

Document Audit 08 Training, Competence and Human Resources Viamed

Revision ID159445

Suggested Upload Document Name: **Risk Assessment For Updating Document ID159445**

Completed by [Derek Lamb](#) 19 Sep 2024

Reason for Risk Assessment

updated tasks 07

Training records are now held electronically. Task IDs 316 and 303. Check the tasks are carried out in a timely manner.

Document Audit 08 Training, Competence and Human Resources Viamed Revision ID159445 Is linked to the Following Standards and processes

Risk Assessment ID159445	Question	Does Update Affect	Risk on Update	Notes On Risk / Benefits statement i required
159445Q0	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 i required
159445Q1	Viamed Ltd ISO13485:2016 Section: 4.1 Quality management system	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 i required
159445Q2	Viamed Ltd ISO13485:2016 Section: 5.5.1 Responsibility and authority Top management shall ensure that responsibilities and authorities are defined, documented and communicated within the organization. Top management shall document the interrelation of all personnel who manage, perform and verify work affecting quality and shall ensure the independence and authority necessary to perform these tasks.	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 i required
159445Q3	Viamed Ltd ISO13485:2016 Section: 6.2 Human resources Personnel performing work affecting product quality shall be competent on the basis of appropriate education, training, skills and experience. The organization shall document the process(es) for establishing competence, providing needed training, and ensuring awareness of personnel. The organization shall: a) determine the necessary competence for personnel performing work affecting product quality; b) provide training or take other actions to achieve or maintain the necessary competence; c) evaluate the effectiveness of the actions taken; d) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives; e) maintain appropriate records of education, training, skills and experience (see 4.2.5). NOTE The methodology used to check effectiveness is proportionate to the risk associated with the work for which the training or other action is being provided.	Does Update Affect? Yes	Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement i required No risk
159445Q4	Viamed Ltd ISO13485:2016 Section: 6.4.1 Work environment The organization shall document the requirements for the work environment needed to achieve conformity to product requirements. If the conditions for the work environment can have an adverse effect on product quality, the organization shall document the requirements for the work environment and the procedures to monitor and control the work environment. The organization shall: a) document requirements for health, cleanliness and clothing of personnel if contact	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 i required

between such personnel and the product or work environment could affect medical device safety or performance;
b) ensure that all personnel who are required to work temporarily under special environmental conditions within the work environment are competent or supervised by a competent person.
NOTE Further information can be found in ISO 14644 and ISO 14698

159445Q5	<p>Viamed Ltd ISO13485:2016 Section: 7.3.2 Design and development planning The organization shall plan and control the design and development of product. As appropriate, design and development planning documents shall be maintained and updated as the design and development progresses. During design and development planning, the organization shall document: a) the design and development stages; b) the review(s) needed at each design and development stage; c) the verification, validation, and design transfer activities that are appropriate at each design and development stage; d) the responsibilities and authorities for design and development; e) the methods to ensure traceability of design and development outputs to design and development inputs; f) the resources needed including necessary competence of personnel</p>	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 i required
159445Q6	<p>Viamed Ltd ISO13485:2016 Section: 8.2.4 Internal audit The organization shall conduct internal audits at planned intervals to determine whether the quality management system: a) conforms to planned and documented arrangements, requirements of this International Standard, quality management system requirements established by the organization, and applicable regulatory requirements; b) is effectively implemented and maintained. The organization shall document a procedure to describe the responsibilities and requirements for planning and conducting audits and recording and reporting audit results. An audit program shall be planned, taking into consideration the status and importance of the processes and area to be audited, as well as the results of previous audits. The audit criteria, scope, interval and methods shall be defined and recorded (see 4.2.5). The selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work. Records of the audits and their results, including identification of the processes and areas audited and the conclusions, shall be maintained (see 4.2.5). The management responsible for the area being audited shall ensure that any necessary corrections and corrective actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities shall include the verification of the actions taken and the reporting of verification results. NOTE Further information can be found in ISO 19011.</p>	Does Update Affect? Yes	Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement i required No risk
159445Q7	<p>5881 Training Records Review Keep Staff Training records upto date See if any records need updating, also see if any records need signing off</p>	Does Update Affect? No	Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 2.Minor Action Required: No Action Required	Notes On Risk / Benefits statement i required
159445Q8	<p>5904 Taking On New Staff Check all new staff in the last 12 months have an Induction form filled in</p>	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 i required
159445Q9	<p>5936 Wages Calculations To print the time sheets and add any extras, overtime, sick days, or commissions.</p>	Does Update Affect? No	Risk Frequency due to Update 2.Remote Risk Likly Due to	Notes On Risk / Benefits statement i required

		Update 2.Minor Action Required: No Action Required	
159445Q10 6837	Personnel Requirements and Training Keep Staff Training records upto date	Does Update Affect? Yes Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 2.Minor Action Required: No Action Required	Notes On Risk / Benefits statement i required No risk
159445Q11 6851	Review Accident Book To look through the accident book and make sure there were no breaches of Health and Safety that were not reported.	Does Update Affect? No Risk Frequency due to Update 2.Remote Risk Likly Due to Update 2.Minor Action Required: No Action Required	Notes On Risk / Benefits statement i required
159445Q12 6877	Alarm Key Holders those that have keys and use the intruder alarm	Does Update Affect? No Risk Frequency due to Update 3.Occasional Risk Likly Due to Update 2.Minor Action Required: No Action Required	Notes On Risk / Benefits statement i required
159445Q13 6928	Eye Tests EYE TESTS Create new MOTD with the following	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 i required
159445Q14 7759	Health Declaration Sheet Information from the staff that would be used in case of emergency health issue. These are filled in by staff and filled securely.	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 i required
159445Q15 5934	Staff Training To check that any training that has been done is valid and then checked off the training record. Including enough detail to describe what has been coved in the training and any material used.	Does Update Affect? No Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 4.Critical Action Required: No Action Required	Notes On Risk / Benefits statement i required
159445Q16 7070	Management Review To discuss any problems, to assess work load and staffing. To review issues.	Does Update Affect? No Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 2.Minor Action Required: No Action Required	Notes On Risk / Benefits statement i required
159445Q17 7713	Review Roles And Responsibilitys Ensure All tasks allocated to active Members of staff,	Does Update Affect? No Risk Frequency due to Update 2.Remote Risk Likly Due to Update 2.Minor Action Required: No Action Required	Notes On Risk / Benefits statement i required

159445Q18 7884 Pay Review Review the staff pay, ensure its above minimum living wage and at a level appropriate to the work	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 i required
159445Q19 7883 Appraisal to review the staff, give feedback and discuss issues	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 i required
159445Q20 7908 Private Information Data remind staff about private information data and that it needs to be looked after and securely.	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 i required
159445Q21 7907 Annual Review Doc Management To review which employees have Access to sensitive areas of Intrastats	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 i required
159445Q22 7937 Diversity Impact Assessment Diversity Impact Assessment	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 i required
159445Q23 7951 Server Review Check the Server space and Size of important files	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 i required
159445Q24 7983 To Check On Line And See If There Have Been Any Changes To Gdpr We Need To Be Aware Of. To Check online and see if there have been any changes to GDPR we need to be aware of. Check web site for GDPR https://ico.org.uk/for-organisations/guide-to-data-protection/guide-to-the-general-data-protection-regulation-gdpr/whats-new/	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 i required
159445Q25 7982 Check There Are No Changes To Employment Law To Check online and see if there have been any changes to Minimum wage or employment law wee need to be aware of.	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 i required
159445Q26 38 Audits Up to Date and Confirm next years Audit schedule Management oversight of Internal Tasks and Audits Issue(s). Review the responses to Tasks and Audits. ensure they are being fulfilled and completed. Ensure Audits performed indendantly of audit area Ensure All ISO Sections linked to an Audit - QC 17 Route Map	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 i required

159445Q27 8054 Team Building Event - June Team Building Event - June	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 i required
159445Q28 8055 Christmas/Team Building Event - December Christmas/Team Building Event - December	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 i required
159445Q29 8067 Training Refresh Issues To Send / Questions To Write Training Refresh Issues to Send / Questions to Write Send issue to staff to re-read training material for the following - month dependant (if nothing has changed) and CH to issue new questions for completion. 1. Temperature Probes 2. TOF 3D 3. Phototherapy 4. Posey/Tidi 5. Envitec Oxygen Monitoring 6. Maxtec Oxygen Monitoring 7. Radiant Warmers 8. Finger Pulse Oximeters 9. Handheld Pulse Oximeters 10. Flow Sensors 11. Oxygen Sensors - Automotive 12. Medical Oxygen Sensors 13. AlcoTrue 14. Blenders IHC 15. Blenders Maxtec 16. V1000	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 i required
159445Q30 Process 7713 Review Roles And Responsibilitys Ensure All tasks allocated to active Members of staff, Current Known Risk That not all jobs will be allocated to a member of staff. That we may not share out jobs in a appropriate way. Risk of being over faced. Current Likly 2 Current Frequency 2	Does Update Affect? No	Risk Frequency due to Update 2.Remote Risk Likly Due to Update 2.Minor Action Required: No Action Required	Notes On Risk / Benefits statement i required
159445Q31 Process 6837 Personnel Requirements and Training Keep Staff Training records upto date Current Known Risk Keep enough trained staff to perform our tasks Current Likly 2 Current Frequency 1	Does Update Affect? Yes	Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 2.Minor Action Required: No Action Required	Notes On Risk / Benefits statement i required No risk
159445Q32 Process 56 Warehouse Outside Heating Guard Check the Boiler system before winter Current Known Risk working temperature incorrect / illegal Employee dissatisfaction Current Likly 1 Current Frequency 1	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 i required
159445Q33 Process 5919 Check Out Side Drain Check outside drain is not BLocked Current Known Risk that we will have a flood Current Likly 2 Current Frequency 1	Does Update Affect? No	Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 2.Minor Action Required: No Action Required	Notes On Risk / Benefits statement i required
159445Q34 Process 5921 Clearing Water Downstairs Check the Archives for Signs of Water, ensure the pump is working Current Known Risk that we will have a flood Current Likly 2 Current Frequency 1	Does Update Affect? No	Risk Frequency due to Update 1.Improbable Risk Likly Due to Update	Notes On Risk / Benefits statement i required

			<div>2.Minor</div> <div>Action Required:</div> <div>No Action Required</div>	
159445Q35	Process 7120 General Maintenance Requirements Review any General Maintenance required on the physical Site(s) Current Known Risk That a general Maintenance requirement may been missed. Current Likly 2 Current Frequency 1	Does Update Affect? <div>No</div>	Risk Frequency due to Update <div>1.Improbable</div> Risk Likly Due to Update <div>2.Minor</div> Action Required: No Action Required	Notes On Risk / Benefits statement i required <div></div>
159445Q36	Process 7742 Boiler Check Get the gas Boilers and Hive thermostat Serviced and the Heating Checked before Winter. Current Known Risk that the heating will not work or that the boiler is not safe to use. Current Likly 1 Current Frequency 2	Does Update Affect? <div>No</div>	Risk Frequency due to Update <div>2.Remote</div> Risk Likly Due to Update <div>1.Negligible</div> Action Required: No Action Required	Notes On Risk / Benefits statement i required <div></div>
159445Q37	Process 7756 Carbon Monoxide Alarm Check Carbon Monoxide Alarm is working Current Known Risk alarm does not work and kills staff Current Likly 2 Current Frequency 1	Does Update Affect? <div>No</div>	Risk Frequency due to Update <div>1.Improbable</div> Risk Likly Due to Update <div>2.Minor</div> Action Required: No Action Required	Notes On Risk / Benefits statement i required <div></div>
159445Q38	Process 7820 North Yorkshire Council Waste Tranfer The renewal of our waste transfer agreement with North Yorkshire County Cououncil Current Known Risk That we cannot get rid of waste or we have a supplier that takes waste but does not dispose of it in the correct legal manor. Current Likly 1 Current Frequency 2	Does Update Affect? <div>No</div>	Risk Frequency due to Update <div>2.Remote</div> Risk Likly Due to Update <div>1.Negligible</div> Action Required: No Action Required	Notes On Risk / Benefits statement i required <div></div>
159445Q39	Process 7821 Controlled Waste Description And Transfer The renewal of our waste transfer agreement with our waste disposal companies Current Known Risk That we cannot get rid of waste or we have a supplier that takes waste but does not dispose of it in the correct legal manor. Current Likly 1 Current Frequency 2	Does Update Affect? <div>No</div>	Risk Frequency due to Update <div>2.Remote</div> Risk Likly Due to Update <div>1.Negligible</div> Action Required: No Action Required	Notes On Risk / Benefits statement i required <div></div>
159445Q40	Process 7835 Electrics Need Checking To get the Electrics checked by External Electrictriction, so certificate can be provided for Employee Safety Current Known Risk Not carried out in a timely manner Current Likly 1 Current Frequency 1	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 i required <div></div>
159445Q41	Process 7836 Central Heating For Winter Reset the Heating for Winter Current Known Risk Building too hot / cold Current Likly 1 Current Frequency 1	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 i required <div></div>
159445Q42	Process 7864 ESD Work Stations Check the workshop benches ESD equipment is in place Current Known Risk can damage equipment if not used or suitable Current Likly 2 Current Frequency 1	Does Update Affect? <div>No</div>	Risk Frequency due to Update <div>1.Improbable</div> Risk Likly Due to Update <div>2.Minor</div> Action Required: No Action Required	Notes On Risk / Benefits statement i required <div></div>

159445Q43	Process 7873 On Site Environment Review Review the Highs and Lows in Temperature of stored stock and products. The temperature range can be found on the temperature page. Current Known Risk Building temperature could affect stock Current Likly 2 Current Frequency 2	Does Update Affect? No	Risk Frequency due to Update 2.Remote Risk Likly Due to Update 2.Minor Action Required: No Action Required	Notes On Risk / Benefits statement i required
159445Q44	Process 54 Gents Toilets Bleech the Gents Toilets Process no longer required no urinal Current Known Risk job not carried out Current Likly 3 Current Frequency 1	Does Update Affect? No	Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 3.Serious Action Required: No Action Required	Notes On Risk / Benefits statement i required
159445Q45	Process 5906 Empty Paper Bins Emptying of the recycling and waste bins into external bin for refuge collectors Current Known Risk Waste is not removed or waste is not correctly placed in bins Current Likly 1 Current Frequency 1	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 i required
159445Q46	Process 5907 Hoover Warehouse Cleaning of floors. Tidying so as to clean more effectively. Current Known Risk Dirty and unhygienic work space. Inadequate supply of cleaning products. Current Likly 1 Current Frequency 1	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 i required
159445Q47	Process 5908 Sweep Warehouse Cleaning of floors. Tidying so as to clean more effectively. Current Known Risk Dirty and unhygienic work space. Inadequate supply of cleaning products. Current Likly 1 Current Frequency 1	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 i required
159445Q48	Process 5909 Empty Warehouse Bins Emptying of the waste bins into external bin for refuge collectors Current Known Risk Waste is not removed or waste is not correctly placed in bins Current Likly 1 Current Frequency 1	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 i required
159445Q49	Process 5910 Clean Duckets Cleaning of duckets Current Known Risk Writing that is still left on the ducket mean that the new information may not be clear. Current Likly 1 Current Frequency 1	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 i required
159445Q50	Process 5911 Clear Cardboard To remove and dispose of the cardboard with in the company Current Known Risk That we will have too much and it will be a trip hazard. It will fill work spaces that we need to use. Current Likly 1 Current Frequency 1	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 i required
159445Q51	Process 7698 Clean Toilets Cleaning of surfaces, equipment, floors. Tidying so as to clean more effectively. Current Known Risk Dirty and unhygienic bathrooms. Inadequate supply of cleaning products. Current Likly 1 Current Frequency 1	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 i required

159445Q52	Process 7172 CE Technical Files Check that no Products / Designs have changed significantly to warrant informing MDD / Bsi / CMDCAS or any other related Body. Current Known Risk Non conforming product out on the market Current Likly 1 Current Frequency 1	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 i required
159445Q53	Process 8057 Emergency Services Show Emergency Services Show Emergency Services Show - September. Can we get a list of what stock and leaflets etc we need getting ready for this. This needs to be given to the marketing and warehouse teams for stock and ordering, well in advance please. Current Known Risk missed booking or supplies Current Likly 1 Current Frequency 1	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 i required
159445Q54	Final Notes No ISO Procedures or Process are negativly affected by updating this document with the new document proposed			

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