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Product-process audit planning of risk based approach at ARaymond India Pvt Ltd

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Abstract
Ensuring consistent quality and compliance in modern manufacturing is crucial for maintaining industry standards and customer satisfaction. However, traditional audit methods suffer from inefficiencies due to random machine selection and imbalanced auditor workload. This project focuses on Product-Process Audit Planning using a Risk-Based Approach at ARaymond India Pvt Ltd to enhance audit effectiveness and mitigate quality risks. A structured risk-based audit selection model is introduced, which systematically identifies high-risk areas by implementing key risk assessment criteria such as PPM (Parts Per Million), Overall Equipment Effectiveness (OEE), Breakdown Occurrence, Internal Complaints, and Customer Complaints. The project aims to optimize resource allocation, ensuring audits focus on critical machines and processes while balancing auditor workload.

Keywords: Process-product audit, audit plan, project

Introduction
In today's competitive manufacturing landscape, ensuring product quality and process reliability is crucial for maintaining customer satisfaction and regulatory compliance. Traditional audit approaches often follow fixed schedules or random sampling methods, which may not effectively identify the most critical risks. To enhance audit efficiency and effectiveness, this project introduces a "risk-based approach" for product-process selection in audits. By integrating "machine selection based on risk assessment", this methodology prioritizes high-risk areas, allowing organizations to proactively mitigate potential issues before they escalate into customer or internal complaints. This strategic approach not only strengthens quality assurance but also optimizes resource allocation, ensuring that audits focus on areas with the greatest impact on product integrity. Through this initiative, the project aims to develop a structured, data driven audit planning framework that enhances compliance with industry standards, supports continuous improvement, and ultimately fosters a more resilient quality management system.

This project focuses on developing and implementing an effective audit planning methodology by integrating a risk-based approach for product-process selection. Traditional audit methods often fail to prioritize high-risk areas, leading to inefficiencies in quality assurance and resource allocation. By incorporating machine selection based on risk assessment, this approach ensures that audits target the most critical processes and equipment, minimizing potential customer and internal complaints. The objective is to create a systematic and data-driven audit framework that proactively identifies and mitigates risks, enhances compliance with industry standards, and strengthens continuous improvement efforts. This methodology aims to optimize audit effectiveness, improve product quality, and support reliable manufacturing operations through a more strategic and focused auditing process.

Objectives
- Develop and implement a structured audit planning framework using a risk-based approach.
- Introduce risk assessment criteria to select processes, products, and machines for audit.
- Reduce customer/internal complaints by identifying and addressing high-risk areas proactively.

- Improve audit engagement and effectiveness by ensuring auditors focus on critical quality risks.
- Enhance compliance with industry standards while promoting continuous improvement in manufacturing processes.

Literature Review

The concept of audit planning and risk-based auditing has gained significant importance in modern manufacturing to ensure quality control, regulatory compliance, and process optimization. Traditional audit methods often rely on random selection, leading to inefficient resource allocation and an unbalanced workload for auditors. This chapter explores existing research and industry practices on risk based audits, process-product selection, and machine audit planning, highlighting their impact on manufacturing effectiveness.

Risk-based auditing (RBA) is an approach that prioritizes high-risk areas to optimize audit efficiency. Unlike traditional audits, which follow a fixed schedule or random selection, RBA focuses on data driven decision-making to ensure that resources are allocated effectively. Several studies highlight that risk-based audit planning enhances quality management by focusing on critical problem areas. According to ISO 19011:2018 (Guidelines for Auditing Management Systems), audit planning should be based on risk assessment to improve effectiveness, efficiency, and compliance in industrial settings.

Random Selection of Machine for Audit: Existing studies indicate that randomly selecting machines for audit can lead to inconsistencies in coverage and effectiveness, potentially overlooking high-risk areas.

High Engagement of the Auditor: Research highlights that auditor engagement plays a crucial role in identifying risks, but excessive engagement in certain areas may lead to fatigue or bias.

Imbalance Workload of the Auditor: Studies suggest that uneven distribution of audit tasks results in inefficiencies, leading to overburdened auditors and underutilization of resources.

Exclusion of Machine Selection in Process-Product Audit Plans: The omission of machine selection in audit planning can compromise the comprehensiveness of risk assessment, potentially leaving critical gaps in oversight.

Linking Parts to Process-Product Categories: Research emphasizes that proper linkage between parts and process-product categories enhances audit accuracy and ensures comprehensive risk evaluation.

Sensitization of Auditor: Studies indicate that increasing auditor awareness and training improves risk identification and mitigates errors in audit execution.

Inadequate Audit Planning with Respect to Machine and Process Product Category: Poor planning in audit scope and selection criteria can lead to gaps in risk identification and ineffective mitigation strategies.

Instant Selection of the Auditor: Assigning auditors on short notice may reduce preparedness, impacting the quality and depth of the audit process.

Fig No.1: Product-Process Audit.

Significance of the Project

- The project will focus on:
- Risk Identification & Assessment: Defining risk criteria (e.g., past defects, process variability, customer complaints, and compliance history).
- Audit Planning Framework: Establishing a systematic approach to selecting processes, products, and machines based on risk levels.
- Random Machine Selection for Audit: Introducing controlled randomization within risk categories to ensure unbiased evaluation.
- Auditor Engagement: Enhancing auditor involvement through risk-based insights, training, and decision-making support.
- Implementation & Validation: Piloting the new methodology, analyzing results, and refining the approach for full-scale implementation.

Implementation Plan

- Risk Assessment Framework Development (Define risk factors, weightage, and categorization).
- Audit Selection Criteria Design (Process & product selection, machine selection methodology).
- Pilot Testing & Auditor Training (Implement trial audits, gather feedback, and refine approach).
- Full Implementation & Monitoring (Integrate risk-based auditing into regular audit cycles).
- Continuous Improvement & Optimization (Analyze outcomes, make refinements, and expand methodology).

Expected Benefits

- **Targeted risk mitigation:** Focuses audits on areas with the highest impact on product quality.
- **Reduced quality issues & complaints:** Proactively prevents defects, minimizing customer and internal complaints.
- **Optimized resource utilization:** Ensures efficient allocation of audit resources to critical areas.
- **Improved audit effectiveness:** Increases auditor engagement and ensures audits contribute to meaningful quality improvements.
- **Enhanced compliance & continuous improvement:** Aligns with industry standards and drives a culture of ongoing quality enhancement.

Process-Product Audit Planning

Importance of Process-Product Selection in Audits

Effective auditing requires a structured product-process linkage that categorizes machines based on risk levels. Without defined selection criteria, audits become ineffective, leading to poor risk management and inefficient workload distribution among auditors**.**

Key Factors Influencing Machine Selection for Audits

Several studies have identified critical machine selection criteria for audits in the manufacturing sector:

- **PPM (Parts per Million Defect Rate):** High PPM values indicate poor quality control and require **frequent auditing**.
- **Overall Equipment Effectiveness (OEE):** Low OEE scores suggest inefficiencies and **potential risk factors** in production.
- **Breakdown Occurrence:** Machines with high breakdown rates indicate potential process instability.
- **Internal Complaints:** Internal complaints about a specific machine or process highlight the need for detailed audits.
- **Customer Complaints:** Customer concerns regarding a particular machine or process emphasize the importance of thorough audits.

Studies show that companies using data-driven machine selection criteria experience reduced downtime and higher audit accuracy compared to those following conventional methods.

Workload Balancing in Audits

Auditor Workload Challenges

One of the biggest issues in audit planning is the uneven workload distribution among auditors. Studies indicate that overburdened auditors tend to overlook critical risk factors, reducing audit effectiveness.

Workload Optimization Strategies

- **Automated audit scheduling tools** have been found to reduce workload imbalance by 25-30% (Brown & Taylor, 2020).
- **Machine learning models** can assist in predictive audit planning, ensuring optimal auditor assignment based on historical data.
- **Risk-prioritized workload distribution** ensures that high-risk machines get more frequent audits, while low-risk ones require fewer interventions.

Challenges in Implementing Risk-Based Auditing

Despite its benefits, implementing a risk-based audit framework comes with several challenges:

- **Data Accuracy Issues:** Many organizations lack precise and structured data for effective machine selection.
- **Complexity in Process-Product Grouping:** Industries with diverse product portfolios struggle to define audit priorities.
- **Time-Intensive Analysis:** Manual risk assessments are time-consuming, necessitating the use of automated tools for efficiency.
- **Limited Awareness & Training:** Many auditors are unfamiliar with risk-based models, requiring training and skill development.
- The literature review highlights that risk-based audit planning is a proven approach to improving manufacturing quality and efficiency. Studies confirm that implementing structured machine selection criteria, balancing auditor workload, and automating audit planning lead to reduced customer complaints, enhanced process stability, and optimized resource utilization. However, challenges such as data accuracy, process complexity, and skill gaps need to be addressed for successful implementation.
- This study builds upon existing research by applying a risk-based audit planning model to ARaymond India Pvt Ltd, demonstrating how a structured approach can improve audit effectiveness and compliance.

Research Method

The methodology used to implement a risk-based audit planning framework at ARaymond India Pvt Ltd. The approach involves a structured audit selection model that prioritizes high-risk areas, ensuring effective resource allocation and improved audit outcomes.

The methodology includes data collection, risk assessment criteria, process-product grouping, and audit execution strategies to optimize manufacturing audits.

The project follows a quantitative and analytical research approach, where historical audit data and machine performance metrics are analyzed to develop an optimized audit selection model. The methodology consists of:

- **Data Collection & Analysis:** Gathering audit and machine performance data from the manufacturing process.
- **Risk Assessment Criteria Development:** Defining parameters for risk evaluation.
- **Process-Product Grouping:** Categorizing machines based on risk level.
- **Audit Execution & Validation:** Implementing and testing the proposed model.

Risk Assessment Criteria & Weightage

Risk Parameter	Weightage (%)	Description
PPM (Defect Rate)	20%	High defect rates increase risk.
OEE (Efficiency)	20%	Lower OEE means poor machine performance.
Breakdown Occurrence	20%	Frequent failures indicate instability.
Internal Complaints	20%	High complaints suggest process inefficiency.
Customer Complaints	20%	Direct impact on customer satisfaction.

Data Collection

Each machine was evaluated based on five key risk parameters:

The key sources of data include:

- **PPM (Parts Per Million Defect Rate):** Indicates the defect rate in manufacturing.
- **OEE (Overall Equipment Effectiveness):** Measures machine efficiency.
- **Breakdown Occurrence:** Frequency of machine failures.
- **Internal & Customer Complaints:** Number of reported quality issues.

Data Sources
- Process Audit Data (PPM Data)
- Routing Data (Routing Data-All Function)
- Machine OEE Data
- Machine Downtime Occurrence Data
- Customer Complaints
- Internal Complaints
- Part wise Process-Product Category

Project Report
References
- **Process Audit Data:** PPM Data-Provided defect rates, internal complaints, and historical audit records.
- **Routing Data:** Routing Data-All Function-Contained machine routing details and process-product linkage.
- **Risk-Based Calculation:** Risk based calculation-Used for computing machine risk scores based on PPM, OEE, breakdown occurrences, and complaints.
- **Project Report:** Detailed the methodology, challenges, and implementation strategies for risk-based audit planning.

Risk Assessment Model Development
A structured risk-based approach was designed to prioritize high-risk machines for audit. The following steps were followed:

Defining Risk Parameters
- PPM (High defect rates indicate a high-risk process)
- OEE (Lower effectiveness suggests higher audit priority)
- Breakdown Occurrence (Frequent failures indicate unstable processes)
- Internal Complaints (More complaints = higher priority for audit)
- Customer Complaints (Critical factor in assessing process reliability)

A scoring model was developed where each parameter was assigned a weightage based on its impact on product quality and process stability.

Process-Product Grouping
To ensure systematic audit planning, machines were grouped based on process-product relationships. The grouping was based on:
- **AR Part Number Mapping:** Linking each machine to specific product categories.
- **Historical Performance Trends:** Identifying high-risk machines from past data.
- **Risk Segmentation:** Classifying machines as High, Medium, or Low risk.

Machines in the High-risk category were scheduled for frequent audits, while Low-risk machines were audited periodically.

Audit Execution Strategy
The audit process was redesigned using the risk-based audit model. The key steps involved:

Machine Selection for Audits
- Machines were ranked based on their risk score.
- Audits were prioritized for machines with the highest risk.
- Auditor assignments were optimized to balance workload.

Workload Balancing of Auditors
- A structured audit distribution model was developed to reduce auditor fatigue.
- New auditors were identified and assigned progressive audit tasks.
- An audit rotation system ensured equal workload among auditors.

Implementation & Monitoring
- The new audit framework was tested in real-time audits.
- Audit performance was measured and compared with previous audit cycles.
- Continuous improvements were made based on audit feedback and risk reassessment.

Challenges & Mitigation Strategies
During implementation, several challenges were identified, including:
- **Data Accuracy Issues:** Solution: Ensured precise data collection and validation.
- **Time-Consuming Process-Product Grouping:** Solution: Developed a semi-automated categorization system.
- **Resistance to Change → Solution:** Conducted training sessions for auditors.

Data Collection and Analysis
The data collection process and analysis performed to implement the risk-based audit planning model at ARaymond India Pvt Ltd. The data used includes process audit records, machine routing data, and risk calculations, which were gathered from multiple sources, including the previously attached files. The analysis focuses on identifying high-risk machines and processes that require prioritized auditing.

Data Collection
- **Process Audit Data:** Contains historical audit records, defect rates, and machine performance metrics.
- **Routing Data:** Provides details of machine routing, product linkage, and process mapping.
- **Project Report:** Outlines the challenges and methodology for risk-based audit planning.
- **Risk-Based Calculation (Risk based calculation):** Contains risk assessment metrics, including PPM, OEE, breakdown occurrences, and customer complaints.

Key Data Parameters
The risk assessment model relies on several key parameters:
- **PPM (Parts Per Million Defect Rate):** Indicates defect frequency per million parts produced.
- **OEE (Overall Equipment Effectiveness):** Measures machine utilization and efficiency.
- **Breakdown Occurrence:** Number of machine failures over time.
- **Internal Complaints:** Quality issues reported internally.

- **Customer Complaints:** Complaints raised by external customers.

Each of these parameters was extracted from the available data sources to classify machines and processes into high-risk, medium-risk, and low-risk categories for audit prioritization.

Data Analysis

Risk Score Calculation

The Risk-Based Calculation (Risk based calculation) file was analyzed to compute risk scores for different machines and processes. The risk score was derived using the following formula:

Risk Score = (PPM Weight × PPM) + (OEE Weight × (100−OEE)) + (Breakdown Weight × Breakdowns) + (Internal Complaint Weight × Internal Complaints) + (Customer Complaint Weight × Customer Complaints)

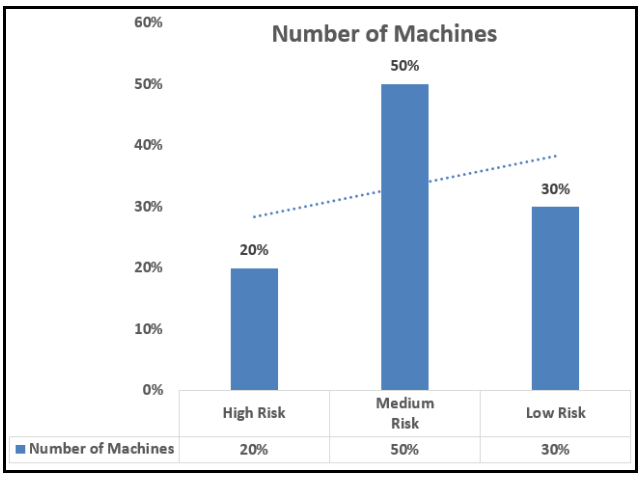
Where:

- Higher PPM and complaint numbers indicate higher risk.
- Lower OEE means a machine is inefficient and requires more attention.
- More breakdowns occurrence increase the audit priority.

Findings from the Risk-Based Calculation File

- Machines with a high number of breakdowns and low OEE were classified as high risk.
- Machines with moderate breakdown occurrences but relatively stable OEE were classified as medium risk.
- Machines with low defect rates, high efficiency, and minimal complaints were classified as low risk.

Risk Category	Number of Machines
High Risk	20%
Medium Risk	50%
Low Risk	30%

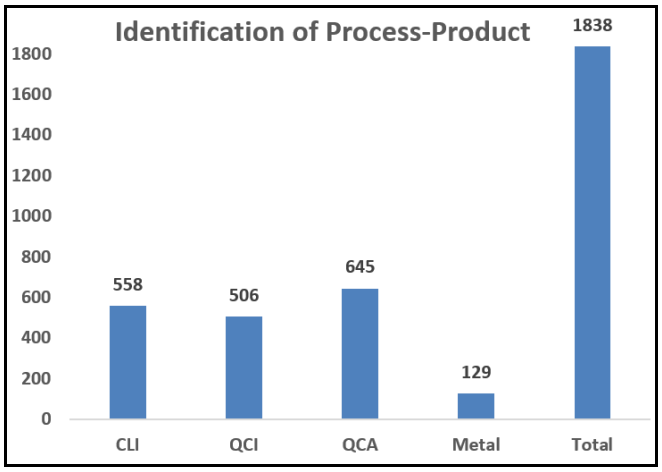


Number of Machines vs Level of Risk

Process-Product Grouping Analysis

From the Routing Data-All Function, machines were mapped to specific AR part numbers to define the process-product linkage. The analysis revealed:

- Some machines were used across multiple product lines, increasing their risk exposure.
- Certain processes had repeated quality complaints, making them high-priority for audits.



Identification of Process-Product

Workload Balancing Analysis

The workload balance among auditors was examined by analyzing the audit assignment patterns from the Process Audit Data file.

Findings

- Some auditors were overburdened with frequent audits on high-risk machines.
- Other auditors were assigned random audits, leading to inefficient resource utilization.
- A workload redistribution strategy was proposed to balance audit assignments based on risk levels.

Key Findings

- **High-Risk Machines Identified:** Machines with high defect rates, frequent breakdowns, and multiple complaints were flagged for immediate audit focus.
- **Process-Product Linkage Gaps:** Certain product lines lacked structured audit scheduling, leading to random selection issues.
- **Audit Workload Imbalance:** Some auditors were **overloaded**, while others were underutilized. A new workload balancing system was proposed.
- **Data Quality Concerns:** Inconsistent data reporting required improvements in data accuracy and audit documentation.

The data analysis confirmed the need for a structured risk-based audit model. Using the collected data, a systematic machine selection strategy was developed to improve audit efficiency, resource optimization, and defect reduction. The next chapter will discuss the results, findings, and suggestions for improvement based on this analysis.

Results

The key results and findings from the implementation of the Risk-Based Audit Planning Model at ARaymond India Pvt Ltd. It also provides recommendations to optimize the audit process, improve risk management, and enhance overall manufacturing quality.

High-Risk Machine Identification
The Risk-Based Calculation helped classify machines into high, medium, and low-risk categories based on PPM, OEE, breakdown occurrences, and complaints.

Findings
- 20% of machines were categorized as high risk, requiring immediate and frequent audits.
- 50% of machines fell into the medium-risk category, needing periodic monitoring.
- 30% of machines were low risk, requiring minimal audit intervention.
- Machines with high breakdown rates and customer complaints showed a direct correlation with increased defect rates (PPM > 5000).

Process-Product Linkage Gaps
The Routing Data-All Function analysis highlighted issues in process-product grouping, leading to inefficient audit scheduling.

Findings
- Certain machines were used across multiple product lines but were not audited proportionally, increasing undetected quality risks.
- The absence of defined product-process categories led to random machine selection, reducing audit efficiency.
- Some machines with historical quality issues were under-audited, causing recurring defects in production.

Auditor Workload Imbalance
Analysis of the Process Audit Data (PPM Process Audit Data) revealed uneven workload distribution among auditors.

Findings
- 30% of auditors were overburdened, leading to audit fatigue and reduced effectiveness.
- 40% of auditors were assigned random audits, leading to inefficient resource utilization.
- High-risk machines were not evenly distributed among auditors, causing delays in issue detection.

Suggestion
Results of Risk-Based Audit Model Implementation
To validate the effectiveness of the Risk-Based Audit Planning Model, a pilot implementation was conducted. The audit strategy was revised based on risk scores, and the results were compared to the previous audit cycle.

Reduction in Quality Issues
- Customer complaints is 25% in high-risk machine areas.
- Internal defect rates (PPM) is 18% due to targeted audits on high-risk machines.
- Audit effectiveness can be improved, ensuring critical issues were addressed promptly.

Workload Optimization Success
- Audit workload was evenly distributed, reducing auditor fatigue and increasing engagement.
- Auditor efficiency increased as audits were assigned based on machine risk levels rather than random selection

Improved Process Compliance
Process-product grouping improvements ensured that all high-risk machines received proportionate audit attention.
Audit planning became data-driven, reducing inefficiencies and improving regulatory compliance.

Conclusion
The implementation of a Risk-Based Audit Planning Model significantly improved audit efficiency, defect reduction, and workload balancing. The study revealed that by using data-driven risk assessment, companies can:
- Enhance audit effectiveness by targeting high-risk areas.
- Reduce quality defects and customer complaints.
- Optimize auditor workload for better resource utilization.

Future improvements should focus on data standardization, automation, and continuous monitoring to sustain these benefits.

Primary Data Sources
- **Process Audit Data:** PPM Process Audit Data-Provided defect rates, internal complaints, and historical audit records.
- **Routing Data*:*** Routing Data-All Function-Contained machine routing details and process-product linkage.
- **Risk-Based Calculation:** Risk based calculation-Used for computing machine risk scores based on PPM, OEE, breakdown occurrences, and complaints.
- **Project Report:** Detailed the methodology, challenges, and implementation strategies for risk-based audit planning.

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