

Focus Visit

Report for:

KHAIRUN-NISA EYE HOSPITAL

LRQA reference:	KRH00000025 / 4832028
Assessment dates:	18-March-2022
Reporting date:	25-March-2022
Client address:	49/4 DR. THARANI ROAD GUJRAT COLONY, JAMSHED TOWN, Karachi 74800, PK
Assessment criteria:	ISO 9001:2015
Assessment team:	Raheel Ehsan
LRQA client facing office:	KRH Pakistan OU

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Attachments:

KRH00000025_APP_MS.docx

This report was presented to and accepted by:

Name: Dr Mazhar Awan

Job title: MS & MR

01. Executive report

Assessment outcome:

This visit was to assess the compliance of the management system of KHAIRUN-NISA EYE HOSPITAL against ISO 9001:2015 as defined in the audit planning documentation. The outcome of the visit is recorded below.

This was the Focus visit of Khairun Nisa Eye Hospital Karachi carried out against ISO 9001:2015 implemented at the Hospital that has showed a lot of maturity which is attributed to the Hospital's Leadership commitment towards system development and continual improvement. In addition to that there is a clearly visible drive and enthusiasm to continuously improve the effectiveness of the System at all levels.

No Major Non-Conformance has been raised during the audit that showed the capability of the system. ISO 9001:2015 certification. for Khairun Nisa Hospital would remain valid.

The certificate would expire in August 2022 at which time a Certificate Renewal Audit will be carried out to ensure continuity of the certification

Continual improvement:

In general the management system was found to be effective and the Hospital's Leadership was committed for bring excellence into the system by introducing new technologies and setting challenging objectives for continual improvement and monitoring their achievement as well.

There have been no complaints regarding the quality of the service from the patients that showed the clients' confidence on the Hospital's management system and the service and also the competence of the system and the staff.

The employees were being trained on the use of modern technologies & equipment.

Internal controls have been employed across the organisation by the management to ensure compliance with the procedure and/or identification and estimation of deviation from them. Any non-conformity observed is being investigated and actions addressing the root cause(s) are initiated to uproot the problem and prevent recurrence



Areas for senior management attention:

Training records: Number of hours of training imparted & Trainer's Name need to be documented for the Internees

02. Assessment findings

Where scheme requirement differs to the standard definition below, the scheme definition will take preference

Major Nonconformity

The absence of, or the failure to implement and maintain, one or more management system elements, or a situation which would, on the basis of the available objective evidence, raise significant doubt of the management to achieve: The policy, objectives or public commitments of the organisation, compliance with the applicable regulatory requirements, conformance to applicable customer requirements, conformance with the audit criteria deliverables.

Minor Nonconformity

A finding indicative of a weakness in the implemented and maintained system, which has not significantly impacted on the capability of the management system or put at risk the system deliverables, but needs to be addressed to assure the future capability of the system.

Reference number	4258078_KRHREX01	Assessment Criteria (Clause)	ISO 9001:2015 (8.5)
Grade	Minor NC	Issue Date	30-October-2021
Status	Closed	Process / Aspect	Front Office
Location(s)	49/4 DR. THARANI ROAD GUJRAT COLONY, Karachi, PK		
Statement of Non Conformity	Patient MR # 58152 Jamil Shaikh Advised for Surgery on 26/10/21, Procedure schedules could not be found in the system.		
Requirement	Clause 8.5 of ISO 9001:2015		
Evidence	Records of Patient MR # 58152 Jamil Shaikh		
Proposed correction, corrective action and timescales	PCA: Procedure will be revised accordingly DOC: 15/1/2022		
Correction	Record updated		
Root Cause analysis	Human error		
Corrective action	Data was entered by the operator but somehow it was not saved in the system. No missing in record found during audit.		
LRQA has reviewed and verified the implementation of actions taken.	Date of closure	18-March-2022	

03. Assessment summary

Visit generic objective:

This was a Focus visit, conducted against objectives previously notified to the client. The objectives of the next visit, including any applicable visit specific objective (theme / focus), are confirmed in the audit plan attached to this report.

Client attendees at the opening and closing meeting:

The Opening Meeting was held at 1000 hrs

The Closing meeting held at 1630 hrs

Participants: Mr Humayun Kalam, Mr Nisar Farooqui, Mr Shabir Almani

Introduction:

This was the Focus Visit (SV5) carried out at the Khairun Nisa Eye Hospital located in Karachi.

The Opening Meeting was held at 1000 hrs

Scope of audit was confirmed and audit methodology was briefed. LRQA audit procedure, audit plan and strategy, reporting mechanism, technical review requirements and confidentiality statement were explained. LRQA policy for continual improvement was also discussed and agreed.

Audit outcomes were presented and discussed during the Closing meeting held at 1630 hrs

The following report highlights the significant audits activities and trails and make references to the findings and areas for improvement that would be followed up in the next visit.



Assessment of:	Management Elements	Assessor:	Raheel Ehsan
Auditee(s):	Mr Shabbir		

Audit trails and sources of evidence:

Changes to organizational context: No major changes in the organization context and processes observed.
Changes made for COVID SOP's implementation as per requirements.

Continual improvement: Processes for continual improvement observed established. Objectives established for each department and being monitored.

Management of change (System & Organisation): Changes to the system being made as result of audit findings and/ or corrective actions required for internal failures and customer complaints.

Corrective action: Corrective actions were identified and taken for internal audit findings and customer complaints.

Management of complaints: System for handling customer complaints observed established and implemented.

Quality Objectives for 2022 have been made and were communicated to all employees

The achievement is monitored on an annual basis during Management Review meetings

Quality Audits were done in Nov 2021 against a schedule of once per year.

7 NCs were identified and corrective actions were initiated and closed out after verification.

Management review meeting on an annual basis. Last done on 16/12/21.

Agenda of Management Review

Minutes of the Meeting were made that included the decisions made, responsibility allocated, and time frame agreed.

Use of Logo. No concerns

Evaluation and conclusions:

Changes to organizational context: Context reviewed in Management reviews.

The internal audits were found effective in identifying the system anomalies and taking effective CA to prevent their recurrence.

Objectives have been developed along with action plan and responsibilities to ensure even better performance in the current year

Management review meetings are held on annual basis involving all HODs.

The minutes of the meeting were evident that the meetings were in line with the requirements of clause 9.3 of the standard.

Continual improvement: Processes for continual improvement observed established.

Management of change (System & Organisation): Changes to the system were made as per change management procedure.

Use of Logo. No concerns

Areas for attention:

None

Assessment of:	Focus Or Certificate Renewal Planning Visit	Assessor:	Raheel Ehsan
Auditee(s):	Mr Shabbir		

Audit trails and sources of evidence:

Review:

Organisational changes; trends in customer satisfaction; complaints and other performance indicators, changes in the documented system; improvement projects; trends in raised non conformities during internal and external audits, quality of management reviews.

Preview:

Developments in the organisation and its environment; strategy, policy and objectives in relation to these developments; the adequacy of the management system.

Planning:

Need for an additional visit (additional stage 1), points of attention during certificate renewal, appropriate audit themes; desirability specialised assessors; agreements on reporting, site visits, etc.

Evaluation and conclusions:

Review: Management was found committed to the implementation and improvement of QMS processes. Risk assessment has been carried out and the objectives for continual improvement were made considering the risk assessment results and Legal Requirements.

Resources were provided by the Top Management and the achievement process was monitored to ensure timely achievement of the objectives and Patient's safety & satisfaction.

Records demonstrated that the Objectives have been achieved by a higher percentage year after year and as a result, the risk level has reduced.

Feedback is obtained by the Patients/attendants that showed a positive trend.

Analysis of the feedback received in 2018-19, 2019-20, and 2020-21 showed a positive trend which is evidence of customers' satisfaction

Findings have been on a downward trend during the internal and external audits, .

Knowledge of Minimum Service Delivery Standard is obtained and communicated to the Service Delivery departments to ensure quality service is provided to the patients

The top management is also reviewing the QMS on a regular basis that is evidence of their commitment.

Preview: The leadership of the organization reviewed its strategy and policy for continuing suitability.

Compliance with MSDS was also ensured.

Resources were provided and training was being conducted to enhance the competence of personnel.

Planning: No additional visit and/or specialized assessor needed for CR.
 CR visit will be undertaken in September 2022 for 2 days and the plan was discussed and agreed upon with the QMR.

Areas for attention:

None

Assessment of:	Front Office	Assessor:	Raheel Ehsan
Auditee(s):	Ms Meena		

Audit trails and sources of evidence:

Internal & external issues: Changes w r t COVID 19 for which Nursing Care holds the main responsibility
 Interested parties & their requirements: No change since the last audit
 Mitigating Actions
 Main activities:
 Information

Reception
 Registration in Electronic Medical Record (EMR) as well as in hard copy
 Appointment as per the requirement
 New Patient Registration: Name, contact number, services required etc. EMR number issued by the system.
 Creating an electronic medical record in the hospital management system as well as a standard hard file.
 Forward to initial assessment.
 Advice by the consultant is mentioned on the file that comes to the front Office for recording and appointment as per available time slot.
 Appointment for any follow up and/or procedure etc. Printed copy provided.
 Schedule of charges available on the system and is updated by Accounts after approval of the management.
 Payment received as per the approved charge list.
 Referred to Welfare in case of needy patients
 Followed up for:
 Patient MR # 86785 Mrs Zubaida w/o M Akram
 Advised for Surgery on 16/03/22 by Dr Adil Saleem. Procedure schedules were traceable with the MR# in the system.
 Blood samples drawn for Hepatitis B & C, HIV, RBS pre Operation.

Evaluation and conclusions:

Front desk: Initial details token provided to the patient for treatment.
 Medical record made in the system is also accessible by the Initial Assessment Both methods of records (Soft and

hard) were found in place for the MR#.
Physical record room was established and all records are maintained in order.

Areas for attention:

None

Assessment of:	Purchase Maintenance (Gen Equipment) Maintenance (Test Equipment)	Assessor:	Raheel Ehsan
Auditee(s):	Mr Nisar Farooqui Mr Hanif Mehr		

Audit trails and sources of evidence:

Maintenance:

List of General Equipment available showing general equipment (no calibration required) and equipment that require calibration.
List of equipment 7.1.3-01 appendix 1
List includes: AC's, fire extinguishers, DG sets, etc.
Schedule of maintenance for DG sets was 200 hours or 3 months (whichever comes first) however no schedule for the inspection of other equipment was found in place. 5/12/21 and next due on 5/6/22
Inspection of fire extinguishers dated 02 Jan 2022, next due on 02 Jan 2023
Equipment Breakdown Complaint form has been converted to Electronic where the user raise the complaint electronically that comes to Maintenance for resolution and updating the complaint format (red, yellow, green).
Audit of the Maintenance revealed that the SOP regarding listing and maintenance of equipment etc. were being followed, records were maintained and controls were in place. Schedule of maintenance for equipment including ACs, Fire extinguishers, DG Sets, Stabilizers, etc. were found in place.

Purchase:

List of approved supplier was found in place.
POs were sampled that was awarded to Sunny Surgical, Cain Medical, Ali Gohar, Pioneer. All suppliers were found approved and listed in the ASL

Evaluation and conclusions:

Audit of the Maintenance revealed that the SOP regarding:
Listing and maintenance of equipment etc. were being followed, records were maintained and controls were in place. Schedule of maintenance for equipment including ACs, Fire extinguishers, DG Sets, Stabilizers, etc. were found in place. A SLA in place with a service provider for providing maintenance services in house. The Maintenance system was found effective

Audit of the Purchase department revealed that the SOP regarding supplier approval, maintaining a list of approved

suppliers, award of PO to the approved suppliers were followed and were found effective.

Areas for attention:

None

Assessment of:	Nursing Care, Infection Control, Laboratory	Assessor:	Raheel Ehsan
Auditee(s):	Ms Roseline Asif Mr Parakash		

Audit trails and sources of evidence:

No change in the Nursing Responsibilities were noticed since the last LRQA Audit. These included:

- 1) Pre Operative, Inter operative and Post operative care
 - 2) Support during Day care/ Diagnostic and invasive Procedures
 - 3) Environment of Care:
 - 4) Infection Control especially in the COVID 19 environment
 - 5) House Keeping
 - 6) Waste Management
- SOP: Nursing care: 8.5-00-E

Nursing Care Checklist: 8.5-05-01 covering the following

- 1) Common Procedure
- 2) Local anesthesia: Hepatitis profile, B, C, HIV
- 3) General Anesthesia: Hepatitis profile, B, C, HIV, ECG

Day Care - Pre Operation:

- 1) Patient Preparation
- 2) Tests
- 3) History
- 4) File completion (all required Documents and Nursing checklist)
- 5) Examination & Lab data in the EMR system.

Sampled case Patient Mrs Rasheeda MR # 86828

Blood samples for Hepatitis B & C, HIV, RBS, drawn Pre Op

Records were entered in the HMS against the MR#

Sampled case Patient Mrs Sultana Malik MR # 85089

Pre Op ECG carried out and the print out were found in the Patient's MR hard copy

Evaluation and conclusions:

Audit of the Nursing Care including Environment of Care, Infection Control, revealed that the SOP regarding: Sanitization/Sterilization, Infection Controls, Hygiene conditions, Waste management, Training of Nursing Staff, Communication with the Front Desk etc. were ensured, were seen in place, guidance was provided to the patients as required, records were maintained and controls were in place.

Areas for attention:

None

Assessment of:	HR/Training	Assessor:	Raheel Ehsan
Auditee(s):	Ms Noreen		

Audit trails and sources of evidence:

SOP for Human Resource 7.1.2, 7.2 & 7.3 was in place covering the activities of Competence & Training.

Job descriptions have been developed for each job that also reflects the competence requirement.

Employment requisition indicating the Position or the JD.

Training needs are identified at the time of employment and then on an annual basis.

Training plan for 2022 was seen in place.

- 1) Child Safeguarding related with School Health for all employees
- 2) Needle stick injury for OT, Lab & Housekeeping staff. Records maintained by Nursing In-charge.
- 3) Training for Internees in Research Methodology & Optometry
- 4) Training delivered to the Internees against a program that is also shared with the HR department

Training effectiveness is determined at the end of the year during annual appraisal.

Evaluation and conclusions:

Procedure for Training needs identification, developing annual training plan, imparting training was found being implemented effectively.

Training effectiveness are determined through comments from the line managers.

Areas for attention:

Training records: Number of hours of training imparted & Trainer's Name need to be documented for the Internees



04. Next visit details

Standard(s) / Scheme(s)	ISO 9001:2015	Visit type	Certificate Renewal		
Audit days	2.00 DAY	Due date	September, 2022		
Team					
Site	Audit days	Delivery Method	Remote Effort	Activity codes	
49/4 DR. THARANI ROAD GUJRAT COLONY, Karachi, PK	2.0 DAY	Onsite	0 DAY	108501	



05. Appendix



Audit Planning Programme and Visit Assessment plans

Audit Planning Programme and visit Assessment plans are contained within the excel document KRH00000025_APP_MS.xlsm

Report Considerations

There has been no deviation from the original assessment plan or any significant issues impacting on the audit programme. There have been no significant changes that affect the management system of the client since the last audit and the scope of certification continues to be appropriate to the activities/products/services of organisation. There are no unresolved issues been identified during the assessment. The organisation was effectively controlling the use of the certification documents and not misleading in their (online) certification statements. The organisation has taken or is taking effective corrective action regarding previously identified nonconformities. The objectives of the visit as defined in the APP, were fulfilled during the visit.

Stage 1 or Focus Visit

The amount of remote audit time for the next cycle, is expected to be less than 50%. The organisation the ability to access and present information, images or video from relevant locations to undertake an effective remote assessment. The plan is to use TEAMS

Remote Audits

This was an onsite visit.

Outside of Regular Working Hours

All processes can be effectively audited during normal office hours. This will be reviewed at the focus visit or if it changes.

Occupational Health and Safety

This audit scope did not include Occupational Health and Safety



Additional information

Opportunities for improvement

If we identify opportunities to improve your already compliant system, we will either record them in the process table applicable to the area being assessed or in the Executive summary of the report if they can deliver improvement at a strategic level.

Confidentiality

We will treat the contents of this report, together with any notes made during the visit, in the strictest confidence and will not disclose them to any third party without written client consent, except as required by the accreditation authorities.

Sampling

The assessment process relies on taking a sample of the activities of the business. This is not statistically based but uses representative examples. Not all of the detailed nature of a business may be sampled so, if no issues are raised in a particular process, it does not necessarily mean that there are no issues, and if issues are raised, it does not necessarily mean that these are the only issues.

Legal entity

The accredited legal entity and client facing office that has provided the assessment service in this report is referenced in the applicable agreement for this service.

Generic audit objectives and team responsibilities

The generic audit objectives and team responsibilities are included in the Client Information Note 'Assessment Process'. Any visit specific objectives for the next visit will be recorded in the report of the previous visit and will be addressed through the visit plan for that visit. The assessment standard and roles of the audit team are defined in the assessment visit confirmation sent to the client.

Audit Criteria

The audit criteria consist of the assessment standard and the client's management system processes and documentation.

Additional observers

Any additional observers will be as formally communicated to the client.

Note

Information on the objectives of the various visits can be found in the Client Information included in the report or on our website www.lrqa.com. Furthermore, on the website there are Client Information Notes available for the various visit types. The audit criteria and team members date and locations are also stated on the front page of the report. Scope of certification and roles and responsibilities of the audit team members are expressed in the Audit Program Plan.