



TITLE : Management Systems Audit Report [Certification/Recertification/Surveillance (I/II)]

DOC: MSC-F6.4-04

ISSUE:12

DATE: Feb 2023

PAGE 1 OF 8

PREPARED BY: HEAD (MSCD)

APPROVED BY: DDG (MSC)

CONFIDENTIAL (when filled)

0.Reference: OHS/WR/A-APP2023075261		0.2 Validity (If applicable):	
0.1 Appl/Licence No.: OHS/WR/A-APP2023075261		NA	
0.3 Name of the Organization	M/s Zydus Hospitals & Healthcare Research Pvt Ltd,		
0.4 Address (Pl. mention Pin Code, State, also)	Plot no 232, Zydus Hospital Road, Thaltej, Ahmedabad - 380054		
0.5 Address(es)of site(s) covered	Same as above		
0.6 Telephone & Email address.	Tel: 07966190200. Email: satishgajjar@zydushospitals.com		
0.7 Name of the concerned Contact Person (with E-mailid)	Mr Satish Gajjar, Associate Engr	0.8 Telephone No. 9601294252	
0.9 Effective no. of personnel	1500	0.10 No. of shifts	G, A, B, C
0.11 Date(s)of Last Audit	07/10/2023	0.12 Shift(s) selected	G, A, B, C
0.13 Audit date(s)	22-25(FN)/01/2024	0.14 Duration (man days/Audit Days)	10.5/3.5
0.15 Technical Sector/Area	: Health & Social Work		
0.16 CPA Code(s)(upto2placeofdecimal)	IAF 38		
0.17 Working Language	English, Hindi		
0.18 Audit Criteria [Management System Standard, organization's documented information (Title, Issue No., Date, No. of Amendments, etc.)]	IS/ISO 45001: 2018. Policy, documents and statutory/regulatory requirements. OHS manual: ZHHRPL/OHSMS/ISO45001.2018/01dt 10/10/2023 ii) Maintained documents, Retained documents, iii) External documents		
0.19 Objectives & Scope of Audit (Organizational and functional units or processes to be audited. For multi-site audit mention the actual sites being audited)	To make assessment with respect to IS/ISO 45001:2018 for consideration Grant of licence.		
Date of report	25/01/2024		
Name of Team Leader	N Banik		
Signature of Team Leader			
MSCO(R)			
DDG(R) _____ -in case audit is undertaken by MSCO(R)			
DDG(MSCD)/ADG -Through MSCO(R) in case audit is undertaken by DDG(R)			

Auditing Organization	Auditee (Organization)
Bureau of Indian Standards	M/s Zydus Hospitals & Healthcare Research Pvt Ltd, Plot no 232, Zydus Hospital Road, Thaltej, Ahmedabad - 380054



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DOC: MSC-F6.4-04

ISSUE:1 2

DATE: Feb 2023

PAGE 1 OF 8

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1. SUMMARY

1.1 **Non-conformities** (Data on NCs raised against Clause/Sub- clause of standard(s) against which firm was audited)

NC	Minor				Major				Total
Clause of IS/ISO									
No. of NCs raised	Nil						Nil	Nil	
No. of NCs cleared									
No. of NCs pending									

1.2 Verification of actions taken by firm on nonconformities pending from surveillance/other audit (for recertification audit) and on pending points from Stage 1 audit (for certification audit)

Date of NC/Points Raised	Clause of IS/ISO	Action taken	Current Status
07/10/2023	---	Pl see Page no 13	All NC/points cleared

1.3 verification of change from the existing licence in structure of licensee (example-change in name, address, management, merger, new sites covered, change of scope etc)
No change

1.4 Non applicability of process(es), where applicable, sought by the firm and verification of justification by the Audit Team-Audit observation sheet also reflect the justifications and evidence related to the applicable processes.
All processes are applicable

1.5 **Scope to be covered in the licence document**
(attach letter from the organization for the scopes sought with details of sites to be covered, duly counter signed by team leader. Ensure that the audit plan and observations cover the scope): (applicable for certification/recertification audit)
Attached

1.6 **Summary of audit process [Also specify the techniques & methodologies used]**

Audit was carried as per audit plan which was prepared after consultation with MR. Audit was carried out by interview, interaction & witnessing ongoing activities/ processes and verifying records.

1.7 Observations on reliability of internal audit and effectiveness of management review

Examining the records and evidence provided by the firm, it was found that the internal audit was reliable and management review is effective.

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ISSUE:1 2

DATE: Feb 2023

PAGE 1 OF 8

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1.8 Review of past performance (based on Continual Improvement, trends and evaluation of conformances and non-conformances observed during surveillance audits/follow-up audit/any other audit conducted since certification)/last recertification audit/System Performance).

NA

1.9 Whether audit objectives have been accomplished within audit scope in accordance with audit plan?

Yes

1.10 Any areas not covered, although within the audit scope

None

1.11 Any unresolved diverging opinions between audit team and auditee.

None

1.12 **Audit Findings** [including positive (noteworthy features) and opportunities for improvement].

OHSMS of the organization based on IS/ISO 45001:2018 have been found to be effectively implemented to meet the OHS Policy and achieve the Objectives.

1.13 Whether any uncertainty and/or any obstacle encountered that could decrease reliability of audit conclusions)?

Nil

1.14 Agreed follow-up action plans for verification of pending non-conformances, if any.

NA

Auditing Organization

Auditee
(Organization)

Bureau of Indian Standards

M/s Zydus Hospitals & Healthcare Research Pvt Ltd, Plot no 232,
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DOC: MSC-F6.4-04

ISSUE:1 2

DATE: Feb 2023

PAGE 1 OF 8

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1.15 Recommendations for follow-up audit (Refer - Also propose auditor(s), mandays required):
NA

1.16 Any disputes referred to and complaints made to BIS against the licensee or appeal made by licensee to BIS. Verification of corrective actions taken by the licensee for its own processes with reference to complaint, dispute and appeal.
Nil

1.17 Verification of actions taken by the firm for changes in their structure/extension of scope/multiple locations (Documents attached at Annex. -):
NA

1.18 For Energy Management Systems (EnMS), scope and boundary of EnMS; evidence related to Energy performance (including, energy planning, energy review, operational controls, design, monitoring measurement and analysis, energy performance improvement, etc Also, during surveillance audits, implementation of actions for energy performance improvement to be demonstrated)
NA

1.19 For audit of Integrated Management Systems, level of integration*: **Nil/ Partly/ Complete**
*level of integration is explained in MSC-G6.2-02

1.20 Audit conclusions and recommendations of audit team
Based on the Audit carried out as per audit plan & schedule with respect to the requirements of IS/ISO 45001:2015, it is found that the organization's OHSMS is in conformity with the requirements of the above standard and found to have been effectively implemented to achieve the OHS policy and objectives. Audit Team recommends Grant of Licence of OHSMS as per IS/ISO 45001:2018 with the scope and site as declared by the organization

2. AUDIT PLAN DATA

2.1 Composition of Audit Team

Sl. No.	Name	Status in Team
1.	Shri Narayan Banik	Team Leader
2.	Shri Rahul Kumar	Auditor & Expert
3.	Smt B Sandhya	Auditor
4.	Shri S D Rane	Auditor in Training

2.2 Audit Plan communication date to the Auditee: 06/01/2024

2.2 Change of Audit Plan, if any, and reasons: All the departments were included which were not considered during stage I audit

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ISSUE:1 2

DATE: Feb 2023

PAGE 1 OF 8

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2.4 Audit preparation details, reference to checklist and sectoral guidelines, if any (*record briefing of team members by the expert about the technical aspects and applicable regulatory requirements. Also record identification of requirements to be audited by expert in Audit Plan Matrix by the expert*):

The activities to be audited were discussed with MR and prepared audit schedule and audit plan matrix and informed MR in advance. The audit team studied the documents and applicable statutory and regulatory requirements

2.5 Audit Plan Matrix (*Attach MSC-F6.4-09, duly filled-in with processes/departments specified, with identification of requirements to be audited with an expert*)

Attached

3. Observation Sheet, Opportunity for improvement, Assessment of regulatory requirements and Expert's Report(*Attach MSC-F6.4-22, MSC-F6.2-10, and others as applicable*)
Observation sheets attached

4. Use of Standard Mark and Accreditation Mark (*Refer MSC-G-6.10-01*) – *Satisfactory/Not satisfactory (Details to be given if not satisfactory)*

NA

5. AUDIT FEE & OTHER CHARGES (*Give details of audit, local travel & stay charges realized/to be realized*)

Audit charges of rupees 162460/paid on 10/01/2024 vide Tax Ref No. ZHDF1667943975

6. ANNEXURES

		Page No
a)	Audit Plan	01-05
b)	Audit Matrix (MSC-F6.4-09)	06-07
c)	Confidentiality report	08-11
d)	Letter for Scope of Certification, if applicable	12
e)	Report of action taken on previous audit findings, if any	13
f)	Audit observations (MSC-F6.4-22)	14-46
g)	Report of Expert, if applicable	---
h)	Non-conformity Reports (MSC-F6.4-14)	---
i)	Opportunity for Improvement (MSC-F6.2-10)	---
j)	Audit Report submitted to auditee (MSC-F6.4-20)	47
k)	Audit Log Sheet (MSC-F7.1-04)	48
l)	Performance evaluation reports, if applicable MSC-F7.4-01	49-51
m)	Participants of Opening and Closing meeting	52-53

Name of Team Leader/Principal Auditor : N Banik

Name of Lead Auditor, if any : ---

Design. & Deptt./RO/BO :---

Date of Report: 25/01/2024

Signature of Principal Auditor/Team Leader:

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TITLE : Management Systems Audit Report [Certification/Recertification/Surveillance (I/II)]

DOC: MSC-F6.4-04

ISSUE:1 2

DATE: Feb 2023

PAGE 1 OF 8

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Review of Audit Report

Propose Reviewer #: It is proposed to get this report reviewed by who is a qualified auditor for the Management System audited in this report.

Only in cases the report is not being reviewed by MSCO (R).

MSCO ()

Approval by DDG ()

Concerned Officer through Controlling Officer

Review

by MSCO (R)/Any Other Officer:

Sl. No.	Subject/Content	Observation/Comment (If required attach separate sheets)
1	Whether all entries filled in the audit report form and all annexures attached	
2	Whether technical area and CPA code correctly indicated	
3	Audit scope adequately verified/covered during the audit (include comments on the evidences verified by the auditor(s) as indicated in the Observation sheets)	
4	Comment on the NCs/opportunity for improvements raised, if any	
5	Justification for Exclusion (if any) of particular clause(s) of the Management System Standard	
6	Reliability of Internal Audit	
7	Effectiveness of Management Review	
8	Was the audit plan communicated in advance and the date of audit plan agreement by Auditee.	
9	Comment on the quality of Observation sheets filled by the Auditor (s)	
10	Any major changes observed during the audit which were not informed prior to conduct of audit and its effect on the certification	
11	Audit fees received or not	
12	Audit conclusion and recommendations of the audit team consistent with audit findings	
13	Timely submission of report	
14	Any other aspect not covered above	

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Bureau of Indian Standards	M/s Zydus Hospitals & Healthcare Research Pvt Ltd, Plot no 232, Zydus Hospital Road, Thaltej, Ahmedabad - 380054



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DOC: MSC-F6.4-04

ISSUE:1 2

DATE: Feb 2023

PAGE 1 OF 8

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15	Conclusions of the review of audit report	
16	Performance valuation of auditors on their reporting filled up or not?	

Date:

Signature :

Name :

Designation:

Auditing Organization	Auditee (Organization)
Bureau of Indian Standards	M/s Zydus Hospitals & Healthcare Research Pvt Ltd, Plot no 232, Zydus Hospital Road, Thaltej, Ahmedabad - 380054

Disclaimer: Auditing is based on a sampling of the available information.



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DOC: MSC-F6.4-04

ISSUE:1 2

DATE: Feb 2023

PAGE 1 OF 8

PREPARED BY: HEAD (MSCD)

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Review of FSMS Requirements

Sl. No.	Subject/Content	Observation/Comment (If required attach separate sheets)
1	Is the identification of Food Chain Category correct	
2	Are the Food Safety Hazards specific to the food chain identified	
3	Comment on CCPs, Critical Limits and CCP monitoring	
4.	Comment on verification of HACCP Plan	
5.	Comment on verification of PRPs & OPRPs	
6.	Whether the effectiveness of withdrawals have been verified	
7	Validation of control measures verified	
8	Comment on effectiveness of FSMS implemented	

Signature :

Name :

Designation :

Auditing Organization	Auditee (Organization)
Bureau of Indian Standards	M/s Zydus Hospitals & Healthcare Research Pvt Ltd, Plot no 232, Zydus Hospital Road, Thaltej, Ahmedabad - 380054



TITLE: Audit Plan

DOC: MSC-F6.4-13

ISSUE: 06

DATE: Feb 2021

Page 1 of 3

Prepared By:

Approved By: DDG(MSCD)

1. Ref: **Application No.** / Licence No: OHS/WR/A-APP2023075261
2. Validity (In case of licence): NA
3. Name of the **Applicant**/Licensee: M/s Zydus Hospitals & Healthcare Research Pvt Ltd, Plot no 232,
Zydus Hospital Road, Thaltej, Ahmedabad – 380054
4. Technical Area: Health & Social Work
5. CPA Code(s): IAF 38
6. Objective of the Audit : For **Stage II** /Recertification/Surveillance/Special Audit

Stage 1 Objectives:	√	Stage 2 objectives:
<ul style="list-style-type: none"> a) Review the client's management system documented information; b) evaluate the client's site-specific conditions and to undertake discussions with the client's personnel to determine the preparedness for stage 2; c) review the client's status and understanding regarding requirements of the standard, in particular with respect to the identification of key performance or significant aspects, processes, objectives and operation of the management system; d) obtain necessary information regarding the scope of the management system, including:— the client's site(s);— processes and equipment used;— levels of controls established (particularly in case of multisite clients);— applicable statutory and regulatory requirements; e) review the allocation of resources for stage 2 and agree the details of stage 2 with the client; f) provide a focus for planning stage 2 by gaining a sufficient understanding of the client's management system and site operations in the context of the management system standard or other normative document; g) evaluate if the internal audits and management reviews are being planned and performed, and that the level of implementation of the management system substantiates that the client is ready for stage 2. 	√	<ul style="list-style-type: none"> a) √ information and evidence about conformity to all requirements of the applicable management system standard or other normative documents; b) √ performance monitoring, measuring, reporting and reviewing against key performance objectives and targets (consistent with the expectations in the applicable management system standard or other normative document); c) √ the client's management system ability and its performance regarding meeting of applicable statutory, regulatory and contractual requirements; d) √ operational control of the client's processes; e) √ internal auditing and management review; f) √ management responsibility for the client's policies

(Tick marks whichever is applicable)

7. Scope of the Audit: All activities as given in the audit schedule



TITLE: Audit Plan

DOC: MSC-F6.4-13

ISSUE: 06

DATE: Feb 2021

Page 2 of 3

Prepared By:

Approved By: DDG(MSCD)

8. Audit Criteria/Reference Documents

a) IS/ISO 45001:2018

b) Policy, documents and statutory / regulatory requirements and records given below:

- (i) OHS Manual,
- (ii) Department manual
- (iii) OHSS Procedures with all amendments
- (iv) Formats / Records/ retained documents
- iv) List of legal and other requirements
- v) External documents

(v) Audit Team (Roles & Responsibilities of auditing personnel are given in MSC-G6.3-02). All auditors and experts have signed the confidentiality statement.

S. No	Name	Status
1.	Shri Narayan Banik	Team Leader
2.	Shri Rahul Kumar	Auditor & Expert
3.	Smt B Sandhya	Auditor
4.	Shri S. D. Rane	Auditor in Training

7. Audit Methodology

- a) Physical observations including site observations,
- b) Interviews and discussions
- c) Document reviews,
- d) Direct measurements, if needed

8. Working and Reporting Language of Audit

English in general; some interviews may be carried out in Hindi/local language.

9. The audit will be carried out at a place convenient to auditee and the auditor mostly at the office of the auditee. If the audit requires visiting various parts of the site, the auditee is requested to extend all the required assistance. The audit plan given below provides a broad guideline; changes in the plan be effected by mutual agreement between the auditor(s) and the auditee. A brief audit report would be submitted by the Team Leader to auditee. The audit report will cover NCs raised, closed, pending, observations on conformity of the organization's management system with certification requirements and its effectiveness and conclusion/recommendation of the audit. Any audit follow-up actions will be discussed with the auditee during closing meeting. Guides/observers/consultants/persons other than auditee should not influence or interfere with the conduct of the audit.

10. **Audit Schedule (includes meetings with the auditee's management and audit team meetings):** To be attached
(Please see Annexure – Attached)

A typical audit schedule is given below for guidance.

DATE (DAY - 1/2/3/..)

Process/Department/Activity	Time	Auditor	Auditee
Opening Meeting			
Plant/Office Visit			
Process X, Y, etc			
Closing Meeting			



TITLE: Audit Plan

DOC: MSC-F6.4-13

ISSUE: 06

DATE: Feb 2021

Page 3 of 3

Prepared By:

Approved By: DDG(MSCD)

11. Audit Plan Matrix is enclosed for the reference of audit team members (Please see Annexure – B attached)

NOTES: (For Team leader/Lead auditor)

- 1) An auditor day is typically a full normal working day of 8 hours out of which 7 hours should be spent on actual audit
- 2) Frequent auditors' meetings may be required & accordingly Team Leader may organize these meetings.
- 3) Team Leader to observe the performance of auditors/auditor-in-training/sub-contractors /experts spending half an hour for each of the team member during the audit. Similarly, lead auditor should observe the performance of the team leader (under training) spending half an hour during the audit. Accordingly, the audit plan should be prepared. The team leader/lead auditor shall mention the above in the audit plan preferably only in the copy of the audit plan to be submitted along with the audit report to BIS.
- 4) The tentative audit plan shall be communicated to auditee in advance with audit objectives, audit criteria, audit plan and audit team composition and the plan shall be agreed to before the audit. If any change in auditor takes place subsequently, it shall be informed to the auditee prior to audit dates. The nomenclature of departments/functions reported for, in the audit matrix shall be same as that given in the audit plan. Justification need to be given if for any change in nomenclature by clubbing/splitting of functions/processes/departments.
- 5) In the case of multi shift operations, EMS audit may be planned in other shifts too to verify controls. In the case of QMS, all processes for products/service realizations to be covered even when it is operated in shifts. In case only one shift is audited, which covers all processes their controls in other shifts and justification for not auditing other shifts to be suitably reported.
- 6) The audit plan shall include organization specific processes and products to be assessed.
- 7) The audit plan for OHSMS shall include activities, products and services within the organization's control or influence that can impact the organization's OH&SMS performance. Temporary sites, for example, construction sites, shall be covered by the OH&SMS of the organization that has control of these sites, irrespective of where they are located.

Signature

N Banik, Team Leader

Date : 06/01/2024

Signature

Coordinator

Date : 06/01/2024



Audit Schedule(Stage II Audit OHSMS)

1. Application Nos: OHS/WR/A-APP2023075261
2. Name of the organization: M/s Zydus Hospitals & Healthcare Research Pvt Ltd, Plot no 232, Zydus Hospital Road, Thaltej, Ahmedabad - 380054
3. Management Systems Std: IS/ISO45001:2018
4. Auditors: 1. Shri Narayan Banik: Team Leader (A)
2. Shri Shri Rahul Kumar: Auditor & Expert (B)
3. Smt B Sandhya: Auditor (C)
4. Shri S D Rane: Auditor in Training (D)
5. Audit Program:

Date	Time(hrs)	Activity/Process	Auditor	Auditee (In-charge of the dept.)	Located Floor
22/01/2024	1000-1030	Opening Meeting	All	As per the list	9 th Floor
	1030-1130	Site Visit	All	All Concerned	
	1130-1330	Centre Head and OHSMS Coordinator	A +D	Dr. Sanjeev Gupta (Center Head), Mr. Satish (Engg. Dept), Dr. Prashant(Lead Quality)	9 th Floor
		Diagnostic Dept (Radiology, CT scan, MRI, X-ray etc)	B	Ms Meera (In-charge Radiology)	Grd Floor
		Nursing	C	Ms. Elizabeth Santosh (Lead Nursing),	8 th Floor
	1330-1400	Lunch		**	2 nd floor
	1400-1730	Centre Head and OHSMS Coordinator, Contd	A+D	Dr. Sanjeev Gupta, Mr. Satish, Dr. Prashant	9 th floor
		OPD(4 nos)	B	Mr. Jasmin Shah (In-charge OPD)	1 st and 2 nd Floor
		Pharmacy	C	Mr. Siddhartha subudhi (In-Charge Pharmacy)	Grd. Floor
	1730-1800	Auditors meeting & interaction with auditee	All	All Concerned	
23/01/2024	1000-1330	Admissions and billing	A	Mr. Amit Gandhi (In-Charge Admi. & Billing)	Grd Floor
		Operation theatre (2 nos to be audited)	B+D	Ms. Jigna, Ms. Smita (In-charge OT)	3 rd and 5 th Floor
		Medical Records	C	Mr. Ishwar (In-charge MRD)	4 th floor
	1330-1400	Lunch		**	2 nd floor
	1400-1730	Admin (purchase, HR, Finance, Kitchen)	A	Mr. Anand, Ms Parag, Mr. Riv (In-charge Purchase, HR, Finance)	UB, 9 th & 13 th Floor
Operation theatre (2 nos to be audited) Contd		B+D	Ms. Jigna , Ms. Smita (In-	3 rd and 5 th	

				charge OT)	Floor
		Security and house keeping	C	Mr. Kamlesh, Mr. Fateh (In-charge Security & HK)	Grd Floor & 8 th Floor
	1730-1830	Auditors meeting & interaction with auditee	All	All Concerned	
24/01/2024	1000-1330	Engg services and utilities	A	Mr. Sandeep Rana (lead Engineering)	UB Floor
		Biomedical Engg services	B	Mr. Terence (Lead BMD)	9 th floor
		Medical Lab and Blood Bank	C+D	Ms. Nisha (Quality associate LAB)	4 th floor
	1330-1400	Lunch		**	2 nd floor
	1400-1730	IT	A	Mr. Nageshwar, Mr. Amrish (Lead IT)	9 th floor
		Fire Safety	B	Mr. Santosh (In-charge Fire Safety)	4 th floor
		Central sterile supply Department	C+D	Mr. Bipin (In-charge CSSD)	4 th floor
	1730-1830	Auditors meeting & interaction with auditee	All	All Concerned	
25/01/2024	0900-1200	General Store	A +D	Mr. Umesh (In-charge Store)	UB Floor
		Emergency, Ambulance services and PCA	B	Mr. Afzal (In-charge Amb. Ser.)	Grd Floor
		IPD (Medical Services)	C	Dr. Chaitasy Mehta (Lead Medical)	4 th floor
	1200-1230	Auditors meeting & interaction with auditee & Report Preparation	All	All Concerned	
	1230-1300	Closing Meeting	AI	To concern	9 th floor

Note: Night shift visit after consultation with the auditee
Night Shift Audit Department: - Kitchen, fire safety, CSSD

Shri N Banik, *N Banik*
BIS Audit Team Leader
Date : 22/01/2024

Satish Gajjar
Satish Gajjar (Engineer)
Coordinator
Date : 22/01/2024



AUDIT PLAN MATRIX FOR OHSMS

Clause	AUDIT PLAN MATRIX	Sub Clause	FUNCTION/PROCESS/ DEPARTMENT(S)										
			A	B	C	D	E	F	G	H	I	J	K
	IS/ISO 45000: 2018 Occupational Health and Safety Management System Requirements												
4	Context of the Organization												
	Understanding the organization and its context	4.1	X	X								X	X
	Understanding the needs and expectations of interested parties	4.2	X	X								X	X
	Determining the scope of OHSMS	4.3	X	X								X	X
	OHSMS	4.4	X	X								X	X
5	Leadership												
	Leadership and commitment	5.1	X										
	OHSMS policy	5.2	X	X	X	X	X	X	X	X	X	X	X
	Organizational roles , responsibilities and authorities	5.3	X	X	X	X	X	X	X	X	X	X	X
	Consultation and Participation	5.4	X	X	X	X	X	X	X	X	X	X	X
6	Planning												
	Actions to address risks and opportunities -General	6.1.1	X	X	X	X	X	X	X	X	X	X	X
	Hazard identification, assessment of risk & opportunity	6.1.2	X	X	X	X	X	X	X	X	X	X	X
	Compliance Obligation	6.1.3	X	X	X	X	X	X	X	X	X	X	X
	Planning action	6.1.4	X	X	X	X	X	X	X	X	X	X	X
	OH&S Objectives & Planning to achieve them												
	Environmental Objectives	6.2.1	X	X	X	X	X	X	X	X	X	X	X
Planning action to achieve Environmental Objectives	6.2.2	X	X	X	X	X	X	X	X	X	X	X	
7	Support												
	Resources	7.1	X	X	X	X	X	X	X	X	X	X	X
	Competence	7.2	X	X	X	X	X	X	X	X	X	X	X
	Awareness	7.3	X	X	X	X	X	X	X	X	X	X	X
	Communication												
		7.4	X	X	X	X	X	X	X	X	X	X	X
		7.5	X	X	X	X	X	X	X	X	X	X	X
	Documented Information												
	General	7.5.1	X										
	Creating and Updating	7.5.2	X	X	X	X	X	X	X	X	X	X	X
	Control of documented information	7.5.3	X	X	X	X	X	X	X	X	X	X	X
8	Operation												
	Operational planning and control	8.1	X	X	X	X	X	X	X	X	X	X	X
	General	8.1.1	X	X	X	X	X	X	X	X	X	X	X
	Eliminating Hazards & reducing OH&S risks	8.1.2	X	X	X	X	X	X	X	X	X	X	X
	Management of change	8.1.3	X	X	X	X	X	X	X	X	X	X	X
	Procurement	8.1.4	X	X	X	X	X	X	X	X	X	X	X
	Emergency preparedness and response	8.2	X	X	X	X	X	X	X	X	X	X	
9	Performance evaluation												
	Monitoring, Measurement analysis & evaluation												
	General	9.1											
	Evaluation of compliance	9.1.1	X	X	X	X	X	X	X	X	X	X	X
	Analysis and evaluation	9.1.2	X	X	X	X	X	X	X	X	X	X	X
	Internal audit												
		9.2	X	X	X	X	X	X	X	X	X	X	X
	Management review												
		9.3	X										
10	Improvement												
	General	10											
	Nonconformity and Corrective action	10.1	X	X	X	X	X	X	X	X	X	X	X
	Continual improvement	10.2	X	X	X	X	X	X	X	X	X	X	X
		10.3	X	X	X	X	X	X	X	X	X	X	
	Auditing Organization BUREAU OF INDIAN STANDARDS		Auditee (Organization) Zydus Hospitals & Healthcare Research Pvt Ltd, Plot no 232, Zydus Hospital Road, Thaltej, Ahmedabad - 380054								Page 1 of 2		
	Doc : MSC-F6.4-35		Issue No. 01				Date : Dec 2018						

A - Centre Head and OHSMS Coordinator, B- Diagnostic Dept (Radiology, CT scan, MRI, X-ray etc), C- Nursing, D OPD(4 nos)-, E- Pharmacy, F- Admissions and billing, G- Operation theatres (2 nos to be audited), H- Medical Records, Admin (purchase,I- HR, Finance, Kitchen), J- Security and house keeping, K- Engg services and utilities

AUDIT PLAN MATRIX FOR OHSMS


Clause	AUDIT PLAN MATRIX	Sub Clause	FUNCTION/PROCESS/ DEPARTMENT(S)															
			L	M	N	O	P	Q	R	S	T							
	IS/ISO 45000: 2018 Occupational Health and Safety Management System Requirements																	
4	<u>Context of the Organization</u>																	
	Understanding the organization and its context	4.1	X	X			X	X					X					
	Understanding the needs and expectations of interested parties	4.2	X	X			X	X					X					
	Determining the scope of OHSMS OHSMS	4.3 4.4	X X	X X			X X	X X					X X					
5	<u>Leadership</u>																	
	Leadership and commitment	5.1	X				X											
	OHSMS policy	5.2	X	X	X	X	X	X	X	X	X	X	X					
	Organizational roles , responsibilities and authorities Consultation and Participation	5.3 5.4	X X	X X	X X	X X	X X	X X	X X	X X	X X	X X	X X					
6	<u>Planning</u>																	
	Actions to address risks and opportunities -General	6.1.1	X	X	X	X	X	X	X	X	X	X	X					
	Hazard identification, assessment of risk & opportunity	6.1.2	X	X	X	X	X	X	X	X	X	X	X					
	Compliance Obligation	6.1.3	X	X	X	X	X	X	X	X	X	X	X					
	Planning action	6.1.4	X	X	X	X	X	X	X	X	X	X	X					
	<u>OH&S Objectives & Planning to achieve them</u>																	
	Environmental Objectives	6.2	X	X	X	X	X	X	X	X	X	X	X					
7	<u>Support</u>																	
	Resources	7.1	X	X	X	X	X	X	X	X	X	X	X					
	Competence	7.2	X	X	X	X	X	X	X	X	X	X	X					
	Awareness	7.3	X	X	X	X	X	X	X	X	X	X	X					
	<u>Communication</u>																	
		7.4	X	X	X	X	X	X	X	X	X	X	X					
	<u>Documented Information</u>	7.5	X															
8	<u>Operation</u>																	
	Operational planning and control	8.1	X	X	X	X	X	X	X	X	X	X	X					
	General	8.1.1	X	X	X	X	X	X	X	X	X	X	X					
	Eliminating Hazards & reducing OH&S risks	8.1.2	X	X	X	X	X	X	X	X	X	X	X					
	Management of change	8.1.3	X	X	X	X	X	X	X	X	X	X	X					
	Procurement	8.1.4	X	X	X	X	X	X	X	X	X	X	X					
	Emergency preparedness and response	8.2	X	X	X	X	X	X	X	X	X	X	X					
9	<u>Performance evaluation</u>																	
	Monitoring, Measurement analysis & evaluation																	
	General	9.1	X	X	X	X	X	X	X	X	X	X	X					
	Evaluation of compliance	9.1.1	X	X	X	X	X	X	X	X	X	X	X					
	Analysis and evaluation	9.1.2	X	X	X	X	X	X	X	X	X	X	X					
10	<u>Internal audit</u>	9.2	X	X	X	X	X	X	X	X	X	X						
	<u>Management review</u>	9.3	X	X	X	X	X	X	X	X	X	X						
10	<u>Improvement</u>																	
	General	10	X	X	X	X	X	X	X	X	X	X	X					
	Nonconformity and Corrective action	10.1	X	X	X	X	X	X	X	X	X	X	X					
	Continual improvement	10.2	X	X	X	X	X	X	X	X	X	X	X					
		10.3	X	X	X	X	X	X	X	X	X	X						
	Auditing Organization BUREAU OF INDIAN STANDARDS		Auditee (Organization) ZyduS Hospitals & Healthcare Research Pvt Ltd, Plot no 232, ZyduS Hospital Road, Thaltej, Ahmedabad - 380054										Page 2 of 2					
	Doc : MSC-F6.4-35		Issue No. 01					Date : Dec 2018										

L- Biomedical engg services, M- QC & Lab, O- IT, P-Medical Lab & Blood Bank, Q- Fire Safety, R-Central Sterile Supply Dept, S-Store, T- Ambulance services & PCA

CONFIDENTIALITY STATEMENT

(For BIS Auditor/Technical Expert and External Auditor/External Technical Expert)

1. **Application/Licence No. OHS/WR/A-APP2023075261**
2. Name & Address of Organization to be audited: M/s Zydus Hospitals & Healthcare Research Pvt Ltd,
Plot no 232, Zydus Hospital Road, Thaltej,
Ahmedabad - 380054
3. Type of Audit: **Third Party Audit (OHMS)**
4. Date(s): **22-25(FN)/01/2024**
5. I accept to work as ~~Auditor-in-training/Auditor/Team Leader-in-Training/Team Leader/Lead Auditor/Technical Expert~~ for conducting Management System audit of above mentioned organization.
6. I declare that,
 - i) I have not acted as Consultant and/or undertaken internal audit or any other work for the above Organization within the last two years;
 - ii) I do not have any commercial interest in the above Organization.
 - iii) I do not have any relationship with the above Organization.
 - iv) I am presently working in MSCD activity of BIS/..... ~~Organization~~. My actions will not lead to in any way threats to impartiality of BIS management system certification activity. ~~My actions lead to threat of impartiality to BIS Management System Certification Activity (Strike out what is not applicable and fill the needed information).~~
7. I undertake that, I shall treat all the documentation and information provided by the organization audited as strictly confidential.
 - i) I shall neither copy any documentation nor divulge any information to any third party without the written prior consent of the organization assessed or Bureau of Indian Standards except as required by law or in demonstrating conformance with the requirements of national accreditation.
 - ii) I shall not act in any way prejudicial to the reputation or interest of Bureau of Indian Standards or the organization assessed.
 - iii) I shall not accept payment, commission, discount or any other profit from the organization assessed or from their representative or from any other interested person.
 - iv) In the event of any alleged breach of this undertaking, I know that BIS can blacklist me and also terminate the use of my services as auditing personnel after giving 15 days' notice.
 - v) In the event of any enquiry/investigation conducted due to unethical practice and breach of this undertaking, I shall fully cooperate with BIS.
 - vi) I undertake that I shall abide by undertaking given in my application for selection as External auditor/External Technical Expert of Bureau of Indian Standards Management Systems Certification.

Signature : 
Name : N Banik
Date : 22-01-2024

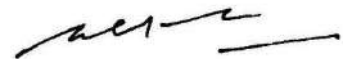
Acceptance by Team Leader/Lead Auditor
MSCO(R)/DDGR

CONFIDENTIALITY STATEMENT

(For BIS Auditor/Technical Expert and External Auditor/External Technical Expert)

1. Application/Licence No : OHS/WR/A-App 2023075261
2. Name & Address of Organization: M/s ZyduS Hospitals & Healthcare Research Pvt Ltd, , Thaltej, Ahmedabad -.38005
3. Type of Audit: Stage 2(initial) audit of OHSMS as per IS/ISO 45001:2018
4. Date(s): 22-25(FN) Jan 2024
5. I accept to work as ~~Auditor in training/Auditor & Expert/Team Leader in Training/Team Leader/Lead Auditor/Technical Expert~~ for conducting OHSMS audit of above mentioned organization.
6. I declare that
 - i) I have not acted as Consultant and/or undertaken internal audit or any other work for the above Organization within the last two years;
 - ii) I do not have any commercial interest in the above Organization.
 - iii) I do not have any relationship with the above Organization.
 - iv) I am presently working in ...MSCD activity of BIS/ Organization. My actions will not lead to in any way threats to impartiality of BIS management system certification activity. My actions lead to threat of impartiality to BIS Management System Certification Activity (Strike out what is not applicable and fill the needed information **(NA)**)
7. I undertake that, I shall treat all the documentation and information provided by the organization audited as strictly confidential.
 - i) I shall neither copy any documentation nor divulge any information to any third party without the written prior consent of the organization assessed or Bureau of Indian Standards except as required by law or in demonstrating conformance with the requirements of national accreditation.
 - ii) I shall not act in any way prejudicial to the reputation or interest of Bureau of Indian Standards or the organization assessed.
 - iii) I shall not accept payment, commission, discount or any other profit from the organization assessed or from their representative or from any other interested person.
 - iv) In the event of any alleged breach of this undertaking, I know that BIS can blacklist me and also terminate the use of my services as auditing personnel after giving 15 days' notice.
 - v) In the event of any enquiry/investigation conducted due to unethical practice and breach of this undertaking, I shall fully cooperate with BIS.
 - vi) I undertake that I shall abide by undertaking given in my application for selection as External auditor/External Technical Expert of Bureau of Indian Standards Management Systems Certification.

Signature :




Name : Rahul Kumar
Date : 21 Jan 2024

Acceptance by Team Leader/Lead Auditor

CONFIDENTIALITY STATEMENT

(For BIS Auditor/Technical Expert and External Auditor/External Technical Expert)

1. Application/Licence No. A-2023075261, IS/ISO 45001:2018
2. Name & Address of Organization to be audited: M/s. Zyodus Hospital and Healthcare Research Pvt Ltd, Ahmedabad
3. Type of Audit: Stage II
4. Date(s): 22-01-2024 to FN of 25-01-2024
5. I accept to work as ~~Auditor in training/Auditor/Team Leader in Training/Team Leader/Lead Auditor/Technical Expert~~ for conducting Management System audit of above mentioned organization.
6. I declare that,
 - i) I have not acted as Consultant and/or undertaken internal audit or any other work for the above Organization within the last two years;
 - ii) I do not have any commercial interest in the above Organization.
 - iii) I do not have any relationship with the above Organization.
 - iv) I am presently working in MSCD activity of BIS as an Ext. Auditor. My actions will not lead to in any way threats to impartiality of BIS management system certification activity. My actions lead to threat of impartiality to BIS Management System Certification Activity (**Strike out what is not applicable and fill the needed information**).
7. I undertake that, I shall treat all the documentation and information provided by the organization audited as strictly confidential.
 - i) I shall neither copy any documentation nor divulge any information to any third party without the written prior consent of the organization assessed or Bureau of Indian Standards except as required by law or in demonstrating conformance with the requirements of national accreditation.
 - ii) I shall not act in any way prejudicial to the reputation or interest of Bureau of Indian Standards or the organization assessed.
 - iii) I shall not accept payment, commission, discount or any other profit from the organization assessed or from their representative or from any other interested person.
 - iv) In the event of any alleged breach of this undertaking, I know that BIS can blacklist me and also terminate the use of my services as auditing personnel after giving 15 days' notice.
 - v) In the event of any enquiry/investigation conducted due to unethical practice and breach of this undertaking, I shall fully cooperate with BIS.
 - vi) I undertake that I shall abide by undertaking given in my application for selection as External auditor/External Technical Expert of Bureau of Indian Standards Management Systems Certification.

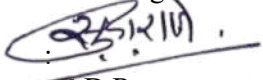
Signature : 
Name : B SANDHYA
Date : 21 JAN 2024

Acceptance by Team Leader/Lead Auditor
MSCO(R)/DDGR

CONFIDENTIALITY STATEMENT

(For BIS Auditor/Technical Expert and External Auditor/External Technical Expert)

1. Application/~~License~~ No: OHS/WR/A-APP2023075261
2. Name & Address of Organization: M/s Zydus Hospital & Healthcare Research Pvt Ltd
to be audited Plot no 232, Zydus Hospital Road, Thaltej, Ahmedabad- 380054
3. Type of Audit: TPA- Stage -II
4. Date(s): 22 to 25 (FN) January 2024
5. I accept to work as Auditor-in-training/~~Auditor/Team Leader in Training/Team Leader/Lead Auditor/Technical Expert~~ for conducting Management System audit of above mentioned organization.
6. I declare that,
 - i) I have not acted as Consultant and/or undertaken internal audit or any other work for the above Organization within the last two years;
 - ii) I do not have any commercial interest in the above Organization.
 - iii) I do not have any relationship with the above Organization.
 - iv) I am presently working in Certification activity of BIS/..... Organization. My actions will not lead to in any way threats to impartiality of BIS management system certification activity. My actions lead to threat of impartiality to BIS Management System Certification Activity (Strike out what is not applicable and fill the needed information).
7. I undertake that, I shall treat all the documentation and information provided by the organization audited as strictly confidential.
 - i) I shall neither copy any documentation nor divulge any information to any third party without the written prior consent of the organization assessed or Bureau of Indian Standards except as required by law or in demonstrating conformance with the requirements of national accreditation.
 - ii) I shall not act in any way prejudicial to the reputation or interest of Bureau of Indian Standards or the organization assessed.
 - iii) I shall not accept payment, commission, discount or any other profit from the organization assessed or from their representative or from any other interested person.
 - iv) In the event of any alleged breach of this undertaking, I know that BIS can blacklist me and also terminate the use of my services as auditing personnel after giving 15 days' notice.
 - v) In the event of any enquiry/investigation conducted due to unethical practice and breach of this undertaking, I shall fully cooperate with BIS.
 - vi) I undertake that I shall abide by undertaking given in my application for selection as External auditor/External Technical Expert of Bureau of Indian Standards Management Systems Certification.

Signature 
Name : S D Rane
Date : 22/01/2024

Acceptance by Team Leader/Lead Auditor
MSCO(R)/DDGR

22-1-2024

To,

DDGW

Western Regional Office, BIS, CETTM, 5th Floor,
M.I.D.C., Technology Street, Hiranandani Garden,
Powai, Mumbai - 400 076

Subject: - Scope of OHSMS certification



Dear Sir,

With reference to the stage II audit for getting to license as per IS/ISO 45001 :2018, The scope of our certification may be taken on as given below.

"To provide healthcare services to patients (primary, secondary & tertiary) ensuring occupational health and safety of our staff, visitors, guests, interested parties & patients meeting their requirements with compliance to applicable regulatory norms."

Dr. Sanjeev Gupta

Centre Head



Dr. Sanjeev Gupta
Centre Head
MBBS, MBA
Zydus Hospitals, Ahmedabad

N Baniak
22/01/2024



Stage I Audit Observation status

Date :- 23-1-2024

Ref :- OHSMSC/WR/A-APP2023075261

Auditing :- M/s Zydus Hospitals and Healthcare Research Pvt Limited Thaltej Ahmedabad

Auditing Body :- Bureau of Indian Standard

Satge 1 audit date :- 7-Oct-2023

Audit Standard :- IS/ISO 45001:2018

Auditor :- Mr. M D Chilakwad

Occupational Health and Safety Management System Certification

Stage 1 Audit observation and status		Remarks	Verification
1	OHSMS Manual is yet to be completed and finalized -	Complied	Manual prepared and uploaded in portal Doc. No. ZHHRPL/OHSMS/ISO 45001-2018/01 Issue Date :- 10/10/2023 Verified NBank
2	Internal Audit of depts is yet to be completed -	Complied	Internal Audit Done on 19/12 to 21/12/ 2023 Covering all the Depts. IA completed for all depts for NBank
3	Management review is yet to be carried out -	Complied	Management review meeting done on 19/1/2024 Verified, B.S. 19
4	HIRA for all depts identified is yet to be completed -	Complied	Departmental HIRA prepared Verified per NBank
5	Operational control procedures to bring OHS risks under Zydus control -	Complied	OCPs have been prepared taking control measures into account Verified per NBank
6	All stair cases, identification radiant strips to be put to avoid accidents-	Complied	Provided at all staircase Verified per NBank
7	Passage way to be painted or radiant strips to be put to avoid accidents/idents	Complied	Provided at required location Verified per NBank
8	Railings to be provided in terrace area where utility equipment are installed to avoid accidents	Complied	Railing provided at terrace area Verified per NBank
9	All instruction sheets available near equipment need to have document number, revision number & date to know the version status	Complied	Instruction sheet number and date provided and it is continual process. Verified per NBank
10	Identification of racks where medical records are stored needs to be made like Rack A, B, C etc and title of the same for easy retrieval of records	Complied	Marking done at all locations Verified, B.S. 19
11	All drums, carbuoys stored need to be kept in tray and on pellet so that any leakage can be arrested to avoid slip, fall etc	Complied	Pellet provided to the drums and carbuoys. Verified NBank
12	Fire protection equipment etc to be enhanced/increased to avoid any accident etc	Complied	Fire protection equipment increased at required location. Fire Blanket and K type extinguisher provided in Kitchen. Verified NBank

Dr. Sanjeev Gupta

Centre Head





भारतीय मानक ब्यूरो BUREAU OF INDIAN STANDARDS

MANAGEMENT SYSTEMS CERTIFICATION

FORMS

TITLE: Audit Observation and Evidence

DOC: MSC-F6.4-45

ISSUE: 01

DATE: April 2019

Page 1 of 1

Prepared By:

Approved By: DDG(MSCD)

App/ Licence Number: OHS/WR/A-APP2023075261

IS/ISO 45001:2018

Process:

Centre Head and Coordinator

Date of Audit: 22/01/2024

Persons contacted with designation:

Dr Sanjeev Gupta, Centre Head
Mr Satish Gajjar, Associate Engr &
Coordinator
Dr Prasant Lead Quality

Process Observation & Evidence

1.*Process Observation:

Zyodus Hospital, Ahmedabad, is a 550 bedded super-specialty medical institution spanning over 17 floors. They offer care in all major medical & surgical specialties with diagnostic & rehabilitation services.

The hospital is accredited by NABH in following:

- Healthcare care organization
- Emergency department
- Radiology department
- Nursing services
- Ethics committee
- Blood bank.
- Laboratory in accredited by NABL

The organization determined its external & internal issues that affect its ability to achieve the intended results of its IMS. The internal & external issues are monitored and reviewed from time to time.

The organization has determined:

the interested parties that are relevant to the OHSMS management system and the requirements of these interested parties.

Some of interested parties and their expectations are: For example, Authority of Pollution Control

Board. They want compliance with the Water, Air, and Noise Pollution act. Employees want a hazard and pollution free working environment.

The scope and boundaries of OHSMS management system have been defined and documented.

Management system and its processes and interaction are given in Different Processes and their Interaction described in OHSMS Manual.

Top management has defined, documented, and endorsed its OHSMS policies, Top management demonstrated leadership and commitment with respect to OHSMS management system by implementing the OHSMS management policies and objectives, promoted process approach and risk-based thinking.

The policy is appropriate to the nature, scale of its activities and facilities and includes a commitment to continual improvement in its performance. The OHSMS policy includes a commitment to eliminate hazards and reduce OHS risks and complying with the applicable legal and other requirements. The policies are displayed at different locations in the factory.

Staffs' participation is ensured through quarterly safety meetings.

Management does take corrective action as early as possible to rectify unsafe conditions and also address grievances immediately. Workers/their representatives are encouraged to give safety suggestions.

Risks and opportunities that can affect conformity of environment and safety have been addressed, Hazard analysis have been done.

Legal requirements and Compliance obligations are maintained. Objectives and targets have been documented.

The organization has determined and provided the resources needed for implementation, maintenance and continual improvement and provided the people necessary for the effective implementation of its OHSMS and control of its


processes.
 The internal and external communications relevant to the management system have been determined.
 Internal communication is done through notice board, verbal, telephone, meeting etc by departmental heads.
 External communication is done by all the departmental heads with the approval of Centre Head.
 The organization's management system includes OHSMS Manuals, Procedures, SOP/OCP and formats. Manual and Procedures are approved by Centre Head. Documents are distributed online. Documents of external origin with latest amendments are maintained. Emergency situation analyzed and Disaster Management Plan document DMP documented.
 Monitoring and measurement analysis and evaluation needed to ensure valid results have been established and Internal Audit planning is done, and audit carried out as per planning & internal audit schedule. Internal audit is carried out once in six months as per schedule.
 Management reviews are done once in six months. Results of internal audits and evaluations of compliance with legal requirements including OHSMS performance of the organization and the extent to which objectives and targets have been met have been reviewed.

2.Audit Evidences:**

Context of the organization described in Cl 4.1 of OHS Manual, Doc No. ZHHRPL/OHSMS/ISO45001-2018/01 dated 10/10/2023.
 Needs and expectations of interested parties, Cl 4.2. Interested parties are government and beneficiaries, employees, contracts, society etc. and Scope and boundaries clause no Cl 4.3.
 Different Processes and their Interaction described in OHSMS Manual
 OHSMS policies have been displayed at different places in the hospital.
 HIRA ZHHRPL/HIRA/Dept name/01 dt 31/12/2023
 Safety committee meetings were held on 09/01/2024. Sixteen members were present.
 All legal requirements are maintained and complied with. Disposal of bio waste Licence BMW 361752 valid up to 21 April 2028. Disposal of bio wastage done through Care biomedical waste; license number 1706 valid up to 31 March 2026. Compliance to GPCB norms were submitted on 15 November 2023.
 DG set stack emission was tested by Enviropius, date of testing 13032023.
 STP discharge was tested by Gujarat test lab Pvt Ltd on 08 December 2023
 Disposal of used oil, battery waste, e-waste is done as par procedure. Air pollution is tested. Noise testing is done.
 Objectives: ZHHRPL/DM/HPS/3.00 Rev 06 dt 02/08/2023.
Objectives and action plans are
 Accurate Identification of the Patients ZHHRPL/DM-HPS/ 03.00
 Effective Communication between Care Givers ZHHRPL/DM-HPS/ 03.00
 Medication safety - Prevention of medication errors ZHHRPL/DM-HPS/ 03.00
 Blood Transfusion Safety ZHHRPL/DM-HPS/ 03.00
 Prevention of Patient fall ZHHRPL/DM-HPS/ 03.00
 Surgical Patient Safety ZHHRPL/DM-HPS/ 03.00
 Prevention of healthcare associated infections ZHHRPL/DM-HPS/ 03.00
 Effective use of Clinical Alarm systems ZHHRPL/DM-HPS/ 03.00
Objectives for employee safety
 Prevention of fire incidents ZHHRPL/DM-DEP /04.00
 Prevention of electrical shock incidents ZHHRPL/DM/ME/19-00
 Prevention of radiation hazard ZHHRPL/DM-IS /13.00
 Inhouse safety awareness given on 20/01/2024. Fire Mock drills carried out on 06/01/2024 near 4th Floor Blood bank.
 Disaster mgt plan documented DMP-ZHHRPL/DM-DEP/4.00 dt 02/08/2023
 Mock drill carried out on 22/07/2023. Emergency action plan is available.
 They have done outsourcing of their housekeeping activities attendant security and laundry
 IA carried out during 19-21/12/2023. 106 NC reported. All are closed
 Management review was conducted on 26/12/2023. Minutes of MRM was verified. All the points as required by the standards have been reviewed.

Audit of all the clauses mentioned in the audit plan matrix have been carried out. Yes/No

Opportunities for Improvement indicated against Clause No(s) _____	<input checked="" type="checkbox"/>	Non-Conformities Issued against Clause No(s) _____	<input checked="" type="checkbox"/>
---	-------------------------------------	---	-------------------------------------

Name of Applicant/Licensee: M/s Zydus Hospitals & Healthcare Research Pvt Ltd, Plot no 232, Zydus Hospital Road, Thaltej, Ahmedabad - 380054	Signature of Auditor 
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* Identification of processes may include identification of key performance parameters/ significant aspects; Identification of objectives; Compliance to Legal and statutory requirements, etc. Use separate sheet for separate process. One department may have many processes.
 ** Evidences clearly state the samples, records of process output verified and witness of activity with verifiable proof



भारतीय मानक ब्यूरो

BUREAU OF INDIAN STANDARDS

MANAGEMENT SYSTEMS CERTIFICATION

FORMS

TITLE: Audit Observation and Evidence

DOC: MSC-F6.4-45	ISSUE: 01	DATE: April 2019	Page 1 of 1
Prepared By:		Approved By: DDG(MSCD)	
App/ Licence Number: OHS/WR/A-APP2023075261		IS/ISO 45001:2018	
Process: Admission & Billing		Date of Audit: 23/01/2024	
		Persons contacted with designation: Mr Amit Gandhi, I/C	

Process Observation & Evidence

1.*Process Observation:
 Planning of admission for example admission in surgical case, emergency admission and OPD admission. In OPD admission Recommendation of the doctor are scrutinized and proper admission process is initiated and accordingly the billing system starts.
 In case of surgical case, all the arrangements are made before the patient is admitted.
 In case of emergency admission patient is immediately admitted and billing process start.

 In all these activities Risks and opportunities that can affect conformity of environment and safety have been addressed, Hazard analysis have been done. the hazards have been identified and HIRA documented.
 For example, one of the hazards identified as incorrect data entry, proper plan category not defined etc. These may lead to safety problem. So they have ensured that the details are taken from Aadhar card.
 As there are 550 beds, getting a bed by a patient is not a problem.
 There is very low billing mistake and online refund has been made, patient satisfaction is ensured.
 Legal requirements and Compliance obligations are maintained. Objectives and targets have been documented.

2.Audit Evidences:**
 Some of the hazards are:
 Invalid or incorrect data is punched into HIMS.
 Proper Plan/Category is not defined for billing purpose.
 Proper approval procedure not followed which causes non repayment by Insurance companies.
 Proper authorization/approval not received, same is not intimated to patient.
 After denial of approval/authorization patient category not changed.
 Corrective actions are taken.

Audit of all the clauses mentioned in the audit plan matrix have been carried out. Yes/No

Opportunities for Improvement indicated against Clause No(s) _____ <input checked="" type="checkbox"/>	Non-Conformities Issued against Clause No(s) _____ <input checked="" type="checkbox"/>
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Name of Applicant / Licensee: M/s Zydus Hospitals & Healthcare Research Pvt Ltd, Plot no 232, Zydus Hospital Road, Thaltej, Ahmedabad - 380054	Signature of Auditor <i>N Bhandari</i>
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* Identification of processes may include identification of key performance parameters/ significant aspects; Identification of objectives; Compliance to Legal and statutory requirements, etc. Use separate sheet for separate process. One department may have many processes.
 ** Evidences clearly state the samples, records of process output verified and witness of activity with verifiable proof



भारतीय मानक ब्यूरो BUREAU OF INDIAN STANDARDS

MANAGEMENT SYSTEMS CERTIFICATION

FORMS

TITLE: Audit Observation and Evidence

DOC: MSC-F6.4-45

ISSUE: 01

DATE: April 2019

Page 1 of 1

Prepared By:

Approved By: DDG(MSCD)

App/ Licence Number: OHS/WR/A-APP2023075261

IS/ISO 45001:2018

Process:

Admin(Purchase, HR, Finance& Kitchen)

Date of Audit: 23/01/2024

Persons contacted with designation:

Mr Anand, I/C Purchase
Mr Parag Bhatt, Lead HR
Mr Riv, I/C Finance
Mr Vijendra, I/C F&B

Process Observation & Evidence

1.*Process Observation:

Purchase department carries out purchases of medicine food and beverages and engagement of all AMCs and CMCs. PO for lift maintenance for lift maintenance ZHHRPL/AHM/WO/23-24/Eng/4689 dt 29/08/2023.

FE WO no ZHHRPL/AHM/WO/22-23/Eng/4109 dt 09/02/2023.

All medicines are purchased from Dr Reddy's lab, Zydus life science etc on contract basis. Dr Reddy's lab contract no ZHHRPL/SCM/RC/Pharmacy/017/2023-24

Main activities of HR is recruitment induction training conducting medical test etc.

Training calendar has been drawn up and training provided as per the training calendar. Objective is to provide 100% medical checkup for all the staff.

Finance department possesses all the financial needs and the hazards are not identified in this department.

Kitchen provides the food of all the patients round the clock and also SAB launch to OPD section. All the leftover foods and garbage of the kitchen are disposed of through M/s Snel Bio Sc, Ahmedabad.

2.Audit Evidences:**

There are 30 AMCs and 37 CMCs(comprehensive AMC)

Training given on prevention of bed shore for nurses on 17th January 2024. At the end of the training I test is taken and those who fail are retrained. Till further training is given the failed nurses work under the guidance of a qualified nurse.

Lift maintenance fire extinguisher maintenance. HIRA

Some of the hazards of Kitchen are:

Physical, Chemical & Biological Contamination during food handling, Food Preparation and Cooking.

Contamination of food while serving, Contamination of food transportation, Food contamination due lack of cleaning and Sanitizing.

Action Plan: Monitoring & evaluation of process HACCP

Food should be covered with lid. Wear hand gloves while handling food items. Keep chemical items away from the food.

Storing Foods -First-In-First-Out.

Personal Hygiene: Bathing, washing hair, wearing clean clothing, and frequent.

Hand hygiene facility & practice. Training given to the staff about food safety.

Do not reuse the chopping boards. Use colour code for chopping board to prevent cross- contamination.

More importantly, to heat foods and destroy harmful microorganisms that may cause illness.

Preparing Foods: Careful preparation is the key to serving safe food. Preparation is the time when food has a greater chance of getting contaminated. Through all stages of food preparation and service monitoring.

Bain Marie Counter: To keep the food hot for serving.

To avoid Cross contamination wear hand gloves.

When food is transported, the risk of contamination is greater.

Keep all Patient foods in a tightly covered container.
 Training given to the staff to plug in food trolley to keep the food warm.
 By sanitizing we reduce the number of disease-causing microorganisms to safe levels. Deep cleaning the utensil in the hot water.
 Kitchen employees happen medically tested for all the requirements FSSAI.
 Internal audit carried out on 20 December 2023 there are 5 inches and the 3 entries clear 2 are pending.
 A visit was paid in the night shift in the canteen and it was found that the procedures and safety precautions as followed during daytime are being followed in the night shift also

Audit of all the clauses mentioned in the audit plan matrix have been carried out. Yes/No

Opportunities for Improvement indicated against Clause No(s) _____ <input checked="" type="checkbox"/>	Non-Conformities Issued against Clause No(s) _____ <input checked="" type="checkbox"/>
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Name of Applicant / Licensee: M/s Zydus Hospitals & Healthcare Research Pvt Ltd, Plot no 232, Zydus Hospital Road, Thaltej, Ahmedabad - 380054

N Banik
Signature of Auditor

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MANAGEMENT SYSTEMS CERTIFICATION

FORMS

TITLE: Audit Observation and Evidence

DOC: MSC-F6.4-45

ISSUE: 01

DATE: April 2019

Page 1 of 1

Prepared By:

Approved By: DDG(MSCD)

Appl/ Licence Number: OHS/WR/A-APP2023075261

IS/ISO 45001:2018

Process:

Engineering services and utilities

Date of Audit: 24/01/2024

Persons contacted with designation:

Mr Sandeep Rana Lead Engineering

Process Observation & Evidence

1.*Process Observation:

These department is looking after the maintenance HVAC, electrical maintenance, Supply of medical gas(O₂, N₂O,CO₂, compressed air), plumbing and fire system.

Hazards identified are Fire, Hazardous Material Spill, Electrical Shock, Power Supply failure, Handling Heavy equipment. Slip and Fall

Mitigation Plan

Fire exits without obstruction with signages.

Adequate quantity / type of fire safety equipment (Extinguisher, Hose-Reel , Hydrant and Hose-box).Including Diesel storage area compatible fire extinguishers

Personal protective equipment for fireman available in-case of Fire they can use for Firefighting.

Mock drills to check preparedness.

Regular preventive maintenance of Electrical Equipment

Regular training of Staff for Fire-safety awareness & Basic Electrical safety

Smoke detector available near Electrical panel

Availability of MSDS

Proper storage & transport of chemicals

Personal protective equipment for managing hazardous material spill & its exposure

Training & development in hazardous material handling

Using proper insulated tools and proper protective equipment during work

Regular Basic electrical safety training for all staff

Safety Protective accessories used in power distribution system and panel like ELCB, MCCB, cuircuit breaker

Protective equipment for preventive maintenance of high voltage panel

Regular Preventive maintenance as per schedule

Regular periodically Testing of alternate sources like DG set and UPS for power back up

Regular servicing and inspection of critical electrical system like Breaker service, Transformer oil filtration, Thermography, DG service, UPS system

Regular Monitoring Of electrical parameter

Handling with proper safety equipment as per reequipment.

Use of antiskid shoe

Information sing board available at high risk location like Escalator, Lifts

check leakage of oil from transformer and DG substation area

Use Personal protective equipment.

trained workers on the importance of securing tools and equipment

2.Audit Evidences:**

What are taste report from Gujarat laboratory detailed 09 October 2023. STP water test report Gujrat Lab dt 08/12/2023. Internal audit was carried out on 21 December 2023. There were 3 NCs one NC is pending.

Audit of all the clauses mentioned in the audit plan matrix have been carried out. Yes/No


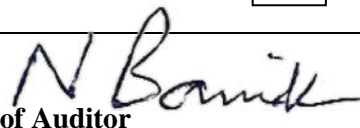
Opportunities for Improvement indicated against Clause No(s) _____

Non-Conformities Issued against Clause No(s) _____

Name of Applicant / Licensee: M/s Zydus Hospitals & Healthcare Research Pvt Ltd, Plot no 232, Zydus Hospital Road, Thaltej, Ahmedabad - 380054


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 भारतीय मानक ब्यूरो BUREAU OF INDIAN STANDARDS MANAGEMENT SYSTEMS CERTIFICATION		FORMS
TITLE: Audit Observation and Evidence		
DOC: MSC-F6.4-45	ISSUE: 01	DATE: April 2019 Page 1 of 1
Prepared By:		Approved By: DDG(MSCD)
Appl/ Licence Number: OHS/WR/A-APP2023075261		IS/ISO 45001:2018
Process: IT		Date of Audit: 24/01/2024
		Persons contacted with designation: Mr Amrish Server Admin, IT Infra Lead. Mr Nageswar, Lead IT Appl Software
Process Observation & Evidence		
<p>1.*Process Observation: Main activity r maintenance of Server, IT security, maintenance of CCTV, telephone, walkie talkie, networking, printer, desktop, laptop and access control and all software related work, Calibration of all medical equipment are done by biomedical team. Any medical equipment with software package are given for maintenance to OEM. Software application like billing for patient guest and employees are done by 3rd party. There are 400 cameras in the hospital. For maintenance of CCTV cameras which are placed at a very high place, work permit to work at height is taken. Objective is to keep all the equipment running and backup is kept. There are 5 infra manpower and 9 IT applications. All employees are master's degree in computer science. IA was carried out on 20 December 2023 there were 2 NCs and all NCs have been cleared.</p>		
<p>2.**Audit Evidences: Some of the hazards are: Hinai Application Slowness / Down, Zydus Portal & Application Slowness / Down, EPABX Call Centre Down. Remedial measures: Daily Check Server Load. Daily Based Backup. Monitoring Daily Server Load and Server Database load. Alternate Avaya available for Backup if any time down then we can switch within 5 mins. Work at height permit no dt 16/12/2023 4 repair work of CCTV camera near gate number 6 parmeet was issued by fire safety officer</p>		
Audit of all the clauses mentioned in the audit plan matrix have been carried out.		Yes/No
Opportunities for Improvement indicated against Clause No(s) _____	<input checked="" type="checkbox"/>	Non-Conformities Issued against Clause No(s) _____
Name of Applicant / Licensee: M/s Zydus Hospitals & Healthcare Research Pvt Ltd, Plot no 232, Zydus Hospital Road, Thaltej, Ahmedabad - 380054		 Signature of Auditor
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MANAGEMENT SYSTEMS CERTIFICATION

FORMS

TITLE: Audit Observation and Evidence

DOC: MSC-F6.4-45	ISSUE: 01	DATE: April 2019	Page 1 of 1
Prepared By:		Approved By: DDG(MSCD)	
App/ Licence Number: OHS/WR/A-APP2023075261		IS/ISO 45001:2018	
Process: Store		Date of Audit: 25/01/2024	
		Mr Umesh, I/C	

Process Observation & Evidence

1.*Process Observation:

Main activities of store department is to receive the incoming material, storing after getting pass certificate from QC and issue of material to user department. HIRA has been documented.
Store items are stationeries, packaged food, grocery, instruments, uniforms, shoes, safety goggles sanitizer etc are stored. FIFO system is followed
All legal requirements are complied with.
Smoke detector and fire alarm system have been installed in different godowns.

2.**Audit Evidences:

Some of the hazards identified are: getting heart due to handling of material, fire hazard.
Fire mock drills are carried out.

Audit of all the clauses mentioned in the audit plan matrix have been carried out. Yes/No

Opportunities for Improvement indicated against Clause No(s) _____ <input checked="" type="checkbox"/>	Non-Conformities Issued against Clause No(s) _____ <input checked="" type="checkbox"/>
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Name of Applicant / Licensee: M/s Zydus Hospitals & Healthcare Research Pvt Ltd, Plot no 232, Zydus Hospital Road, Thaltej, Ahmedabad - 380054

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MANAGEMENT SYSTEMS
CERTIFICATION

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TITLE: Audit Observation and Evidence

DOC: MSC-F6.4-45

ISSUE: 01

DATE: April 2019

Page 1 of 2

Prepared By:

Approved By: DDG(MSCD)


Application Number/ Licence Number: OHS/WR/A-App 2023075261		OHS as per IS/ISO 45001:2018
Process: Diagnostic Dept (Radiology, CT scan, MRI, X-ray etc)	Date of Audit: 22-25(FN) Jan 2024	
	Persons contacted with designation: 1. Ms Meera Rajyaguru-operation head 2. Dr Ajay Patel, HOD-radiology	
Process — Observation & Evidence =		
<p>*Process Observation:</p> <ul style="list-style-type: none"> • The department is responsible for monitoring /prevention /QA of radiation during imaging activities viz X ray , CT scan , cath lab , mammography, ultrasound • Hospital is having radiology safety officer approved by AERB, Consent to operate imaging services is obtained from AERB .Employees exposed to radiation are provided with TLD badges to check radiation level exposure.. TLD badges are sent for checking radiation level at Renentech lab approved by AERB. Employees/technician wear lead apron, thyroid apron. The imaging room doors are sealed with lead lining to prevent leakage of radiation , if any . All employees under go yearly medical test • Bio medical waste is segregated in yellow, blue, red , white baskets • Radiation safety meeting chaired by Senior consultant radiologist is held once in six months • The required documented information for OHSMS as per the established system procedures are available. • OHSMS policy has been established, and is displayed at prominent locations. Awareness about Policy observed during interaction • Objective and targets to prevent/ monitor/minimize radiation, infection, fire safety have been documented . These are monitored by respective departmental head/safety committee • Adequate resources provided. Role and responsibilities are defined in manual • Regulatory requirements have been identified. Consent for CT scan from AERB up to 10 June 2025 found obtained • Hazard Identification & Risk Assessment (HIRA) has been found documented which include radiation, fire, exposure to gases, infection, injury etc. Control measures are also specified in HIRA doc • .WIs/OCPs are available • No action pending on last IQA • Mock drills are periodically organised by fire safety department • Fire extinguisher, fire hydrants available and found being maintained 		

****Audit Evidences:**

- OHSMS manual ZHHRPL/OHSMS/ISO 45001-2018/01 , rev 0 dated 10 Oct 2023
- Hospital & patient safety manual ZHHRPL/DM-HS/03.00 , rev 08 dated 2 Aug 2023
- Infection prevention manual ZHHRPL/DM-IP/05-00
- Radiology imaging manual ZHHRPL/DM-IS/13.0 rev 07 dated 22 Aug 2022
- Organization chart /responsibility p-42 of OHSMS manual
- OHSMS policy , p-18 of OHSMS manual
- Hazard identification and risk assessment Doc HIRA-radiology
- QA/examination/calibration of lead apron done on 6 Dec 23
- All employees exposed to radiation found wearing TLD badges. TLD badges are sent quarterly for testing of radiation . Report July - Sep23 from Renentech Lab checked.
- Doors of x ray room has lead lining for protection
- Approval of radiology safety officer by AERB GJ:26275-1 NST from 10 Feb 2021 to 10 Feb 2024
- Biomedical waste found being segregated
- Medical check up report of Ms Meera 27 Sep 2023
- Records of radiology safety meeting held on 19 June 2023. Participation of workers is ensured
- Mock drill records dated 6 Jan 2024 and 20 April 2023

Audit of all the clauses mentioned in the audit plan matrix have been carried out.	yes
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Opportunities for Improvement indicated against Clause No(s): <input type="checkbox"/> none	Non-Conformities Issued against Clause No (s) : <input type="checkbox"/> None
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Name of Applicant /Licensee: M/s Zydus Hospitals &Healthcare Research Pvt Ltd, , Thaltej, Ahmedabad -	 Rahul Kumar
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ISSUE: 01

DATE: April 2019

Page 1 of 2

Prepared By:

Approved By: DDG(MSCD)

Application Number/ Licence Number: OHS/WR/A-App 2023075261		,OHS as per IS/ISO 45001:2018
Process: OPD(4 nos)	Date of Audit: 22-25(FN) Jan 2024	
	Persons contacted with designation: 1. Mr. Jasmin Shah, Head - operation	

Process — Observation & Evidence =

***Process Observation:**


- The department is responsible for registration, consultation , treatment, diagnosis of outpatient department(OPD) .
- Hospital has several OPDs viz Neurology , cardiology, gastro , orthopaedics , nephrology , ENT , dental , ophthalmology etc. Each patient is directed to registration counter and patient is assigned unique no/medical record identifier number. They are guided to approach to concerned doctor examination chamber. Pathology, radiology /diagnostic tests are carried out as required. OHSMS checked in gastro , neurology , gastro , cardiology OPD
- Daily mopping, cleaning, washing of common area , washrooms, in OPD is done as infection control measures. Special chemical Virex 256 is used for prevention of contamination
- Bio medical waste is segregated in yellow, blue, red , white baskets
- The required documented information for OHSMS as per the established system procedures are available.
- OHSMS policy has been established, and is displayed at prominent locations. Awareness about Policy observed during interaction
- Objective and targets to prevent/ monitor/minimize radiation, infection, fire safety have been documented . These are monitored by respective departmental head/safety committee
- Adequate resources provided. Role and responsibilities are defined in manual
- Regulatory requirements have been identified.
- Hazard Identification & Risk Assessment (HIRA) has been found documented which include radiation, fire, exposure to gases, infection, injury etc. Control measures are also specified in HIRA doc
- .WIs/OCPs are available
- No action pending on last IQA
- Mock drills are periodically organised by fire safety department
- Fire extinguisher, fire hydrants available and found being maintained

****Audit Evidences:**

- OHSMS manual ZHHRPL/OHSMS/ISO 45001-2018/01 , rev 0 dated 10 Oct 2023
- Hospital & patient safety manual ZHHRPL/DM-HS/03.00 , rev 08 dated 2 Aug 2023
- Infection prevention manual ZHHRPL/DM-IP/05-00
- Radiology imaging manual ZHHRPL/DM-IS/13.0 rev 07 dated 22 Aug 2022
- Organization chart /responsibility p-42 of OHSMS manual
- OHSMS policy , p-18 of OHSMS manual
- Hazard identification and risk assessment Doc HIRA-OPD
- Biomedical waste found being segregated
- Mock drill records dated 6 Jan 2024 and 20 April 2023
- Mopping , cleaning records
- Training record on bio medical waste 28 Oct 23

Audit of all the clauses mentioned in the audit plan matrix have been carried out.	yes
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Opportunities for Improvement indicated against Clause No(s): <input type="checkbox"/> none	Non-Conformities Issued against Clause No (s) : <input type="checkbox"/> None
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Name of Applicant /Licensee: M/s Zydus Hospitals &Healthcare Research Pvt Ltd, , Thaltej, Ahmedabad -	 Rahul Kumar
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DOC: MSC-F6.4-45

ISSUE: 01

DATE: April 2019

Page 1 of 2

Prepared By:

Approved By: DDG(MSCD)

Application Number/ Licence Number: OHS/WR/A-App 2023075261

,OHS as per IS/ISO 45001:2018

Process: Operation theatre (2 nos to be audited) , OT(laparoscopy 4 and 5 robotics)

Date of Audit: 22-25(FN) Jan 2024

Persons contacted with designation: 1. Ms. Jigna , Associate OT

Process — Observation & Evidence =

***Process Observation:**


- The department is responsible for elective and emergency operation. The manual giving entire process has been documented. Hospital has several OTs fully equipped as per requirement
- Air clean quality , velocity is ensured
- Calibration of medical equipment is ensured
- PPEs as required are used
- Bio medical waste is segregated in yellow, blue, red , white baskets
- The required documented information for OHSMS as per the established system procedures are available.
- OHSMS policy has been established, and is displayed at prominent locations. Awareness about Policy observed during interaction
- Objective and targets to prevent/ monitor/minimize radiation, infection, fire safety have been documented . These are monitored by respective departmental head/safety committee
- Adequate resources provided. Role and responsibilities are defined in manual
- Regulatory requirements have been identified.
- Hazard Identification & Risk Assessment (HIRA) has been found documented which include radiation, fire, exposure to gases, infection, injury etc. Control measures are also specified in HIRA doc
- .WIs/OCPs are available
- No action pending on last IQA
- Mock drills are periodically organised by fire safety department
- Fire extinguisher, fire hydrants available and found being maintained

****Audit Evidences:**

- OHSMS manual ZHHRPL/OHSMS/ISO 45001-2018/01 , rev 0 dated 10 Oct 2023
- Hospital & patient safety manual ZHHRPL/DM-HS/03.00 , rev 08 dated 2 Aug 2023
- Infection prevention manual ZHHRPL/DM-IP/05-00
- Radiology imaging manual ZHHRPL/DM-IS/13.0 rev 07 dated 22 Aug 2022
- Operation theatre manual OT-manual
- Organization chart /responsibility p-42 of OHSMS manual
- OHSMSMS policy , p-18 of OHSMS manual
- Hazard identification and risk assessment Doc HIRA-OT
- Biomedical waste found being segregated
- Use of scrub suite and apron observed in OT
- Required steps for infection controls are taken
- Air quality grade A class 100 ensured. Certificate S no 95001816005
- TC for high efficiency particulate air filter (HEPA filter) dated 12 Sep 2023. Max permitted particulate / cubic meter , report CAV/PC/001

Audit of all the clauses mentioned in the audit plan matrix have been carried out.	yes
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Opportunities for Improvement indicated against Clause No(s): <input type="checkbox"/> none	Non-Conformities Issued against Clause No (s) : <input type="checkbox"/> None
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Name of Applicant /Licensee: M/s Zydus Hospitals &Healthcare Research Pvt Ltd, , Thaltej, Ahmedabad -	 Rahul Kumar
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DOC: MSC-F6.4-45

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DATE: April 2019

Page 1 of 2

Prepared By:

Approved By: DDG(MSCD)

Application Number/ Licence Number: OHS/WR/A-App 2023075261		,OHS as per IS/ISO 45001:2018
Process: Biomedical Engineering (BME) services	Date of Audit: 22-25(FN) Jan 2024	
	Persons contacted with designation: 1. Mr. Terence, HOD and Head- projects 2. Mr. Prem Kumar-associate bio medical engineering	

Process — Observation & Evidence =

***Process Observation:**

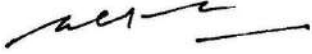
- The department is responsible for organizing preventive maintenance , calibration , procurement , installation of biomedical equipments viz CT scan , MRI , X ray , BP instruments , nebulizer , syringe pumps etc
- Preventive maintenance and calibration activity is given on contract to original supplier/ reputed organization. Procedures/OCPs are documented in BME manual. Annual preventive maintenance and calibration is prepared. Service providers are consulted and compliance of maintenance / calibration plan is ensured. Regular monitoring is done through software. Breakdown maintenance are attended by department and supplier are contacted if required
- The required documented information for OHSMS as per the established system procedures is available.
- OHSMS policy has been established, and is displayed at prominent locations. Awareness about Policy observed during interaction
- Objective and targets to prevent/ monitor/minimize radiation, infection, fire safety have been documented . These are monitored by respective departmental head/safety committee
- Adequate resources provided. Role and responsibilities are defined in manual
- Regulatory requirements have been identified.
- Hazard Identification & Risk Assessment (HIRA) has been found documented which include radiation, fire, exposure to gases, infection, injury etc. Control measures are also specified in HIRA doc
- .WIs/OCPs are available
- No action pending on last IQA
- Mock drills are periodically organised by fire safety department
- Fire extinguisher, fire hydrants available and found being maintained

****Audit Evidences:**

- OHSMS manual ZHHRPL/OHSMS/ISO 45001-2018/01 , rev 0 dated 10 Oct 2023
- Hospital & patient safety manual ZHHRPL/DM-HS/03.00 , rev 08 dated 2 Aug 2023
- Infection prevention manual ZHHRPL/DM-IP/05-00
- Bio medical engineering manual ZHHRPL/DM-BME/16.0 , rev 07 dated 22 Aug 2022
- Organization chart /responsibility p-42 of OHSMS manual
- OHSMS policy , p-18 of OHSMS manual
- Hazard identification and risk assessment Doc HIRA-radiology
- Mock drill records dated 6 Jan 2024 and 20 April 2023
- Records of PM of defibrillator dated 27 Oct 2023
- Calibration of infusion pump dated 17 April 2023
- PM record of cath lab dated 21 Nov 2023, calibration of BP apparatus record dated 2 Jan 2024-01-26
- Maintenance contract CMC dated 15 march 2023 for cath lab

Audit of all the clauses mentioned in the audit plan matrix have been carried out.	yes
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Opportunities for Improvement indicated against Clause No(s): <input type="checkbox"/> none	Non-Conformities Issued against Clause No (s) : <input type="checkbox"/> None
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Name of Applicant /Licensee: M/s Zydus Hospitals &Healthcare Research Pvt Ltd, , Thaltej, Ahmedabad -	 Rahul Kumar
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Page 1 of 2

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Application Number/ Licence Number: OHS/WR/A-App 2023075261

,OHS as per IS/ISO 45001:2018

Process: Fire safety

Date of Audit: 22-25(FN) Jan 2024

Persons contacted with designation: 1. Mr Santosh Kumar Rout , Associate- operations


Process — Observation & Evidence =

***Process Observation:**

- The department is responsible for organising maintenance and operations of fire hydrants , fire extinguisher , pumps . They are also responsible for meeting legal requirement and also conducting mock drills
- The department is headed by Associate- Operations . In addition two firemen are placed from security agency. The equipments are maintained by assigning maintenance contract for fire extinguisher , hydrants pumps .
- Fire safety NOC available from Chief fire officer which is valid up to 30 March 2024 . calibration of pressure gauges is got done periodically
- The required documented information for OHSMS as per the established system procedures is available.
- OHSMS policy has been established, and is displayed at prominent locations. Awareness about Policy observed during interaction
- Objective and targets to prevent/ monitor/minimize radiation, infection, fire safety have been documented . These are monitored by respective departmental head/safety committee
- Adequate resources provided. Role and responsibilities are defined in manual
- Regulatory requirements have been identified.
- Hazard Identification & Risk Assessment (HIRA) has been found documented which include radiation, fire, exposure to gases, infection, injury etc. Control measures are also specified in HIRA doc
- .WIs/OCPs are available
- No action pending on last IQA
- Fire extinguisher, fire hydrants available and found being maintained
- Mock drills are periodically organised by fire safety department

****Audit Evidences:**

- OHSMS manual ZHHRPL/OHSMS/ISO 45001-2018/01 , rev 0 dated 10 Oct 2023
- Hospital & patient safety manual ZHHRPL/DM-HS/03.00 , rev 08 dated 2 Aug 2023
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- Bio medical engineering manual ZHHRPL/DM-BME/16.0 , rev 07 dated 22 Aug 2022
- Organization chart /responsibility p-42 of OHSMS manual
- OHSMS policy , p-18 of OHSMS manual
- Hazard identification and risk assessment Doc HIRA-safety
- Mock drill records dated 6 Jan 2024 and 20 April 2023
- Fire safety report and electrical safety report of external agency i,e Dev consultant done in July 2022
- Noise level monitoring. Observed around 30 db
- Pressure gauge calibration UB pump room PU/P/20953/23 on 29 July 2023
- Hydrant maintenance and fire extinguisher inspection record checked. Done in Nov 23

Audit of all the clauses mentioned in the audit plan matrix have been carried out.		yes
Opportunities for Improvement indicated against Clause No(s): <input type="checkbox"/> none	Non-Conformities Issued against Clause No (s) : <input type="checkbox"/> None	
Name of Applicant /Licensee: M/s Zydus Hospitals &Healthcare Research Pvt Ltd, , Thaltej, Ahmedabad -		 Rahul Kumar
<p>* <i>Identification of processes may include identification of key performance parameters/ significant aspects; Identification of objectives; Compliance to Legal and statutory requirements, etc. Use separate sheet for separate process. One department may have many processes.</i></p> <p>** <i>Evidences clearly state the samples, records of process output verified and witness of activity with verifiable proof.</i></p>		



TITLE: Audit Observation and Evidence

DOC: MSC-F6.4-45

ISSUE: 01

DATE: April 2019

Page 1 of 2

Prepared By:

Approved By: DDG(MSCD)

Application Number/ Licence Number: OHS/WR/A-App 2023075261 ,OHS as per IS/ISO 45001:2018

Process: Emergency, ambulance services and patient care attendant

Date of Audit: 22-25(FN) Jan 2024

Persons contacted with designation: 1. Mr. Mohammad Afzal, Associate- operation

Process — Observation & Evidence =

***Process Observation:**


- The department is responsible for providing ambulance services , medical services in emergency department , patient care attendant
- The department is having its well equipped ambulance. They have also entered in contract with Dalk health care for use of their services on call basis. Ambulance cleanliness, hygiene, free from infection, availability of all equipment is ensured. Feed back of users/patient is obtained
- All patients brought in ambulance and other critical patients are attended in emergency. Emergency department is fully equipped to treat critical patient and has all safety measures required for OHSMS
- The required documented information for OHSMS as per the established system procedures is available.
- OHSMS policy has been established, and is displayed at prominent locations. Awareness about Policy observed during interaction
- Objective and targets to prevent/ monitor/minimize radiation, infection, fire safety have been documented . These are monitored by respective departmental head/safety committee
- Adequate resources provided. Role and responsibilities are defined in manual
- Regulatory requirements have been identified.
- Hazard Identification & Risk Assessment (HIRA) has been found documented which include radiation, fire, exposure to gases, infection, injury etc. Control measures are also specified in HIRA doc
- .WIs/OCPs are available
- No action pending on last IQA
- Fire extinguisher, fire hydrants available and found being maintained
- Mock drills are periodically organised by fire safety department
- Bio medical waste is segregated in yellow, blue, red , white baskets

****Audit Evidences:**

- OHSMS manual ZHHRPL/OHSMS/ISO 45001-2018/01 , rev 0 dated 10 Oct 2023
- Hospital & patient safety manual ZHHRPL/DM-HS/03.00 , rev 08 dated 2 Aug 2023
- Infection prevention manual ZHHRPL/DM-IP/05-00
- Bio medical engineering manual ZHHRPL/DM-BME/16.0 , rev 07 dated 22 Aug 2022
- Organization chart /responsibility p-42 of OHSMS manual
- OHSMS policy , p-18 of OHSMS manual
- Hazard identification and risk assessment Doc HIRA
- Mock drill records dated 6 Jan 2024 and 20 April 2023
- Contract copy with Dalk health care for procurement of ambulance services dated 23 Jan 2023
- Relevant PPEs are available and are used
- Bio medical waste found being segregated and kept in designated baskets

Audit of all the clauses mentioned in the audit plan matrix have been carried out.	yes
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Opportunities for Improvement indicated against Clause No(s): <input type="checkbox"/> none	Non-Conformities Issued against Clause No (s) : <input type="checkbox"/> None
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Name of Applicant /Licensee: M/s Zydus Hospitals &Healthcare Research Pvt Ltd , Thaltej, Ahmedabad -	 Rahul Kumar
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** Identification of processes may include identification of key performance parameters/ significant aspects; Identification of objectives; Compliance to Legal and statutory requirements, etc. Use separate sheet for separate process. One department may have many processes.*

*** Evidences clearly state the samples, records of process output verified and witness of activity with verifiable proof.*



MANAGEMENT SYSTEMS CERTIFICATION

TITLE: Audit Observation and Evidence

DOC: MSC-F6.4-45

ISSUE: 01

DATE: April 2019

Page 1 of 1

Prepared By:

Approved By: DDG(MSCD)

Application Number/ License Number : A-2023075261	IS/ISO: IS/ISO 45001:2018
Process: Central Sterile Supply Department	Date of Audit: 22-01-2024 to FN of 25-01-2024
	Persons contacted with designation: Mr. Bipin Solanki, Incharge
Process — Observation & Evidence	
<p>1. *Process Observation : CSS Department works in 3 shifts reporting to Medical Services department. 7 technicians, one incharge, 4 attendants (outsourced) employed in CSSD. CSSD receive surgical instruments and accessories like scissors, artery forceps, long forceps, kidney tray, bowl etc for sterilization. After receipt of the instruments they are segregated into metal, plastic, silicon, rubber as per the material. They are taken into cleaning, washing and disinfection. The cleaned metal equipment are received in clean zone and lubricated with water soluble spray to facility easy handling of instruments having hinges, avoid rusting etc. Cleaned instruments are assembled as per the requirement of respective departments and packed in SMS (spunbond Meltbondand spun bond polypropylene sheet) or plastic pouches resistant to sterilization. Sterilization is done in two ways either by steam or plasma based on the type of material. Sterilized instruments are finally stored in sterile storage room and issued to the departments as per requirement. Plasma sterilizer 1000 litres, steam sterilizer 600 litres (134 °C), Ethylene Oxide sterilizer of 300 litres (40°C). OH &S policy, roles and responsibilities are documented and maintained. HIRA identified 7 of which 2 are high risk, 4 moderate risk and one low risk. No history of incidents, near miss or accidents in CSSD department. Internal audit of the department was done on 20-12-2023 and the non compliances observed in the audit were addressed by the department with corrective actions and duly reviewed by management during management review meeting held on 19-01-2024. OH & S policy and objectives established and communicated to all the relevant parties and maintained as documented information. Consultation and participation of workers in development, planning, implementation, performance evaluation and actions for improvement in OH& S ensured through internal meetings. Resources needed for the establishment, implementation, maintenance and continual improvement of OH&S management system ensured. The department established, implemented and maintained the process(es) needed for the internal and external communications relevant to the OH&S management system. Activities of CSSD have been observed during the night shift and found to be normal and under control.</p>	
<p>2. **Audit Evidences: Effectiveness of steam sterilization is checked by using Bowi Dick Test/ Process Challenge Device. Each batch of sterilization set is issued with sterilization date as well as expiry date before which the sterilized equipment can be put in use. ZH21769 dated 24-01-2024 is maintained for sterilized equipment in Steam sterilizer no.2. Biological Indicator is checked for each sterilizer once in a week. ZH21750 dated 22-01-2024 maintained for sterilized equipment along with check of biological indicator in sterilizer. Steam sterilization log register maintained for the sterilizer listing the number and detail of equipments sterilized in each batch. Training regarding Hazardous materials is done on 20-01-2024. Internal audit was held on 20/12/2023. ZHHRPL/LDm-CSSD/20.00 dated 16/08/2021 Revision 06 Central Sterile & Supply department manual developed, established and maintained. Stock indent SRQ-100024002630 dated 19th Jan 2024 issued to central store for supply of PPE Disposable surgeon cap, face mask etc. Medical health record of Employee MR No. 10002015000320 for the check up done on 30-03-2023 certified that the employee is clinically and physical fit for the job. Vaccination also provided for the employee. Medical health record of Employee MR No. 10002022345289 for the check up done on 29-07-2023 certified that the employee is clinically and physical fit for the job. MR No. 10002022319030 physical, medical check up held on 08-01-2023 and also vaccinated as per the schedule.</p>	
Audit of all the clauses mentioned in the audit plan matrix have been carried out.	Yes/No
Opportunities for Improvement indicated against Clause No(s) _____	Non-Conformities Issued against Clause No (s)
Name of Applicant /Licensee: M/s Zydus Hospitals & Healthcare Research Pvt Ltd, Ahmedabad	 Signature Of Auditor

* *Identification of processes may include identification of key performance parameters/ significant aspects; Identification of objectives; Compliance to*

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MANAGEMENT SYSTEMS CERTIFICATION

TITLE: Audit Observation and Evidence

DOC: MSC-F6.4-45

ISSUE: 01

DATE: April 2019

Page 1 of 1

Prepared By:

Approved By: DDG(MSCD)

Application Number/ License Number : A-2023075261	IS/ISO: IS/ISO 45001:2018
Process: House Keeping Department	Date of Audit: 22-01-2024 to FN of 25-01-2024
	Persons contacted with designation: Mr. Fateh Singh Rathode, House Keeping Incharge
Process — Observation & Evidence	
<p>1. *Process Observation : House keeping department reports to Operations Manager. The department is having 120 house keeping personnel of which 5 are supervisors on pay rolls. House keeping activity has been outsourced and M/s. Orion Enterprises Pvt Ltd. Housekeeping activity is carried out in 2 shifts of 12 hours each. Each disinfectant and cleaner procured by housekeeping is issued with MSDS. OH &S policy, roles and responsibilities are documented and maintained. The department has identified 13 HIRA of which 2 are of high risk and 10 are moderate risk and one is of normal risk. Control measures are developed, established and maintained for control of hazards to keep it under 'normal risk'. Training record maintained for the internal trainings given to the house keeping personnel on various topics. PPEs namely gloves, masks, gum boots, aprons, goggles, head caps, are issued to the house keeping personal on regular basis. Laundry service comprising washing of soiled aprons, bedsheets, scrub suits, towels, patient linen etc outsourced and engaged to M/s. The Spic & Span laundry & housekeeping service. Internal audit of the department was held on 21-12-2023 in which 2 non conformities identified have been duly addressed with corrective actions and reviewed by management during management review held on 19-01-2024. OH & S policy and objectives established and communicated to all the relevant parties and maintained as documented information. Consultation and participation of workers in development, planning, implementation, performance evaluation and actions for improvement in OH& S ensured through internal meetings. Resources needed for the establishment, implementation, maintenance and continual improvement of OH&S management system ensured. The department established, implemented and maintained the process(es) needed for the internal and external communications relevant to the OH&S management system.</p>	
<p>2. Evidence: MSDS OF Sodium Hypochlorite is documented and maintained. Eye wash facilities provided in each floor at nursing station to immediately wash the eyes in case of chemical spill etc. Training given to house keeping personnel on 'Bio Medical waste management' on 01-01-2024. ZHHRPL/AAC/2.0 maintained for House keeping standard operating procedures. Housekeeping staff deployment register maintained for attendance, their allocation, grooming along with the briefing points discussed during briefing before duty allocation. BMW Auth NO: BMW-361752 valid up to 21-04-2028 issued to hospital for Collection, Generation, Segregation and storage of biomedical waste in the premises. Final disposal of Bio-Medical waste is outsourced to M/s. Care B M W Incinerator authorized by GPCB is valid up to 31st March 2024. M/s. Care BMW Incinerator is issued with licence by GPCB vide BMW Auth No: BMW-353251 Valid upto 22-09-2025. Medical health record of Employee MR No. 10002018115419 for the check up done on 30-06-2023 certified that the employee is clinically and physical fit for the job. Hepatitis B vaccination given and Tetanus vaccination given as and when hazard arised. Medical health record of Employee MR No. 10002023409698 for the check up done on 27-09-2023 certified that the employee is clinically and physical fit for the job. Hepatitis B vaccination given and Tetanus vaccination given as and when hazard arised. Bio Medical waste data maintained to monitor the waste quantities vis a vis quantities permitted by GPCB. Document no. SRC-100024000579 dated 18th Jan 2024 issued for PPE stock received by housekeeping department.</p>	
Audit of all the clauses mentioned in the audit plan matrix have been carried out.	Yes/No <input type="checkbox"/>
Opportunities for Improvement indicated against Clause No(s) _____	Non-Conformities Issued against Clause No (s)
Name of Applicant /Licensee: M/s Zydus Hospitals & Healthcare Research Pvt Ltd, Ahmedabad	 Signature Of Auditor
<p>* Identification of processes may include identification of key performance parameters/ significant aspects; Identification of objectives; Compliance to Legal and statutory requirements, etc. Use separate sheet for separate process. One department may have many processes.</p> <p>** Evidences clearly state the samples, records of process output verified and witness of activity with verifiable proof.</p>	



MANAGEMENT SYSTEMS CERTIFICATION

TITLE: Audit Observation and Evidence

DOC: MSC-F6.4-45

ISSUE: 01

DATE: April 2019

Page 1 of 1

Prepared By:

Approved By: DDG(MSCD)

Application Number/ License Number : A-2023075261	IS/ISO: IS/ISO 45001:2018
Process: MEDICAL RECORDS	Date of Audit: 22-01-2024 to FN of 25-01-2024
	Persons contacted with designation: Mr. Ishwar Sinh Sodha, Associate MRD
Process — Observation & Evidence	
<p>1. *Process Observation : Medical Records department is coming under Medical Services Department. The department is comprising of 3 permanent employees and one attendant under outsourcing contract. The department works in one shift from 9.00 to 18.30 hrs. Objective of the department is to retain all the medical records of the patients comprising, birth, treatment, death etc for a period of 2 years. Thereafter, the records will be transferred to Zydus Hospital at Anand to retain the records as per the stipulated time norms. OH & S policy, roles and responsibilities are documented and maintained. The department identified 10 HIRA of which 1 is of high risk and 9 are of medium risk before the control measures and will keep them under control by reducing the risk. Internal audit of the department was held on 20-12-2023 and issued with two non conformities have been closed in time with due corrective actions. Management review of the OH & S System was held on 19-01-2024 in which the internal audit observations and the status of corrective action was reviewed and duly addressed. OH & S policy and objectives established and communicated to all the relevant parties and maintained as documented information. Consultation and participation of workers in development, planning, implementation, performance evaluation and actions for improvement in OH& S ensured through internal meetings. Resources needed for the establishment, implementation, maintenance and continual improvement of OH&S management system ensured. The department established, implemented and maintained the process(es) needed for the internal and external communications relevant to the OH&S management system. Pest control measures are taken every week by applying pest control chemicals through MoU by third party M/s. Rex Environment Science (P) Ltd. Mock drill for the department was held on 30-09-2023 at 12.34 hrs. During the audit, the employee demonstrated the steps to be followed in case of Fire emergency. Medical health of the employees checked annually. IP MRD file issue register is maintained for the movement of patient file.</p>	
<p>2. **Audit Evidences: ZHHRPL/IMS/07-00 dated 02/08/2023 Procedure for Maintenance of medical records is documented established and maintained in the department. Pest Control Register maintained indicating the treatment done by the third party agency. Latest pest control treatment was done on 20/01/2024. Work order No. ZHHRPL/AHM/WO/23-24/GEN/4356 dated 03 May 2023 issued to M/s. Rex Environment Science P Ltd for integrated pest management in the hospital. Patient File movement of Patient No. 10002023422129 was recorded for the file copy issued to the patient on 18-01-2024. Patient File movement of Patient No. 10002022333539 was recorded for the file issued to Neurosurgery department on 19-01-2024 and returned to MRD on 19-01-2024. Medical health check up of the employee No. 11610008, Mr Umesh Makhwana was done on 11-10-2023 and reported that the employee is physically and clinically fit for the job. Medical health checkup of the employee no. 11503015, Mr Iswar Sinh Sodha was done on 30-03-2023 and reported that the employee is physically and clinically fit for the job.</p>	
Audit of all the clauses mentioned in the audit plan matrix have been carried out.	Yes/No <input type="checkbox"/>
Opportunities for Improvement indicated against Clause No(s) <input type="checkbox"/>	Non-Conformities Issued against Clause No (s) <input type="checkbox"/>
Name of Applicant /Licensee: M/s Zydus Hospitals & Healthcare Research Pvt Ltd, Ahmedabad	 Signature Of Auditor
<p>* Identification of processes may include identification of key performance parameters/ significant aspects; Identification of objectives; Compliance to Legal and statutory requirements, etc. Use separate sheet for separate process. One department may have many processes.</p> <p>** Evidences clearly state the samples, records of process output verified and witness of activity with verifiable proof.</p>	



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BUREAU OF INDIAN STANDARDS

FORMS

MANAGEMENT SYSTEMS CERTIFICATION

TITLE: Audit Observation and Evidence

DOC: MSC-F6.4-45

ISSUE: 01

DATE: April 2019

Page 1 of 1

Prepared By:

Approved By: DDG(MSCD)

Application Number/ License Number : A-2023075261	IS/ISO: IS/ISO 45001:2018
Process: MEDICAL SERVICES	Date of Audit: 22-01-2024 to FN of 25-01-2024
	Persons contacted with designation: Dr. Chaitasy Mehta, Lead Medical Services
Process — Observation & Evidence	
<p>1. *Process Observation : The department is comprising of One Lead Medical Services, 25 Medical admins . Medical services department is looking after all the clinical departments (medical records, Cath lab, neurology, nephrology, transplant sciences, renal sciences, CSSD, Ortho sciences, emergency, IPD, OPD, Infectious diseases, pediatrics, obstetrics, robotics, laparoscopic surgery, interventional radiology, neuro cath so on) and 170 consultants (full time doctors), 22 registers (specialists) and 90 associate para medical staff. All the patients safety is looked after by Medical services. All the SOPs in the clinical departments are prepared, documented, established and maintained by committees such as Infection Control Committee, Drug and therapeutic committee, quality steering committee and safety committee in which Lead Medical Services is a member and ensure control measures for OH & S aspects. Medical Services department follows the HIRA of the respective departments where they would visit for monitoring the activities. Near miss incidents and injuries to doctors are reported, investigated and corrective action taken to control the risk. OH & S policy and objectives established and communicated to all the relevant parties and maintained as documented information. Consultation and participation of workers in development, planning, implementation, performance evaluation and actions for improvement in OH& S ensured through internal meetings. Resources needed for the establishment, implementation, maintenance and continual improvement of OH&S management system ensured. The department established, implemented and maintained the process(es) needed for the internal and external communications relevant to the OH&S management system.</p>	
<p>2. **Audit Evidences: Medical health record of employee of Medical Services Department evaluated documented and maintained. Needle stick injury to Dr. Maulik Parmar Employee no. 32204001 happened on 21-08-2023. The incident was investigated, corrective action taken and the employee was clinically evaluated on 21 08 2023 keeping in view the clinical history of the patient such as Vaccination etc. Medical health record of consultants reported to Medical services department is evaluated, documented and maintained. Dr Niraj Vasavada, Spine Surgeon Emp no. 32307002 was examined on 03-07-2023 and reported physically and clinically fit for the job. DrVatsal Limbani, Associate Medical Services Emp no. 91612011 was examined on 29-12-2023 and reported physically and clinically fit for the job. Induction trainings are given to the newly appointed doctors covering the OH & S topics namely Fire Safety, Infection Control, Emergency codes etc. Training given to Dr Tarlika Kalasva Emp ID 92311003 on 01-11-2023, Dr Chirag Panchala Emp ID 92311010 on 20-11-2023.</p>	
Audit of all the clauses mentioned in the audit plan matrix have been carried out.	Yes/No
Opportunities for Improvement indicated against Clause No(s) _____	Non-Conformities Issued against Clause No (s) _____
Name of Applicant /Licensee: M/s Zydus Hospitals & Healthcare Research Pvt Ltd, Ahmedabad	Signature Of Auditor
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भारतीय मानक ब्यूरो
BUREAU OF INDIAN STANDARDS

FORMS

MANAGEMENT SYSTEMS CERTIFICATION

TITLE: Audit Observation and Evidence

DOC: MSC-F6.4-45

ISSUE: 01

DATE: April 2019

Page 1 of 1

Prepared By:

Approved By: DDG(MSCD)

Application Number/ License Number : A-2023075261	IS/ISO: IS/ISO 45001:2018
Process: NURSING	Date of Audit: 22-01-2024 to FN of 25-01-2024
	Persons contacted with designation: Mr Elizabeth Santhosh, Lead Nursing; Mr Jakey Devadiya, Deputy Nursing
Process — Observation & Evidence	
<p>1. *Process Observation : Nursing department is looking after nursing activities in IP, OP, OT, Emergency, Cathlab, Endoscopy, Emergency and day care. The department works in 3 shifts and reporting to Centre Head. The department is employed with 450 staff comprising nurses, 23 nursing incharges, 4 nursing supervisor, one floor supervisor, 23 incharges, one infection control nurse, one educator employed in the department. The scope for OH& S has been defined in OH & S Manual. OH & S policy and objectives established and communicated to all the relevant parties and maintained as documented information. The department identified 12 HIRA of which one is High risk and 11 are moderate risk. Control measures are in place either to control or eliminate the risk associated with the hazards. Incidents, near miss are identified, reported and investigated to avoid or control the risk. Observations in Internal audit were addressed with suitable corrective action and duly reviewed in Management review meeting. Consultation and participation of workers in development, planning, implementation, performance evaluation and actions for improvement in OH& S ensured through internal meetings. Resources needed for the establishment, implementation, maintenance and continual improvement of OH&S management system ensured. The department established, implemented and maintained the process(es) needed for the internal and external communications relevant to the OH&S management system. Trainings on OHSMS topics such as appropriate use of PPE, patient safety, reporting of near miss incidents etc ensured. Health check up for the employees is done annually along with due vaccination where essential. Quality of work area is ensured by regular checking of indoor/work place air quality as per the frequency stipulated by regulatory authority. Eye wash facility provided at each nursing station for washing of eyes in case of chemical hazards.</p>	
<p>2. **Audit Evidences: NSI/BFE Record maintained for Needle Stick Injury/Body Fluid Exposure to the nurses detailing the report of the incident occurred on 28th December 2023, Viral marker investigation done vide 10002023417213 dated 29th December 2023 keeping in view the VMI of the patient held on 27th November 2023 vide report no. 100020197679. Health check of the injured employees is also done on 29th December 2023 by doctor for medication. NSI Prevention & management of Basic IC practices training given to the staff on 18/12/2023. ZHHRPL/DM-NS/11.00 dated 01/08/2015 Revision 08 Clinical Nursing Manual maintained for the Patient Care activities comprising of OH & S aspects related Patient as well as Nurse. Medical records are maintained at HR department for each nurse separately. Employee NO.51503027 Mr Anil Patel was checked on 11-03-2023 and found fit for the duties. Emp No. 51502029 Ms Deepa P Raysingani was checked on 30-05-2023 and found fit for the duties. Indoor Air quality is monitored and checked through third party laboratory. Test report no. GL/06230710001 dated 10 July 2023 issued for CT Scan Ground floor indicating the physical, chemical and microbiological parameters within the stipulated parameters. ZHHRPL /HIRA /Nursing /01 HIRA developed established and maintained. Internal audit of the department was held on 20-12-2023, observations and non compliance were duly understood and addressed with suitable corrective action. Management review meeting was held on 19/01/2024 in which internal audit observations were discussed and advised for closure before the stipulated date.</p>	
Audit of all the clauses mentioned in the audit plan matrix have been carried out.	Yes/No
Opportunities for Improvement indicated against Clause No(s)_____	Non-Conformities Issued against Clause No (s)
Name of Applicant /Licensee: M/s Zydus Hospitals & Healthcare Research Pvt Ltd, Ahmedabad	 Signature Of Auditor

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BUREAU OF INDIAN STANDARDS

FORMS

MANAGEMENT SYSTEMS CERTIFICATION

TITLE: Audit Observation and Evidence

DOC: MSC-F6.4-45


ISSUE: 01

DATE: April 2019

Page 1 of 1

Prepared By:

Approved By: DDG(MSCD)

Application Number/ License Number : A-2023075261	IS/ISO: IS/ISO 45001:2018
Process: PHARMACY	Date of Audit: 22-01-2024 to FN of 25-01-2024
	Persons contacted with designation: Mr. Siddhartha Subudhi, Lead Pharmacy
Process — Observation & Evidence	
<p>*Process Observation : Pharmacy department comprising of 9 pharmacies with the idea of every floor having every pharmacy relevant to the activities in each floor such as Central Pharmacy, IP Pharmacy, OP Pharmacy, OT Store Pharmacy, Cathlab Pharmacy, ICU Pharmacy, Dialysis Pharmacy. The department is employed with around 40 pharmacists, 20 pharmacy assistants. Pharmacy department is reporting to medical services department. The scope for OH& S has been defined in OH & S Manual. OH & S policy and objectives established and communicated to all the relevant parties and maintained as documented information. The department identified 8 HIRA of which 4 are of high risk and 4 are of moderate risk. Control measures are in place to either eliminate or bring the risk under control. Consultation and participation of workers in development, planning, implementation, performance evaluation and actions for improvement in OH& S ensured through internal meetings. Resources needed for the establishment, implementation, maintenance and continual improvement of OH&S management system ensured. The department established, implemented and maintained the process(es) needed for the internal and external communications relevant to the OH&S management system. Legal requirements applicable to the department namely FSSAI licence for keeping the nutrition items, pharmacy licence for keeping the medicines from CDSCO are maintained and valid as on date. The department developed, documented and maintained procedures for safe handling of Bio-Medical waste, use of spillage kit in case of breakage of liquid medicines. Few of the medicines are of hazardous in nature are handled and stored as per the MSDS of the respective medicines. Incidents, hazards near miss are reported, investigated and corrective actions and measures are taken to either eliminate or control the risk. Measures were taken to eliminate the occurrence of the incidents and the patient condition also was observed due to erroneous medication impacts. Nearing expiring medicines are identified once in month and damaged medicines are categorized as 'Condemned medication'. Inventory of condemned medicine is quantified, documented and stored separately for final disposal. Eye wash facility provided for washing of eyes in case of chemical hazards.</p>	
<p>2. **Audit Evidences: MSDS for hazards chemicals is documented and maintained. Chemwatch 74-2029 Version No2.1.1.1 dated 20/01/2017 of Mikrozid HP 10. Document No. ZHHRPL/MOM/06.00 dated 01-08-2015 documented and maintained for SOP of high risk medicines handled in the pharmacy. MRN 10002021312658 dated 18/01/2024 reported for the incident 'Dispensation Error' identified at OP Pharmacy. Narcotic drug transaction like receiving, handling and dispensing etc are maintained in Narcotic Register stipulated by Excise Department and Prohibition and Nashabandhi Office. Vide report dated 31st December 2023, Rs 11343/- worth medicines were disposed off due to expiry/damage etc. Medical Health records of the pharmacists maintained. MR No. 2022342372 dated 11-07-23 issued for Mr Rajanikant Chavda indicating fitness for the job clinically and physically. MR No. 2022351988 dated 6/9/23 issued for MS Binal Patel indicating fitness for the job clinically and physically. Internal audit of the department was held on 21/12/2023 and the corrective actions were taken for the observations of the audit and closed the observations. Management review was done on 19-01-2024 in which the audit observations, action plan for the corrective actions were reviewed by management.</p>	
Audit of all the clauses mentioned in the audit plan matrix have been carried out.	
Yes/No	
Opportunities for Improvement indicated against Clause No(s) _____	Non-Conformities Issued against Clause No (s)
Name of Applicant /Licensee: M/s Zydus Hospitals & Healthcare Research Pvt Ltd, Ahmedabad	 Signature Of Auditor

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MANAGEMENT SYSTEMS CERTIFICATION

TITLE: Audit Observation and Evidence

DOC: MSC-F6.4-45

ISSUE: 01

DATE: April 2019

Page 1 of 1

Prepared By:

Approved By: DDG(MSCD)

Application Number/ License Number : A-2023075261	IS/ISO: IS/ISO 45001:2018
Process: QC & LAB, Blood Bank	Date of Audit: 22-01-2024 to FN of 25-01-2024
	Persons contacted with designation: Ms. Nisha Bhindora, Deputy Quality Manager
Process — Observation & Evidence	
<p>1. *Process Observation : Blood bank and lab staff 70, total phlebotomist 18, 10 consultant pathologists, one microbiologist, one transfusion consultant. OPD and IPD sample collection and testing of blood, urine, body fluids, stool, swab sample, PCR, culture. Donor registration, donor collection, donor screening, donor counselling, donor blood sample testing, TTI testing, blood grouping, antibody screening, cross matching, component separation apheresis procedure. Door to door sample collection is also facilitated based on patient request. The department works in 3 shifts. OH & S policy, roles and responsibilities are documented and maintained. The department has identified 13 HIRA of which 2 are of high risk and 10 are moderate risk and one is of normal risk. Control measures are developed, established and maintained for control of hazards to keep it under 'normal risk'. PPE issue and consumption details are maintained. OH & S policy and objectives established and communicated to all the relevant parties and maintained as documented information. Consultation and participation of workers in development, planning, implementation, performance evaluation and actions for improvement in OH& S ensured through internal meetings. Resources needed for the establishment, implementation, maintenance and continual improvement of OH&S management system ensured. The department established, implemented and maintained the process(es) needed for the internal and external communications relevant to the OH&S management system. Mockdrills for the applicable CODEs such as 'Fire', 'Disaster' etc were conducted as per the stipulated frequency and the employees demonstrated the steps to be followed during respective mockdrill. Data generated by the laboratory is protected with required backups and anti virus. Confidentiality of data is ensured through the protocols assigned to the testing equipment which automatically issue the reports to the concerned after generation of report. Legal requirements applicable to the department such as licence for Blood bank, handling of bio-medical waste, wastewater etc ensured and control measures are in place. Incidents, near miss are reported, investigated and controlled with corrective measures. Internal audit of the department was held on 19-12-2023, the non conformities are addressed with due corrective actions and management reviewed the corrective actions during the meeting held on 19-01-2024.</p>	
<p>2. **Audit Evidences: Mock drill for FIRE was done on 06th January 2024. Mock drill for Blue Code 'Cardiac Arrest' was held on 13th December 2023. Backup of the Data of the Lab and Blood bank is done daily and protected with antivirus. Privacy policy is in place through which generated test report is automatically issued to the concerned namely patient, IP Department, OP Department etc. GB/173 dated 03/03/2016 issued for operation of Blood centre valid till 02-03-2026. Adverse Incident record no. ZYH/AHM/DOC145 dated 23 June 2019 reported for the incident of 'Buffer solution contact with skin', root cause analysis done, corrective action taken. ZHHRPL/FMS/11-00 dated 01-01-2023 developed, maintained and established in place. ZHY/AHM/Doc1146 dated 21/12/2023 maintained for the induction training given to newly appointed employees regarding lab procedures including safety aspects. ZYH/AHM/Doc 84 Monthly internal training record maintained for OH & S aspects for year 2024. SOP for safety of laboratory personnel ZYH/AHM/LM/SOP/Gen 08 dated 29/12/2015 issued with amendment no.3 dated 27-05-2023 developed, maintained and established. MSDS collected, maintained and followed for Product 'Eryclone Anti -a Monoclonal' issued by the manufacturer Doc no. MSDS/101. Equipment verification plan is prepared and maintained at frequency of every six months. Equipment Verification report ZYH/AHM/DOC 103 dated 08-06-2023 verified Hematology analyzer Advia/2120I. For the incident 'needle stick injury' to the employee Ms. Priya Sooraj, Emp ID 21707009 reported on 28-06-2023, investigation of the incident was carried out vide report dated 28-06-2023. ZYH/LAB/FF/127-A dated 13 Dec 2023 Lab services feedback received from OPD patient indicating satisfactory feedback on laboratory services. Medical health record of Employee No. 21612003 Mr Ketan Leuva done on 13 Dec 2023 indicating physically and clinically fit for the job. Medical health record of Employee No. 21707009 Ms Priya Sooraj done on 24 July 2023 indicating physically and clinically fit for the job.</p>	
Audit of all the clauses mentioned in the audit plan matrix have been carried out.	Yes/No
Opportunities for Improvement indicated against Clause No(s) _____	Non-Conformities Issued against Clause No (s)

Name of Applicant /Licensee: M/s Zydus Hospitals & Healthcare Research Pvt Ltd, Ahmedabad



Signature Of Auditor

* *Identification of processes may include identification of key performance parameters/ significant aspects; Identification of objectives; Compliance to*

Legal and statutory requirements, etc. Use separate sheet for separate process. One department may have many processes.

** *Evidences clearly state the samples, records of process output verified and witness of activity with verifiable proof.*



भारतीय मानक ब्यूरो
BUREAU OF INDIAN STANDARDS

FORMS

MANAGEMENT SYSTEMS CERTIFICATION

TITLE: Audit Observation and Evidence

DOC: MSC-F6.4-45


ISSUE: 01

DATE: April 2019

Page 1 of 1

Prepared By:

Approved By: DDG(MSCD)

Application Number/ License Number : A-2023075261	IS/ISO: IS/ISO 45001:2018
Process: SECURITY DEPARTMENT	Date of Audit: 22-01-2024 to FN of 25-01-2024
	Persons contacted with designation: Mr. Kamlesh Panchal, Security Officer
Process — Observation & Evidence	
<p>1. *Process Observation : Security Department is reporting to Operations department. Strength of the department is 3 supervisors, 88 security guards including lift man, lady security guards and outsourced to M/s. Checkmate Security Services Pvt Ltd. The department works in 2 shifts of 12hrs for every day The scope for OH& S has been defined in OH & S Manual. OH & S policy and objectives established and communicated to all the relevant parties and maintained as documented information. The department identified 11 HIRA of which 3 are of high risk and 8 are of moderate risk. Control measures are in place either to control or eliminate the risk associated with the hazards. Internal audit of the department was held on 21-12-2023 in which the 2 non conformities reported have been addressed with correction actions and duly reviewed by management in review meeting held on 19-01-2024. Health of the security guards is checked once in year. No history of incident or near miss observed. Consultation and participation of workers in development, planning, implementation, performance evaluation and actions for improvement in OH& S ensured through internal meetings. Resources needed for the establishment, implementation, maintenance and continual improvement of OH&S management system ensured. The department established, implemented and maintained the process(es) needed for the internal and external communications relevant to the OH&S management system.</p>	
<p>2. Evidence: Medical health check of security supervisor employee no. 12205002, Mr Bhautik Patel was done on 19-05-2023 and reported physically and clinically fit for the duties. Medical health check of security supervisor employee no. 11610003, Mr Lakshman Asari was done on 17-10-2023 and reported physically and clinically fit for the duties. Doc No.SRC-100024001342 dated 6th Jan 2024 documented and maintained for the PPE obtained from stores for the use of the security personnel. ZHHRPL/DM-DEP /04.00 dated 02-08-2023 Disaster and Emergency preparedness documented established and maintained for the role of Security department in Code Red: fire hazard, Code Pink:Child missing, Code Black: Bomb threat, Code Grey:Violance, Code Yellow: External emergency.</p>	
Audit of all the clauses mentioned in the audit plan matrix have been carried out.	Yes/No
Opportunities for Improvement indicated against Clause No(s) _____	Non-Conformities Issued against Clause No (s)
Name of Applicant /Licensee: M/s Zydus Hospitals & Healthcare Research Pvt Ltd, Ahmedabad	 Signature Of Auditor
<p>* Identification of processes may include identification of key performance parameters/ significant aspects; Identification of objectives; Compliance to Legal and statutory requirements, etc. Use separate sheet for <input type="checkbox"/> separate process. One department may have many processes. <input type="checkbox"/></p> <p>** Evidences clearly state the samples, records of process output verified and witness of activity with verifiable proof.</p>	



भारतीय मानक ब्यूरो
BUREAU OF INDIAN STANDARDS
MANAGEMENT SYSTEMS CERTIFICATION

FORMS

TITLE: Brief Audit Report (Initial/Renewal/Surveillance/Special Audit)

DOC: MSC-F6.4-44

ISSUE: 01

DATE: April 2019

Page 1 of 1

Prepared By:

Approved By: DDG(MSCD)

1	Reference	OHS/WR/A-APP2023075261
2	Name of the Organization	Zydus Hospitals & Healthcare Research Pvt Ltd,
3	Address	Plot no 232, Zydus Hospital Road, Thaltej, Ahmedabad - 380054
4	Type of audit	TPA Stage II of OHSMS
5	IS/ISO	IS/ISO 45001:2018
6	Date(s) of audit	22-25(FN)/01/2024
7	No. of NCs raised	Major : Nil Minor : Nil No. of NCs pending: Nil (Pl see Appendix -I):
8	Concerns raised	Nil
9	Observation (report of conformity of the organization's management system with certification/registration requirements and effectiveness of the management system)	Based on the Audit carried out as per audit plan & schedule with respect to the requirements of IS/ISO 45001:2018, it is found that the organization's Environment management System is in conformity with the requirements of the above standard and found to have been effectively implemented to achieve the OHS policy and objectives.
10	Conclusion/recommendation of the audit	Audit Team recommends Grant of OHS licence as per IS/ISO 45001:2018 with the scope and site as declared by the organization

(To be submitted to MR/CEO)

You are requested to give your comment, if any, on the above report and the findings of the audit within 7 days to MSCO(W).

Root Cause Analysis to be carried out and corrective actions taken shall be informed to MSCO (W) within 30 days.

Please also give your comments on the performance of the auditor(s).

Signature(s) N Banik

Shri N. Banik, Team Leader

Date: 25/01/2024

CEO/MR ✓





DOC : MSC-F7.1-04
 ISSUE : 04
 DATE : OCT 2016
 PAGE : 1 OF 1
 APPROVED BY : DDG

**AUDIT LOG SHEET OF PERSONNEL FOR AUDITING
 (BIS AUDITOR/EXPERT AND EXTERNAL AUDITOR/EXPERT)**

1. Name & address of Applicant/Licensee: M/s Zydus Hospitals & Healthcare Research Pvt Ltd, Plot no 232, Zydus Hospital Road, Thaltej, Ahmedabad - 380054
2. Management System Standards Audited : IS/ISO 45001: 2018
3. Tele: 9106487580 Email: sgajjar@yahoo.com
4. Type of Audit: Initial/ Stage II/Recertification/Surveillance

Please use **BLOCK LETTERS**

Sno	Employee No/ Auditor Reg No	Names of Auditors/ Expert/Auditor in training	Role of auditor	Date(s) of Audit	Audit Duration (in days) (see Note 1)		Verification by Auditee (Signature, name, position within organization)	BIS Verification (by MSCO(R) for Lead Auditor and Team Leader & by Team Leader for others) Sign., Name & Contact Details
					On Site	Off Site		
1	1089	SHRI NARAYAN BANIK	TEAM LEADER	22-25(FN)/01/2024	3.5	1.0	 Mr. Parag Bhatt, Lead HR	 N Banik 9163570303
2	0860	SHRI RAHUL KUMAR	AUDITOR & EXPERT	22-25(FN)/01/2024	3.5	1.0		
3	62600	SMT B SANDHYA	AUDITOR	22-25(FN)/01/2024	3.5	1.0		
4	62219	SHRI S D RANE	AUDITOR IN TRAINING	22-25(FN)/01/2024	3.5	1.0		

AUDIT CARRIED OUT ON BEHALF OF : BUREAU OF INDIAN STANDARDS, NEW DELHI

Notes: 1. Duration – Total time (to nearest half day) On-Site: Time spent on actual auditing activities including Opening & Closing meetings. Off-Site: Time spent on planning/preparation, document review and report writing. It may be calculated on the basis that overall, for each On-Site day's work around half-day Off-Site time may be required.

Completed log sheet should be sent to MSCO(R) who would forward the original to Head (MSCD)/PTO and retain a copy.

MSCO(W)/Head(MSCD)/PTO



**TITLE: Evaluation Report from Team Leader about performace of
BIS Auditor/Expert and External Auditor/Expert**

DOC: MSC-F7.4-01

ISSUE: 04

DATE: October 2018

PAGE: 1 of 1

Prepared By:

Approved By: DDG(MSCD)

- Name of the Auditor /Expert: Shri Rahul Kumar Registration no. 0860
- Role in the Team: Auditor & Expert
- Name & Address of the Organization audited M/s Zydus Hospitals & Healthcare Research Pvt Ltd,
Plot no 232, Zydus Hospital Road, Thaltej, Ahmedabad - 380054

4. Application No/Licence No.: OHS/WR/A-APP2023075261

5. Date of Audit: 22-25(FN)/01/2024

6. Ref Standards: IS/ISO 45001:2018

7. Type of Audit: Stage II Audit/ Changeover /Re-certification/Surveillance

8. Auditing ability

9

(Based on witness evaluation by Team Leader on a) Auditing Techniques, b) Communication and
c) Findings of auditor d) time management e) Team involvement)

9. Audit reporting ability

9

(Based on the evidence collected and reported by auditor on verification of a) Procedure, b) Statutory
compliance, c) Significant Processes/objectives, d) Aspects/ Impact /Risk, e) Operational
Programmes, f) Key performance indicators and g) Technical areas etc.)

10. Knowledge of legal requirements in the area

9

Based on team discussions and reports –Applicable to Expert /Auditor-Expert only)

11. Knowledge of Food Safety requirements, (For FSMS audit only)

NA

(PRPs, HACCP, Hazard analysis relevant to the food chain category)

12. Application of knowledge

9

[Analysis and decision making]

Signature:

N Banik

Name of TL: N Banik

Place: Chandrapur

Date: 25/01/2024

11) Any other remarks:

MSCO Ratings assigned by MSCO

MSCD

Note : Each aspect to be evaluated on a scale of 10. Needs Improvement

≤ 5

Very good

>5 and <9

Excellent

≥ 9



**TITLE: Evaluation Report from Team Leader about performace of
BIS Auditor/Expert and External Auditor/Expert**

DOC: MSC-F7.4-01

ISSUE: 04

DATE: October 2018

PAGE: 1 of 1

Prepared By:

Approved By: DDG(MSCD)

- Name of the **Auditor** /Expert: Smt B Sandhya Registration no. 62600
- Role in the Team: Auditor
- Name & Address of the Organization audited** M/s Zydus Hospitals & Healthcare Research Pvt Ltd,
Plot no 232, Zydus Hospital Road, Thaltej, Ahmedabad - 380054

4. **Application No/Licence No.:** OHS/WR/A-APP2023075261

5. **Date of Audit:** 22-25(FN)/01/2024

6. **Ref Standards:** IS/ISO 45001:2018

7. **Type of Audit:** Stage II Audit/ Changeover /Re-certification/Surveillance

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(PRPs, HACCP, Hazard analysis relevant to the food chain category)

12. Application of knowledge

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[Analysis and decision making]

Signature:

Name of TL: N Banik

Date: 25/01/2024

Place: Chandrapur

11) Any other remarks:

MSCO Ratings assigned by MSCO

MSCD

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**TITLE: Evaluation Report from Team Leader about performace of
BIS Auditor/Expert and External Auditor/Expert**

DOC: MSC-F7.4-01

ISSUE: 04

DATE: October 2018

PAGE: 1 of 1

Prepared By:

Approved By: DDG(MSCD)

- Name of the Auditor /Expert: Shri S D Rane Registration no. 62219
- Role in the Team: Auditor in Training
- Name & Address of the Organization audited M/s Zydus Hospitals & Healthcare Research Pvt Ltd,
Plot no 232, Zydus Hospital Road, Thaltej, Ahmedabad - 380054

4. Application No/Licence No.: OHS/WR/A-APP2023075261

5. Date of Audit: 22-25(FN)/01/2024

6. Ref Standards: IS/ISO 45001:2018

7. Type of Audit: Stage II Audit/ Changeover /Re-certification/Surveillance

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[Analysis and decision making]

Signature:

N Banik

Name of TL: N Banik

Date: 25/01/2024

Place: Chandrapur

11) Any other remarks:

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MSCD

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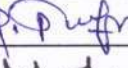

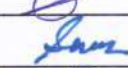
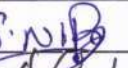
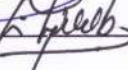
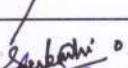
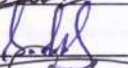


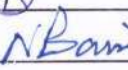


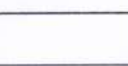


Very good

>5 and <9

Excellent


≥9

Zydus Hospitals And Healthcare Research Pvt. Ltd., Ahmedabad

Topic / Subject :		OHSMS Opening Meeting		
Date		22/1/24		
Venue				
Time				
Trainer				
Sr.	Employee Code	Employee Name	Department	Signature
	12302001	Dr. Sandeep Gupta	Admin	
	12211006	Mr. Anand Wariel	SCM	
	12307001	Mr. Parag Bhatt	HR	
	12209006	Mr. Suresh K. Raut	Operations	
	11607006	Fateh Singh Rathore	Housekeeping	
	12208015	Pran Kumar P	Bio-Medical	
	11502002	Amish Vyas	IT Infra	
	11504008	Mr. Jeevin Shah	Operations	
	11904004	Mr. Sandeep Rane	Engineering	
	12305012	Mr. S. Jagdishwar Rajdeo	IT	
	51573013	Mrs. K. Pooja Suresh	Medical Admin	
	10658	DR. PRASHANT PATEL	Pharmacy	
	12204014	Mr. Siddhanta Subudhi	Pharmacy & Stores	
	1161005	Mr. Satish Chandra	Engg	
	11907007	Dr. Chaitany Mehta	Medical Services	
	11904002	S. D. Rane	BIS, Rajkot	
		B. Sandhya	BIS	
		Mr. N. BANIK	BIS Team Leader	
		Rahul Kumar	BIS Auditor - Rajkot	

Name and Signature of Facilitator

Zydus Hospitals And Healthcare Research Pvt. Ltd., Ahmedabad

Topic / Subject :		OHSMS Closing Meeting		
Date		25/1/2024		
Venue		9th floor CONFERENCE ROOM		
Time		12:30 PM TO 1:15 PM		
Trainer		—		
Sr.	Employee Code	Employee Name	Department	Signature
		Mr. Parag Bhatt	H.R Dept.	
	1161005	Mr. Satish Gajjar	Engineering	L. Lal
	10658	Mr. Parishant Patel	Quality Dept.	Patel
		Dr. Sangita Rewatkar (MBBS MD)	Health Center	Rewatkar
	12209006	Mr. Sanfesh Raut	Operation	Raut
	11904002	Mr. Sandeep Rana	Engineering	Rana
	12307030	Mr. Rahul Salanki	Engineering	Salanki
	11702001	Ms. Rima Jain	Kim Quality	Rima
	12211006	Mr. Anand Warier	SCM	Warier
	5150013	L. Hrushik Santhosh	Nursing	Hrushik
	12305012	S. Nagar wada Reddy	IT	Nagar
	12204014	Siddhanta Subudhi	Pharmacy	Subudhi
	11504008	Jalmin Shah	Operations	Shah
		N. BANIK, Team Leader	BPS	N. Banik
		Rahul Kumar - Auditor - Expert	BIS	Rahul
		B. Sandhya	BIS	B. Sandhya
		S.D. Rane	BIS	S.D. Rane

Name and Signature of Facilitator

Patel