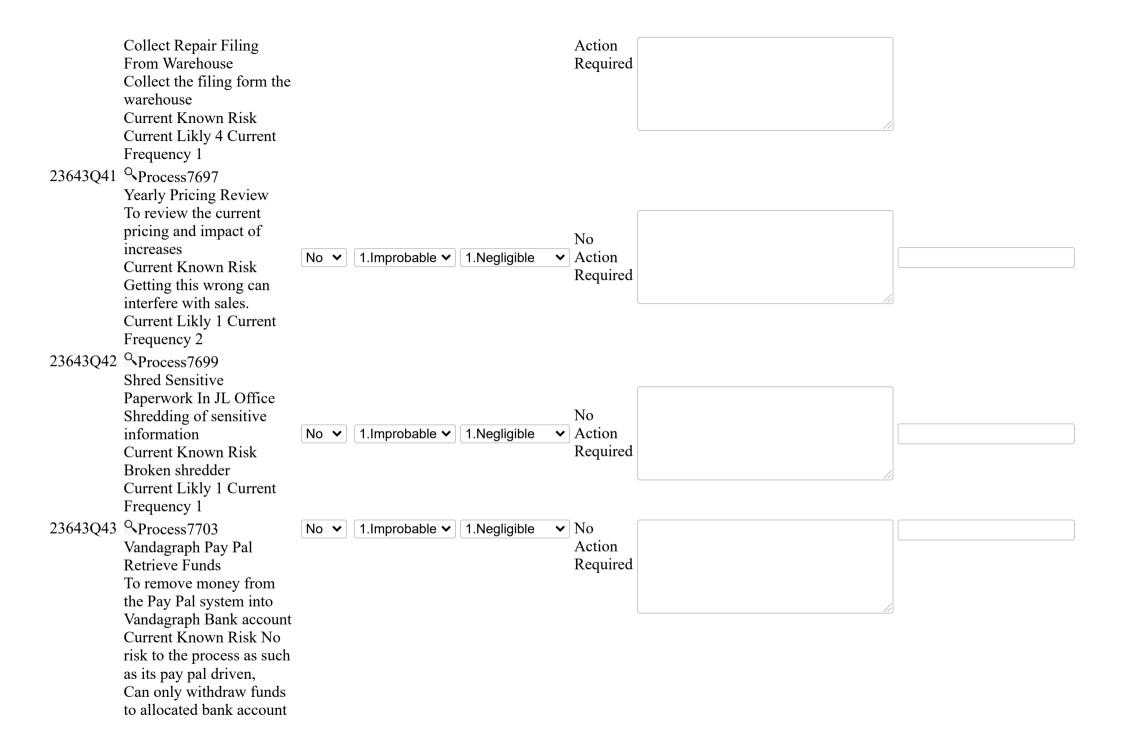


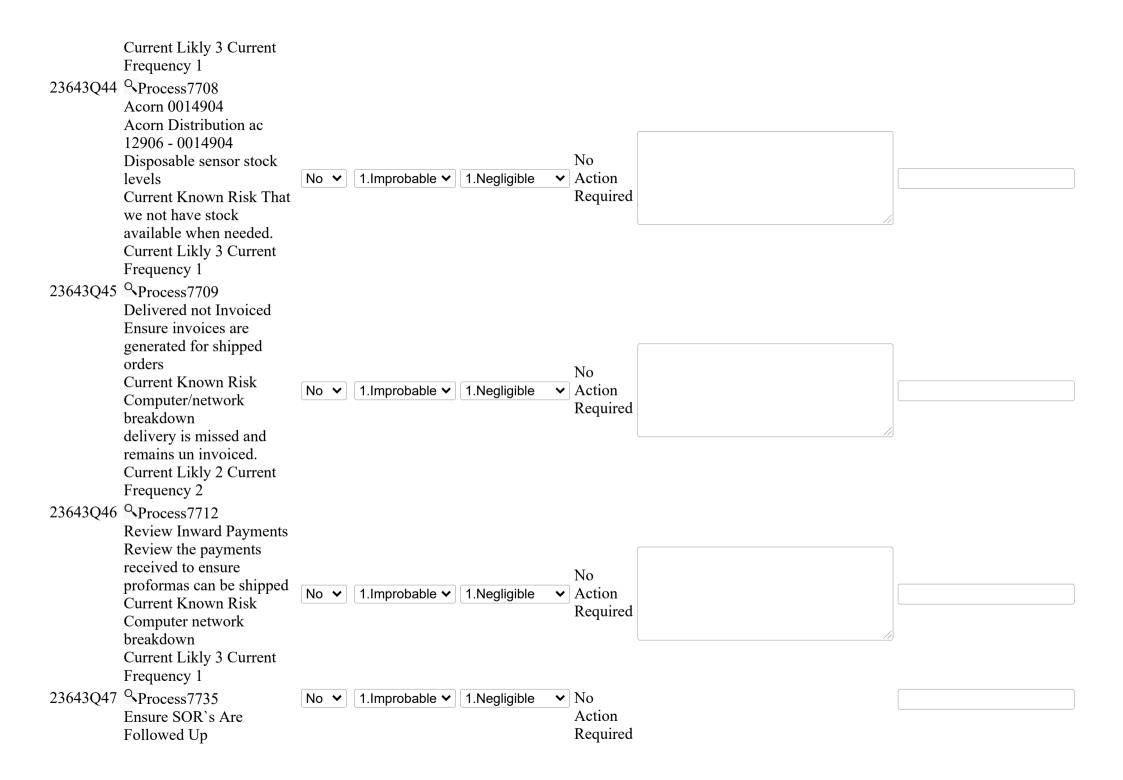
23643Q28	To review the GHX Web Pricing Current Known Risk That the prices are in correct and we may have to let them have the old price if we have not up dated them Current Likly 3 Current Frequency 2  Process6954 Back Orders Review - By Customer To check the back orders	Required	
	in the tray in goods out and check the active list back orders has been reviewed Current Known Risk goods not shipped in a timely manner Current Likly 1 Current Frequency 1	No ✓ 1.Improbable ✓ 1.Negligible ✓ Action Required	
23643Q29	Process7670 Humanmed general Issues Review of Humanmed sales and orders and clear any duplicates or problems. Current Known Risk That there are duplicate orders o the system due to errors. Current Likly 3 Current Frequency 1	No ▼ 1.Improbable ▼ 1.Negligible ▼ Action Required	
23643Q30	QProcess7673 Check Expiry Dated Stock To check that all the stock on the selves are within their use by dates.	No V 1.Improbable V 1.Negligible V No Action Required	





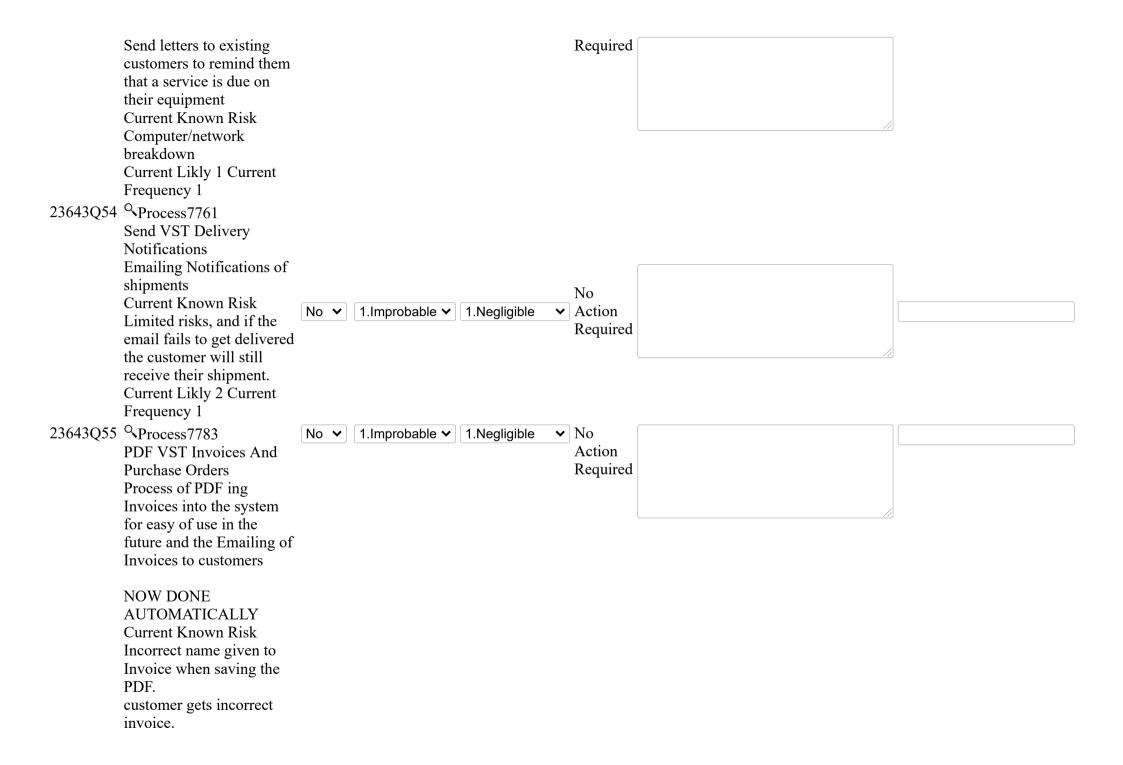


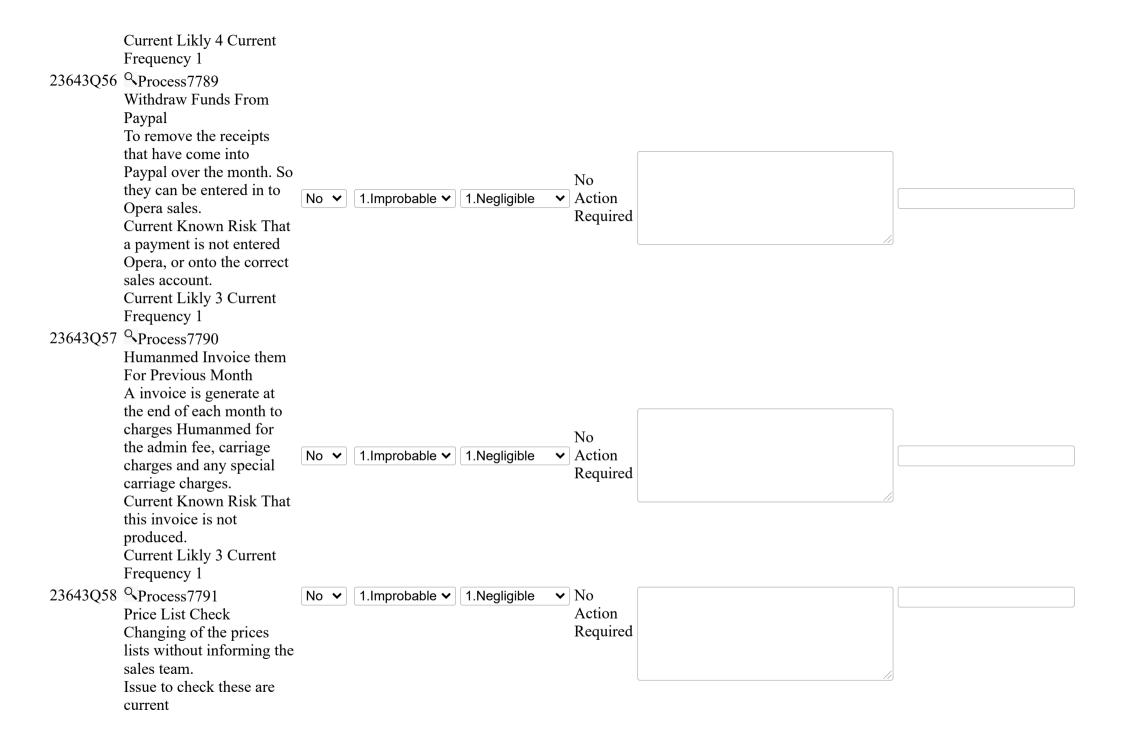


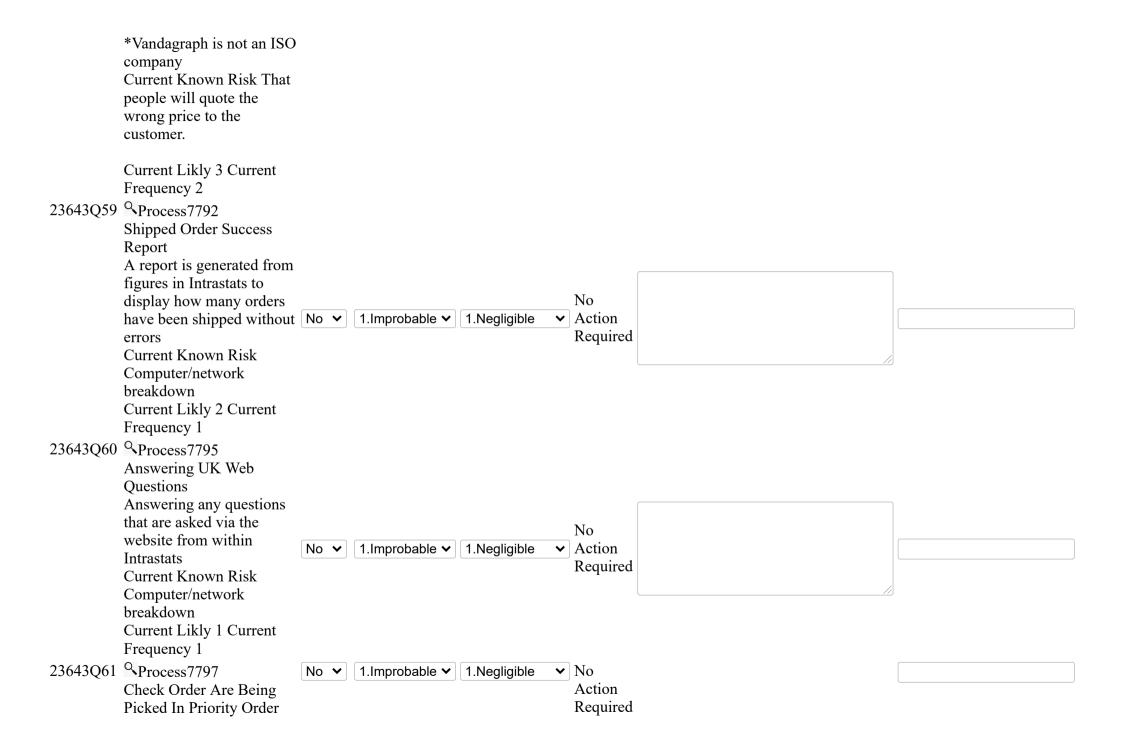


Ensure samples and Sale or Return items are followed up after 4 weeks for feedback and the item(s) is returned as appropriate Current Known Risk Computer/network breakdown Current Likly 4 Current Frequency 1 23643O48 • Process 7743 **Customer Complaints** Paper File Major Customer Complaints get escalated to Paper Customer Complaints file. does not change this process No Check the File is being 1.Improbable 1.Negligible **∨** Action Yes **∨** Maintained and any Required relevant documentation is in the File. Current Known Risk **Customer Complaints** could be missed or not filed correctly Current Likly 2 Current Frequency 1 23643Q49 \( \text{Process}7748 **∨** No 1.Improbable 1.Negligible **Check Repair Orders** Action Check the orders against Required the customer paperwork, that we have generated, for the repair we have received in. Current Known Risk That details will be incorrect and it will affect the





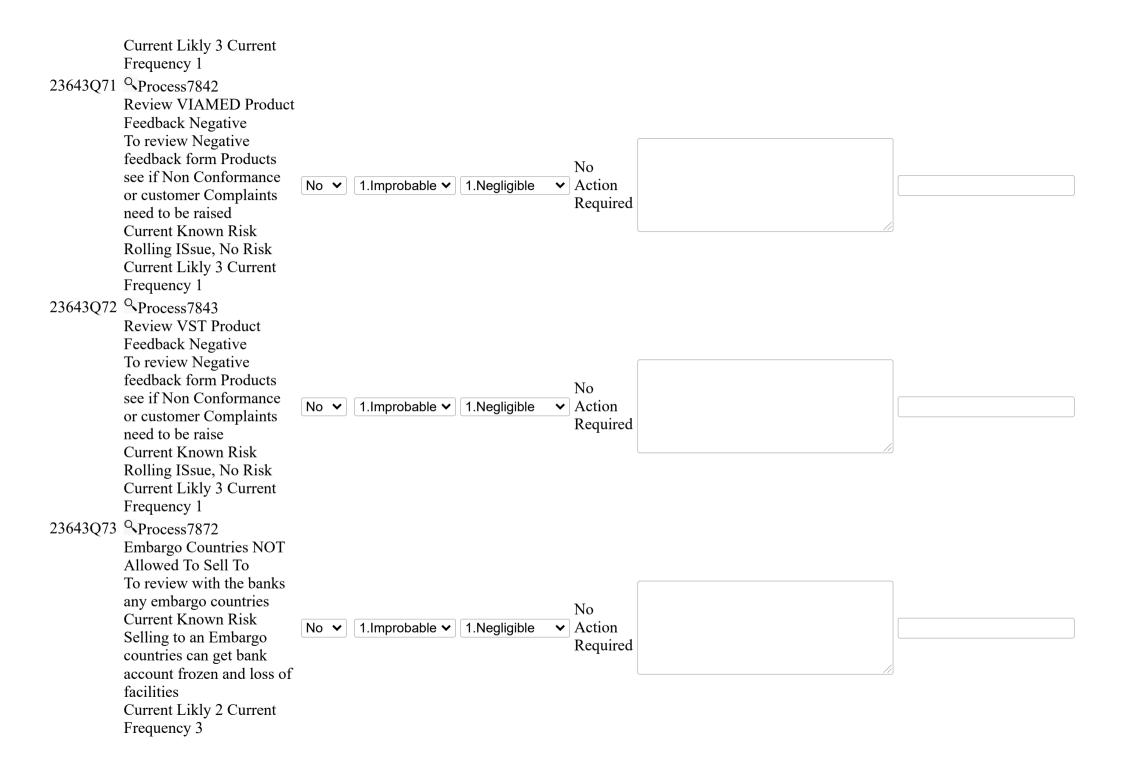






	Sales rep for special sales in the relevant area. and make a loss on the sale Current Likly 3 Current Frequency 1  Process7822 Review Oxylink Stock To check we have the stock available to supply our customer Oxylink.  NOTE THIS PROCESS HAS BEEN STOPPED.  Part number has been superseded Current Known Risk The we do not have the stock needed to satisfy the orders for this customer. Current Likly 3 Current Frequency 1  Process7830 Review Q.A. Failures	No V 1.Improbable	e 🗸 1.Negligible	No Action Required		
	Report To review the Quantities of Failed product per Stock reference Passing through the Q.A. system Current Known Risk No	Yes 🗸 1.Improbable	e 🗸 1.Negligible	No Action Required	does not change this process	
23643Q67	risk Current Likly 3 Current Frequency 1  Process7838 Review VIAMED Feedback - Customer Feedback Negative Review Customer	No ✔ 1.Improbable	e 🕶 1.Negligible	No Action Required		

Feedback Negative Current Known Risk Rolling Issues No risk to process Current Likly 3 Current Frequency 1 23643Q68 QProcess7839 **Review VIAMED** Feedback - Customer does not change this process Complaints No To Review Viamed 1.Improbable > 1.Negligible **∨** Action Yes **∨ Customer Complaints** Required Current Known Risk Rolling Issue No Risk Current Likly 3 Current Frequency 1 23643O69 CProcess7840 Review VST Feedback -Customer Feedback Negative To review Negative No feedback form Products 1.Improbable ➤ 1.Negligible **∨** Action see if Non Conformance No 🗸 Required or customer Complaints need to be raised Current Known Risk Rolling ISsue, No Risk Current Likly 3 Current Frequency 1 23643O70 \( \text{Process7841} \) 1.Improbable ➤ 1.Negligible **∨** No Yes **∨** does not change this process Action Review VST Feedback -**Customer Complaints** Required To review Customer Complaints see if Non Conformance need to be raised Current Known Risk Rolling ISsue, No Risk



23643Q74 Process7953
Vandagraph Delivery
Notifications
To Send Vandagraph
Delivery notifications
Current Known Risk task
not carried out
Current Likly 1 Current
Frequency 1

No
Action
Required

23643Q75 Final Notes

Method of locating existing sold Stock has been improved records can be recall immediatly

No 1.Improbable 1.Negligible

Method Improvement, does not affect the ISO System or pose a risk to the system