Surveillance 1

Report for:

KHAIRUN-NISA EYE HOSPITAL

LRQA reference:	KRH00000025 / 5611196
Assessment dates:	26-April-2023
Reporting date:	03-May-2023
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

Contents

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 SV1 visit of Khairun Nisa Eye Hospital Karachi carried out against ISO 9001:2015 implemented at the Hospital.

No Major or Minor Non-Conformance was raised during the audit that showed the capability of the system.

ISO 9001:2015 certificate of Khairun Nisa Hospital would remain valid.

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:

None

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	5126838_KRHREX02	**Assessment Criteria (Clause)**	ISO 9001:2015 (9.3.2)
Grade	Minor NC	**Issue Date**	08-October-2022
Status	Closed	**Process / Aspect**	Management Elements
Location(s)		49/4 DR. THARANI ROAD GUJRAT COLONY,Karachi,PK	
Statement of Non Conformity		MRM for 2022 has not been conducted due to the delay in internal audits and is now planned to be conducted on 18th of this month. Review of the agenda of the meeting revealed that it does not cover all requirements of clause 9.3.2	
Requirement		ISO 9001:2015 clause 9.3.2: Management Review inputs	
Evidence		Agenda of the MRM planned to be held on 18/10/2022 revealed that it does not cover all requirements of clause 9.3.2 e.g. 1. changes in external and internal issues 2. process performance and conformity of services; 3. the performance of external providers; 4. the effectiveness of actions taken to address risks and opportunities	
Proposed correction, corrective action and timescales		PCA: Agenda will be revised to include all requirements of the clause and the agenda will be formally mentioned in the MRM SOP for consistent compliance DOC: 18/10/2022	
Correction		Agenda of MRM has been revised	
Root Cause analysis		Audits were delayed due to shortage of trained auditors	
Corrective action		IA training has been imparted. Agenda of MRM has been revised and the revised agenda found complying with the requirements of the standard.	

LRQA has reviewed and verified the implementation of actions taken.	**Date of closure**	26-April-2023

Reference number	5126838_KRHREX01	**Assessment Criteria (Clause)**	ISO 9001:2015 (10.2)
Grade	Minor NC	**Issue Date**	08-October-2022
Status	Closed	**Process / Aspect**	Management Elements
Location(s)		49/4 DR. THARANI ROAD GUJRAT COLONY,Karachi,PK	
Statement of Non Conformity		Corrective Actions (CA) on the NCs have been taken by the auditees and confirmed to the auditors that the actions have been completed however no formal documentation and record was available.	
Requirement		ISO 9001:2015 clause 10.2: Records of CA need to be maintained	
Evidence		CA on the NCs identified during the Internal Audit 24-28/09/22 have not been documented.	
Proposed correction, corrective action and timescales		PCA: CA taken by the auditees will be documented and in future no CA will be closed out without formal documentation and record DOC: 30/11/2022	
Correction		the procedure of CA has been revised and implemented.	
Root Cause analysis		Due to shortage of trained auditors the IA was delayed therefore the CAR formats were not made properly	
Corrective action		No undocumented CA was found during audit	
LRQA has reviewed and verified the implementation of actions taken.		**Date of closure**	26-April-2023

03. Assessment summary

Visit generic objective:

This was a Surveillance 1 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:

Opening and closing meetings were held at 0900hrs and 1630hrs respectively
Patricians:
Mr Humayun Kalam, Mr Nisar Farooqui and Mr Shabir Almani

Introduction:

This was the Sv1 carried out at the Khairun Nisa Eye Hospital located in Karachi.
The Opening Meeting was held at 0930 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 1600 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):	Ms Noreen		

Audit trails and sources of evidence:

Quality policy of the Hospital was reviewed by the management however no change was brought in the text.

Internal Audit: 17 to 19 April 2023,
Whole Organization was covered
Findings from each audit were listed in the report
Findings discussed with the auditees and also with the Management and the CA is agreed.
A follow up is carried out to close out the NC

Quality Objectives have been made and were communicated to all employees. The achievement is monitored on an annual basis during Management Review meetings

MRM has been conducted however the formal minutes were yet to be compiled.
Review of the agenda of the MRM revealed that all requirements of clause 9.3.2 have not been covered

Evaluation and conclusions:

• 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 QMS performance in the current year.

• The agenda of the management review meeting were evident that the meetings were in line with the requirements of clause 9.3 of the standard.

Areas for attention:

None

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

Audit trails and sources of evidence:

Internal & external issues: No changes since the last audit
Mitigating Actions
Main activities: Provision of Information, Patient Registration, Fees Collection, Surgical procedures appointments
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 and the needy patients are referred to Welfare.
Followed up for:
Patient Mr Abdul Malik Qureshi MR # 90821 registered dated 27/03/2023
Treatment plan: Advised for Avastin Injection for 3 months.
Theatre booking dated 4/4/23 made for the first dose.

Patient Ms Mariyam MR # 95651.
Treatment plan by Dr Sana: Right Eye Phaco
Advised for Surgery on 03/04/23. Procedure schedules were traceable with the MR# in the system.

Patient Mr Qadir Baksh MR # 95399.
Treatment plan by Dr Sana: Right Eye Phaco
Advised for Surgery on 03/04/23. Procedure schedules were traceable with the MR# in the system
Lab tests for Hepatitis B & C, HIV, RBS would be done a day before the surgery.
Patient file with name, MR number & CNIC number were found in the system and the treatment plan, theatre booking and the Lab test reports, etc. were traceable with them

Evaluation and conclusions:

Front desk: Patient details, MR#, treatment plan, test reports and fee details were recorded in the system as well as hard copies.
Physical record room was established and all records are maintained in order.

Areas for attention:

None

Assessment of:	Assessment & Diagnostics	**Assessor:**	Raheel Ehsan
Auditee(s):	Ms Fatima		

Audit trails and sources of evidence:

Main activities:
Symptoms, Medical History, Known drug allergies, Past ocular history

1) IOP
2) Vision test and number

All results recorded in the hard file and entered in the computerized record against the EMR number.

Special investigation& Procedure Room:

1. OCT Optical Coherence Tomography
2. YAG Laser
3. Biometry
4. B Scan U/S
5. FFA Fluorescent Fundus Angiography
6. VF Visual Field Perimeter
7. Argon Laser

Temperature monitoring of the above room was done and maintained 20C-24C.
Equipment are cleaned by alcohol swabs after each patient and procedure and in case of infected patient, thorough cleaning and sterilization is performed.
The procedure chair also need to be cleaned.
Housekeeping was done as per the schedule and was seen of a high standard during the audit.

Evaluation and conclusions:

Audit of the Initial Assessment department revealed the following:
- SOP were being followed,
- initial assessment results of the patients were recorded both in the hard files and in the computerized system,
- assessments were conducted by competent and trained personnel,
- hygiene conditions were ensured & infection controls were seen in place,
- guidance was provided to the patients as required,
- medical records were maintained and controls were in place.
- Equipment used was found properly functional, maintained and calibrated.

Areas for attention:

None

Assessment of:	Maintenance Purchase	**Assessor:**	Raheel Ehsan
Auditee(s):	Mr Nisar Farooqui		

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.

- Inspection & maintenance for DG sets GE-44 was carried out on 04/12/22, next due 4/06/23
- Inspection & refilling of fire extinguishers on an annual basis
- Passenger Lift was also inspected on a monthly basis.
- Water dispenser monthly inspection carried out

Equipment Breakdown Complaint form has been converted to Electronic where the user raises the complaint electronically that comes to Maintenance for resolution.

Purchase:
List of approved supplier was found in place.
POs were sampled and were found awarded to the suppliers listed in the ASL
Suppliers performance evaluation done on an annual basis, last done in Jan 2023

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) House Keeping
5) Waste Management

SOP: Nursing care: 8.5-00-E and 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 Ms Maryam Bibi surgery was due on 03/04/23 but was postponed due to increased heart rate.
The patient was referred to the Cardiac specialist.
Lab test reports RBS, HIV, Hep B&C were found in the Medical record of the patient

Sampled case Patient Mr Qadir Baksh MR# 95399 who was advised for Surgery on 03/04/23.
Lab test reports RBS, HIV, Hep B&C were found in the Medical record of the patient
Blood samples for Hepatitis B & C, HIV, RBS, drawn Pre Op
Nursing care checklist was found in the record covering:

- Pre-Op

- Day of Surgery
- Theatre Nursing
- Post-Op
- Emergency

Records were entered in the HMS against the MR#

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:

Training needs are identified at the time of employment and then on an annual basis.
Training plan for 2023 was seen in place.

1) CPR and Bleeding Control training dated 23/2/23

List of attendees maintained

2) Training for Internees in Research Methodology dated 03/03/23
3) Training in QMS & ISO 9001 dated 03/03/23 where 8 sessions will be delivered @ one session per week
4) Rehabilitation of Blindness dated 13/02/23
5) Contact Lens Workshop dated 13/02/23

Evaluation and conclusions:

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

Areas for attention:

None

Assessment of:	Operation Theatre (OT)	**Assessor:**	Raheel Ehsan
Auditee(s):	Mr Kelash Kumar		

Audit trails and sources of evidence:

Procedure time agreed with the patient and communicated to the Theatre.
Operation Plan provided a day in advance including patient name and IOL number
All OT equipment & infrastructure sterilization and fumigation as per the schedule
Mostly all disposable items are being used.
Critical equipment (requiring calibration)
Washing/Cleaning & Sterility of OT equipment by Chlorine solution followed by Autoclaving as per the schedule that is cross checked by the OT Staff & Nursing Supervisor
Fumigation done by Chlorine solution, Dettol, and disinfectant as per the schedule that is cross checked by the Nursing Supervisor
A SOP 8.5_00_F has been developed for the above mentioned activities.
Medical & Surgical supplies & Sterile supplies for which a record is maintained and the stock level is maintained by the OT staff through Stores
Crash Cart maintained in the OT and managed by the Nursing Staff who are available at the time of Surgery.
Review of the OT essentials including IOL and medicines reviewed and ensured by OT Staff a day before the procedures.

Evaluation and conclusions:

Audit of the Operation Theatres revealed that the SOP regarding:
Sanitization/Sterilization, Infection Controls, Hygiene conditions, Waste management, Provision of OT equipment and their functionality, Medical & Surgical supplies, Controlled Environment, Rota for the OT & Nursing Staff Surgeon’s availability & confirmation, Communication with the Front Desk etc. 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:	Welfare Office	**Assessor:**	Raheel Ehsan
Auditee(s):	Ms Samina Mazhar		

Audit trails and sources of evidence:

Appointment as per the Front Office system
Front Office refers the unaffordable patients to the Welfare Office
At the Welfare Office, the patient or attendant are interviewed to determine the eligibility for Welfare and extent of Welfare support.
Form fill out to get the patient's consent
Sampled a few cases however the names & MR# is deliberately not mentioned
Contribution from the patient and from Welfare are also mentioned on the form.
Information regarding Welfare is entered into the EMR that has limited access including Top Management, Welfare Manager and the Accountant.

Evaluation and conclusions:

Audit of the Welfare department revealed that the SOP were being followed, interview of the patient and/or attendant were conducted and welfare eligibility was determined, guidance was provided to the patients as required, approvals were made for the eligible patients, record were maintained and controls were in place

Areas for attention:

None

04. Next visit details

Standard(s) / Scheme(s)	ISO 9001:2015	**Visit type**		Surveillance 2	
Audit days	1.00 DAY	**Due date**		September, 2023	
Team					
Site		**Audit days**	**Delivery Method**	**Remote Effort**	**Activity codes**
49/4 DR. THARANI ROAD GUJRAT COLONY,Karachi, PK		1.0 DAY	Onsite	0 DAY	EA37,EA38,EA39

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

This visit was not a Stage One or a focus visit (Certificate Renewal Planning)

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.