Internal Audit Check list

VIAMED LTD PROCESS VERIFICATION TO MANAGEMENT

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Audit Date	5-11-2025	Auditor Helen Lamb	

Company / ISO Section	Criteria of ISO Section	Auditor Comments / Issues
Viamed Ltd ISO13485:2016 4.1.3	**Quality management system** For each quality management system process, the organization shall: a) determine criteria and methods needed to ensure that both the operation and control of these processes are effective; b) ensure the availability of resources and information necessary to support the operation and monitoring of these processes; c) implement actions necessary to achieve planned results and maintain the effectiveness of these processes; d) monitor, measure as appropriate, and analyse these processes; e) establish and maintain records needed to demonstrate conformance to this International Standard and compliance with applicable regulatory requirements (see 4.2.5).	Roles + tasks Management Renew Route Maps Audits Doc Index
Viamed Ltd ISO13485:2016 4.1.4	**Quality management system** For each quality management system process, the organization shall: The organization shall manage these quality management system processes in accordance with the requirements of this International Standard and applicable regulatory requirements. Changes to be made to these processes shall be: a) evaluated for their impact on the quality management system; b) evaluated for their impact on the medical devices produced under this quality management system c) controlled in accordance with the requirements of this International Standard and applicable regulatory requirements.	Roles + tasks Management Renew Route Map Tech files
Viamed Ltd ISO13485:2016 4.2.1 General	**Documentation requirements** The quality management system documentation (see 4.2.4) shall include: a) documented statements of a quality policy and quality objectives; b) a quality manual; c) documented procedures and records required by this International Standard; d) documents, including records, determined by the organization to be necessary to ensure the effective planning, operation, and control of its processes; e) other documentation specified by applicable regulatory requirements.	Doc index Route Map Management Renew
Viamed Ltd ISO13485:2016 4.2.2 Quality manual	**Documentation requirements** The organization shall document a quality manual that includes: a) the scope of the quality management system, including details of and justification for any exclusion or non-application; b) the documented procedures for the quality management system, or reference to them;	Doc index Route Map Procedure

	c) a description of the interaction between the processes of the quality management system. The quality manual shall outline the structure of the documentation used in the quality management system.	
Viamed Ltd ISO13485:2016 5.1	**Management commitment** Top management shall provide evidence of its commitment to the development and implementation of the quality management system and maintenance of its effectiveness by: a) communicating to the organization the importance of meeting customer as well as applicable regulatory requirements; b) establishing the quality policy; c) ensuring that quality objectives are established; d) conducting management reviews; e) ensuring the availability of resources.	Procedures meetings Roles + tasks management Renew
Viamed Ltd ISO13485:2016 5.4.1	**Quality objectives** Top management shall ensure that quality objectives, including those needed to meet applicable regulatory requirements and requirements for product, are established at relevant functions and levels within the organization. The quality objectives shall be measurable and consistent with the quality policy.	management Renew Route map Roles + tasks
Viamed Ltd ISO13485:2016 5.4.2	**Quality management system planning** Top management shall ensure that: a) the planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives; b) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.	Route Map management Renew Doc index Roles + tasks
Viamed Ltd ISO13485:2016 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.	Roles + tasks Doc index management Renew
Viamed Ltd ISO13485:2016 5.5.2	**Management representative** Top management shall appoint a member of management who, irrespective of other responsibilities, has responsibility and authority that includes: a) ensuring that processes needed for the quality management system are documented; b) reporting to top management on the effectiveness of the quality management system and any need for improvement; c) ensuring the promotion of awareness of applicable regulatory requirements and quality management system requirements throughout the	Roles + tasks Doc index Procedures

	organization.	
Viamed Ltd ISO13485:2016 5.6.3	**Review output** The output from management review shall be recorded (see 4.2.5) and include the input reviewed and any decisions and actions related to: a) improvement needed to maintain the suitability, adequacy, and effectiveness of the quality management system and its processes; b) improvement of product related to customer requirements; c) changes needed to respond to applicable new or revised regulatory requirements; d) resource needs.	Doc Index management renew QA system Route map
Viamed Ltd ISO13485:2016 6.1	**Provision of resources** The organization shall determine and provide the resources needed to: a) implement the quality management system and to maintain its effectiveness; b) meet applicable regulatory and customer requirements.	management renew route map procedures
Viamed Ltd ISO13485:2016 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.	Audit Calendar route map Rdest tasks management renew
Viamed Ltd ISO13485:2016 8.3.4	**Rework** The organization shall perform rework in accordance with documented procedures that takes into account the potential adverse effect of the	Procedures

	rework on the product. These procedures shall undergo the same review and approval as the original procedure. After the completion of rework, product shall be verified to ensure that it meets applicable acceptance criteria and regulatory requirements. Records of rework shall be maintained (see 4.2.5).	QA System Doc Index
Viamed Ltd ISO13485:2016 8.5.3	**Preventive action** The organization shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be proportionate to the effects of the potential problems. The organization shall document a procedure to describe requirements for: a) determining potential nonconformities and their causes; b) evaluating the need for action to prevent occurrence of nonconformities; c) planning and documenting action needed and implementing such action, including, as appropriate, updating documentation; d) verifying that the action does not adversely affect the ability to meet applicable regulatory requirements or the safety and performance of the medical device; e) reviewing the effectiveness of the preventive action taken, as appropriate. Records of the results of any investigations and of action taken shall be maintained (see 4.2.5).	Doc Index procedure management Review Review meetings.

	INTERNAL PROCESS VERIFICATION A. Management System: B. Management Responsibility C. Resource Management D. Product Realisation E. Design & Development F. Product Provision G. Process Monitoring The following are questions that should be asked and answered either through Internal audits or at this meeting		
1	Review Last years Audit. Update processes if required. Are all follow on Issue resolved satisfactory. No non conformances.	Nothing outstanding	Y
	A – MANAGEMENT SYSTEM		
2	Is the Quality Statement Policy and Objectives reviewed annually. ISO – Document Index Task ID (300). Search Issues and review.	Issue 373456 up to date	Y

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3	Is the process manual up to date. ISO – Document Index Task ID (548). Search Issues and review.	Issue 578508 ✓ up to date	Y
4	Is VOP / VOP documentation checked prior to formal approval and issue.		Y
5	Check that there is a system in operation for the request for amendments.		Y
6	Verify that amendments are updated electronically and old copies archived.		Y
7	Are sales orientated records filed and archived correctly.	Digital and Automatic attached to contact order	Y
8	Has organisation Chart changed. VM3COP02.02		No
9	Has personnel responsibility descriptions changed. Roles Titles Processes and Procedures ADMIN Over View for complete list	SH left Jobs reassigned	Y
10	Check that the CE files are maintained by sole responsibility.		Y
11	Check that the Notified body is informed of major changes to Documentation.		Y
12	Check that electronic documents are regularly backed up and secure off site. ISO – Document Index Task ID (452). Search Issues and review.	Issue upto date 379919 ✓	Y
13	Does the management system comprise a series of process controls and are they in place throughout the organisation. Are processes identified.	Intrastats, Audit 10	Y
14	Check the system for its policies and objectives and its control of the above processes and procedures. Is the Standards Manual up to date and does it indicates the company's objectives. Are procedures in place – VM3COP Are they available to all personnel – Doc Index Are other company documents i.e. Technical Drawings, Standards; Operators Manuals etc. also available and controlled – Doc index	Intrastats, Audit 10 Roles and Responsibilities.	Y
15	Are the latest revision of documents controlled by version and date status and are they easily accessible. Is the Managing Director or designate manager still giving final approval for document changes.	Intrastats, Audit 10	Y
16	Has the Business Continuity Plan has expired. ISO – Document Index Task 266. Issue up to date 355537 ✓		Y
	B - MANAGEMENT RESPONSIBILITY		

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17	Is Top management showing full commitment to the overall system and are communication lines in place. Manage Review Task 290. 379406 up to date	Intrastats, Director in control of QA system	Y
18	Are all customer requirements defined and met.	Contract Review Audit 2	Y
19	Are all the processes and objectives, undertaken within the company, documented in Intrastats and have a procedure. Is it measurable. Check process for measurable task 114 380039 – Issues up to date Documented in Staff – Audit of Roles, titles and procedures.		Y
20	Does the person responsible for the management systems have the authority to implement actions and reports directly to top management with the need for these actions	Managing Director	Y
21	Are reviews of the management system undertaken regularly and the results and actions relayed throughout the organisation. Task 290 for weekly review ✓ Task 114 for bigger overview ✓ Task 746 for total review Being planned at present	Issues, Message of Day, company meetings, management meetings, Management weekly reviews	Y
22	Are all required actions undertaken in a timely manner and closed where appropriate.	Intrastats Issues	Y
23	Are all output requirements in such a format that verification against inputs, is applicable and appropriate. Is fitness for Purpose validated and is it measurable. Staff – Audit of Roles, titles and procedures – click into details - review Scope and Risks. To check relevance. Staff – Audit of Roles, titles and procedures check down the page for gaps in the IP 1-6 (end tick boxes)		Y
24	Are actions recorded against verifications completed in a timely and responsible manner.	Intrastats Issues	Y
25	Are design changes recorded and all the relevant information filed in the appropriate places. No design	Design control Audit 3 Intrastats	Y
	C - RESOURCE MANAGEMENT		
26	Has top management established a mechanism for identifying and providing required resources, training etc.	Training Audit 8 management review	Y
27	Does this include existing and new personnel.	Training Audit 8	Y
28	Has top management identified the competency levels and attributes required for existing and new personnel.	Training Audit 8 appraisals	Y
29	Is the competency of personnel monitored, verified and the	Training Audit 8	Y

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	appropriate records maintained		
30	Are personnel responsibilities defined.	Roles and Responsibilities	Y
31	Do individuals know their responsibilities, reporting and communicating lines. Each employee has 'My Roles' Link Task 314 373629 issues up to date	Intrastats communication	Y
32	Verify that all procedures, detail who is responsible for it.		Y
33	Check these roles and responsibilities also include Health & Safety tasks – Health and Safety Controller.		Y
34	Is the need for equipment, plant, services etc. identified and acted upon where necessary. Task 13 Part of audit 19 371416 issues up to date ✓	Production meetings, management meetings Health and Safety Questionnaire.	Y
35	Has the basic working infrastructure been planned with conformity to requirements in mind.	Health & safety Audit 19	Y
36	Are there adequate mechanisms in place for the identification, handling etc. of product through all stages.	COP/07	Y
37	Are the controls in place, to safeguard customer property, adequate for full protection against loss damage etc.	COP/09	Y
38	Is the process for monitoring and measurement of product in place at all stages throughout the production process.	Production COPs	Y
39	Is the process for control of measuring equipment adequate for the monitoring of product verifications.	Calibration Audit 06	Y
40	Are validity processes in place to safeguard product integrity.	Bar coding traceability	Y
	D - PRODUCT REALISATION		
41	Is the planning process for the realisation of product undertaken at the relevant stages.		Y
42	Does planning identify documentation, testing and other such activities as required and that all appropriate records are maintained.		Y
43	Are all customer requirements being addressed, including statutory and regulatory and that the capabilities are identified to meet those requirements.	Contract Review Audit 02	Y
44	Establish that mechanisms are in place to review all customer requirements prior to any commitments by the organisation.	Contract Review Audit 02	Y
45	Check that there are adequate arrangements for customer communications and feedback.	Contract Review Audit 02	Y
46	Is collation and analysis of all relevant data determined and effective. Is corrective actions identified.		Y
47	Are these actions completed in a timely and adequate manner and are these actions part of continual improvements.		Y
48	Does the organisation have preventive measures in place to control potential non-conformities.		Y

49	Are all the above actions are reviewed adequately.		Y
	E - DESIGN & DEVELOPMENT Nc Design		
50	Are procedures in place to ensure adequate planning of product design and that all relevant stages are identified.	Design control Audit 3	Y
51	Are the interfaces and assignments of responsibilities identified.	Design control Audit 3	Y
52	Are all input requirements determined. Is the documentation identified.	Design control Audit 3	Y
53	Are all output requirements in such a format, that verification against inputs is applicable and appropriate. Is Fitness for Purpose validated.	Design control Audit 3	Y
54	Are actions recorded against verifications completed in a timely and responsible manner.	Design control Audit 3	Y
55	Are validation processes in place and are they determined in accordance with the relevant requirements.	Design control Audit 3	Y
56	Are design changes recorded and all the relevant information filed in the appropriate places.	Design control Audit 3	Y
	F - PRODUCT PROVISION		
57	Are supplier profiles adequate and appropriate for the organisation. Are they monitored, for their ability to provide the requirements, is this monitoring controlled.	Purchasing Controls (Supplier Performance) Audit 5	Y
58	Is all the required information necessary, forwarded to suppliers in the correct format. Will be system controlled.	Purchasing Controls (Supplier Performance) Audit 5	Y
59	Are goods and services received correct to the requirements stipulated.	Goods Inward Audit 9	Y
60	Are the provisions available, suitable for control of production and service, including procedures and equipment etc.	Production Audit 15	Y
61	Are there adequate mechanisms in place for the identification, handling etc. of product through all stages.	Production Audit 15	Y
62	Are the controls in place to safeguard customer property adequate for full protection against loss damage etc.	Production Audit 15	Y
63	Is the process for monitoring and measurement of products in place at all stages throughout the production process.	Production Audit 15	Y
64	Is the process, for control of measuring equipment, adequate for the monitoring of product verifications.	Calibration Audit 6	Y
	G - PROCESS MONITORING		
65	Are mechanisms in place to monitor all relevant processes, including customer satisfaction. Are these verified against known criteria. Check process ID 114 380039 ✓ Issues Up to Date		Y
66	Are controls in place for non-conforming product and processes. Are adequate to prevent unintended uses.	Goods Inward Audit 9	Y
67	Where non-conforming product / process have been detected is	Goods Inward Audit 9	Y

	appropriate action taken.		
68	Is collation and analysis of all relevant data determined and effective Is corrective actions identified.		Y
69	Are these actions completed in a timely and adequate manner. Are these actions part of continual improvements. •		Y
70	Are all the above actions are reviewed adequately. Check process ID 114 380039✓ issue up to date	Annually	Y
71	Are regular analyses undertaken to identify any outstanding requirements.	Intrastats	Y
72	Are necessary changes implemented where and when required.		Y
73	Is any outsourcing done.		NO
74	Check the documented system for its policies, objectives and its control of the above processes and procedures. Intrastats – document index – VM3COP00.00 / VM3COP00.01. Check documents for location of objectives and policies.	Intrastats	Y
75	Are records of inspections filed.	Audits	Y

Sub Processes Linked to Audit

Review the below processes tasks and audits and ensure they are completed in a timely manner.

List Processes Per Title

Managing Director				
Process Scope	**Roll Task** **Roll Audit**	**Risk**	**Action**	N
PROCESSID **7837** To Review the External Parties Influencing The QMS VST / Viamed Checked the Scopes and Risks, Review the Underlining Processes and Tasks	Task: 743 376739✓ Managing Director Audit :784 379685✓ Company Secretary	Freq 1 Risk 1 Overall 1	Task 12M Audit 12M	
PROCESSID **7845** Determine, provide and maintain the environment necessary for the operation of its processes and to achieve conformity of products and services. Merged into 7729 can close the tasks	Task: 745 Audit :	Freq 1 Risk 1 Overall 1		
PROCESSID **7846** To Comply with Top Level Re-authorise the Current Audits for next 12 Months	Task: 746 371466 Managing Director Nov due.	Freq 1 Risk 1 Overall 1	Task 12M	

Cover the Agenda as Per VOP13	Audit :			
PROCESSID **7848** To Review the Scope of the ISO 9001 / ISO 13485 Standards	Task: 749 376486 Managing Director Audit :	Freq 1 Risk 1 Overall 1	Task 12M	
PROCESSID **7871** To review the Exclusions / boundaries to ISO 13485:2016 for Viamed	Task: 790 371470 Managing Director Audit :	Freq 1 Risk 1 Overall 1	Task 12M	
ISO and Compliance Controller				
Process Scope	**Roll Task** **Roll Audit**	**Risk**	**Action**	N
PROCESSID **6866** Review the Internal Process and Verification`s are suitable for the current standards PROCESS NOW CANCELLED AS REPEAT OF AUDIT 20	Task: 55 Audit :	Freq 1 Risk 1 Overall 1		
PROCESSID **7827** To review the Quality policy and check it is still valid and upto date.	Task: 301 373457 Managing Director Audit :	Freq 1 Risk 1 Overall 1	Task 12M	
PROCESSID **7828** To review the Quality policy and check it is still valid and upto date.	Task: 723 373496 Managing Director Audit :	Freq 1 Risk 1 Overall 1	Task 12M	
IT Controller				
Process Scope	**Roll Task** **Roll Audit**	**Risk**	**Action**	N
PROCESSID **7701** Amazon Web Services, is an online service, which basically simply provides a Linux PC out on the Web. Viamed uses this, for Web development of Websites: It hosts a working backup of many websites. Viamed / vst / vandagraph etc..	Task: 511 377820 Office Processes Audit :	Freq 3 Risk 1 Overall 3	Task 12M	
PROCESSID **7755** To Send Invoices for online services to Helen every 12 months on the issue	Task: 597 377835 Office Processes Audit :	Freq 3 Risk 1 Overall 3	Task 12M	
PROCESSID **7832** Backup of all Sent Emails sent to External Address for Verification	Task: 731 380072 Office Processes Audit :1243 378274 Managing Director	Freq 1 Risk 1 Overall 1	Task 2W Audit 12M	
PROCESSID **7850** Test the Goods out process disabling picking of items not	Task: 752 Goods Out 374024	Freq 1 Risk 1	Task 9M Audit 12M	

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relating to an order	Audit :753 354355 ✓ Managing Director	Overall 1		
PROCESSID **7851** To test intrastats does not allow picking of unprocessed products to live customer orders	Task: 754 366887 ✓ Goods Out Audit :755 354356 ✓ Managing Director	Freq 1 Risk 1 Overall 1	Task 6M Audit 12M	
PROCESSID **7852** To attempt to Scan a product that has gone past its expire date.	Task: 756 377841 ✗ in terms Goods Out Audit :757 357131 ✓ Managing Director	Freq 1 Risk 1 Overall 1	Task 12M Audit 12M	
PROCESSID **7853** Warehouse shelfs 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	Task: 759 376026 ✓ Goods Out Audit :760 348619 ✓ Managing Director	Freq 1 Risk 3 Overall 3	Task 12M Audit 12M	
PROCESSID **7854** 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	Task: 761 376741 ✓ Goods In Audit :762 379682 ✓ Managing Director	Freq 2 Risk 2 Overall 4	Task 3M Audit 6M	
PROCESSID **7855** Software Validation - Production Lists Review the current active production lists inintrastats to the actual in progress production lists	Task: 761 376741 ✓ Goods In Audit :762 379682 ✓ Managing Director	Freq 2 Risk 2 Overall 4	Task 3M Audit 6M	
PROCESSID **7856** To check order picking cannot pick against an unchecked order	Task: 764 350940 ✓ Office Processes Audit :765 348620 ✓ Managing Director	Freq 2 Risk 2 Overall 4	Task 12M Audit 12M	
PROCESSID **7857** To confirm Software Validation Stock Tracking Check, is functioning as expected	Task: 763 377454 ✓ Goods In Audit :1155 357163 ✓ Managing Director	Freq 2 Risk 1 Overall 2	Task 6M Audit 12M	
PROCESSID **7858** Test the QA System that Staff not trained for QA are unable to QA a Product.	Task: 766 365827 ✓ Office Processes Audit :1175 355071 ✓ Managing Director	Freq 1 Risk 3 Overall 3	Task 6M Audit 12M	
PROCESSID **7861** Software Validating Of Training Documents via Forced Required Reading	Task: 768 377169 ✓ Managing Director Audit :	Freq 1 Risk 2 Overall 2	Task 12M	

PROCESSID **7865** 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.	Task: 779 377455 Managing Director Audit :781 378013 Managing Director	Freq 1 Risk 1 Overall 1	Task 12M Audit 12M	
PROCESSID **7870** Scope to check the automatic system of tagging product non conformance and other issues to the post market surveillance review report.	Task: 789 378259 Managing Director Audit :	Freq 1 Risk 1 Overall 1	Task 12M	
PROCESSID **7875** To test document control is working as intended.	Task: 802 378525 Managing Director Audit :803 379686 Company Secretary	Freq 1 Risk 1 Overall 1	Task 12M Audit 12M	
PROCESSID **7879** To check the Scheduled Tasks and Audits is working as Intended. To also Check the Out of Date documents is working as Intended.	Task: 808 353229 Managing Director Audit :809 379075 Company Secretary	Freq 1 Risk 1 Overall 1	Task 12M Audit 6M	
PROCESSID **7880** To confirm the out of documents computer software functions as expected flagging out of date items on to the list	Task: 808 353229 Managing Director 379075 Audit :809 Company Secretary	Freq 1 Risk 1 Overall 1	Task 12M Audit 6M	
PROCESSID **7881** To compare Opera Live Orders to Intrastats Back order Active List NO LONGER REQUIRED Opera is now out of the system	Task: 810 Audit :	Freq 1 Risk 1 Overall 1		
Audits				
Process Scope	**Roll Task** **Roll Audit**	**Risk**	**Action**	*N
PROCESSID **7723** To carry out Audit 10b Process Verification Viamed Now Defunct - See Audit 20	Task: Audit :3	Freq 1 Risk 2 Overall 2		
PROCESSID **7730** To carry out Audit 20 Process Verification To Management Viamed Any follow on issues must be identified with Observation Issue or a Non Conformance Issue. If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.	Task: Audit :172 379629 Audit Company Secretary	Freq 1 Risk 2 Overall 2	Audit 12M	
PROCESSID **7771**	Task:	Freq 1		

To carry out Audit 10b Process Verification VST Now Defunct - See Audit 20	Audit :177		Risk 2 Overall 2	
PROCESSID **7778** To carry out Audit 20 Process Verification To Management VST Any follow on issues must be identified with Observation Issue or a Non Conformance Issue. If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.	Task: Audit :181 Company Secretary 379630x Audit		Freq 1 Risk 2 Overall 2	Audit 12M

Rolling Tasks Linked to Document :Task (3) Task (172) Task (177) Task (181) Task (55) Task (301) Task (723) Task (743) Task (745) Task (746) Task (749) Task (790) Task (511) Task (597) Task (731) Task (752) Task (754) Task (756) Task (759) Task (761) Task (764) Task (763) Task (766) Task (768) Task (779) Task (789) Task (802) Task (808) Task (810)