

Document VM3COP29.03.01 Viamed Warehouse Goods Out Picking Procedure

Revision ID76119

Suggested Upload Document Name: **Risk Assesment For Updating Document ID76119**

Completed by [Derek Lamb](#) 26 Nov 2021

Reason for Risk Assesment

PDF of existing DOC file no risk





Document VM3COP29.03.01 Viamed Warehouse Goods Out Picking Procedure Revision ID76119 Is linked to the Following Standards and processes

Risk Assesment Question ID76119	Does Update Risk on Update Affect	Risk Frequency due to Update	Notes On Risk / Benefits statement if required	Further Action Required on Issue
76119Q0 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
76119Q1 Viamed Ltd ISO13485:2016 Section: 7.5.1 Control of production and service provision Production and service provision shall be planned, carried out, monitored and controlled to ensure that product conforms to specification. As appropriate, production controls shall include but are not limited to: a) documentation of procedures and methods for the control of production (see 4.2.4); b) qualification of infrastructure; c) implementation of monitoring and measurement of process parameters and product characteristics; d) availability and use of monitoring and measuring equipment; e) implementation of defined operations for labelling and packaging;	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

f) implementation of product release, delivery and post-delivery activities. The organization shall establish and maintain a record (see 4.2.5) for each medical device or batch of medical devices that provides traceability to the extent specified in 7.5.9 and identifies the amount manufactured and amount approved for distribution. The record shall be verified and approved.

76119Q2	<p>VST Ltd ISO9001:2015 Section: 8.5.1</p> <p>Control of production and service provision</p> <p>The organization shall implement production and service provision under controlled conditions.</p> <p>Controlled conditions shall include, as applicable:</p> <p>a) the availability of documented information that defines:</p> <p>1) the characteristics of the products to be produced, the services to be provided, or the activities to be performed;</p> <p>2) the results to be achieved;</p> <p>b) the availability and use of suitable monitoring and measuring resources;</p> <p>c) the implementation of monitoring and measurement activities at appropriate stages to verify that criteria for control of processes or outputs, and acceptance criteria for products and services, have been met;</p> <p>d) the use of suitable infrastructure and environment for the operation of processes;</p> <p>e) the appointment of competent persons, including any required qualification;</p> <p>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;</p> <p>g) the implementation of actions to prevent human error;</p> <p>h) the implementation of release, delivery and post-delivery activities</p>	<p>Does Update Affect? <input type="button" value="No"/> ▼</p> <p>Risk Frequency due to Update <input type="button" value="1.Improbable"/> ▼</p> <p>Risk Likly Due to Update <input type="button" value="1.Negligible"/> ▼</p> <p>Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p> <div></div>	<p>Further Action Required on Issue</p> <div></div>
76119Q3	<p>VST Ltd ISO9001:2015 Section: 8.6</p> <p>Release of products and services</p> <p>The organization shall implement planned arrangements, at appropriate stages, to verify that the product and service requirements have been met.</p> <p>The release of products and services to the customer shall not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, as applicable, by the customer.</p>	<p>Does Update Affect? <input type="button" value="No"/> ▼</p> <p>Risk Frequency due to Update <input type="button" value="1.Improbable"/> ▼</p> <p>Risk Likly Due to Update <input type="button" value="1.Negligible"/> ▼</p> <p>Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p> <div></div>	<p>Further Action Required on Issue</p> <div></div>

The organization shall retain documented information on the release of products and services. The documented information shall include:
a) evidence of conformity with the acceptance criteria;
b) traceability to the person(s) authorizing the release

76119Q4	 Process7797 Check Order Are Being Picked In Priority Order Check order are being picked in order of priority and date.	Does Update Affect? <div>No ▾</div>	Risk Frequency due to Update 1.Improbable ▾ Risk Likly Due to Update 2.Minor ▾ Action Required: No Action Required	Notes On Risk / Benefits statement if required <div></div>	Further Action Required on Issue <div></div>
76119Q5	 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	Does Update Affect? <div>No ▾</div>	Risk Frequency due to Update 1.Improbable ▾ Risk Likly Due to Update 2.Minor ▾ Action Required: No Action Required	Notes On Risk / Benefits statement if required <div></div>	Further Action Required on Issue <div></div>
76119Q6	 Process6954 Back Orders Review - By Customer To check the back orders in the tray in goods out and check the active list back orders has been reviewed	Does Update Affect? <div>No ▾</div>	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 <div></div>	Further Action Required on Issue <div></div>
76119Q7	 Process7691 Ship Sale Or Returns Review the sale or return shelf and ship those items.	Does Update Affect? <div>No ▾</div>	Risk Frequency due to Update 1.Improbable ▾ Risk Likly Due	Notes On Risk / Benefits statement if required <div></div>	Further Action Required on Issue <div></div>

to Update
2.Minor
Action
Required:
No Action
Required

76119Q8	<div>Process7748</div> <div>Check Repair Orders</div> <div>Check the orders against the customer paperwork, that we have generated, for the repair we have received in.</div>	<div>Does Update Affect?</div> <div>No</div>	<div>Risk Frequency due to Update</div> <div>1.Improbable</div> <div>Risk Likely Due to Update</div> <div>2.Minor</div> <div>Action Required:</div> <div>No Action Required</div>	<div>Notes On Risk / Benefits statement if required</div> <div></div>	<div>Further Action Required on Issue</div> <div></div>
76119Q9	<div>Process7749</div> <div>Check Repair Quotes</div> <div>Check the quotes that we send out for the repairs we have received in.</div>	<div>Does Update Affect?</div> <div>No</div>	<div>Risk Frequency due to Update</div> <div>2.Remote</div> <div>Risk Likely Due to Update</div> <div>2.Minor</div> <div>Action Required:</div> <div>No Action Required</div>	<div>Notes On Risk / Benefits statement if required</div> <div></div>	<div>Further Action Required on Issue</div> <div></div>
76119Q10	<div>ProcessProcess 5858</div> <div>Opera Stock Adjustments</div> <div>Opera Counts bulk stock in and issues stock out against orders.</div> <div>Multiple processes cause stock to be used internally,</div> <div>Opera requires a weekly update to bring the stock count into line with whats been used outside the invoicing systems</div> <div>NO LONGER REQUIRED, New system live counts these now</div> <div>Current Known Risk Stock valuations will get inaccurate if the process is not performed.</div> <div>Current Likly 2 Current Frequency 1</div>	<div>Does Update Affect?</div> <div>No</div>	<div>Risk Frequency due to Update</div> <div>1.Improbable</div> <div>Risk Likely Due to Update</div> <div>2.Minor</div> <div>Action Required:</div> <div>No Action Required</div>	<div>Notes On Risk / Benefits statement if required</div> <div></div>	<div>Further Action Required on Issue</div> <div></div>
76119Q11	<div>ProcessProcess 5935</div>	<div>Does Update Affect?</div> <div>No</div>	<div>Risk Frequency due to Update</div> <div>1.Improbable</div> <div>Risk Likely Due to Update</div> <div>2.Minor</div> <div>Action Required:</div> <div>No Action Required</div>	<div>Notes On Risk / Benefits statement if required</div> <div></div>	<div>Further Action Required on Issue</div> <div></div>

Stock Allocations

To allocate stock that has not automatically be linked to a repair or invoice.
Current Known Risk Items that should be linked to a invoice are not in the allocations list.

That items are allocated incorrectly on the list.

Current Likly 2 Current Frequency 1

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

required

on Issue

76119Q12 ProcessProcess 6838

Opera Negative Stock

To find and correct opera when it reads Negative stock values.

Current Known Risk Damage Opera.

Current Likly 1 Current Frequency 1

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

76119Q13 ProcessProcess 6850

Current Stock Levels

Review current stock levels

Current Known Risk If the levels are incorrect or we have a shortages then
customers will not receive their goods in a timely manor.

Current Likly 2 Current Frequency 1

Does Risk Frequency
Update 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

Further Action Required
on Issue

76119Q14 ProcessProcess 6945

Missing Stock or Adjustments

To synchronise Opera stock Count against Intrastats internal movement of
stock,

E.G. Items that wont uniquely appear on an opera order - such as production
parts.

TASK IS NO LONGER REQUIRED





Current Known Risk Opera and Intrastats go out of sync





Current Likly 1 Current Frequency 1





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

76119Q15	 Process 6955 Production Requirements To set production job for any stock item that is needed for customer back order, warehouse requests or marketing Current Known Risk that jobs will not be added and customers orders will be delayed Current Likly 2 Current Frequency 1	Does Update Affect? <input type="button" value="No"/>	Risk Frequency due to Update <input type="button" value="1.Improbable"/> Risk Likly Due to Update <input type="button" value="2.Minor"/> Action Required: No Action Required	Notes On Risk / Benefits statement if required <div></div>	Further Action Required on Issue <div></div>
76119Q16	 Process 7048 Control of monitoring and measuring devices Control of monitoring and measuring devices Current Known Risk that equipment will be missed Current Likly 1 Current Frequency 2	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="1.Negligible"/> Action Required: No Action Required	Notes On Risk / Benefits statement if required <div></div>	Further Action Required on Issue <div></div>
76119Q17	 Process 7673 Check Expiry Dated Stock To check that all the stock on the selves are within their use by dates. Current Known Risk Stock being dispatched that is pasts its date. Current Likly 1 Current Frequency 2	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="1.Negligible"/> Action Required: No Action Required	Notes On Risk / Benefits statement if required <div></div>	Further Action Required on Issue <div></div>
76119Q18	 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 Affect? <input type="button" value="No"/>	Risk Frequency due to Update <input type="button" value="1.Improbable"/> Risk Likly Due to Update <input type="button" value="2.Minor"/> Action Required: No Action Required	Notes On Risk / Benefits statement if required <div></div>	Further Action Required on Issue <div></div>

76119Q19	 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 Affect? <input type="button" value="No"/>	Risk Frequency due to Update <input type="button" value="1.Improbable"/> Risk Likly Due to Update <input type="button" value="2.Minor"/> Action Required: No Action Required	Notes On Risk / Benefits statement if required <div></div>	Further Action Required on Issue <div></div>
76119Q20	 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 Affect? <input type="button" value="No"/>	Risk Frequency due to Update <input type="button" value="1.Improbable"/> Risk Likly Due to Update <input type="button" value="2.Minor"/> Action Required: No Action Required	Notes On Risk / Benefits statement if required <div></div>	Further Action Required on Issue <div></div>
76119Q21	 Process 7682 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	Does Update Affect? <input type="button" value="No"/>	Risk Frequency due to Update <input type="button" value="1.Improbable"/> Risk Likly Due to Update <input type="button" value="2.Minor"/> Action Required: No Action Required	Notes On Risk / Benefits statement if required <div></div>	Further Action Required on Issue <div></div>
76119Q22	 Process 7689 Move Stock From QA Shelf To Stock Shelf Monday Move Stock From QA Shelf To Stock Shelf Current Known Risk That stock is not replaced so it will take longer to pick goods for orders. Current Likly 2 Current Frequency 1	Does Update Affect? <input type="button" value="No"/>	Risk Frequency due to Update <input type="button" value="1.Improbable"/> Risk Likly Due to Update <input type="button" value="2.Minor"/> Action Required: No Action Required	Notes On Risk / Benefits statement if required <div></div>	Further Action Required on Issue <div></div>

<p>76119Q23  Process 7694</p> <p>Move Stock From QA Shelf To Stock Shelf Tuesday Move Stock From QA Shelf To Stock Shelf Current Known Risk That stock is not replaced so it will take longer to pick goods for orders. The stock is not on the correct shelf. Current Likly 2 Current Frequency 1</p>	<p>Does Update Affect? <input type="button" value="No"/></p> <p>Risk Frequency due to Update <input type="button" value="1.Improbable"/></p> <p>Risk Likly Due to Update <input type="button" value="2.Minor"/></p> <p>Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p> <div></div>	<p>Further Action Required on Issue</p> <div></div>
<p>76119Q24  Process 7695</p> <p>Top Up Quick Shipping Shelves Move Stock From QA Shelf To Quick Shipping Shelves Current Known Risk That stock is not replaced so it will take longer to pick goods for orders. Current Likly 1 Current Frequency 1</p>	<p>Does Update Affect? <input type="button" value="No"/></p> <p>Risk Frequency due to Update <input type="button" value="1.Improbable"/></p> <p>Risk Likly Due to Update <input type="button" value="1.Negligible"/></p> <p>Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p> <div></div>	<p>Further Action Required on Issue</p> <div></div>
<p>76119Q25  Process 7736</p> <p>Production Start Job List When a new production is needed we the production job to the list of procedures.</p> <p>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</p>	<p>Does Update Affect? <input type="button" value="No"/></p> <p>Risk Frequency due to Update <input type="button" value="2.Remote"/></p> <p>Risk Likly Due to Update <input type="button" value="2.Minor"/></p> <p>Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p> <div></div>	<p>Further Action Required on Issue</p> <div></div>
<p>76119Q26  Process 7737</p> <p>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.</p> <p>Audit is carried out and production is reviewed and chased at this point.</p> <p>Current Known Risk Production jobs is finished but not been QA, may get lost</p>	<p>Does Update Affect? <input type="button" value="No"/></p> <p>Risk Frequency due to Update <input type="button" value="2.Remote"/></p> <p>Risk Likly Due to Update <input type="button" value="2.Minor"/></p> <p>Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p> <div></div>	<p>Further Action Required on Issue</p> <div></div>

in the system
Current Likly 2 Current Frequency 2

76119Q27	 Process 7830 Review Q.A. Failures Report To review the Quantities of Failed product per Stock reference Passing through the Q.A. system Current Known Risk No risk Current Likly 3 Current Frequency 1	Does Update Affect? <div>No</div>	Risk Frequency due to Update <div>1.Improbable</div> Risk Likly Due to Update <div>3.Serious</div> Action Required: No Action Required	Notes On Risk / Benefits statement if required <div></div>	Further Action Required on Issue <div></div>
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76119Q28	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 Update Affect? <div>No</div>	Risk Frequency due to Update <div>1.Improbable</div> Risk Likly Due to Update <div>1.Negligible</div> Action Required: No Action Required	Notes On Risk / Benefits statement if required <div></div>	Further Action Required on Issue <div></div>
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76119Q29	Final Notes <div>PDF of existing DOC file no risk</div>
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SAVE FORM