International Standards Certifications (Global) FZ LLC

AUDIT REPORT

Mariveles Mental Hospital

Surveillance 1 Audit for compliance to ISO 9001:2015

Team Leader: Dr. Ricardo F. Adriano Jr.

Date of Audit: 06 August 2018

Client File No: QAC/R63/0118

CLIENT INFORMATION				
Client:	Mariveles Mental Hospital			
Client Contact	Dr. Lourdes Evangelista	**E-mail/ website:**	Mmh_doh63@yahoo.com	
Position:	Chief of Hospital I	**Phone:**	047.935.41.38	

AUDIT DESCRIPTION				
Standard	ISO 9001:2015			
Audit Type: *(please highlight relevant box)*	Initial Stage 1 ☐	Initial Stage 2 ☐	Surveillance 1	Triennial ☐
Duration	3 Mondays			
Audited Sites	Head Office: P. Monroe Street, Poblacion Mariveles , Bataan, PHILIPPINES			
	Site 1: n/a			
Audit team	Team leader	Ricardo Adriano Jr.		
	Auditor(s)	Glaizelle Sayas Irene Calantog Eduardo Cabanatan Jr.		
	Technical expert	n/a		
	Observer(s)	n/a		
Audit Plan	Sent: 31 July 2018			

Site sampling methodology:	Total number sites :	Sites sampled :	N/ A ☒
Description of temporary sites :			N/ A ☒
Pre triennial review conducted:			N/ A ☒
Previous certification details:			N/ A ☒

CERTIFICATION INFORMATION			
Scope of Certification Provision of Curative, preventive and rehabilitative psychiatric services. Services are Out-Patient, In-Patient, Admission Crisis intervention and occupational therapy.			
Employee Numbers:	120	ANZSIC: 8612	

CHANGES IN CLIENT INFORMATION AT THIS AUDIT **none**			
Client Name/Address		Scope	
Employee Numbers		Other	

EXECUTIVE SUMMARY

An audit of Mariveles Mental Hospital Management System was conducted on the above date by International Standards Certifications (Global) in accordance with the requirements outlined in ISO 17021-1:2015.

Audit Objectives

The purposes of the audit were; to verify compliance of the client's management system to the requirements of ISO 9001:2015 and to ensure that the management has a system in place to identify applicable legal, statutory and contractual obligations.

Summary of Audit Findings

The audit was indeed accomplishing. The team was able to scrutinise all the vital areas of the process. There were some observations and improvements noted but there were no non – conformities specified. Best practices were also highlighted. The audit ran for a day with fruitful results and learning gained from all its stakeholders.

Audit objectives were met	Yes x	No ☐
Non-conformances were identified at this audit:	Yes ☐	No x
Number and category of non-conformances:		None
Description of non-conformances: n/a		

Recommendation

Recommended for Certification/Continued Certification: Yes x No ☐

DESCRIPTION OF CLIENT OPERATIONS

The Client is a centre institution built to provide care for the mentally-ill patients. Currently, the hospital was spearheaded by Dr. Lourdes Evangelista who acts as the Medical Center Chief. Ms. Emily Raymundo was still the Chief Administrative Officer and together with the ISO Core Team, the organization strives harder to be an independent arm of the Department Health dedicated to deliver services that will improve the well – being of all its stakeholders.

Client Representatives:
Dr. Lourdes Evangelista - Medical Center Chief
Ms. Emily Raymundo – Chief Administrative Hospital

AUDIT INFORMATION

Clause 4.0- Context of the organisation

Understanding the organisation and its context, Understanding the needs and expectations of interested parties, determining the scope of the, Quality management system.

The organisation has presented its context for the year through a presentation where all aspects of the business process have been considered. Legal requirements as part of compliance was ensured by the organisation by assuring that all the permits and license have been validated up to date. Among the verified permits includes the PRC license of all personnel, driver's license, water analysis, sanitary permits, laboratory contract of various equipments and fire arm licenses. There is an increase of manpower as reported by the human resource department whereas; the organisation reported a total manpower of 339 from 2017 and a total number of 360 to date. Understanding the organisation's context, the hospital has crafted officers to address all its interested parties. Among these includes the appointment of Public Assistance and Complaint Desk Officer and the designation of a Data Protection Officer. The change in name from Health Emergency Management Staff (HEMS) to Disaster Risk Reduction and Management in Health (DRRMH) was also noted. Issues that may affect the business operations were also declared such as the ratification of Philippines Mental Health Act RA 11036 and the inclusion of the Mental Health Illnesses in the new Philhealth universal Health Package.

Audit Findings

Observations/Opportunities for Improvement/ NCR:
None

Clause 5.0- Leadership

Leadership and commitment, Customer focus, Quality policy, Organisational roles, responsibilities and authorities,

Commitment and compassion of management was very evident and manifested through improved infrastructure projects of the hospital. Top management strongly supports additional programs to improve the

delivery of services. As part of the management's commitment, the hospital was able to conduct the following activities that will benefit the service they render to their clients:

1. Supervisory and Leadership Skills Seminar – 19 to 20 April 2018
2. ISO Awareness Seminar for newly hired employees – 07 May 2018
3. Risk and Opportunities Seminar – 08 May 2018
4. IQA Training for new auditors – 9,10 and 28 May 2018
5. 5S Awareness Seminar – 2 batcher, 25 and 27 July 2018

There were no changes as to the declared quality policy. Staffs recite the MMH Quality Policy during flag ceremonies. Organisational structures are still intact and there were no major changes to the established organisational chart as noted. Positions are well defined together with its corresponding functions that can be found on the JD of each personnel.

Audit Findings

Observations/Opportunities for Improvement/ NCR:
None

Clause 6.0 Planning for the quality Management system

Actions to address risks and opportunities, Quality objectives and planning to achieve them, Planning of changes,

Risk and Opportunities are identified per unit and documented in the Risk and Opportunity Registry **(MMH-QAC-04-15-00)**. Risks are identified based on sighted IQA nonconformity, sentinel events, customer complaints, incident report and supplier's nonconformity. **The Risk Identification Report (MMH-QAC-04-04-00)** follows a format that details information such as the area, process**,** possible risk involved**,** impact**,** control / mitigation and opportunities identified. Sample from the last years evaluation includes the process of Admission and Evaluation with associated risks involved like poor history taking, mental status and physical examination, unreliable / no informant (undefined patients), inappropriate admission forms, physical harm / threat to MD caused by patient, patient disruptive behaviour. Impact includes misdiagnosis and treatment, poor assessment, treatment error, dissatisfied client, prolonged hospitalization, legal accountability, inadequate information and history, physical injuries and emotional trauma to MD, hospitalization, financial burden, and work disruption, physical harm to self and other. Control mitigation process includes enhance skill in history taking and mental examination, revision of admission forms, presence of skilled and trained nursing attendant / security guard and provision of physical restraints. Opportunities identified includes accurate diagnosis, Training on ICD 10 and DSM, Client satisfaction, decreased hospital stay, Adequate information and history, safe working environment, zero incidence of harm and adequate functional CCTV camera, monitor and warning device and a dedicated staff to monitor and send immediate response to the area involved.

For this year, random samplings were also specified from 3 departments:

1. Materials Management Unit – Storage error of medicine and medical supplies that could lead damage of product of which is noted with an interpretation of high risk. Score identified was 20.
2. Security – Loss of keys that could be a threat for security. Medium risk was identified with a score of 15.

3. IHOMP Unit – Failure to purchase licensed softwares that could lead to legal non – compliance of which score is 15 interpreted as medium.
4. Engineering and Facilities Unit – Unsecured storage of chemicals that could lead to incidence of poisoning. The score is 15 interpreted as medium risks.

The above mentioned risks are treated with proper actions of mitigation to ensure that all risks can be controlled properly if happened and immediate actions will be fulfilled.

Audit Findings

Observations/Opportunities for Improvement /NCR:

1. Need to analyse the increasing high risk mentioned in the risk assessment report from 22 in 2017 to 39 in 2018,
2. May include target time for each action plan for proper monitoring of status in the Risk Registry Form.

Clause 7.0 - Support

Resources, People, Environment for the operation of processes, Monitoring and measuring resources, Organisational knowledge, Awareness, Communication

Mariveles Mental Hospital's support team has been noted with good standing during every audit. Nonetheless, the following points for improvement were discussed below.

Audit Findings

Observations/Opportunities for Improvement /NCR:

DCC

1. Proof of evidence in retrieving documents is necessary
2. Ensure the date of registration is different from date of effectivity (CIP: revised documents).
3. May consider to study the ruling on revision.
4. May review the procedure in order to delete some procedure included that may not necessary.

Training

1. Documentation of impact evaluation training effectiveness is needed.
2. Strictly followed of forms used such as Training Request form
3. May have a provision related on not attending the training thru letter or phone calls was accepted
4. May consider to maintain a copy of list of trainer for reference.

IHOMP

1. May consider establishing new objectives aligned with the new identified risks such as compliance with the software license. Plans and programs shall also be established to address the risk.

Security

1. May consider specialized training for security especially in handling escapee or in case of emergency.

Clause 8.0 - Operation

Operational planning and control, Requirement for product and services, Customer communication, Determination of requirement related products and services, Review of requirements related to products and services, Design and development of products and service, Control of externally provided products and services,

Production and services provision; Identification and traceability, Property belonging to customers and external providers, Preservation,

Post-delivery activities, Control of changes, Release of product and services, Control of nonconforming outputs

Audit Findings

Observations/Opportunities for Improvement/ NCR:

Materials Management

1. Consider legal compliance in the identification of risk and opportunities applicable to the unit. Identify specific guidelines/ruling from Hospital Property and Supply Management Manual for easy verification of compliance.
2. IPCR implementation and clarity of task performance definition is commendable. (Positive)

Admitting

1. All processes are properly implemented accordingly. (Positive)

Pharmacy

1. To establish a strict inventory system for all e-carts (CIP: OPD and ACIU e-cart monitoring).
2. May consider practicing Clinical Pharmacology in the department.

CCU (Female)

1. Best to incorporate the date of admission and discharge on the Discharge Slip for easy traceability.

Psychology

1. Ensure availability of proof of purchase for all psych testing materials.
2. To ensure efficiency of the service, the organisation may enter into a MOA partnership with psychological societies to help in the assessment of the patients.

Clinical Departments and Committees

Positive

1. Letter of appointments duly signed with conforme and valid.
2. Job Descriptions are specifically described and documented.
3. Minutes of the meeting duly documented with attached attendance sheet.
4. Manuals are updated and fully documented.

Laboratory

1. All the licenses are updated and cleanliness is noted on the area. (Positive)

X-ray

1. Using filmless is appreciated and noted (Positive)

Procurement

1. All the staff are attentive and procedures implemented accordingly. (Positive)

Dietary

1. Updated clearances and licences for all personnel of Dietary Unit is commendable. (Positive)
2. May consider coordination with LPG supplier for a detail checklist applicable with the leak testing procedure for LPG piping system.

Clause 9.0 – Performance evaluation

Monitoring, measuring, analysis and evaluation, Customer satisfaction, Analysis and evaluation, Internal audit, Management review

The organisation has reported a total of 687 admissions as of June 2018.Top 10 leading cause of admission includes schizophrenia, bipolar affective disorder, acute and transient psychotic disorder, mental and behavioural disorder due to brain disease damage and dysfunction, mental and behavioural disorder due to multiple substance abuse, depressive episode, mental and behavioural disorder due to use of alcohol, schizoaffective disorder, mental retardation and unspecified non – organic psychosis. Infection rate from 1st quarter was .31% and 2nd quarter reports .55% increase. As to customer's satisfaction, the hospital reports a total score rating of 99.41%.

The latest internal audit was noted with 2 non – conformity, 0 observation, 13 improvement and 12 positive remarks. On the other hand, management review was done last 28 June 2018. Documents such as Audit Program (MMH-QAC-04-02-02), Attendance Sheet (MMH-PET-04-14-01), IQA Observation / Improvement findings corrective action reports (MMH-QAC-04-08-01) were noted during the audit.

Audit Findings

Observations/Opportunities for Improvement:

IQA

1. IQA done May 28, 2018 with detailed minutes of the meeting, audit notice and plan, attendance sheet duly signed attached. (Positive)
2. Need to upgrade to the new standards of IQA (ISO 19011:2018).

Customer Service

1. Improved monitoring and retrieval of forms. (Positive)
2. 99.4% satisfaction rating from August 2017 to July of 2018. (Positive)
3. May suggest conducting review on how rating is done (CIP: rating each department for easy monitoring and traceability).

Internal Audits

Frequency:	Monthly	Six-monthly	Yearly	Other

☐	☐	x	☐

Date of most recent audit:	28 May 2018
Date of audit preceding last:	21 – 23 June 2017
Audit performed by :	
During the audit, the internal Audit Plan, dated 18 May 2018 and internal Audit Report, dated 28 May 2018, were verified.	
Forward planning is informed by the most recent two audits, information from the analysis of data and information from critical processes	Yes x No ☐

Management Review Meeting

Frequency:	Monthly ☐	Six-monthly x	Yearly ☐	Other ☐

Date of most recent meeting:	26 June 2018
Date of meeting prior to last:	26 March 2018
Management review chaired by :	OIC Chief of Hospital I
The continuing suitability, adequacy and effectiveness of the management system was confirmed by the top management.	Yes x No ☐

Clause 10.0 – Improvement

Nonconformity and corrective action, continual improvement

The hospital has presented complete documented information with total CAR 36 all closed prior third party audit.

Audit Findings

Observations/Opportunities for Improvement:

none

ADDITIONAL INFORMATION

Use of Marks and Logos

No misuse seen

Previous Non-conformances Closed/Open and Action Taken

None

Complaints

(Comment on complaints received or dealt with. Include reference number for traceability)

Triennial review

Documents Reviewed for Pre-Triennial Review			
Docs reviewed	Audit Log ☐	Previous NCs ☐	Previous Reports X
Comments on Documents:	The continued review of documents and review of implementation based on actual processes were consistent in the requirements of the ISO standard.		

Outstanding Issues

None

Site Specific Summary (if applicable) n/a

Site 1:

Site 2:

CONCLUSION

Statement of Conclusion

The hospital was able to sustain and maintain the requirements of the standard they're applying for. Continuous commitment and mastery of ISO implementation was seen and observed to this organisation that led them to earn more recognitions and awards from various entities.

Recommendation

Recommended for Certification/Continued Certification.	Yes x	No ☐
Recommended Surveillance Interval	Once a year	
Next Audit Date	**August 2019**	

DISCLAIMER

Some issues, non-compliances or required improvements within the organisation may not have been identified in this report, due to the sampling size and time available during the audit. The organisation's management is responsible for implementing a surveillance system (based on internal audits) to identify non-conformances/continuous improvement opportunities and to take the necessary controls to ensure the quality management system implemented is effective and meets organisational and regulatory requirements.

CONFIDENTIALITY STATEMENT

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ISC (Global), its employees, auditors and contractors and accreditation bodies have signed confidentiality agreements and will only receive confidential information as per the requirement of the standards being audited.

Report by:	**Ricardo Adriano Jr.**		**17 Sept. 2018**
	Team Leader (name)	**Signature**	**Date**

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Table 1 - Audit Program Elements to be audited

Elements in **bold** to be audited at every audit
Schedule may be subject to change.

Triennial Audit Program Section title		Audit Type Initial Stage 2 Year 20__	Surveillance 1 Year 2019	Surveillance 2 Year 2020	Triennial /Recert. Year 2021
1	General Review	✓	✓	✓	✓
2	**Leadership (Clause 5.0)** Leadership and commitment, Customer focus, Quality policy, Organisational roles, responsibilities and authorities,	✓	✓	✓	✓
3	**Planning for the quality management System (Clause 6.0)** Actions to address risks and opportunities, Quality objectives and planning to achieve them, Planning of changes,	✓	✓	✓	✓
4	**Support (Clause 7.0)** Resources, People, Environment for the operation of processes, Monitoring and measuring resources, Organisational knowledge, Awareness, Communication	✓		✓	✓
5	**Operation (Clause 8.0)** Operational planning and control, Determination of requirement for product and services, Customer communication, Determination of requirement related products and services, Review of requirements related to products and services. Control of externally provided products and services, Production and services **(select or delete as**	✓	✓	✓	✓

Triennial Audit Program Section title		Audit Type Initial Stage 2 Year 20__	Surveillance 1 Year 2019	Surveillance 2 Year 2020	Triennial /Recert. Year 2021
	appropriate) *e.g. Sales/Marketing* *Design and development of products and services;* *Project Management;* *Purchasing;* *Production;* *Inspection and Testing;* *warehousing, Packaging, preservation and dispatch;*				
6	**Performance evaluation (Clause 9.0)** Monitoring, measuring, analysis and evaluation Customer satisfaction, Analysis and evaluation, **Internal audit** **Management review**	✓	✓		✓
7	*Documentation Status*	✓		✓	✓
8	*H.O, Site Visit or Visits (including Addresses)*	✓	✓	✓	✓
9	*Site visits for Temporary Sites*	✓	✓	✓	✓
10					

ISO 9001

ISC GLOBAL

ISO 9001:2015

Certificate of Registration

THIS IS TO CERTIFY THAT THE
QUALITY MANAGEMENT SYSTEM OF

Mariveles Mental Hospital

P. Monroe Street, Poblacion
Mariveles, Bataan

PHILIPPINES

Has been assessed and registered as complying with the requirements of the International Standard shown above for the following Scope. Further clarifications regarding the scope of this certificate and the applicability of ISO 9001:2015 requirements may be obtained by consulting the organisation.

Provision of Curative, preventive and rehabilitative psychiatric services. Services are Out-Patient, In-Patient, Admission Crisis intervention and occupational therapy.

MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT IAF

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Tony Wilde
Group Chairman
ISC (Global), License #1150/2011 CC

Registration Number:	QAC/R63/0118
Original Registration Date:	24-Jul-2014
Re-certification Date:	29-Sep-2017
Expiry Date:	24-Jul-2020

ISC GLOBAL

ISC (Global), Building 11, 7th Floor, Bay Square, Business Bay, Dubai, UAE.

This certificate is valid until the Expiry Date on the condition that audits are conducted and paid for as per the Certification Agreement. Should this condition not be met, cancellation procedures will be initiated and the client will be removed from the JAS-ANZ register. This Certificate remains the property of International Standards Certifications (Global) FZ LLC and must be returned upon request. It must not be altered in any way. Intentional misuse of this certificate will result in cancellation without prior notification.