Internal Quality Audit Checklist

Audited Unit:

Date:

HALCYON MARINE
HEALTHCARE SYSTEMS

Audited by: _____

Signature:_____

_____

Signature: _____

Auditee:

_____

Signature:_____

Clause No.	Requirement	Applicable Unit		Audit Items	Y/N	Evidence	Observation/Findings
4	**Context of the Organization**						
4.1	Understanding the Organization and its Context	All Units	1	is the auditee aware of the internal and external issues in his/her unit? Can the auditee differentiate these issues?			
			2	Are there present internal issues that the unit is encountering? What are those issues?		E-mail Memo Minutes of the Meeting	
			3	Are those issues given corrective actions and are being monitored and implemented? How?		CAR Logbook/Forms and actual	
			4	Are the issues properly communicated to the unit by the management for awareness? Is there a documented evidence?		E-mail Memo Minutes of the Meeting	
			5	Are the corrective actions from the issues incorporated in the procedures		Procedures	
4.2	Understanding the Needs and Expectations of Interested Parties	All Units	1	Is the auditee aware of the interested parties of the unit? Can they determine those interested parties?			
		All Units	2	Is the auditee aware of the client's requirements? Is he/she can identify identify client's requirements based on medical package wherein the audited unit is covered?		Medical package on database vs. approved medical package	
		All Units	3	Is the auditee aware that the requirements of interested parties are reviewed and updated? i.e revision of client's packages. How?		Minutes of the meeting (Contract review)	
		All Units	4	Is the auditee monitored or ensured functionality and accuracy of testing tools and equipments? How?		Service report for repairs Calibration certificates /Stickers	
		All Units	5	Is the auditee ensures completeness of the unit's supply to ensure smooth operations? How?		Purchase requests Supplies monitoring	
4.3	Determining the Scope of the Quality Management System	All Units	1	Is the auditee aware of the products and services offered by the clinic? What are they?			
		All Units	2	Is the auditee aware of the requirement of the products and services offered by the clinic? and by his handled unit? how?			

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		All Units	3	Is aware with the International Standard and how to apply in his/her process to provide the required products and services?	Work Instructional Manuals vs. practice	
4.3	Determining the Scope of the Quality Management System	All Units	4	Is the auditee knowledgeable on his/her Work Instructional Manual? Including the following items below and how? 4.1 controls to ensure quality service/products? 4.2 required resources & availability 4.3 can explain his/her Job description 4.4 knows area to monitor? 4.5 Can explain when and how monitoring is being used? 4.6 Knows changes in the unit's process? How?	Work Instructional Manuals vs. practice	
		All Units	5	Is the auditee reviews his/her Work instructional Manual for update? When and How?	Work Instructional Manuals	
4.4	Quality Management System and its Processes	All Units	1	Are there documented information to support the unit's process/procedure? What are they?	Quality Manuals Work Instructional Manuals	
		All Units	2	How they are kept or saved?		
		All Units	3	Are the documented information updated in its latest revision?		
		All Units	4	Are the forms used updated and in its latest revision?		
		All Units	5	Are there external references used to ensure the unit's compliance to legal or regulatory requirements? i.e. DOH , DPA, etc.	DOH reference guidelines Client Guidelines	
5	**Leadership**					
5.1	Leadership and Commitment for the Quality Management System	Management	1	Is the management able to demonstrate active pariticipation and support with the ISO 9001:2015 and had improvement plans? How?	Management review Minutes of the meeting	
			2	Is the company's vision and mission reviewed? When and How?	Management review Minutes of the meeting	
5.1.2	Customer Focus		3	Is the top management shows customer focus in ensuring that qms and other regulatory or statutory requirements are met?	Minutes of the meeting	
			4	Is there a system to identify risk and oppurtunities in the unit or with the management?	Quality Manual- Objectives/Policies	
		Management/All Units	5	Is the Management/unit has system to enhance customer satisfaction?	Quality Manual- Objectives/Policies	
			1	Is the quality policy aligned with the company's Vision and Mission? How?		
			2	Is the company's quality policy reviewed? When and How?		

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5.2	Quality Policy	All Units	3	Is the company quality policy communicated to the auditee? How?		Management review Minutes of the meeting	
			4	Is the auditee aware and understood the the company's quality policy?			
			5	Is the auditee aware of ISO 9001: 2015 related activities implemented by the management?		Memo Scheduled audits	
5.3	Organizational roles, responsibilities and authorities	Management	1	Does management ensure that the responsibilties and authorities are assigned, communicated and understood in the organization for implementation of QMS? How?		Job description	
			2	Is management ensures conformance to the QMS requirements by assigning responsibility and authority to ensure maintenance?		Job description	
		All Unit	3	Has auditee signed his/her Job description?		Job description	
		All Unit	4	Has auditee understood his assigned duties and responsibility?		Actual interview	
		All Unit	5	Has understood his job description		Actual interview	
6	**Planning**						
6.1.	Actions to Address Risks and Opportunities	All Units	1	Is the unit has a process or procedures to identify the risk and opportunities in the current system? How?		Contingency plans Improvement plans	
		All Units	2	How the unit prevents or reduces undesirable services/ products to achieve continual improvemt?		Quality Objectives	
		All Units	3	Are the actions ro address undesirable services/products recorded? How?		CAR DCR and Revised Manuals	
		All Units	4	Are actions evaluated for effectiveness?		Revised Manuals	
		All Units	5	Are the actions consistently implemented?		Revised Manuals vs. actual practice	
6.2	Quality Objectives and Planning to Achieve Them	All Units	1	Is there a Quality objectives in the unit?		Quality Manual	
		All Units	2	Has the auditee undertstood the quality objectives and its consistency with the quality policy to enhance customer satisfaction?			
		All Units	3	Are they measurable?			

		All Units	4	Are the quality objectives are monitored and evaluated? How?		Monitoring	
		All Units	5	Are quality objectives reviewed and updated? Every when and How?			
6.3	Planning of Changes	Top management	1	Is top management has planning for changes ih the Quality Management system? Every when?		Management review Minutes of the meeting	
		All Units	2	Is the planning of changes includes to address customer complaints?		Management review Minutes of the meeting	
		All Units	3	Is the planning of changes includes to address unit defficiences procedures or policies?		Management review Minutes of the meeting	
6.3	Planning of Changes	Top management	4	Does it includes avaialbility of all resources? Man, machine and Infrastructure?		Management review Minutes of the meeting	
			5	Does it include improvement plans?		Management review Minutes of the meeting	
7	**Support**						
7.1.1	Resources: Supplies	All Units	1	Is the unit has a system to determine needed supplies? How? a.) office supplies b.) medical consumables? c.) medicines/vaccines? d.) testing tools? e.) solutions?		Supplies monitoring	
		Purchasing	2	Are supplies within standard specification and expiry/validity dates to ensure quality?		Product package/label indication	
		Purchasing	3	Are supplies monitored and always available for use? How		Inventory monitoring	
		Purchasing	4	Are suppliers readily available in cases of concerns?		List of Supplier-Name of Contact person	
		Purchasing	5	Are suppliers readily available in cases of repairs?		List of Supplier-Name of Contact person Service Report for Repairs	
7.1.2	Resources: People	All Units	1	Does the unit has a system to determine needed manpower? How?		Manpower request form	
		All Units	2	Are manpower in the unit adequate?		Attendance	
		All Units	3	Does the unit has contigency plan when there is inadequate manpower?			
		All Units	4	Are manpower in the unit competent and qualified? How?		Training Certificate Updated PRC	
		All Units	5	Are manpower in the unit has alloted training program?			

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7.1.3	Resources: Infrastructure	All Units	1	Does the unit has a system to determine needed and required infrastructure(i.e electrical, water supply? telecommunication? How?			
		All Units	2	Is the unit facility suitable for operations?			
		All Units	3	Is infrastructure in the unit in good working condition?			
		All Units	4	Is infrastructure in the unit well maintained?			
		All Units	5	Are needed/required repairs immediately done?			
7.1.4	Resources: Environment for the Operation of Processes	All Units	1	Is the unit's working environment safe?			
			2	Is the unit's working environment within required temperature?		Temperature Monitoring	
			3	Are the medical supplies stored in the unit within favorable temperature?		Temperature Monitoring	
			4	Are temperature specification monitored regularly? How?		Temperature Monitoring	
			5	Are for repairs? If yes, are they immediately done?		Service Report for repairs	
			1	Are resources are within specification to ensure suitability and purpose of its use?		Calibration /PM sticker	

7.1.5	Resources: Monitoring and Measuring Processes	All Units	2	Is the unit can show documented information where the measuring resources/testing equipment is fit or suitable for use? Is it within the validity date?		Calibration/PM certificate	
		All Units	3	Are the measuring tools and equipment timely calibrated? how?		Calibration Schedule vs. Calibration sticker	
		All Units	4	Are there standards documented in the certificates? Is the measuring tools/equipment reach the standard specification?		Calibration/PM certificate	
		All Units	5	Are measuring tools and equipment protected from damage and deterioration? How?		Calibration/PM certificate	
7.1.6	Resources: Organizational Knowledge	HR	1	Is the organization has a system when and where to obtain personnel with knowledge on operations to ensure product and service conformity? How?		HR training plan	
			2	How to maintain this knowledge and how do you make it available to the extent necessary?		HR training plan	
			3	How do you consider current knowledge and how do you acquire additional knowledge when addressing changing needs and trends?		HR training plan	
		All Units	4	Is the unit encourages personnel knowledge and considers it for the benefit of its operations?			
		All Units	5	Is personnel knowledge shared in the organization and implemented?			
7.2	Competence	HR	1	Are personnel in the unit competent? How? a.) education b.) training c.) experience		Manpower criteria vs. resume Psychological Test and other HR testings and interview	
			2	Is personnel undergone trainings for job competency?		HR training records Certificates	
			3	Are training needs identified and analyzed?			
			4	Are training effectiveness monitored? How?			
			5	Maintained records for education, experience, training and qualification as evidence of competence?			
7.3	Awareness	All Units	1	Is the auditee aware of his/her contribution for the effectiveness of QMS?			
		All Units	2	Is the auditee aware of the company's performance? /units performance?			
		All Units	3	Is the auditee aware what are the effects of there are product and service non-conformances? Complaints?			

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		All Units	4	Is auditee aware of the current policies implemented by Management? How?		
		All Units	5	Is auditee aware of the unit's policies? revisions on procedures or new packages? How?		

7.4	Communication	All Units	1	Is communication coordination present in the unit to carry out task required by QMS ? How?		Endorsement logbook
		All Units	2	Is there a record of communication?		Memo Endorsement logbook
		All Units	3	Is record of communication verifiable and traceable?		
		All Units	4	Is auditee aware of any external communication coming from clients? How?		
		All Units	5	Is auditee aware on the effect of not conforming with the QMS requirements?		
7.5	Documented Information	QMS	1	Does the organization has a system in creating and updating documents?		Document Change request Quality System Standard
7.5.2	Documented Information: Creating and Updating		2	Does the organization has a process in controlling documents/records in the following manner, 2.1 Access 2.2 Distribution 2.3 Retrieval and Use		Quality System Standard
			3	Does the organization considers storage and preservation of documents and forms?		Quality System Standard
			4	Does the organization has document /record disposition process?		
			5	Are back up files readily available? How		
			6	Are documents contained the following , 5.1 Identification 5.2 Description 5.3 Revision status for changes 5.4 Prepared and aprroved by for suitability and adequacy? 5.5 In hadcopy or digital format?		Quality System Standard
			7	Is the organization has a system to identify external document/ from external origin? Is the unit has external document/forms used?		Quality System Standard
7.5.3	Documented Information: Control of Documented Information	Unit	1	Are records and logbooks poroperly stored and protected?		Forms and logbooks
			2	Are records and logbooks readily available for use?		Forms and logbooks
			3	Are recorded logs on forms and logbooks readable and verifiable?		Forms and logbooks
			4	Are records stored at its appropriate retention period?		Forms and logbooks
			5	Are forms, logbooks and folder in their updated control numbers?		Forms and logbooks
			6	Are there identified external forms or document reference in the unit? Is it controlled?		Forms and logbooks
8	**Operations**					
8.1	Operational Planning and Control	All Units	1	Are there document processes in place to ensure requirements for products and services are met? What are these processes?		
			2	How are acceptance for products and services determined?		

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			No.	Question		Evidence	
			3	Does the unit has documented evidence to show product or service conformity?		Records	
			4	Does the documented evidence verified and validated by Specialists?		Records	
			5	Does the documented evidence approved by Management?		Records	
8.1	Operational Planning and Control	All Units	6	How do you control planned changes?		Management review Contract Review	
			7	How do you review the consequences of unintended changes?		DCR	
			8	What action is taken to mitigate any adverse effects?			
			9	Are output from the planning process implemented? How?		DCR	
			10	Are the output from planning process communicated to all concerned for awareness?		Attendance record	
			11	How do you control outsourced processes?			
8.2 & 8.2.1	Requirements for Product and Services and Customer Communication	PEME Account specialist	1	How are Client's requirements identified?		Medical package	
			2	Are client's requirements approved and documented?		DCR of medical Package	
			3	Is there processes for communicating with Clients in providing information relating to PEME, medical services and certification?		Emails	
			4	Is there a communication process in handling inquiries, contracts including changes and endorsement through phone?		Emails Contract review	
			5	Is communication available in case of client feedback and complaints?		Emails and CARs	
		Units	1	Are correct medical packages used ? How are they monitored?		Medical package	
			2	How errors are monitored in medical packages?			
			3	Are the errors addressed? How?			
			4	Are the errors initiate changes in the process or procedure? How?			
			5	Are the errors communicated to all concerned for awareness?			
8.2.2	Determination of Requirements for Products and Services	PEME Account specialist	1	Are medical packages compliant with the requirements and format of Clients or principals?		Client requirement vs. Medical package	
			2	Are medical packages compliant with the requirements of local government-DOH?			
			3	Are medical packages compliant with P & I club or ship owners?			
		All Unit	4	Are medical packages duly approved and updated as per Document Change request?			
		All Unit	5	Are all medical packages used active and existing? No obsolete medical packages?			

8.2.3	Review of Requirements Related to Products and Services	All Unit	1	Is there a process to determine the requirements for products and services to patients and clients? What is the documented evidence?		
			2	Are product and service requirements are met? How?		
			3	Is there a process to review customer requirements for delivery and post delivery?	Contract review meeting details	
8.2.3	Review of Requirements Related to Products and Services	All Units	4	Are service contract in place including the review of product and service requirements?		
			5	Is there a system to review the requirements prior commiting to supply products and services?		
8.2.3	Review of Requirements Related to Products and Services	All Units	6	Is there a documented evidence that new or changed requirements for products and services are retained?	Client Profile vs. Medical package vs. DCR	
			7	is there a documented information containing changes to products and services		
			8	How do you ensure that relevant personnel are made aware of those changes?	Attendance record on minutes of the meeting	
8.4.1	Control of Externally Provided Products and Services: General	Purchasing	1	Is there a process to ensure that externally provided products and services conform to requirements? How and what?	P.O vs. actual Medical package vs. ticket	
		Pur/Admin/HR/MIS	2	Are there outsourced products or services in the unit?		
		Pur/Admin/HR/MIS	3	Is there a criteria of evaluation? Is there an documented evidence for it?	Calibration/PM certificate	
		Purchasing	4	Is there monitoring of performance and re-evaluation of external providers? How?	Evaluation records	
		Purchasing	5	How is the selection process? Is there a documented evidence?	Canvassing	
		Purchasing	6	How to assess performance on their ability to provide products and services in accordance with specified requirements?	Evaluation records	
		Purchasing	7	Is there a documented evidence on the evaluation results suppliers/providers? Are the result evaluatedonitored? How to address failed performance evaluation?	Evaluation records	
		Unit	8	What verification or other activities do you have to ensure externally provided processes, products and services do not adversely affect your ability to consistently deliver conforming products and services to your customers?	Ticket Logbooks	
		Purchasing	9	Is the organization knows when processes or functions are to be outsourced? What are the controls?		

		HR/Purchasing/Ope rations	10	How do we communicate with external providers? in terms of the following, a. Products and services to be provided or the processes to be performed on behalf of the organization; b. Approval or release of products and services, methods, processes or equipment; c. Competence of personnel, including necessary qualification; d. Their interactions with the organization's quality management system; e. The control and monitoring of the external provider's performance to be applied by the organization; f. Verification activities that the organization, or its customer, intends to perform at the external provider's premises.		

8.5	PRODUCTION AND SERVICE PROVISION						
8.5.1	Production and Service Provision: Control of Production and Service Provision	All Units	1	Are there controlled conditions in service provision during delivery and post delivery activities?		Medical package Ticket Surveys	
			2	Are there documented information where characteristics of products and services are defined?		Medical package	
			3	Are there documented information in defining activities to be performed and results to be achieved? c) monitoring and measurement activities at appropriate stages to verify that criteria for control of processes and process outputs, and acceptance criteria for products and services, have been met. d) the use, and control of suitable infrastructure and process environment; e) the availability and use of suitable monitoring and measuring resources; f) the competence and, where applicable, required qualification of persons; g) the validation, and periodic revalidation, of the ability to achieve planned results of any process for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement; h) the implementation of products and services release, delivery and post-delivery activities		Manuals Logbooks Monitoring logs employee certificate and training	
8.5.2	Production and Service Provision: Identification and Traceability	All Units	1	Are there process involved to ensure output are within conformity?		Medical results Logs	
		All Units	2	How do you control the unique identification of process outputs, where applicable? What documented information do you retain?		Ticket	
8.5.3	Production and Service Provision: Property Belonging to Customers or External Providers	Purchasing		Are external customer's/provider's property identified? How?			
		Purchasing	2	Is there external property in the unit? What was the identification?			
		Purchasing	3	What care do you provide for customer or external provider's property while under your control?			
		All Unit	4	How do you identify, verify, protect and safeguard that property which is provided for use or incorporation into your products or services? How?			
		All Unit	5	Is there a system in place on how to report external customer/external provider's property in case it was lost, damaged or unsuitable for use?			
8.5.4	Production and Service Provision: Preservation	All Unit	1	Are sample specimen, X-ray, ultrasound images, dental x-rays, testing unit results, tracings, medical certificates preserved? How?			
			2	Are patient's personal effects preserved? How?			
			3	Are medical and laboratory supplies are stored and preserved? How?			

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	Production and Service Provision: Preservation		4	Is laboratory and testing units have procedure to handle accidents so as to preserve speciman samples and medical results on hand?		
			5	How to preserve speciman on send out laboratory?		
8.5.5	Production and Service Provision: Post - Delivery Activities	All Units	1	Is the unit ensures to meet post delivery requirements or PEME results and certificates to patients? How?	ticket Medical package	
			2	Has tests with specified validity?		
			3	Does the unit ensures that customer requirements are met? How?		
			4	Does the unit ensures that medical results give are correct? How		
			5	Accepts patient feedback on the medical result and knows to address them? How?		
8.5.6	Production and Service Provision: Control of Changes	All Units	1	Is there evidence that changes in packages, PEME procedures,forms and certification format are controlled? How?		
			2	Are changes discussed? Every when?		
			3	Is there a documented information of the changes?	DCR	
			4	Is there a procedure to confirm and validate correctness of test results prior releasing to the client? How?		
8.6	Release of Products and Services	Documentation	6	Does it show conformity with the medical package?	Medical certificate	
		Documentation	7	Is it traceable to the personnel who authorized the release? How?	Medical certificate	
		All Units	8	Test results document are traceable? How?		

8.7	Control of Non-Conforming Process Outputs, Products and Services	QMS	1	Is the organization has a procedure to control non-conforming products and services?		QSS	
		All Units	2	What procedure does it indicate?			
			3	Are non-conforming medical results or medical reports identified and properly segregated? How?			
			4	Is the procedure in the control of non-conforming products includes correction, containment, informing the customer and obtaining authorization for approval? How?			
		QMS	5	Is there a documented non-conformance report in place?		QSS	
		All Units	6	Is the unit has reported non-conformance?			
			7	Are non-conformance reports monitored? How?			
			8	Are the corrective actions implemented to address non-conformance? How?			
9	**Performance Evaluation**						
9.1.1	Monitoring, Measurement, Analysis and Evaluation: General	All Units	1	Is the organization has a system in evaluating unit's performance? How?		Quality Objectives	
			2	Is client or patient satisfaction monitored? How?			
			3	Is client or patient dissatisfaction or complaint considered? How?			
		Purchasing	4	Is there an analysis and evaluation on the performance of external providers, such as suppliers? How?		Evaluation records	
			5	Is there an analysis and evaluation from specialists? How?			
9.1.2	Monitoring, Measurement, Analysis and Evaluation: Customer Satisfaction	All units	1	What documented information can you show that monitoring and measurement activities have been implemented in accordance with determined requirements?		Monitoring logs	
			2	Does it evaluates the quality performance and the effectiveness of the QMS?			
			3	How do you monitor customer perception of the degree to which requirements have been met?		Surveys	
			4	How do you obtain information relating to customer views and opinions of your products and services?			
			5	What methods for obtaining and using this information do you have?			

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9.1.3	Monitoring, Measurement, Analysis and Evaluation: Analysis and Evaluation	All Units	1	Are the medical results being analyzed and evaluated?How?		Medical results	
			2	Is the medical results being analyzed and evaluated considers conformity with client requirements? or enhance customer satisfaction?		Monitoring logs	
			3	Are the documnented information maintained? How?		Monitoring logs	
			4	Ensure conformity and effectiveness of the QMS?			
			5	Does it helps to improve the QMS?			
9.2.1	Internal Audit	QMS	1	Is there Internal Quality Audit system in place in the organization?		QSS	
			2	Is this practiced consistently based on the defined interval? How?		QSS	
			3	Is there a documented evidence on the implementation?			
			4	Are there Internal Auditors?		List	
			5	Are they competent? How?		Attendance record & certificates	
9.3.1	Management Review	QMS	1	Is the organization has Management Review?		QSS	
			2	Is the program consistenly implemented?			
			3	Is there a documented evidence?		Management review report	
			4	What are the coverage for the Management reviews?		Management review report	
			5	Are issues identified and are monitored? How?		Management review report	
			6	Are minutes of the meeting available?		Management review report Attendance	

10 Improvement

10.2.1	Nonconformity and Corrective Action	QMS	1	Organization has system to control, address and monitor non-conforming products or services?		QSS	
		All Units	2	Is there a reported CAR in the unit? How was it addressed?		QSS and CAR	
			3	Are corrective actions planned and verified properly prior documenting and implementing? How		CAR	
			4	Are the corrective actions implemented?		Manuals vs. Actual	
			5	Are other personnel aware of the corrective actions being implemented?			
10.3	Continual Improvement	All Units	1	Is the unit has improvement projects or improvement plans?			
			2	Are there documented evidence of improvement plan? When is the target?			
			3	Are status of improvement plan monitored?			

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			4	How is the unit addressing late implementation of target?			
			5	Are responsible person identified to handle improvement projects?			

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