International Journal of Biology, Pharmacy
and Allied Sciences (IJBPAS)

'A Bridge Between Laboratory and Reader'

www.ijbpas.com

SIGNIFICANCE OF VENDOR AUDITING IN THE PHARMACEUTICAL INDUSTRY: A COMPREHENSIVE REVIEW

MUHAMMED RASHID CK[1], MANIMARAN V[2*], DAMODHARAN N[2] AND PAVITHRA K[2]

1: Department of Pharmaceutical Quality Assurance, SRM College of Pharmacy, SRM Institute of Science and Technology, Kattankulathur, India

2: Department of Pharmaceutics, SRM College of Pharmacy, SRM Institute of Science and Technology, Kattankulathur, India

*Corresponding Author: Dr. V. Manimaran: E Mail: manimarv@srmist.edu.in

ABSTRACT

Auditing plays an important role in the pharmaceutical sector by facilitating extensive evaluations of organizational processes and practices. An essential aspect in the pharmaceutical industry is vendor auditing, which significantly impacts operational efficiency, quality assurance, and regulatory compliance. This review article presents a thorough exploration of the many aspects that highlight the importance of vendor auditing. Initially it explains about auditing process as a methodical assessment of organizational alignment. Then, the critical role of vendor auditing during external audits, ensuring regulatory congruence and expanding operational improvements. Data is gathered in order to analyse how the criteria will be satisfied. As part of an external audit a company evaluates its vendor to see if they are following regulatory bodies. As a result, the company or organization may run a better system and enhance operations. The vendor management system encourages timely delivery, excellent services, reasonable pricing and the development of close and strong relationships. An audit reveals the capabilities of the supplier allowing the manufacturer to base purchases on audit's results. It can also help the manufacturer update the ideas about the capacity of an unaudited supplier. Additionally, the review elucidates how vendor certification serves as a crucial mechanism that ensures the consistency of supplier products, streamlining quality control procedures.

1. INTRODUCTION

In Pharmaceutical sector, it's really important to make sure that the products are of high quality, safe to use, and follow all the rules set by regulators. To make sure of this, a process called vendor auditing has become crucial. An audit is a methodical, unbiased, and recorded procedure for gathering audit data and objectively assessing it to ascertain the degree to which predetermined criteria are met. Audits are necessary for the monitoring and verification. It provides information on how well a business or industry controls the quality of its operations, procedures, and output. Pharmaceutical businesses must undergo audits by the Food and Drug Administration and the Good Manufacturing Practises to assure product conformity with regulatory authorities and to assess the efficacy of their quality control systems [1]. Supplier or vendor: A person or business that sells its products and services to consumers is known as a vendor or supplier. The licenced individual or business is the one that supplies the active pharmaceutical ingredients, together with other raw materials [2]. The current review provides a comprehensive exploration of how vendor auditing acts as a cornerstone of excellence in pharmaceutical manufacturing. It underscores how this practice contributes to maintaining product quality, patient safety, and the overall credibility of pharmaceutical organizations, all while adhering to stringent regulatory requirements.

2. TYPES OF AUDITS

a) Internal audit

Self-audits and first-party audits are common names for this type of audit. The same corporation employs both parties engaged in an audit. Internal auditors advise businesses on how to more successfully achieve their goals as part of their profession [3]. An organised process to assess organisational problems or commercial processes and offer suggestions is internal auditing [4].

b) External audit

Second-Party Audit is another name for this kind of audit. It alludes to a consumer auditing a contractor or supplier [5]. Despite the fact that this control is not subject to any specific legal restrictions. It is always sound to assess the skill of the contractors we use to make our products, analyse our commodity, or do any other GMP-compliant activity [6].

c) Regulatory audit

It is an audit that the inspector or regulators do. Any organisation seeking to be accredited for its quality system must undergo this kind of audit. This kind of audit could occur without notice. These inspections are carried out by organisations like Australia's Therapeutic Goods Administration (TGA), South Africa's

Medicines Control Council (MCC), the United States Food and Drug Administration (USFDA), the UK's Medicines and Healthcare Products Regulatory Agency (MHRA), etc.**[7]**. The audit will be carried out by a team, and this team must include audit inspectors and a varied group of business employees **[8]**.

3. VENDOR AUDIT

Finding suppliers who can offer the customer the correct items and/or services at the right price, in the right quantities, and at the right time is referred to as the supplier selection process. An impartial evaluation of all vendor or contractor processes is done as part of a vendor audit in order to prove compliance with the customer's needs, specifications, standards, procedures, laws, rules, and regulations. Vendor assessment is a technique for rating the supplier's performance across a range of variables. It is crucial for efficient and high-quality shopping. In today's extremely competitive economy, buying managers must now take supplier assessment and selection into serious consideration. The bigger portion of the overall cost is made up of the product's raw ingredients.as a result, the buyer ought to receive higher value **[9]**.

Choosing a supplier is a critical step since the ingredient purchased from the provider will be directly utilised in the end product's production process. When low-quality raw materials are employed, the end product's quality suffers.

a) Q.U.E.S.T Approach

Q=Question phase: What is necessary for the highest-grade medicine product. The supplier must prepare raw materials of the highest grade stipulated by the producer.

U=Understanding phase: During this step, all requirements for finalising the excipients are conformed based on pre-trials.
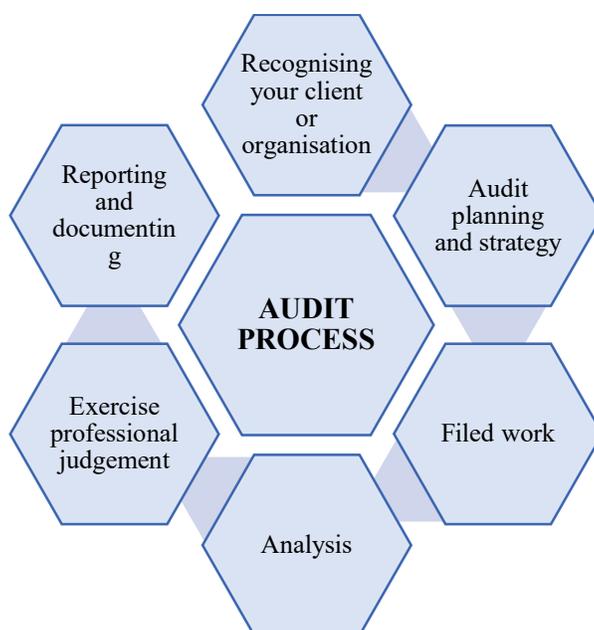
E=Evaluation phase: Based on the requirements, the best possible provider is determined.

S=Site audit phase verification: The on-site audit must be performed for verification depending on the specificity of the excipient.

T=Track phase: Examine and keep an eye on things. The performance of the vendor must be examined on a regular basis. The monitoring technique comprises assessing any problems with the vendor's goods or services. Periodic requalification is performed **[10]**.

b) Audit process

An audit is a review or assessment of a section of a business or organisation to see if it complies with the necessary standards. Audits come in a variety of forms and include a number of phases that are intended to get the best results. Depending on the type of audit, the step could change **[11]**.

AUDIT PROCESS

Recognising your client or organisation

Reporting and documenting

Audit planning and strategy

Exercise professional judgement

Filed work

Analysis

i. **Notification:** The auditing agency informs the organisation or company that will be audited. They also remind clients of the audit's beginning date, the initial meeting with corporate executives, a document required by the auditor, and soon **[9]**.

ii. **Planning:** Following notice, the auditor intends to meet with the company's head and do fieldwork which he makes preparations **[12]**.

iii. **Initial meeting:** The external auditor meets with the company's top executives. There may be administrative workers present. The meeting's purpose is to establish various auditing techniques and provide the company a chance to resolve its issues **[12][13]**.

iv. **Fieldwork:** During the real-time auditing stage, the auditor questions senior people. He examines sample documents to assess the clarity of the company's paperwork. Research may be undertaken by some examiner or as a team, based on the scope of the audit and size of company **[12]**.

v. **Communication:** After finishing fieldwork, the group should interact with one another in order to ensure that the method is followed and that correct access to records is granted. The draught document outlines the audit's purpose, the auditor's procedure, the documents scrutinized, and the audit results **[12]**.

vi. Governance measures: The final draft is submitted to administration for review and reaction once all auditing revisions and the audit report have been completed. After analysing the paper, say if the audit agrees or disagrees with the concerns raised, the strategy for resolving any found issues or flaws, and the targeted date by which all problems will be remedied.

vii. Exit Meeting: A formal departure occurs after the governance response, which may be officially linked to the ultimate audit report.

viii. Distribution of Audit Report: The finalised audit report is delivered to all essential parties, both inside and outside the region inspected.

ix. Feedback: At last, the audited firm makes the modifications, and the auditor evaluates how successfully the improvements decrease the issue, and the response loop be amid the organisation and the auditor keep up until the problem is settled and the audit cycle begins again [14].

4. PRINCIPLES OF AUDITING

Numerous auditing principles should direct the audit's execution, act as trustworthy tools to support management controls and policies, and provide recommendations for how the organisation may perform better. In sequence to provide germane and appropriate audit ending and to operate severally of one another to provide comparable results under similar conditions, auditors must adhere to these rules [15].

a) Virtue: The core of expertise

The auditors and the individual who administer an audit schedule imperative: execute their tasks honestly, diligently, and responsibly;

- Watch and obey with all applicable legal obligation;
- Show proficiency while carrying out their duty;
- Be keen to any sway that may be used to cloud verdict while conducting an audit.

b) Fair demonstration: The liability to report sincerely and verbatim

The audit's operations should be honestly and accurately reflected in the audit's discovery, conclusions, and reports. It is important to highlight significant audit-related challenges and unresolved disagreements within the auditing team and the organisation being audited. The message should be sincere, precise, impartial, timely, clear, and comprehensive.

c) Due master care: The application of perseverance and sagacity in auditing

The importance of their position and the trust that the audit client and other interested parties place in them must be correctly considered by auditors. Making sensible

decisions in all audit conditions is one of the most crucial components of completing job with the required professional care.

d) Secrecy: Security of information

Auditors should utilise and safeguard the information they have acquired while doing their job with caution. The use of audit information for the auditor's or audit client's benefit or in a way that jeopardises the auditee's legitimate interests is inappropriate. This idea also includes how sensitive or secret material should be handled.

e) Independent: The basis for the fairness of the audit and objectively of the audit cessation

The auditors should, if possible, be impartial and perform without prejudice or conflicts of interest. They should also be independent of the activity being scrutinized. Internal audits require auditors to remain impartial towards the operational management of the function being examined. For audit findings and conclusions to be founded only on audit evidence, auditors must retain neutrality throughout the review process.

Although internal auditors for small organisations might not be entirely unbiased and objective, every effort must be taken to eradicate prejudice and promote objectivity.

f) Proof-based way: Cogent method for achieving reliable and logical audit conclusion in a methodical audit process.

Collaboration of the audit's supporting documents is required. An audit will frequently be based on instances of the information that is already available since it is directed in a limited duration and with finite resources. It is important to employ sampling effectively since it has a direct impact on the degree of trust that may be present in the audit results **[16]**.

5. MANAGING AN AUDIT PROGRAM

It is subjected to the size, makeup, and nature of the organisation that has to be audited, an audit programme may comprise one or more audits. These audits may include joint (many auditing organisations) or combination (QMS AND EMS) audits, as well as having a range of purposes. The actions required for planning and organising the types and quantity of audits, as well as for allocating resources to enable their successful and timely completion, include the management of an audit programme.

The company's senior management should give authority to oversee the audit programme. The person in charge of managing the audit programme should:

1) Plan, establish, implement, monitor, review, and improve the audit program.

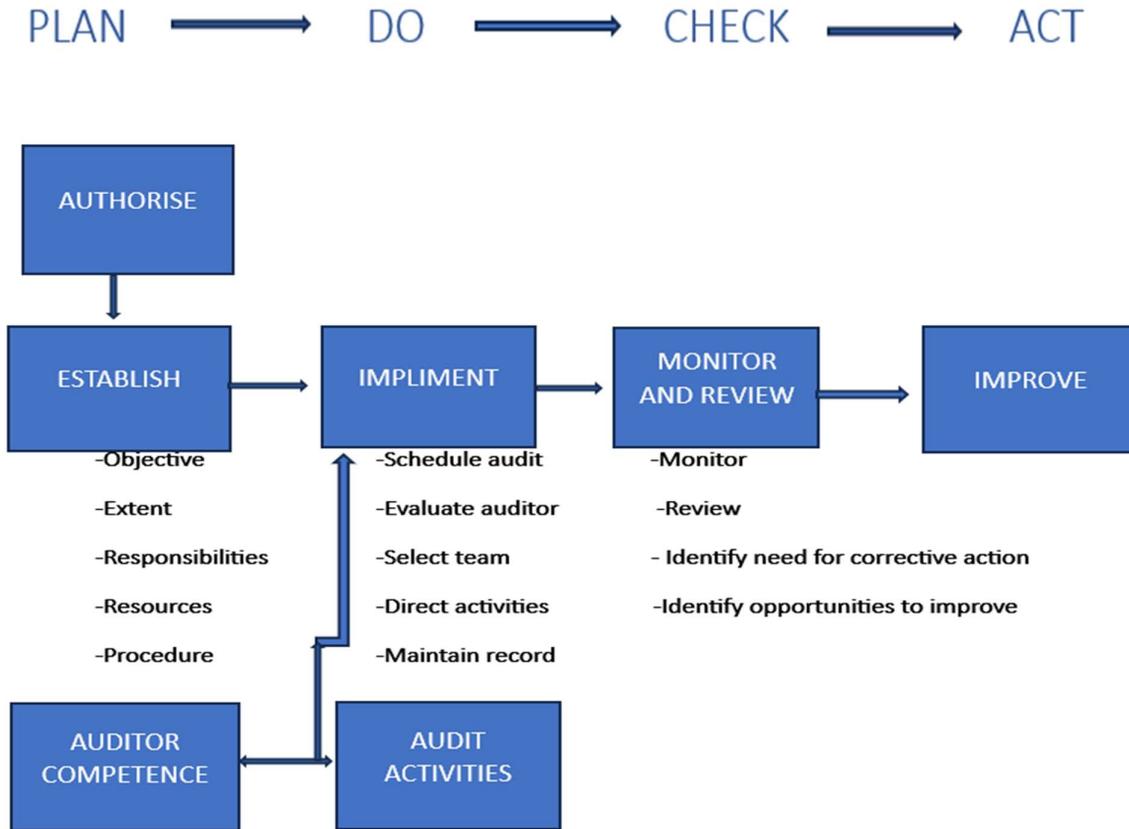2) Recognise the resources that are required and make sure they are available.

PLAN → DO → CHECK → ACT

AUTHORISE

ESTABLISH
-Objective
-Extent
-Responsibilities
-Resources
-Procedure

IMPLIMENT
-Schedule audit
-Evaluate auditor
-Select team
-Direct activities
-Maintain record

MONITOR AND REVIEW
-Monitor
-Review
- Identify need for corrective action
-Identify opportunities to improve

IMPROVE

AUDITOR COMPETENCE

AUDIT ACTIVITIES

Figure 1: Managing an audit program-process flow[17][18]

6. AUDIT ACTIVITIES

The following process flow or life cycle is involved in the preparation for and execution of audit activities:

Initiating the audit					
Appointing the audit team leader	Defining audit objectives,scope and criteria	Selecting the audit team	Establising contacting with the auditee	Preliminary visit	Conduct document review

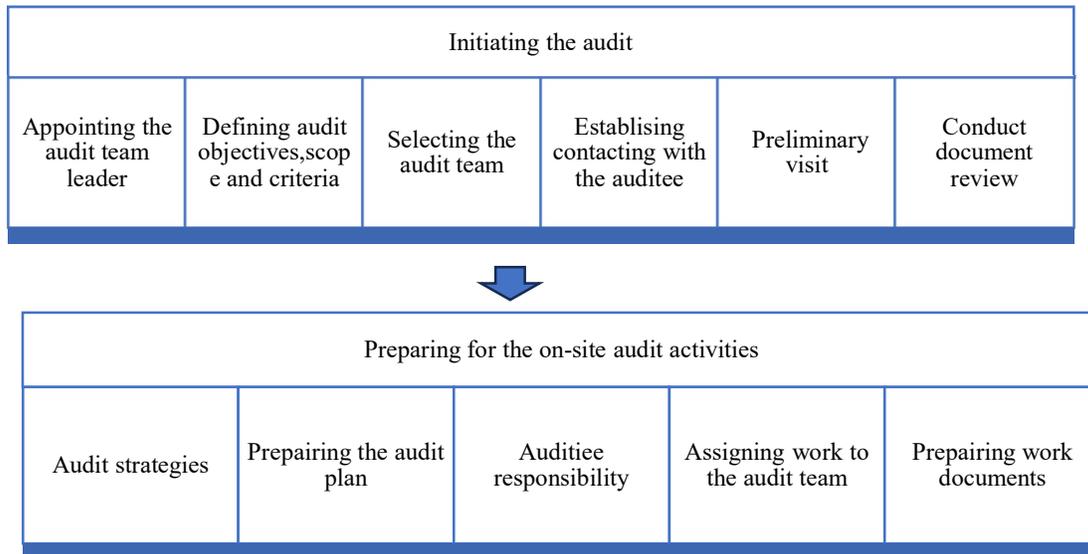| Preparing for the on-site audit activities				
Audit strategies	Preparing the audit plan	Auditiee responsibility	Assigning work to the audit team	Preparing work documents

Figure 2: Various steps of audit activities [17]

7. INFORMATION GATHERING

Facts or information that is provided or obtained are all that constitute information. It could be expressed explicitly in printed or digital materials, or implied in people's thinking.

For the audit to be relevant to the goal, scope, and bench mark, information on interfaces across functions, activities, and processes should also be acquired and evaluated. Audit evidence may only be based on confirmed data, which must be documented **[19]**.

Audit evidence is any data utilised by the examiner to assess if the examined details complies with the set rule and to reach the inference that constitute the basis of the audit report Any kind of info, process, procedure, vouchers, payment, memoranda, agreements, or trade are examples of internal audit evidence **[12][13]**.

The internal audit evidence gathered would be determined by the following factors:

- Audit processes to use: particular methods must be specified for audit teaching.
- Size of sample: the number of objects to be evaluated for each audit method.
- Objects to select: decide what objects from the populace must be chosen.

- Timing: timing might change from the start of the review period to the end of it.

8. NOVEL APPROACHES FOR IMPROVING VENDOR CONTROL

Robotic Process Automation and Hard Intelligence

In Robotic process automation (RPA) is the usage of code to conduct work accordance with rule in a online environment by simulating user experience to get the identical or better outcomes. RPA frequently makes use of numerous systems. general, it increases the efficiency and effectiveness of repeated manual tasks. Hard intelligence (HI), which goes beyond RPA, comprises human language technology and generation, machine intelligence, and robotics.

HI can extract ideas and connections from info, "understand" their significance, and make good use of data patterns and past encounters. Both RPA and HI are being used in work and lower -level tasks, notably in commercial service and other data-centric industries. besides several advantages, RPA and HI involve functional, economic, legal, organisational, and technological risks. fortuitously, the related danger may usually be mitigated by broadening current procedures **[20][21]**.

Digital risk assessment Many businesses have developed digital transformation goals, formed segregated squads to create apps,

internet domain, and other digital means, and integrated first- and second-line squad into these initiatives. However, Internal control is often behind in terms of knowing the technology, processes, and instruments used in technological endeavours. These involve techniques for creating applications, dev-ops crews (comprised of production and operations specialist), and control automation technologies. Many Internal Audit departments continue to use old mindsets and procedures, in contrast with technological entrepreneurs who utilize more adaptable and automated tactics. Application and online resources used in obtaining client and engagement might expose users to a variety of identification, confidentiality, and safety issues. However, many businesses lack the risk management skills and strategies required to deal with the complexity and difficulty of these risks, as well as those given by the external partners that supply these innovative tools, processes, and solutions **[22][23]**.

Network security over the past few years, online security inspection has mostly concentrated on meeting legal regulation on subject like privacy of information, information technology security, and business continuity This inspection typically confirmed conformity with legislation and standards (such as ISO 27000). Acquiescence will remain a focus for most firms, particularly US-listed organisations,

with the Securities and Exchange Commission making cyber safety a priority in its National Exam Programme and the recent formation of a Cyberspace under its investigation division. In addition, new regulations are being drafted on a daily basis in line with the new AICPA cybersecurity risk management test. Companies should maintain their focus on assurance while acknowledging that compliance with existing standards does not ensure high, or even appropriate, cyber risk management. Organisations implicated in a number of recent popular cyber events were almost certainly in conformity with relevant cyber legislation. In fact, while most cyber security initiatives centre on the IT department, commercial email, and the like, the largest dangers today come from firm teams that use systems hosted in the cloud, collaborate with outside programmer and use apps that are not provided by IT.

The majority this behaviour goes unnoticed by the CIO, CISO, and Internal Audit, and it poses major dangers. The task today is to detect a wider spectrum of cyber dangers before they materialise **[24][25]**. Internal examination analytics is the strongest tool for increasing internal inspection's performance and effectiveness. As a result of the company's digitalization, a great quantity of data is created, which analytics may transform into meaningful information and business insights. Data analysis and

visualisation technologies are getting simpler, less costly, more generally available, and simpler to use. Finally, stakeholders want greater confidence, comprehension, and risk prediction than ever before **[26]**.

EVALUATION CRITERIA FOR VENDORS [27][28]

Quantity	Quality	Pricing	Time & Services	Source & Place

The Following are the specific evaluation criteria that help organizations ascertain the most suitable vendors for their unique needs. When evaluating potential vendors, these criteria provide a comprehensive framework to assess various aspects of the supplier's suitability for specific organization's needs. It's important to assign appropriate weights to each criterion based on their significance to industry and business goals. Additionally, having a standardized evaluation process that involves cross-functional teams can help in making informed vendor selection decisions.

1) Figure out if the supplier is fresh to the firm: This criterion focuses on whether the vendor is a new supplier to your organization. Assessing whether the supplier has had prior engagements with your firm helps in understanding their familiarity with your requirements and processes.

2) Assess the supplier's reputation: Evaluating the supplier's reputation involves gathering information about their standing within the industry, their track record with other clients, and any reviews or feedback available. A positive reputation can indicate reliability and professionalism.

3) Check the FDA, GMP inspection records, and reports: This criterion pertains to regulatory compliance. You should review records of inspections and reports related to GMP or regulatory approvals, particularly if your industry is subject to strict quality and safety standards.

4) Interactions with other businesses: Understanding how the supplier interacts with other businesses can provide insights into their collaborative capabilities, communication skills, and ability to meet diverse client needs.

5) Vendor failure and recall history: Investigating any history of vendor failures or product recalls is crucial, especially in industries where product safety is paramount. This

helps in assessing the vendor's attention to quality control and risk management.

6) Checking the vendor's capacity: Assessing the vendor's capacity involves understanding their production capabilities and whether they can handle the volume of orders or services required by your organization.

7) Checking the vendor's location: Vendor location can impact factors like shipping costs, lead times, and proximity to your operations. It's important to consider how the vendor's location aligns with your logistical needs.

8) Checking the API seller price and API parameters for evaluation: This criterion is specific to industries that deal with APIs or similar raw materials. Evaluating the price and quality parameters of APIs is essential for ensuring the integrity of your products.

9. VENDOR CERTIFICATION

It is the system that ensures that the supplier's product is manufactured under controlled circumstances, resulting in consistent quality conformity to requirements. It is a customer-supplier collaboration [1].

a) **Selection of vendor to be certified**: The director of production, the director of purchasing, and the director of quality assurance should mutually choose the vendor to be certified [29].

b) **Review of historical data and test result**: Analyse the quality information for the various batches that were supplied during the previous three years, and then create a trend analysis. Consider out-of-specification circumstances, typical failure rates, and remedial and preventative action when analysing report variances.

c) **Site audit**: Any authorised individual, such as the quality assurance manager, may conduct an on-site audit.

- To ascertain: Test accuracy, precision, dependability, vendor inspection data.

- Process productivity and repeatability should be examined, as should GMP compliance, the danger of contamination and mix-ups, the application of statistical process control by vendors' in-process controls, and the absence of any serious online issues.

d) **Recommendation:** On-site inspections are not always

necessary; as an alternative, historical data may be assessed using questionnaires, and all quality data and reports may be examined by considering how they performed over the preceding three years.

e) **Decision on certification**: The QA manager reviews the data acquired via these stages before sending it to QC for end-release authorization. Production and buying must also approve the data **[30]**.

f) **Step after certification**: QC or QA will scale back the amount of quality checks and new items inspections that were agreed upon in the certification report following vendor acceptance **[31]**.

CONCLUSION

The vendor's reliability is demonstrated via certification. As a consequence, there are fewer inbound inspections and more work is produced. The supplier of goods for that material loses certification if the supplier or vendor does not meet the customer's needs and standards. The possibility of recertification may exist, depending on the type of failure.

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