



AQC GLOBAL LLC

(An ISO Certification Body)

ISO 45001:2018

Stage 2 Audit Report

Name of the Organization	M/s SHILPA PHARMA LIFE SCIENCES LTD UNIT 01	
Address	PLOT NO. 1A & 1A 'P', 1B,2, 2A, 2B, 3A TO 3E, 4A,5A,4B & 5B, DEOSUGUR INDUSTRIAL AREA, DEOSUGUR – 584170, RAICHUR DISTRICT, KARNATAKA, INDIA	
Site Address (If ny)	AS ABOVE	
No. of Employees	500	
E mail id	yvreddy@shilpapharma.com	
Contact Person	MR Y V REDDY	
Telephone/Fax	96111 31876	
Scope	MANUFACTURE AND SUPPLY OF ACTIVE PHARMACEUTICAL INGREDIENTS (APIs), INTERMEDIATES AND POLYMERS-BIOMEDICAL & HIGH ENERGY APPLICATION	
Technical Area	FCATORY LICENSES	
Legal, Statutory and Regulatory requirements for company.	LABOUR LICENSES / WORKMEN ACT	
Audit Team	Lead Auditor: Mr Rajkumar R Auditor: Technical Expert:	Audit duration Man days: 02
Start Date of Audit	15.2.2022 (Tuesday)	
End Date of Audit	16.2.2022 (Wednesday)	
Brief about the organization	IT IS WELL ESTABLISHED ORGANISATION, ENJOY GOODWILL OF EXISTING CUSTOMERS WHO GIVE REPEAT ORDERS	
Audit Objective	To verify the implementation of the ISO 45001:2018 System as per the Standards Requirement, verification of records for the conformity of the implementation.	

CHANGE DETAIL:

Audit Duration for Stage 2	
Are quoted man-days adequate?	Yes



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Any change in employee detail?	No
Any Change in Scope?	No
Any additional Information:	Nil



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ATTENDENCE SHEET:

NAME OF PERSON	DESIGNATION
Mr Y V Reddy	DGM-Engg
Mr Sandeep	OHS Coordinator

SUMMARY OF AUDIT

AREA OF IMPROVEMENTS	
01	To become Member of National safety Council
02	To strive for State Awards
03	To Intensify More Training Programmes for Outsourced workers for use PPEs and Aspect and Impacts on environments

Non Conformities Raised

__NIL__ Minor/Major Non-conformance identified in the Stage 2 audit, details of Non Conformance in F50
Please respond by using your own corrective action form and include the root cause analysis with systemic corrective action. Failure to include root cause analysis with systemic corrective action will result in your responses being rejected by Lead Auditor

Team Leader Declaration (Tick or cross Each Column as per applicability)	
Y	Auditing is based on a sampling process of the available information
Combined	Audit is combined, joint or integrated;
Y	The effectiveness of corrective actions taken regarding previously identified
Y	nonconformities has verified
Y	outcomes are effective and complying.



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Y	The internal audit and management review process are effective and complying with the requirements.
Y	The scope of certification is appropriate.
Y	The capability of the management system to meet applicable requirements and expected
Y	The audit objectives has been fulfilled and achieved.



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Recommendation:

YES	The OHSMS system complies with the requirements of the reference standard: Congratulations, on the basis of the above summary, Lead Auditor is pleased to put forward a recommendation for Issuance of Certificate. The organization can use the AQC Mark
	The OHSMS system complies with the requirements of the reference standard with exception of minor NC: Congratulations, Team Leader is pleased to put forward a recommendation for Issuance of the certificate of Organization upon off-site verification of closure of all minor NC within 60 days from the date of Stage 2 audit. Responses to the non-conformances should be submitted to AQC and must include supporting evidence of closure to allow for off-site verification. In responding to the non-conformances, the organization should consider the root cause of the non-conformance and the potential for related issues in other parts of system. If all non-conformances are not closed within 60 days, a full reassessment may be required.
	Evidence of major non conformities: Organization is not recommended for Issuance of Certificate and at this time. Follow-up audit will be scheduled to allow for on-site verification and closure of all issues within 60 days from the date of Stage 2. Once all non-conformances are closed, the recommendation for Issuance of certification may be recommended. If all non-conformances are not closed within 60 days, a full reassessment may be required.
	Not Recommended: Organization is not recommended for Issuance of certificate at this time. Full Stage 2 audit is required as the organisation has not implemented the system and process at pace. .
Proposed Audit Date for 1st Surveillance Audit 14.02.2023	
Sign Off: (Date) 16.2.2022	
AQC Report Submission	Client Acceptance for Report
Name of Team Leader: Mr.RAJKUMAR.R Signature:  	Name: Y V Reddy Sign  Designation: DGM-Engg



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AUDIT CHECKLIST

VERIFICATION OF DOCUMENTATION & RECORDS AS PER STD REQUIREMENT (C- Conformity, NC-Non Conformity, O-Observation)

Clause Number	C/NC/O	Document Verification detail with statement of Conformity
4. CONTEXT OF ORGANISATION		
4.1 Understanding the organization and its context (Internal and External issues)	C	The EHS Manager and Team has identified both internal and External Issues and taking Corrective actions to achieve effective OHSAS Performance
4.2 Understanding the needs and expectations of workers and other interested parties	NC	The Organisation has to take Society Needs and Expectations and live up them
4.3 Determining the scope of the OH&S management system (documented and having boundaries as well as considering context of organization and need and expectation or workers and workers and interested parties)	C	MANUFACTURE AND SUPPLY OF ACTIVE PHARMACEUTICAL INGREDIENTS (APIs), INTERMEDIATES AND POLYMERS-BIOMEDICAL & HIGH ENERGY APPLICATION
4.4 OH&S management system (established, implement, maintain and continually improve OHSMS)	C	EFFECTIVE
5 Leadership and worker participation		
5.1 Leadership and commitment (Leader shall be from Top Management and have Leadership skill in any other role)	C	ALL OFFICERS ARE FOUND TO BE VERY SENSITIVE AND RESPONSIVE FOR WORKER PARTICIPATIONS
5.2 OH&S policy (Documented and communicated and available)	C	Well Documented and Displayed
5.3 Organizational roles, responsibilities and authorities (Documented, assigned and communicated)	C	Well documented. The Organisation chart is available



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Page 6 of 7



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5.4 Consultation and participation of workers (Mechanism, Time, Training and Resources)	C	There is Very good Coordination among ALL to make workers Participate for Joint Consultations for assessing OHSAS performance /Risk assessments /risk reductions /Removals /Training needs and Resources Requirements
6 Planning		
6.1 Actions to address risks and opportunities (Documented Risk & opportunities, Consider Hazards, OHS Risk, OHS opportunities and Legal Requirements	C	The Organisation is always taking Efforts to address Risks and opportunities to Reduce /Minimise OHS risks so as to COMPLY with Legal requirements It is documented.



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<p>6.1.2 Hazard identification and assessment of risks and opportunities <i>(Process mechanism for hazard identification by considering work situation, routine and unroutine matter, past incident, Potential emergency, People and other issues, changes and opportunities)</i></p>	C	<p>They have Registers /Records to record identified Risks and Opportunities to effect Improvements to in OHS Performances They also consider associated risks while carrying out Routine and un routine Activities and take Cover for such activities in a Proactive manner. They also do Risks on Pre Monsoon and Heavy rains and be Prepared for Potential Emergencies to Safeguard People ,Property ,Buildings ,Equipments , Fire Fighting systems , testing Emergency Nos and Evacuation Possibilities.</p>
<p>6.1.3 Determination of legal requirements and other requirements <i>(Documented information for legal and other requirements)</i></p>	C	Well Documented
<p>6.1.4 Planning action <i>(Action to risk and opportunities, legal & other requirements, respond to emergency)</i></p>	C	They plan in a Proactive Manner to address risks and Opportunities to Optimise maximum protection to achieve OHSAS performance
<p>6.2 OH&S objectives and planning to achieve them <i>(Documented information and plan to achieve objectives and shall determine what, who, when and how)</i></p>	C	<p>Yearly Targets set and analysed on quarterly Basis. There is well documented system to verify Target achievements with Regard to</p> <ol style="list-style-type: none"> 1 No of accidents 2 No of Hospitalisations 3 No of near Misses 4 No of Violations by Outsourced workers 5 No of Mock drills Conducted 6 No of Deaths Occurred 7 No of Fire Incidents 8 Updated Registers and Records
7 Support		
<p>7.1 Resources <i>(Determine resource requirements for OHSMS)</i></p>	C	Adequately supported for Security /Housekeeping / Fire Safety resources / Availability of PPEs / Mock drills
<p>7.2 Competence <i>(Documented Information for competence)</i></p>	C	Observed that only Qualified and Experienced Employees Work in all Depts and Drive safety in all areas.



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7.3 Awareness <i>(Workers shall made aware OHS policy, Objective, Incident, hazards, risk & opportunities)</i>	C	All Work-related Safety policies /procedures are made known during Induction training and other trainings Conducted. It is also applicable to Outsourced Workers also. They have a Training Calendar being implemented in all Depts. Documents are maintained
7.4 Communication <i>(documented information of process of communication of internal and external)</i>	C	All communications are made through Mails and whats-app Groups to maintain Transparency and ethical Practices to prevent /avoid accidents or near



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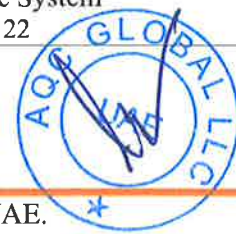
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		misses and effective surveillance activities by EHS Team to ensure ZERO Accidents
7.5 Documented information (Creation, Identification, Formats, review and approval, distribution, Storage and preservation, retention and disposition and external origin document)	C	They have a Master List of Policies / Procedures /Indexed and available at Point of use and reference All documents are preserved as per Policy All documents Categorized as Internal and External /kept separately. Updated. Control of Documents are in place. All obsolete Forms /formats are out of use and Circulations. All documents are approved with 3 signatories and Review dates / Year in Place
8 Operation		
8.1 Operational planning and control (Establish, maintain and implemented Process and Plan for operations)	C	ALL Process are defined after taking into People Health safety before conducting all Operations. Afterwards, Occupational Hazards and safety are monitored and safeguarded. In case of any un wanted Incidents, Incident reports are generated and CAPA is made and kept as Organisation Knowledge. This is discussed in the MRM
8.1.2 Eliminating hazards and reducing OH&S risks (Establish, maintain and implemented Process for eliminating hazards and reducing the OH & S risks)	C	It is being done on daily basis, using checklists at all levels and checked for its use /signed. This way the Organisation reduces OH & S risks to acceptable Level.
8.1.3 Management of change (Establish, maintain and implemented Process for management of change)	C	There is clear cut process, documented as SOP to record and maintain any CHANGES in the Location or Area of work or change of scope of work is reflected in the Risk assessments, done after changes is planned
8.1.4 Procurement & Outsource (Establish, maintain and implemented Procurement process with contractor and controlling of outsource procees)	C	All outsourced processes are controlled and monitored to reduce OH& S Risks to acceptable Level. They are Trained for safe working and encouraged to report any risks. Use of PPE by those outsourced workforce is controlled and monitored
8.2 Emergency preparedness and response (Documented information and Establish, maintain and implemented Emergency preparedness and response)	C	Documents and Records Entire workforce have been trained to act in Emergency Situations with Clear cut Roles and Responsibilities to safeguard People /Buildings and other Assets in a swift manner with SOPs /Manuals to refer and understand. Mock drills are conducted to assess People Sensitiveness and Response System Last Mock drill held in Oct 22



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Page 10 of



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9 Performance evaluation

9.1 Monitoring, measurement, analysis and performance evaluation
(*documented information for result of monitoring, measurement, analysis and performance evaluation and calibration*

C

Registers and Records show Continuous Monitoring and analysis of Performance Evaluation at all stages and get Reported to Management



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Page 11 of



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<i>or verification of measuring equipment)</i>		
9.1.2 Evaluation of compliance <i>(Documented information of the compliance evaluation result)</i>	C	DONE ANNUALLY
9.2 Internal audit <i>(Documented information of the Internal Audit Program and audit results)</i>	C	Done once in year of all depts. with Pre defined Parameters. All previous NC's are closed. Last IA was done in Dec-21
9.3 Management review <i>(Documented information of the Management Review results)</i>	C	Done once in year All Records relating to MRM are retained. Last MRM was done in Jan-22.
10 Improvement		
10.1 Incident, nonconformity and corrective action <i>(Documented information of the incident or non conformities and corrective action taken and effectiveness)</i>	C	All Improvements are aimed at and done after getting incident reports, NC's closure and suggestions form Workers Participations Corrective actions are taken after Feasibility and acceptance of actions
10.2 Continual improvement <i>(Documented information of the Continual Improvement evidence)</i>	C	There is Record kept, reflecting continual Improvements, reducing OH&S Risks, keeping health Workforce for continuity of Operations.

END OF REPORT



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Page 12 of



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Stage 2 Audit Report

Name of the Organization	M/s SHILPA PHARMA LIFE SCIENCES LTD 100% EOU UNIT 02	
Address	PLOT NO. 33, 33A & 40-47, RAICHUR INDUSTRIAL GROWTH CENTRE, CHICKSUGUR - 584134, DIST. & TALUK RAICHUR, KARNATAKA, INDIA	
Site Address (If any)	AS ABOVE	
No. of Employees	900	
E mail id	sharath@shilpapharma.com	
Contact Person	MR K Sharath Reddy	
Telephone/Fax	9845745068	
Scope	MANUFACTURE AND SUPPLY OF ACTIVE PHARMACEUTICAL INGREDIENTS (APIs), INTERMEDIATES AND POLYMERS-BIOMEDICAL & HIGH ENERGY APPLICATION	
Technical Area	FACTORY LICENSES	
Legal, Statutory and Regulatory requirements for company.	LABOUR LICENSES / WORKMEN ACT	
Audit Team	Lead Auditor: Mr Rajkumar R Auditor: Technical Expert:	Audit duration Man days: 02
Start Date of Audit	17.2.2022 (Thursday)	
End Date of Audit	18.2.2022 (Friday)	
Brief about the organization	IT IS WELL ESTABLISHED ORGANISATION, ENJOY GOODWILL OF EXISTING CUSTOMERS WHO GIVE REPEAT ORDERS	
Audit Objective	To verify the implementation of the ISO 45001:2018 System as per the Standards Requirement, verification of records for the conformity of the implementation.	

CHANGE DETAIL:

Audit Duration for Stage 2



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Are quoted man-days adequate?	Yes
Any change in employee detail?	No
Any Change in Scope?	No
Any additional Information:	Nil



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ATTENDANCE SHEET:

NAME OF PERSON	DESIGNATION
Mr Sharath Reddy	DIRECTOR
Mr Juluri Raghu	EHS Manager

SUMMARY OF AUDIT

AREA OF IMPROVEMENTS	
01	To become Member of National safety Council
02	To strive for State Awards
03	To Intensify More Training Programmes for Outsourced workers for use PPEs and Aspect and Impacts on environments

Non Conformities Raised

__NIL__ Minor/Major Non-conformance identified in the Stage 2 audit, details of Non Conformance in F50

Please respond by using your own corrective action form and include the root cause analysis with systemic corrective action. Failure to include root cause analysis with systemic corrective action will result in your responses being rejected by Lead Auditor

Team Leader Declaration (Tick or cross Each Column as per applicability)

Y	Auditing is based on a sampling process of the available information
Combined	Audit is combined, joint or integrated;
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Y	nonconformities has verified
Y	outcomes are effective and complying.
Y	The internal audit and management review process are effective and complying with the requirements.



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Y	The scope of certification is appropriate.
Y	The capability of the management system to meet applicable requirements and expected
Y	The audit objectives has been fulfilled and achieved.



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Recommendation:

YES	The OHSMS system complies with the requirements of the reference standard: Congratulations, on the basis of the above summary, Lead Auditor is pleased to put forward a recommendation for Issuance of Certificate. The organization can use the AQC Mark
	The OHSMS system complies with the requirements of the reference standard with exception of minor NC: Congratulations, Team Leader is pleased to put forward a recommendation for Issuance of the certificate of Organization upon off-site verification of closure of all minor NC within 60 days from the date of Stage 2 audit. Responses to the non-conformances should be submitted to AQC and must include supporting evidence of closure to allow for off-site verification. In responding to the non-conformances, the organization should consider the root cause of the non-conformance and the potential for related issues in other parts of system. If all non-conformances are not closed within 60 days, a full reassessment may be required.
	Evidence of major non conformities: Organization is not recommended for Issuance of Certificate and at this time. Follow-up audit will be scheduled to allow for on-site verification and closure of all issues within 60 days from the date of Stage 2. Once all non-conformances are closed, the recommendation for Issuance of certification may recommended. If all non-conformances are not closed within 60 days, a full reassessment may be required.
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	Proposed Audit Date for 1st Surveillance Audit 16.02.2023
Sign Off: (Date) 18.2.2022	
AQC Report Submission	Client Acceptance for Report

Rajkumar
R. RAJKUMAR
QMS,EMS,OHSMS,EnMS
LEAD AUDITOR



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Name of Team Leader: Mr RAJKUMAR.R
Signature:

Name: K SHARATH REDDY
Sign:
Designation: Director



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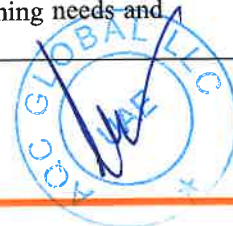
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AUDIT CHECKLIST

VERIFICATION OF DOCUMENTATION & RECORDS AS PER STD REQUIREMENT
(C- Conformity, NC-Non Conformity, O-Observation)

Clause Number	C/NC/O	Document Verification detail with statement of Conformity
4. CONTEXT OF ORGANISATION		
4.1 Understanding the organization and its context (<i>Internal and External issues</i>)	C	The EHS Manager and Team has identified both internal and External Issues and taking Corrective actions to achieve effective OHSAS Performance
4.2 Understanding the needs and expectations of workers and other interested parties	NC	The Organisation has to take Society Needs and Expectations and live up them
4.3 Determining the scope of the OH&S management system (<i>documented and having boundaries as well as considering context of organization and need and expectation of workers and workers and interested parties</i>)	C	MANUFACTURE AND SUPPLY OF ACTIVE PHARMACEUTICAL INGREDIENTS (APIs), INTERMEDIATES AND POLYMERS-BIOMEDICAL & HIGH ENERGY APPLICATION
4.4 OH&S management system (<i>established, implement, maintain and continually improve OHSMS</i>)	C	EFFECTIVE
5 Leadership and worker participation		
5.1 Leadership and commitment (<i>Leader shall be from Top Management and have Leadership skill in any other role</i>)	C	ALL OFFICERS ARE FOUND TO BE VERY SENSITIVE AND RESPONSIVE FOR WORKER PARTICIPATIONS
5.2 OH&S policy (<i>Documented and communicated and available</i>)	C	Well Documented and Displayed
5.3 Organizational roles, responsibilities and authorities (<i>Documented, assigned and communicated</i>)	C	Well Documented .The Organisation chart is available
5.4 Consultation and participation of workers (<i>Mechanism, Time, Training and Resources</i>)	C	There is Very good Coordination among ALL to make workers Participate for Joint Consultations for assessing OHSAS performance /Risk assessments /risk reductions /Removals /Training needs and Resources Requirements



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6 Planning		
6.1 Actions to address risks and opportunities <i>(Documented Risk & opportunities, Consider Hazards, OHS Risk, OHS opportunities and Legal Requirements)</i>	C	The Organisation is always taking Efforts to address Risks and opportunities to Reduce /Minimise OHS risks so as to COMPLY with Legal requirements It is documented.



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6.1.2 Hazard identification and assessment of risks and opportunities <i>(Process mechanism for hazard identification by considering work situation, routine and unroutine matter, past incident, Potential emergency, People and other issues, changes and opportunities)</i>	C	They have Registers /Records to record identified Risks and Opportunities to effect Improvements to in OHS Performances They also consider associated risks while carrying out Routine and un routine Activities and take Cover for such activities in a Proactive manner. They also do Risks on Pre Monsoon and Heavy rains and be Prepared for Potential Emergencies to Safeguard People, Property, Buildings, Equipments , Fire Fighting systems , testing Emergency Nos and Evacuation Possibilities.
6.1.3 Determination of legal requirements and other requirements <i>(Documented information for legal and other requirements)</i>	C	Well Documented
6.1.4 Planning action <i>(Action to risk and opportunities, legal & other requirements, respond to emergency)</i>	C	They plan in a Proactive Manner to address risks and Opportunities to Optimise maximum protection to achieve OHSAS performance
6.2 OH&S objectives and planning to achieve them <i>(Documented information and plan to achieve objectives and shall determine what, who, when and how)</i>	C	Yearly Targets set and analysed on quarterly Basis. There is well documented system to verify Target achievements with Regard to 1 No of accidents 2 No of Hospitalisations 3 No of near Misses 4 No of Violations by Outsourced workers 5 No of Mock drills Conducted 6 No of Deaths Occurred 7 No of Fire Incidents 8 Updated Registers and Records
7 Support		
7.1 Resources <i>(Determine resource requirements for OHSMS)</i>	C	Adequately supported for Security /Housekeeping / Fire Safety resources / Availability of PPEs / Mock drills
7.2 Competence <i>(Documented Information for competence)</i>	C	Observed that only Qualified and Experienced Employees Work in all Depts and Drive safety in all areas.



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7.3 Awareness <i>(Workers shall made aware OHS policy, Objective, Incident, hazards, risk & opportunities)</i>	C	All Work related Safety policies /procedures are made known during Induction training and other trainings Conducted. It is also applicable to Outsourced Workers also. They have a Training Calendar being implemented in all Depts. Documents are maintained
7.4 Communication <i>(documented information of process of communication of internal and external)</i>	C	All communications are made thro Mails and WhatsApp Groups to maintain Transparency and ethical Practices to prevent /avoid accidents or near



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		misses and effective surveillance activities by EHS Team to ensure ZERO Accidents
7.5 Documented information (Creation, Identification, Formats, review and approval, distribution, Storage and preservation, retention and disposition and external origin document)	C	They have a Master List of Policies / Procedures /Indexed and available at Point of use and reference All documents are preserved as per Policy All documents Categorized as Internal and External /kept separately. Updated. Control of Documents are in place. All obsolete Forms /formats are out of use and Circulations. All documents are approved with 3 signatories and Review dates / Year in Place
8 Operation		
8.1 Operational planning and control (Establish, maintain and implemented Process and Plan for operations)	C	ALL Process are defined after taking into People Health safety before conducting all Operations. Afterwards , Occupational Hazards and safety are monitored and safeguarded . In case of any un wanted Incidents , Incident reports are generated and CAPA is made and kept as Organisation Knowledge. This is discussed in the MRM
8.1.2 Eliminating hazards and reducing OH&S risks (Establish, maintain and implemented Process for eliminating hazards and reducing the OH & S risks)	C	It is being done on daily basis, using checklists at all levels and checked for its use /signed. This way the Organisation reduces OH & S risks to acceptable Level.
8.1.3 Management of change (Establish, maintain and implemented Process for management of change)	C	There is clear cut process, documented as SOP to record and maintain any CHANGES in the Location or Area of work or Change of scope of work is reflected in the Risk assessments, done after changes is planned
8.1.4 Procurement & Outsource (Establish, maintain and implemented Procurement process with contractor and controlling of outsource process)	C	All outsourced processes are controlled and monitored to reduce OH& S Risks to acceptable Level . They are Trained for safe working and encouraged to report any risks. Use of PPE by those outsourced workforce is controlled and monitored



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8.2 Emergency preparedness and response (Documented information and Establish, maintain and implemented Emergency preparedness and response)	C	Documents and Records Entire workforce have been trained to act in Emergency Situations with Clear cut Roles and Responsibilities to safeguard People /Buildings and other Assets in a swift manner with SOPs /Manuals to refer and understand. Mock drills are conducted to assess People Sensitiveness and Response System Last Mock drill held in Oct 22
9 Performance evaluation		
9.1 Monitoring, measurement, analysis and performance evaluation (documented information for result of monitoring, measurement, analysis and performance evaluation and calibration)	C	Registers and Records show Continuous Monitoring and analysis of Performance Evaluation at all stages and get Reported to Management



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<i>or verification of measuring equipment)</i>		
9.1.2 Evaluation of compliance (Documented information of the compliance evaluation result)	C	DONE ANNUALLY
9.2 Internal audit (Documented information of the Internal Audit Program and audit results)	C	Done ONCE in Year of all depts. with Pre defined Parameters. Last IA was done in Dec-21. All previous Ncs are closed .
9.3 Management review (Documented information of the Management Review results)	C	Done ONCE in Year Last MRM was done in Jan-22 All Records relating to MRM are retained.
10 Improvement		
10.1 Incident, nonconformity and corrective action (Documented information of the incident or non conformities and corrective action taken and effectiveness)	C	All Improvements are aimed at and done after getting incident reports, NC's closure and suggestions form Workers Participations Corrective actions are taken after Feasibility and acceptance of actions
10.2 Continual improvement (Documented information of the Continual Improvement evidence)	C	There is Record kept, reflecting continual Improvements, reducing OH&S Risks, keeping health Workforce for continuity of Operations.

END OF REPORT



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