ISO Monitoring System (IMS) Ver 1.0	

# **User Manual**



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# Introduction

The ISO Monitoring System is a robust web application designed to streamline the management and compliance of ISO standards within organizations. It facilitates document generation based on ISO requirements, enables seamless updates and revisions, and ensures an organized storage system for all document versions. The system supports efficient workflows for approvals, monitoring, and reporting, ensuring that ISO compliance is consistently maintained. With its centralized platform, user-friendly interface, and comprehensive tracking capabilities, the ISO Monitoring System empowers organizations to uphold ISO standards effectively, promoting operational excellence and continuous improvement. The application is divided into two key modules

- 1. ISO Documents Generation
- 2. Audit Module

## **Dashboard**

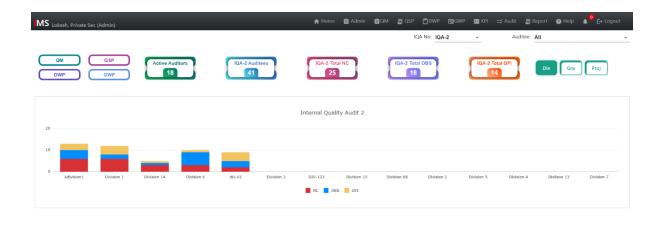
The Dashboard serves as a centralized and interactive interface, providing users with real-time insights and easy access to key features and metrics related to the ISO Monitoring System. It includes the following components

- **1. Document Access:** Users can directly open Quality Manual (QM), Quality System Procedures (QSP), Divisional Work Procedures (DWP), and Group Work Procedures (GWP) for quick reference and updates.
- 2. Key Metrics: The dashboard displays
  - Count of active auditors and auditees
  - Total number of **Non-conformities** (NC), observations and **Opportunity for Improvement** (OFI).
  - Division-wise, group-wise, and project-wise counts of NCs, Observations, and OFIs.
- **3. KPI Graph: Key Performance Indicator (KPI)** graphs are available for each auditee, offering a visual representation of their performance and audit outcomes based on the Internal Quality Audit (IQA).

#### 4. Role-Based Access:

- Admin, Director, Management Representative (MR), and MR Representative can view the complete dashboard with all divisions, groups, and projects.
- Divisional MR, Auditees, and Auditors can view dashboard metrics and insights specific to their divisions, groups, or projects only.

This structured and role-based dashboard enhances user experience by providing targeted insights, facilitating informed decision-making, and supporting continuous monitoring and improvement.





# **ISO Documents Generation**

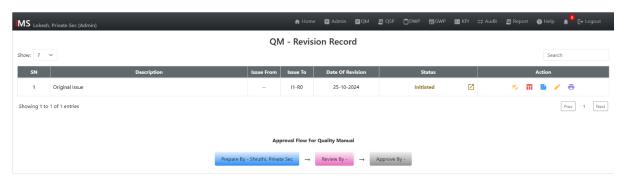
The ISO Document Generation module facilitates the creation, revision, and organized storage of documents in compliance with ISO standards, ensuring accurate and up-to-date documentation. This module focuses on generating four key documents essential for ISO compliance

- 1. Quality Manual
- 2. Quality System Procedure
- 3. Divisional Work Procedure
- 4. Group Work Procedure

#### **Quality Manual**

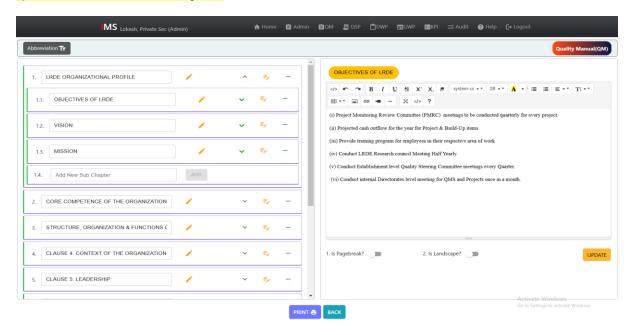
The **Quality Manual (QM)** is a foundational document prepared by the **Management Representative (MR)** to meet ISO standards. It serves as the primary reference for developing all other quality documents within the establishment, ensuring consistency and alignment with ISO requirements. Each establishment will have a single Quality Manual, making it a central resource for quality management. Once the Quality Manual is prepared then it is forwarded for approval. This structured process ensures standardization and compliance with ISO standards.

Steps 1 - Create new record



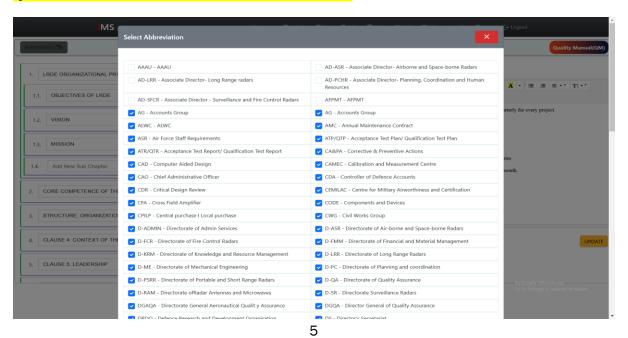
Steps 2 - Add description for the document

#### QM ---> Edit ---> Add Description



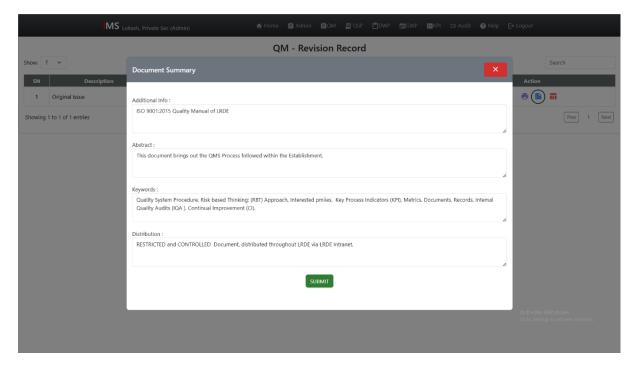
#### **Steps 3 - Select Abbreviation**

#### QM ---> Edit ---> Abbreviation ---> Select Abbreviation



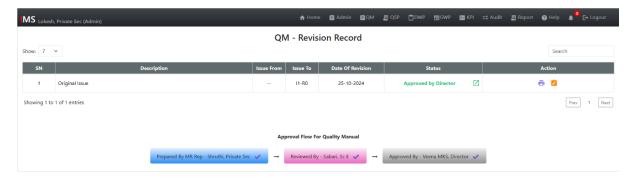
#### Steps 4 - Update document summary

#### QM ---> Document Summary ---> Add Document Summary



#### **Steps 5 - Approval Flow**

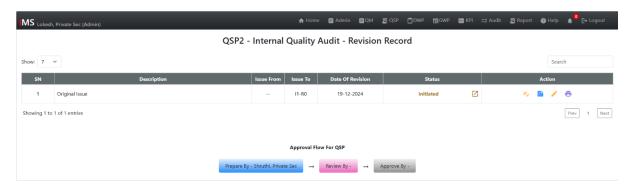
#### MR Rep ---> MR ---> Director



#### **Quality System Procedure**

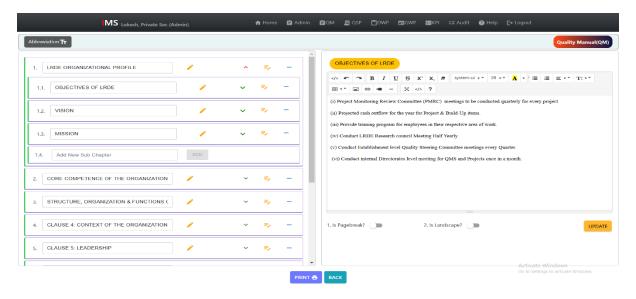
The **Quality System Procedure (QSP)** document is available at the lab level and can exist in multiple versions to address different quality management processes. Currently, nine QSPs need to be generated through this tool, including: Control of Documents & Records, Internal Quality Audit, Management Review Meeting, Non-Conformity & Corrective Action, Quality Objectives & Continual Improvement, Analysis of Data, Customer Feedback Analysis, and Risk Management. The software provides users with the flexibility to add, edit and amend these QSPs, ensuring that each procedure is tailored to the specific needs of the lab and compliance with ISO standards.

Steps 1 - Create new record



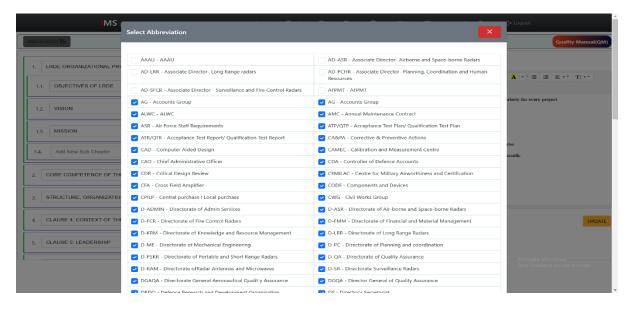
Steps 2 - Add description for the document

QSP ---> Select QSP ---> Edit ---> Add Description



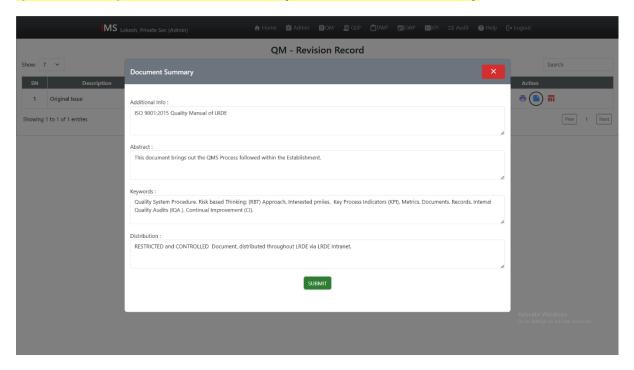
#### **Steps 3 - Select Abbreviation**

QSP ---> Select QSP ---> Edit ---> Select Abbreviation



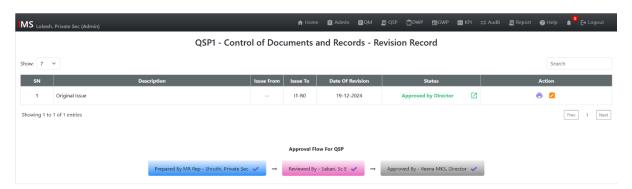
#### Steps 4 - Update document summary

QSP ---> Select QSP ---> Document Summary ---> Add Document Summary



**Steps 5 - Approval Flow** 

MR Rep ---> MR ---> Director

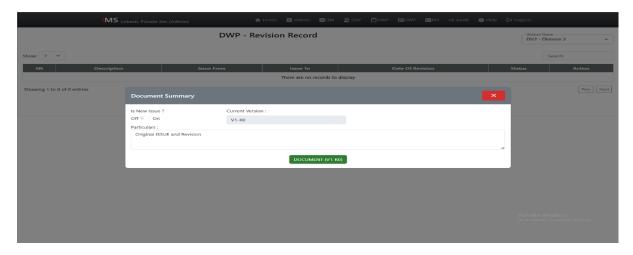


#### **Divisional Work Procedure**

The **Divisional Work Procedure (DWP)** outlines the specific procedures and processes followed within each division to ensure consistency and compliance with ISO standards. This document is designed to address the unique requirements and operational practices of each division while aligning with the overall quality management system. The DWP provides clear guidelines for division-specific tasks, ensuring that all activities are performed efficiently and in accordance with established quality standards. It serves as a critical reference for division employees and helps maintain uniformity across processes within the organization, contributing to continuous improvement and ISO compliance.

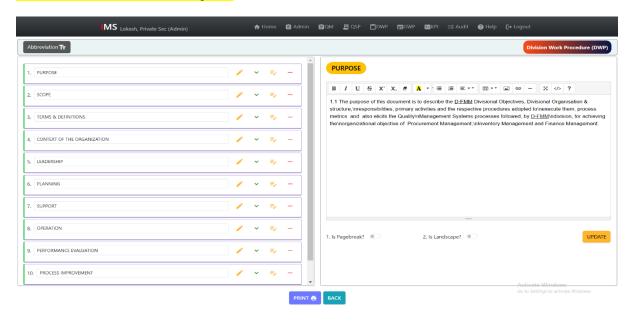
Steps 1 - Create new record

DWP ---> Add Issue ---> Add Particulars ---> Submit



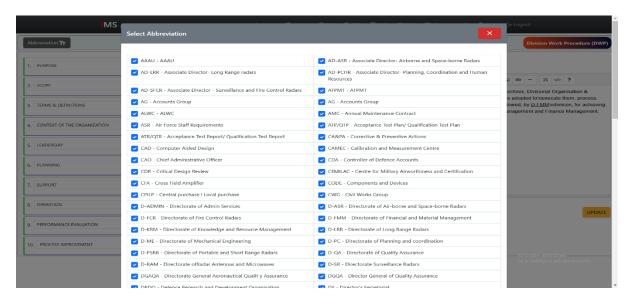
Steps 2 - Add description for the document

#### DWP ---> Edit ---> Add Description



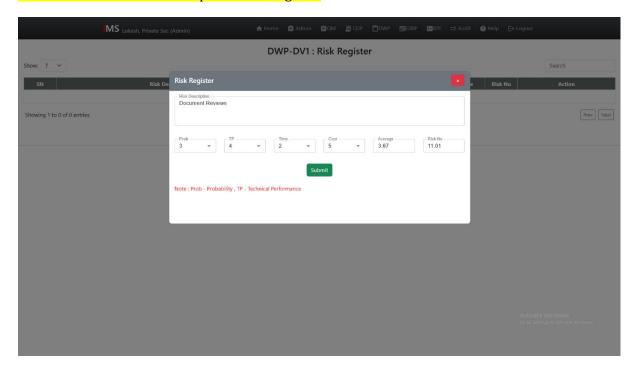
#### **Steps 3 - Select Abbreviation**

#### DWP ---> Edit ---> Abbreviation ---> Select Abbreviation



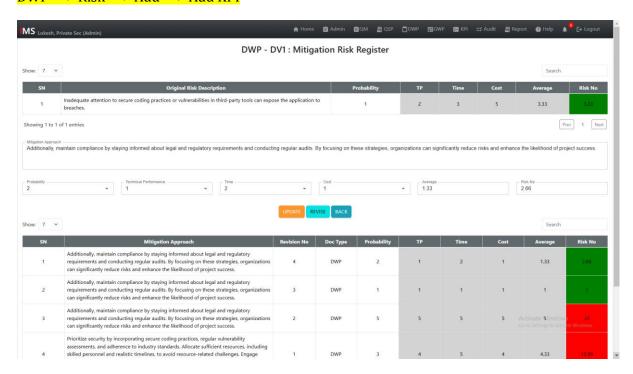
#### Steps 4 - Update the Risk Register

#### DWP ---> Risk ---> Add ---> Update Risk Register



#### Steps 5 - Update Risk Mitigation Register

#### DWP ---> Risk ---> Add ---> Add KPI

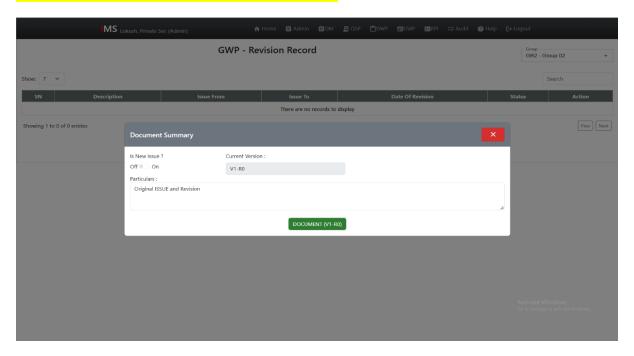


#### **Group Work Procedure**

The **Group Work Procedure (GWP)** defines the standardized processes and practices followed by specific groups within the organization to ensure adherence to ISO standards. This document provides detailed instructions for the tasks and responsibilities of each group, ensuring that their activities align with the overall quality management system. The GWP serves as a guideline for group members to perform their duties effectively, maintaining consistency and compliance with established quality norms.

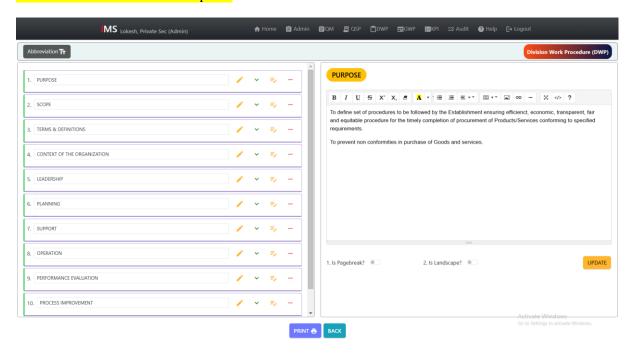
#### Steps 1 - Create new record

#### GWP ---> Add Issue ---> Add Particulars ---> Submit



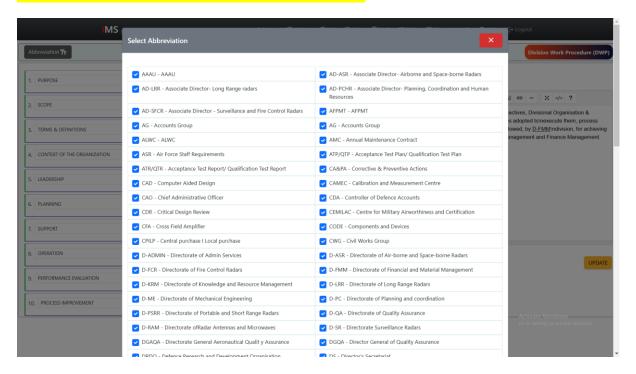
Steps 2 - Add description for the document

#### GWP ---> Edit ---> Add Description



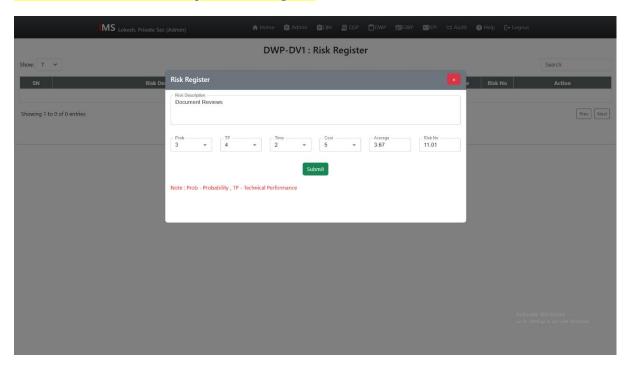
#### **Steps 3 - Select Abbreviation**

#### GWP ---> Edit ---> Abbreviation ---> Select Abbreviation



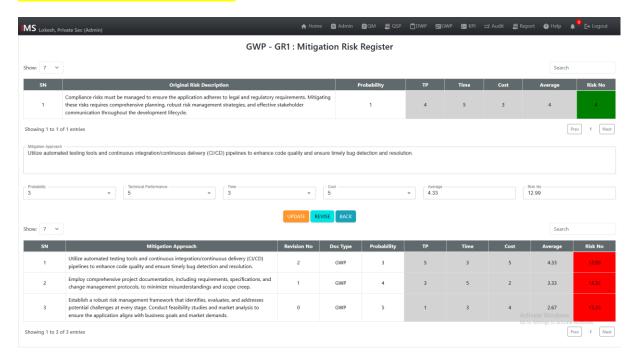
#### Steps 4 - Update the Risk Register

GWP ---> Risk ---> Add ---> Update Risk Register



Steps 5 - Update the Risk Mitigation Register

#### GWP ---> KPI ---> Add ---> Add KPI



### **KPI**

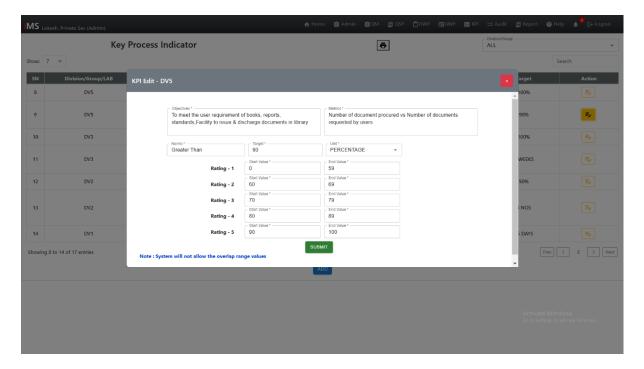
The **KPI (Key Performance Indicator)** Module is designed to define, manage, and track performance metrics across the organization, divisions, and groups. It serves as a centralized system for monitoring and evaluating organizational performance against predefined standards, ensuring alignment with ISO standards and continuous improvement objectives. The KPI Module ensures that performance metrics are clearly defined, consistently tracked, and transparently reported.

#### **KPI Master**

The **KPI Master** Module allows users to create and define KPIs across three levels:

- **1. Common KPIs:** Applicable to the entire organization, providing a unified benchmark for performance evaluation.
- **2. Division KPIs:** Specific to each division, including their unique KPIs as well as lab-related KPIs.
- **3. Group KPIs:** Unique to each group, along with lab-related KPIs.

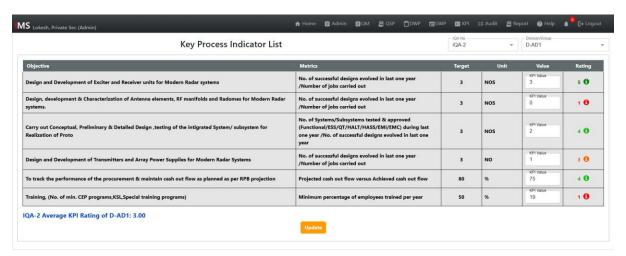
While creating a KPI, users must define the objective, metrics, norms, target, unit and rating.



#### **KPI List**

The **KPI List** Module enables the entry of actual KPI values for each division and group. Based on these values:

- The system calculates the average KPI for each division and group.
- The system generates a KPI graph for each division and group which is displayed in the dashboard.
- The performance data is displayed visually, facilitating comparison and trend analysis.



## **Audit**

The Audit Module streamlines the planning, execution, and tracking of audits, providing tools for creating auditor lists, scheduling audits, and managing approvals. Conducted twice a year, this module ensures efficient oversight and thorough evaluation of compliance with ISO standards. By offering a centralized platform for monitoring and reporting, the Audit Module empowers organizations to maintain ISO compliance, drive operational excellence, and foster continuous improvement. The main objectives of the audit are

- Organization complies with those documented standards, processes, systems, and/or plans during the execution of its work activities.
- Organization's standards, processes, systems, and/or plans and their implementation are effective, in other words, the policies, requirements, and objectives are actually being met.
- Resources, including people and other non-human resources, are being efficiently and effectively utilized.
- Audits also help identify areas for continual improvement and identify best practices within the organization that need to be propagated to other areas.

There are two types of audits: Internal Audit and External Audit.

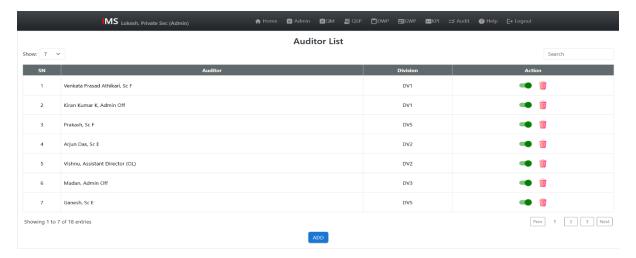
**Internal Audit:** An audit that an organization performs on itself. In this type of audit, the people conducting the audit **(auditors)**, the people being audited **(auditees)**, and the client (the person or organization that requested the audit) are all members of the same organization. The audit criteria for an internal audit can come from both inside and outside the organization.

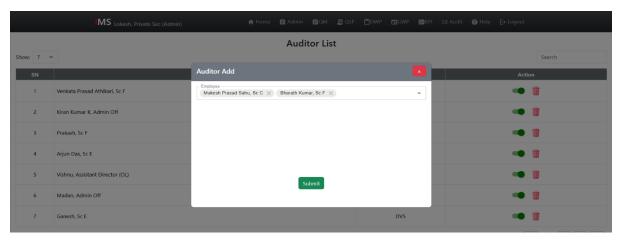
**External Audit:** An audit performed on an auditee by an external auditor. In this type of audit, the client may be the organization being audited.

#### **Auditor List**

The Auditor List Module is designed to facilitate the efficient management of auditors involved in the ISO compliance process. This module enables the creation and updating of a comprehensive list of auditors, ensuring that the right personnel are assigned to conduct audits based on their expertise and availability.

Flow: Audit ---> Auditor List ---> Add

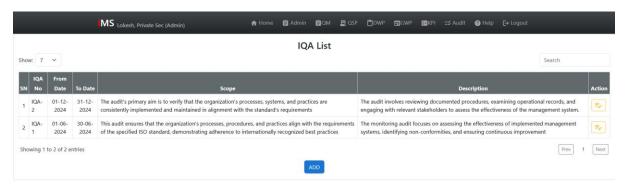


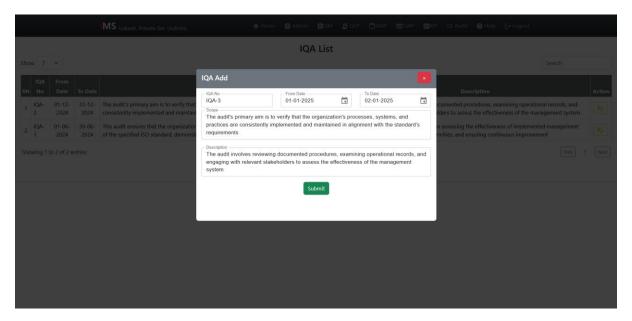


#### **IQA List**

The IQA List Module is designed for creating and managing **Internal Quality Audits (IQAs)** within the ISO compliance framework. This module allows users to define key details for each IQA, including the start date, end date, scope, and a detailed description. By capturing and organizing this information, the IQA List Module ensures that all audits are systematically planned and documented. This facilitates thorough tracking and monitoring of internal quality audits.

Flow: Audit ---> IQA List ---> Add



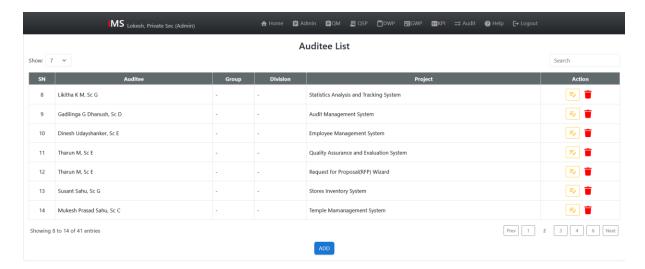


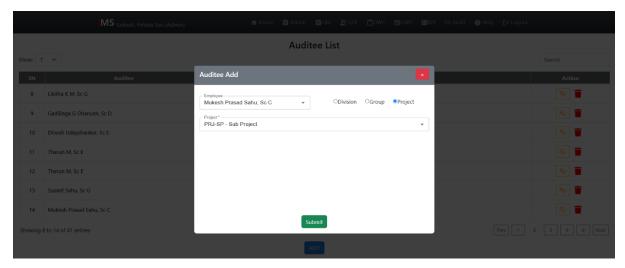
#### **Auditee List**

The Auditee List Module is designed to manage and organize the details of auditees based on the type of audit being conducted. In this system, there are three types of auditees:

- 1. **Division Audits:** The Division Head is designated as the auditee
- **2. Group Audits:** The Group Head is designated as the auditee
- 3. Project Audits: The project Director is designated as the auditee

Flow: Audit ---> Auditee List ---> Add

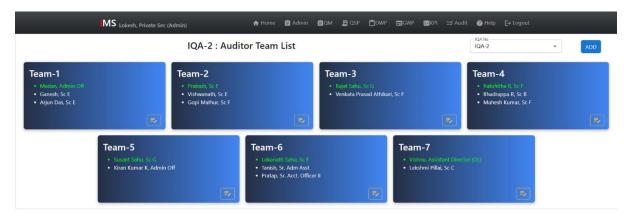


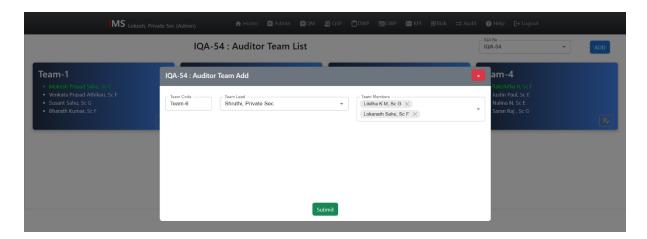


#### **Audit Team List**

The Audit Team List Module is designed to create and manage the team responsible for conducting audits, ensuring effective planning and execution. Each audit team includes a designated **Lead Auditor**, who plays a pivotal role in the audit process. The Lead Auditor is responsible for acknowledging the audit schedule and overseeing the team's activities to ensure the audit is conducted efficiently and in compliance with ISO standards. By streamlining audit team management, the module ensures a structured and systematic approach to audits.

Flow: Audit ---> Audit Team List ---> Add

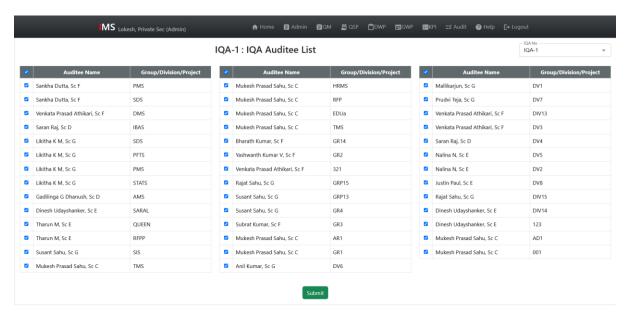




#### **IOA Auditee List**

The IQA Auditee List Module is designed to record and manage auditees specific to each Internal Quality Audit (IQA). By maintaining a detailed record of auditees linked to each IQA, the module ensures clarity and accountability in the audit process. It facilitates accurate tracking, efficient communication, and streamlined audit planning, ensuring that all relevant personnel are included in the audit.

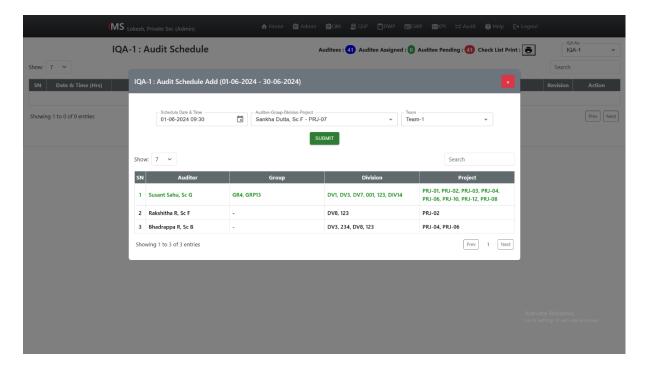
Flow: Audit ---> IQA Auditee List ---> Add

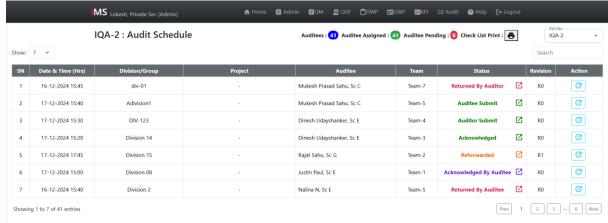


#### **Audit Schedule**

The Audit Schedule Module is designed to facilitate the planning and management of audit schedules within the ISO compliance framework. This module enables users to create schedules for auditees by specifying details such as the date, time and the audit team responsible for conducting the process. A key feature of this module is its validation mechanism, which prevents the creation of a schedule if the auditee is part of the assigned audit team. By maintaining a structured and conflict-free scheduling process, the module promotes efficient audit execution and adherence to timelines.

Flow: Audit ---> Audit Schedule ---> Add

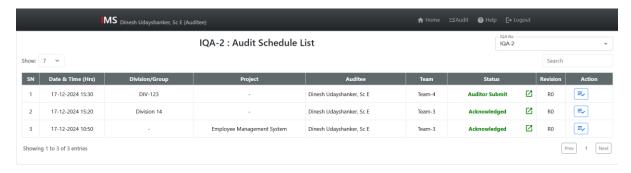


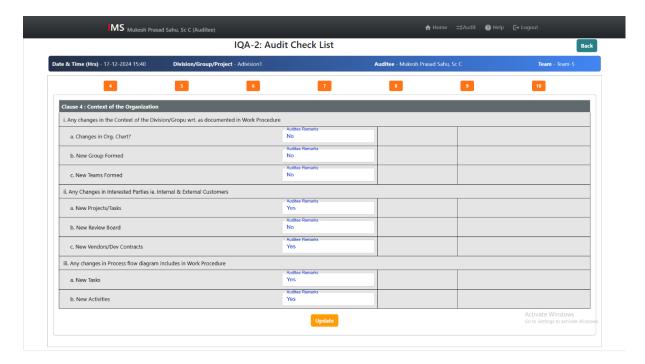


#### **Schedule List**

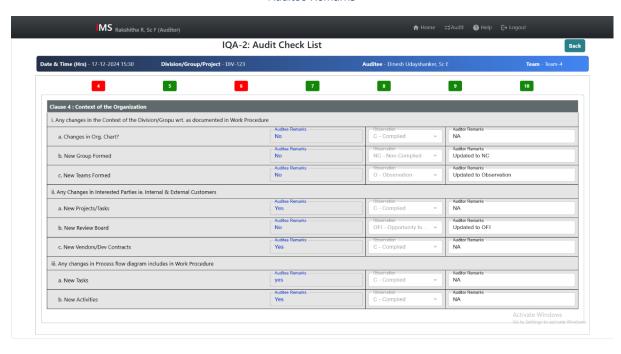
The Schedule List Module is designed to manage and track audit schedules, serving as a centralized platform for auditees and auditors to acknowledge scheduled audits and record audit details. This module ensures that both parties confirm their availability and readiness for the audit. Additionally, it provides a space to document key audit details, such as observations, findings, and outcomes, ensuring a comprehensive record of the audit process. Schedule List Module supports efficient audit management by streamlining communication and documentation.

Flow: Audit ---> Schedule List ---> Acknowledge ---> Add the audit findings





**Auditee Remarks** 

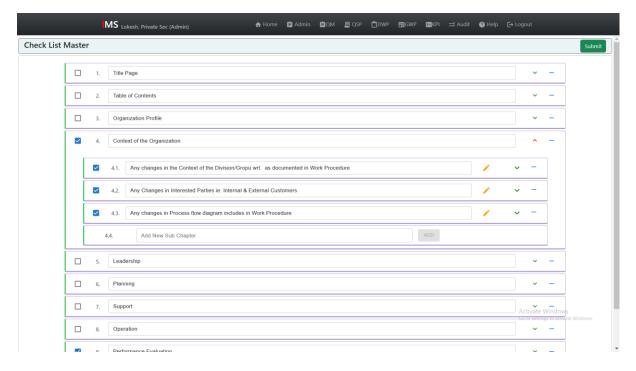


**Auditor Findings** 

#### **Checklist Master**

The Checklist Master Module is designed to create and manage audit checklists, which serve as essential tools for conducting audits. The checklists are prepared by the Management Representative (MR) to ensure alignment with ISO standards and the organization's quality objectives. This module allows for the creation of detailed, structured checklists covering all necessary audit criteria, providing a standardized framework for auditors to follow during the audit process.

Flow: Audit ---> Checklist Master ---> Add



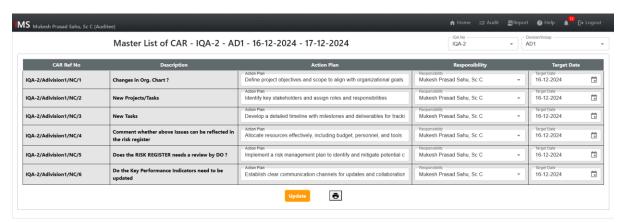
#### **CAR Master**

The CAR (Corrective Action Report) Master Module is a critical component for managing and addressing Non-Conformities (NCs) identified during the audit process. Once the auditee accepts the checklist forwarded by the auditor, the list of NCs raised during the audit is automatically displayed in the CAR Master Module. The CAR Master Module streamlines the process of managing NCs by providing a centralized platform for planning, tracking, and monitoring corrective actions. It ensures that corrective measures are effectively assigned and executed within defined timelines.

#### Flow: Audit ---> CAR Master ---> Submit

In this module the auditee is responsible for:

- **1. Defining the Action Plan:** For each NC raised, the auditee outlines a detailed corrective action plan to address the issue and ensure compliance.
- **2. Assigning Responsibility:** The auditee assigns a primary executive who will take responsibility for implementing the corrective action, ensuring accountability and ownership.
- **3. Setting Target Dates:** A specific target date is defined for each NC, establishing a timeline for completion of corrective measures.



#### **CAR Report**

The **CAR Report** Module is designed to document and track the resolution process for Non-Conformities (NCs) raised during audits, ensuring effective corrective actions are implemented and verified. This module facilitates the collaboration between various stakeholders to close NCs efficiently. The CAR Report Module ensures a structured and transparent process for resolving NCs. It enables detailed documentation of root causes and corrective measures.

Flow: Audit ---> CAR Report ---> Action by Primary Executive ---> Verification by GD ---> Review and Closure by MR

#### 1. Action by Primary Executive:

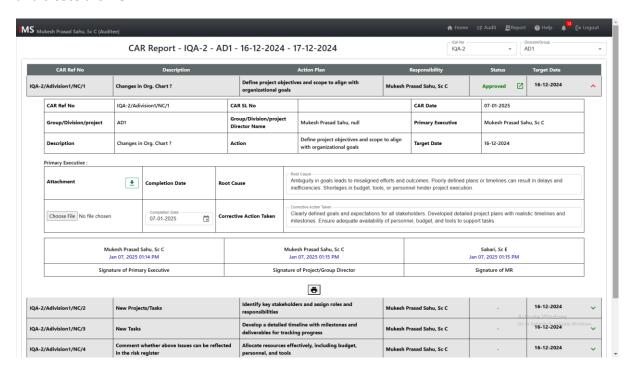
The primary executive, nominated in the CAR Master Module, specifies the **root cause** of the NC, details of the **corrective action taken**, along with supporting **evidence** (e.g., documents, images) and also provides the **completion date** for the corrective action and forwards the report.

#### 2. Verification by GD:

Depending on the auditee of the NC, the respective head (Division Head, Group Head, or Project Director) reviews the corrective actions and evidence provided. The GD ensures that the actions are appropriate and effectively address the root cause before forwarding the report for final review.

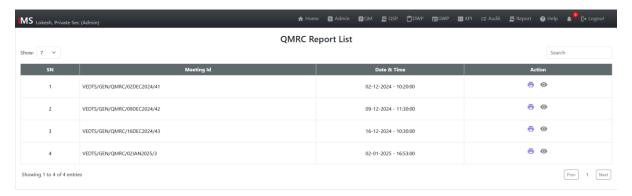
#### 3. Review and Closure by MR:

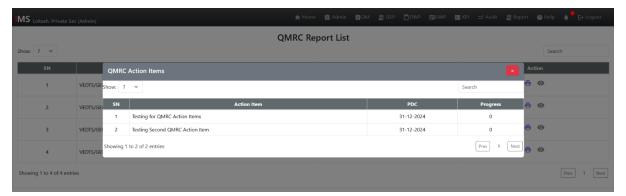
The Management Representative (MR) performs the final review of the corrective actions and evidence. If the actions are satisfactory and meet ISO compliance requirements, the MR approves and closes the NC.



#### **QMRC Report**

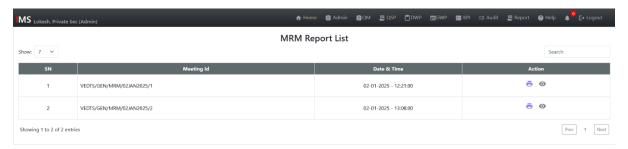
The QMRC (Quality Management Review Committee) Report Module serves as a centralized platform for viewing the recorded Minutes of Meeting (MOM) and associated action points from each QMRC meeting conducted at the end of every Internal Quality Audit (IQA). This module displays the action items discussed during the QMRC meeting, enabling easy tracking of responsibilities and progress and also generates the Minutes of Meeting.

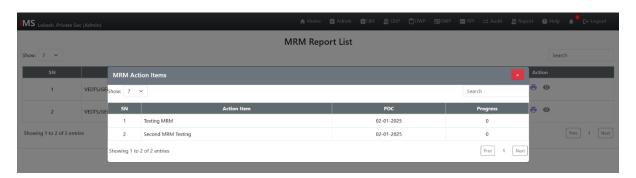




#### **MRM Report**

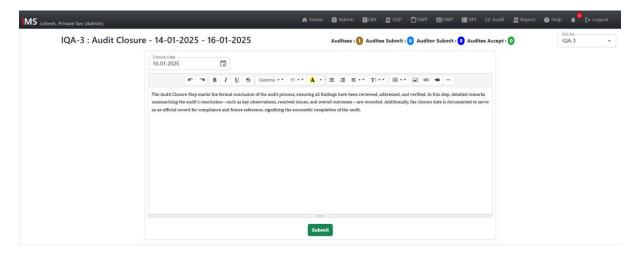
The MRM (Management Review Meeting) Report Module serves as a centralized platform for viewing the recorded Minutes of Meeting (MOM) and associated action points from each MRM. This module displays the action items discussed during the MRM meeting, enabling easy tracking of responsibilities and progress and also generates the Minutes of Meeting.





#### **Audit Closure**

The **Audit Closure** Module is the final step in the audit process, ensuring the formal conclusion of an audit after all findings have been addressed and verified. This module provides a section for entering detailed remarks summarizing the audit's conclusion, including key observations, resolved issues, and overall outcomes and also captures the date on which the audit is officially closed, serving as a record for future reference and compliance purposes.



## **Audit Process**

The Audit Process is a structured sequence of activities designed to evaluate an organization's compliance with ISO standards and identify areas for improvement. It involves the following key steps:

- **1. Audit Initiation:** Audit Initiation is the first step in the audit process, setting the foundation for a structured and effective evaluation of compliance with ISO standards.
- **2. Audit Planning:** Audit Planning focuses on structuring the audit to achieve its objectives effectively. The key details are defined for IQA, including the start date, end date, scope, and a detailed description. A detailed audit schedule is developed specifying the date, time, assigned auditees, and the audit team
- **3. Checklist Generation:** The Management Representative (MR) prepares a comprehensive checklist, aligning it with ISO standards.
- 4. Audit Execution: The Audit Execution Process begins with the created audit schedule being forwarded to both auditors and auditees for acknowledgment. The schedule can be rescheduled up to two times to accommodate the availability of auditee or auditors. Once the schedule is acknowledged, the auditee reviews the checklist and provides remarks for each item, offering context or initial inputs relevant to the checklist. Following this, the auditor conducts the audit based on the checklist and the auditee's remarks. During the audit, the auditor evaluates the processes, collects evidence, and documents findings under categories such as Complied, Non-Complied (NC), observations, and Opportunity for Improvement (OFI). These findings are then compiled into a report. Once completed, the auditor forwards the report for further review or approval.
- **5. Corrective Action:** The Corrective Action Process allows auditees to address non-conformities or observations identified during the audit. For each corrective action, the auditee provides a detailed description outlining the steps taken to resolve the issue or improve the process. Supporting evidence, such as documents, images, or reports, can be uploaded to substantiate the corrective action. Additionally, the auditee specifies the date of completion to indicate when the corrective measures were implemented.
- **6. NC Closure Action:** The Closure Action Process performed by the MR marks the final step in resolving audit findings. After reviewing the corrective actions taken by the auditee, the auditor evaluates the evidence provided and verifies whether the non-conformities or observations have been addressed and forwards to MR for the closure of NC. Once satisfied, the MR approves and closes the audit findings, ensuring compliance and completeness.
- 7. Audit Closure: The Audit Closure Step marks the formal conclusion of the audit process, ensuring all findings have been reviewed, addressed, and verified. In this step, detailed remarks summarizing the audit's conclusion—such as key observations, resolved issues, and overall outcomes—are recorded. Additionally, the closure date is documented to serve as an official record for compliance and future reference, signifying the successful completion of the audit.