Surveillance 3

Report for:

KHAIRUN-NISA EYE HOSPITAL

LR reference:	KRH00000025 / 3783784
Assessment dates:	05-February-2021
Reporting date:	12-February-2021
Client address:	49/4 DR. THARANI ROAD GUJRAT COLONY,JAMSHED TOWN,Karachi 74800, PK
Assessment criteria:	ISO 9001:2015
Assessment team:	Raheel Ehsan
LR Client Facing Office:	KRH Pakistan OU

Contents

Attachments:

KRH00000025_APP_KNE_QMS_SV3_RE.doc

This report was presented to and accepted by:

Name: Dr Mazhar Awan

Job title: MS

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

This was the Surveillance audit ISO 9001:2015 standard at Khairun Nisa Hospital.

The objective of the visit was to determine the standard of the management system established and implemented at the company. The visit was undertaken as per the plan agreed with the QMS Team.

The management system is gaining maturity and a high level of compliance with the requirements of standards and the company procedures

The certificate would remain valid

Continual improvement:

The top management of the company was found fully committed for improving the effectiveness of the Quality Management System. The management system was seen effective in satisfying requirements related to QMS & legal requirements related to health this being confirmed by the high standard of systems established during the LRQA visit. Procedures developed for QMS were found being established and were also being reviewed at appropriate intervals.

🔍 Areas for senior management attention:

3783784_KRHREX01: Data backup of the Hospital Management System need to be made to ensure that the computerized data is not lost.
3783784_KRHREX02: Incidents & accident regarding the environment of care and infection control records to be maintained.

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	3210662_KRHREX01	**Assessment Criteria (Clause)**	ISO 9001:2015 (9.2.2)
Grade	Minor NC	**Issue Date**	10-July-2020
Status	Closed	**Process / Aspect**	Management Elements
Location(s)		49/4 DR. THARANI ROAD GUJRAT COLONY,Karachi,PK	
Statement of Non Conformity		A specific checklist of internal audit need to be made for each department	
Requirement		Clause 9.2.2 (a)(b) of ISO 9001:2015	
Evidence		No specific checklist of internal audit is made for each department	
Proposed correction, corrective action and timescales		PCA: IA checklist will be made for each department. DOC: 31/10/2020	
Correction		Checklist of internal audit have been made for each department	
Root Cause analysis		System improvement	
Corrective action		Checklist of internal audit have been made for each department. Audit checklist of Front Office evidenced.	
LR has reviewed and verified the implementation of actions taken.		**Date of closure**	05-February-2021

Reference number	3210662_KRHREX02	Assessment Criteria (Clause)	ISO 9001:2015 (9.3.2)
Grade	Minor NC	Issue Date	10-July-2020
Status	Closed	Process / Aspect	Management Elements
Location(s)		49/4 DR. THARANI ROAD GUJRAT COLONY,Karachi,PK	
Statement of Non Conformity		The agenda of MRM need to be aligned with the requirements of the clause 9.3 of the standard	
Requirement		Clause 9.3.2 (b) of ISO 9001:2015	
Evidence		changes in external and internal issues were not discussed in the MRM	
Proposed correction, corrective action and timescales		PCA: The agenda of MRM will be revised accordingly . DOC:30/9/2020	
Correction		The agenda of MRM have been revised	
Root Cause analysis		Understanding improved	
Corrective action		The agenda of MRM have been revised and the agenda observed aligned with the requirements of the clause 9.3 of the standard. CA found effective.	
LR has reviewed and verified the implementation of actions taken.		Date of closure	05-February-2021

Reference number	3210662_KRHREX03	Assessment Criteria (Clause)	ISO 9001:2015 (7.2)
Grade	Minor NC	Issue Date	10-July-2020
Status	Closed	Process / Aspect	Training
Location(s)		49/4 DR. THARANI ROAD GUJRAT COLONY,Karachi,PK	
Statement of Non Conformity		A mechanism of training need identification need to be developed	
Requirement		Clause 7.2 (c) of ISO 9001:2015	
Evidence		No mechanism of training need identification is developed	
Proposed correction, corrective action and timescales		PCA: mechanism of training need identification will be developed DOC: 30/9/2020	
Correction		Training procedure revised	
Root Cause analysis		Understanding improved	
Corrective action		Training needs were identified for the 2021. TNA evidenced.	
LR has reviewed and verified the implementation of actions taken.		Date of closure	05-February-2021

Reference number	3210662_KRHREX04	Assessment Criteria (Clause)	ISO 9001:2015 (7.5)
Grade	Minor NC	Issue Date	10-July-2020
Status	Closed	Process / Aspect	Front Office
Location(s)		49/4 DR. THARANI ROAD GUJRAT COLONY,Karachi,PK	
Statement of Non Conformity		The main power switch for record room need to be provided outside the room so that it is switched off to prevent any short circuit in the room destroying the hard files.	
Requirement		Clause 7.5 of ISO 9001:2015	
Evidence		The main power switch for record room is placed in side the room	
Proposed correction, corrective action and timescales		PCA: The main power switch will be placed outside the record room DOC: 31/8/2020	
Correction		The main power switch have been placed outside the record room	
Root Cause analysis		Understanding improved	
Corrective action		The main power switch have been placed outside the record room. CA found effective.	
LR has reviewed and verified the implementation of actions taken.		Date of closure	05-February-2021

Reference number	3783784_KRHREX01	Assessment Criteria (Clause)	ISO 9001:2015 (7.5)
Grade	Minor NC	Issue Date	05-February-2021
Status	New	Process / Aspect	Front Office
Location(s)		49/4 DR. THARANI ROAD GUJRAT COLONY,Karachi,PK	
Statement of Non Conformity		Data backup of the Hospital Management System need to be made to ensure that the computerized data is not lost.	
Requirement		Clause 7.5 of ISO 9001:2015	
Evidence		No mechanism developed for data backup	
Proposed correction, corrective action and timescales		PCA: A mechanism will be developed for data backup DOC: 15/5/2021	
Correction			
Root Cause analysis			
Corrective action			
LR has reviewed and verified the implementation of actions taken.		Date of closure	

Reference number	3783784_KRHREX02	Assessment Criteria (Clause)	ISO 9001:2015 (7.5)
Grade	Minor NC	Issue Date	05-February-2021
Status	New	Process / Aspect	Infection Control
Location(s)		49/4 DR. THARANI ROAD GUJRAT COLONY,Karachi,PK	
Statement of Non Conformity		Incidents & accident regarding the environment of care and infection control records to be maintained.	
Requirement		Clause 7.5 of ISO 9001:2015	
Evidence		Incidents & accident records not maintained.	
Proposed correction, corrective action and timescales Correction		PCA: Incidents & accident records will be maintained DOC: 1/3/2021	
Root Cause analysis			
Corrective action			
LR has reviewed and verified the implementation of actions taken.		Date of closure	

03. Assessment summary

Visit generic objective:

This was a Surveillance 3 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 with Dr Mazhar Awan MS & MR
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.

The Closing meeting was held at 1630 hrs with Mr Shabbir
Audit outcomes were presented and discussed during the Closing meeting

Introduction:

This was the Surveillance visit 3 carried out at the Khairun Nisa Eye Hospital located in Karachi.

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

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

Audit trails and sources of evidence:

Changes to organizational context, Management review, Internal Audits, Continual improvement, Management of change (System & Organisation), Corrective action, Management of complaints, Performance against the client's management system objectives, Use of Logo.

Evaluation and conclusions:

Quality Objectives have been made and were communicated to all employees

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

Quality Audit were done against a schedule of once per year.

NCs were identified and corrective actions were initiated. NC and CAR format need to be filled in.

Management review meeting on an annual basis.

Agenda of Management Review

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

Areas for attention:

None

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

Audit trails and sources of evidence:

Purchase:

Approved supplier List

PO to approved suppliers

Maintenance & Calibration of Medical Equipment
IOP (Inter Ocular Pressure meter) CME-OPD-020

Maintenance & Calibration done on 01/06/2020. Next due on 31/05/2021

Fundus Camera 949198

Chart Projector 825689

Lens Meter LM-S1

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 of the equipment was found in place.

List of approved supplier was found in place.

A few POs were sampled that were awarded to Sunny Surgical, Parazelus, F Abdullah, Premier Agencies etc. All these were found in the ASL

Last evaluation for suppliers was done on 30/0/2020, next due on 31/06/2021

All Suppliers were categorized as Grade A

Areas for attention:

None

Assessment of:	Initial Assessment & Diagnostics	Auditee(s):	Mr Hanif Mehar	Assessor:	Raheel Ehsan

Audit trails and sources of evidence:

Internal & external issues

Interested parties & their requirements

Mitigating Actions

 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.

Maintenance & Calibration of Medical Equipment

IOP (Inter Ocular Pressure meter) CME-OPD-020

Maintenance & Calibration done on 01/06/2020. Next due on 31/05/2021

Fundus Camera 949198

Chart Projector 825689

Lens Meter LM-S1

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

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

Evaluation and conclusions:

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: New patient MR # 76908 M Rafiq Surgery planned on 10/02/2021

Revisit Patient MR # 76890 Mrs Basmina Surgery planned on 10/02/2021

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:

3783784_KRHREX01: Data backup of the Hospital Management System need to be made to ensure that the computerized data is not lost.

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

Audit trails and sources of evidence:

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

1) Pre Operative, Inter operative and Postoperative care

2) Support during Daycare/ 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 dated 20/8/18

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

1) Common Procedure

2) Local anaesthesia: Hepatitis profile, B, C, HIV

3) General Anaesthesia: 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 New patient MR # 76908 M Rafiq Surgery planned on 10/02/2021

        Revisit Patient MR # 76890 Mrs Basmina Surgery planned on 10/02/2021

Records were found In HMS

Theatre: Nursing cover throughout from operation till recovery Medication as advised by the Surgeon/Consultant Monitoring for Infection Control: housekeeping, sanitization

Vitals monitoring on arrival including Blood Pressure, Heat rate, Oxygen Saturation, Hep B, C, HIV, RBS and Hb A1C

KPI for Infection Control :

1) Hand Hygiene

2) Needle stick injury management

3) Danger box monitoring and management

4) Waste Management and Disposal

5) COVID 19 Procedures where a working group has been made heading by Dr Mazhar, Dr Fatima, Ms Roselene

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:

3783784_KRHREX02: Incidents & accident regarding the environment of care and infection control records to be maintained.

![Lloyd's Register](LR logo)

04. Next visit details

Standard(s) / Scheme(s)	ISO 9001:2015		Visit type		Surveillance 4	
Audit days	1.00 DAY		Due date		September, 2021	
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	108501,109015	

05. Appendix

1. Audit Programme/Plan

Both the audit plan and the programme are dynamic and must be in line with the client's developments. Any (last minute) changes are possible with valid reasons e.g. organisational changes, processes, management review results etc. Prior to the closing meeting the audit team should (re)confirm the programme and identify any changes,
E.g. to the management system, extent, time or dates of the audit, competences...

Visit Type	Stage 1	Stage 2	SV1	SV2	SV3	SV4	Focus visit	Certificate Renewal
Due Date			03/20	09/20	03/21	09/21	03/22	09/22
Start Date	18/07/19	26/09/19	9/7/20		5/2/21			
End Date	same	27/09/19	10/7/20		same			
Audit Days	01	02	1+1		1	1	1	tba
Separate assessment plan?	N	N	N		N	Y/N	Y/N	Y/N
Any change in workforce numbers that may impact visit duration (if yes add new number)	N	N	N		N	Y/N	Y/N	Y/N
Where identified above see separate current assessment plan for further detail.								
Process / aspect / theme / location *Final selection will be determined after review of management elements and actual performance*								
Opening meeting	✓		✓	✓	✓	✓	✓	✓
Closing meeting	✓		✓	✓	✓	✓	✓	✓
Changes to organizational context	✓		✓	✓	✓	✓	✓	✓
Management Review	✓		✓	✓	✓	✓	✓	✓
Internal Audits	✓		✓	✓	✓	✓	✓	✓
Continual Improvement	✓		✓	✓	✓	✓	✓	✓
Management of change	✓		✓	✓	✓	✓	✓	✓
Corrective action	✓		✓	✓	✓	✓	✓	✓
Complaint Management	✓		✓	✓	✓	✓	✓	✓
Use of Logo (LR & Accreditation Marks)	✓		✓	✓	✓	✓	✓	✓
Performance against the client management system objective	✓		✓	✓	✓	✓	✓	✓
Shift details and coverage in audit								
Front Office		✓		✓		✓		✓
Initial Assessment & Diagnostics		✓	✓	✓	✓	✓	✓	✓
Consultants		✓		✓		✓		✓
Welfare Office		✓			✓		✓	✓
Nursing		✓	✓	✓	✓	✓	✓	✓
Operation Theatre		✓	✓		✓		✓	✓
Environment of Care/Infection Control		✓	✓		✓			✓
HR		✓		✓		✓		✓
Purchase		✓			✓			✓
Maintenance		✓		✓			✓	✓
Electronic Medical Record		✓		✓		✓		✓

Scope
Any revised scope will be as agreed in formal correspondence between LR and the client or defined in section 4 of the previous LR visit report.

Scope	**Management and Delivery of Healthcare in relation to Eye care.**
Exclusion	Design & Development

Visit start time (approximate)	09:00	Visit end time (approximate)	16:30
The actual start and finish times for the visit will be agreed at the pre-visit contact with the assessor and recorded in the report introduction.			

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.

2. Separate Assessment Plan

Note: if the visit involves more than one team member and is more than one day duration, an additional plan detailing the activities of each member of the team on each day will be required.

(Date   Day 1)

Introductory meeting with management to explain the scope of the visit, assessment methodology, method of reporting and to discuss the company's organisation (approximately 30 minutes). The Team Leader will agree a time to meet with top management to discuss policy and objectives for the management system.

LR team briefing for a team of two or more assessors or (experts).

<Name> (Team Leader)   <Name>

Discussion of all outstanding issues
from previous visits.

Lunch.   Lunch.

Report writing.   Report writing.

Close.   Close.

(Date   Day 2)

Review of findings from previous day. Review of the assessment plan for the day.

Lunch   Lunch

Report writing.   Report writing.

Close   Close

(Date   Day 3)

Review of findings from previous day. Review of the assessment plan for the day.

Lunch   Lunch

Review of day's findings   Review of day's findings

Preparation of final report   Preparation of final report

Closing meeting with management to present a summary of findings and recommendations.

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.lr.org. 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.

3. Report Considerations

LR Report considerations		
Have there been any deviation from the original assessment plan:	No	If yes detail these in the introduction section of the report along with the reasons for the deviations
Have there been any significant issues impacting on the audit programme:	No	If yes detail these in the introduction of the report and amend the APP
Have there been any significant changes that affect the management system of the client since the last audit took place:	No	If yes detail these within the executive summary section of the report
Have any unresolved issues been identified during the assessment:	No	If yes detail these within the executive summary section of the report
Was the audit undertaken a combined or integrated audit:	No	If yes confirm what type of audit and the standards covered in the introduction to the report.
Was the organisation effectively controlling the use of the certification documents and marks:	Yes	If no document within the reporting table covering the mandatory elements
If applicable has the organisation taken effective corrective action regarding previously identified nonconformities:,	Yes	Record outcome in the findings log against the relevant findings.
Does the management system of the organisation continue to meet the applicable requirements and meet the expected outcomes:	Yes	If no details reasons within the executive summary of the report
Does the scope of certification continue to be appropriate to the activities/products/services of organisation:	Yes	If no then document the actions necessary in relation to the scope in the executive summary of the report and amend the APP as required.
Were the objectives of the visit as defined in the APP fulfilled during the visit:	Yes	If no detail the reasons and any necessary actions in the executive summary of the report and amend/update the APP