

ISO 9001:2015

Audit Guide and Checklist



Patrick Ambrose

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Forward

Creation of this new guidebook and checklist was a result of many, many discussions with internal auditors, would be internal auditors and those responsible for the outcomes and value of internal audits. A common problem was the conflict between a desire to do process audits that are not driven by meaningless checklist questions, and the needs of auditors who often spend only a very small fraction of their time doing management system audits. It seemed that there was no getting away from some kind of resource that auditors could use to help them through their audits. Yet checklists had proven to be non-value added. The result is this book. The questions listed in this book are by definition a checklist, however the intent is that the questions will be used by the auditor, not asked of the auditee. The questions are those that the auditor must answer through the process of finding evidence. Then, based on the evidence they must determine the effectiveness of the system being audited. Many of the questions listed are ones that can be answered through observation. Many will be answered in conjunction with other information gathered during the audit. Other questions ask the auditor to make a value judgment. In this way it is hoped that auditors will have a guide, while enabling them to use a process approach when auditing. This book could not have been written without help, and I received a great deal of help from some very special people. My wife Patricia was my editor, proof reader, cheerleader and motivator. Without her constant support, I probably would not have finished this book. And, my son Devon reviewed it and did nearly all of the editing and software work. Devon is also knowledgeable and experienced in auditing management systems. He has a very sharp mind and I respect and appreciate his opinions.

And finally I would like to thank you, the user of this book. I sincerely hope you will use this book to provide your management with the information to achieve their goals and objectives, to effectively satisfy their customer's expectations, and to provide their employees with a stable, interesting and exciting place to work.

Sincerely

Pat Ambrose

INTRODUCTION

There is an important consideration to make before choosing to use the checklist included in this Guidebook. You should carefully determine your objective with regard to your ISO 9001 Quality Management System. If what you are looking for is the easiest way to get ISO 9001 registered, or if your aim is to do the very minimum needed for conformance, this IS NOT the checklist for you. Every question included in this checklist is designed to promote best practice. The checklist is designed to provide value to organizations that have a desire to get their money's worth and more out of their systems. The questions strive to provide a value added effective and efficient quality management system. This checklist will help your organization to satisfy your customers, provide added value to your customers and provide value to your stakeholders but at no time does it dwell on the minimum. The interpretations of the requirements and the questions it drives are designed at all times to help create a value added system. Certainly you have the right and I would expect that you will skip questions that you believe, have no value to your organization. I would also expect that you may modify questions or even add additional questions of your own. I welcome your participation in this. In addition to audit questions, this checklist provides guidance for auditors during the process. AP or (Audit Process) notes provide valuable direction as to how and when to take note of specific data that will become important further on in the audit. These notes are the result of many years of best practice audit experience. Also within the checklist are BP (Best Practice) questions which are there to help organizations that want all of the value possible from their systems. As you can see, this is not just an audit checklist. It was designed from the beginning to promote a high value, effective and efficient management system.

1.0 AN INTRODUCTION TO ISO 9001:2015

With this new International Standard, some of the clause structure and terminology in ISO 9001:2008, have been changed to improve alignment with other management systems standards.

Basic Changes

- The adoption of the HLS (standardized High Level Structure)
- An explicit requirement for risk-based thinking to support and improve the understanding and application of the process approach.
- Fewer prescribed requirements.
- Less emphasis on documents.
- Improved applicability for services.
- A requirement to define the boundaries of the QMS.
- Increased emphasis on organizational context. (Link between customer expectations, organizational objectives, the Quality Policy, process objectives and process measurement)
- Increased leadership requirements. (Active Participation)
- Greater emphasis on achieving desired outcomes to improve customer satisfaction. (Performance Measurement)

Major differences in terminology between ISO 9001:2008 and ISO 9001:2015

Products from 2008 has become Products and services. Exclusions are No longer used in 2015. Documentation, Records is now Documented Information. Work Environment has morphed into Environment for the operation of processes. Purchased Product is

now externally provided products or services. Suppliers are now External Providers and Preventive Action is gone.

It is important to recognize that the changes in the structure and terminology do not need to be reflected in the documentation of an organization's quality management system. As in the 2008 version of the ISO 9001 standard, the structure of clauses is intended to provide a coherent presentation of requirements rather than a model for documenting an organization's QMS (Quality Management System). There is no requirement and no intention for the structure of an organization's quality management system documentation to mirror that of this International Standard.

There is also no requirement for the terms used in an organization's QMS to be replaced by the terms used in this International Standard. Organizations can choose to use terms which suit their operations. For example:

ISO 9001; 2015 could be

'external provider' 'supplier', 'partner' or 'vendor'

'Management Review' Monthly Operations Meeting

'Nonconformance' ITBF – Issue To Be Fixed

In fact unique terms adopted for your organization can enhance the effectiveness of the system by eliminating old biases, and criticisms born from misapplications and misunderstandings of the intent of terms used in the past.

The basic concept of a process based system has not changed with the 2015 standard and is if anything enhanced. Stressed in 2015 is the requirement to consider and analyze risk. While understanding risk was implied in the 2008 version of the standard it is much more explicit in this new standard.

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2.0 AN INTRODUCTION TO PROCESS BASED AUDITING

Even though the change to process based auditing became the intended practice at the turn of the century, many organizations and some auditors still rely on a clause-based or a shall-based audit process. The problem with auditing 'shalls' or clauses is that the methodology can miss important elements of the process. This 'Shalls' or 'Clauses' approach often leads to the use of basic preprinted 'Go-NoGo' 'Yes – No' checklists. Typical checklists are 10 to 15 questions long and just cover the 'shalls'. In the worst cases these checklists don't change over time making the audit process no more than a repetitive and predictable exercise with very little if any value to the organization. Even when checklists are created as a onetime list, the focus on shalls or clauses relies on a short list of questions to discover actual causal factors related to poor performance. This approach is comparable to looking for a needle in a haystack by picking ten particular spots in the haystack in advance, looking there and expecting to find the needle (i.e. the non-conformance).

Process based auditing is designed to explore the interconnectivity of functions and activities within organizations. The process approach follows both a systemic investigation of the process and a PDCA (Plan – Do – Check – Act) approach. The systemic component of the audit gathers data about the process in a method that builds from the foundation on up gathering linked data as the audit continues. At each step of this analysis the auditor follows the PDCA of the process as a whole as well as following PDCA for components and activities within the process. This approach covers all activities in the process in a way that follows the process through in an organized structured manner while ensuring that all of the elements of the process are functioning effectively.

Process auditing follows the 'story' of the process. Best practice process auditing uses the 'Turtle Diagram' as its primary tool. It is

important to note that the Turtle Diagram is not a form used for auditing, it is a process used for auditing. A Turtle Diagram Form if used, should only be used as a training aid for auditors to get used to the process, but once an auditor is comfortable with the process, the only 'Turtle Diagram' needed resides in the auditor's brain.

Visit systemsthinking.works to purchase a 'Process Audit Toolkit' which includes a Turtle Diagram form and step by step instructions on how to use it for process-based audits.

How This Checklist is Different

This checklist first of all isn't made up of yes or no questions they are evidence based questions such as: 'Is there evidence of conformity?' Second the questions are arranged to follow a Turtle Diagram methodology and PDCA cycles. And third there are a total of 1,248 questions with a minimum of 48 questions for any one process and as many as 100 questions so subjects are covered in depth. By conducting an audit using this checklist you are conducting an in depth assessment of your management systems using the Turtle process. But the Turtle and the checklist are only a part of a process-based audit. Preparation is important as is described in the next section.

Some Examples of Questions taken from the Checklist

63. Does evidence show that there is sufficient and effective measurement information to effectively monitor and control: (9.1)

- Product Conformity?

- Process efficiency and effectiveness?
- Customer Satisfaction?
- Suppliers of goods or services to the organization?
- The overall effectiveness of the QMS?

\$30. For this process, has the organization determined manpower requirements needed in order to achieve customer requirements as well as requirements of other interested parties? (7.1)

R55. Is there a process for disposal of records? Does it comply with Statutory, Regulatory and /or Customer requirements? Do records show that it is effectively implemented? (7.5)

SR26. Have objectives been identified for this process that are consistent with the Mission of the organization, the strategic goals of the organization and the stated Quality Policy? (6.2)

The Process of Process Auditing

There are 5 steps in conducting a Process Audit. Four of those steps are preparation. 1 Determine the Scope, 2. Check Performance, 3. Review Documentation, 4. Plan your audit. Step 5 – Conduct Your Audit

Determine the Scope of the audit

- o Where does the process (or processes) to be audited start? Where does it end? What is included? What is not included? Is it an audit of the complete QMS or specific contracts, part numbers or production processes?
- o What criteria will apply to this audit? ISO 9001? Multiple standards? The organization's quality management system? Specific Customer Requirements? All of the above?
- o What is the purpose for the audit: conformance to the standard, compliance with customer or statutory requirements, problem investigation, review of the status of corrective action, contract completion or improvement action?
- o What is the physical location for the audit? One building in one city? Multiple buildings? Including warehouses, sales offices etc.?
- o What products, product lines, commodities or services are included?

Check Performance

- o Look at recent management review activity. Look specifically at customer satisfaction performance, customer complaints, and any external or internal performance measures related to the process, processes or audit purpose that you will be auditing. This information will provide one of three answers.
 - ☐ Performance is good – Your audit will be focused on changes to employees, documentation, objectives and opportunities for continual improvement projects.
 - ☐ Performance is poor – Your audit will focus on finding causal factors that could be contributing to the poor performance.

□ Performance is intermittent. The process works well most of the time but occasionally there are significant issues – Your audit will focus on finding causal factors for the intermittent issues.

o Make a list of potential weak processes or weak functions within the related process or processes as indicated by the performance. For instance if delivery performance from a process is poor, consider functions within the process that directly affect delivery such as production scheduling, production efficiency, order make-up, pick-pack, etc.

Review Documents

o Review the QMS (Quality Management System) documents related to the process or processes that you will be auditing. Look specifically at parts of the process associated with potentially weak areas of the process as identified during your review of performance. Remember that there is no particular need (unless this process has never before been audited) to check documents to make sure that all related elements of the standard are covered not to mention that in modern quality management systems not every element of the standard needs to be documented.

o Make a list of steps in the documentation which if done incorrectly might cause the types of negative issues identified in your performance review. Find the appropriate questions in your checklist and make a note of your findings. This way when you get to that question you will have your previously identified evidence ready.

o Determine whether there are any (COPs) Customer Oriented Processes within the process you will be auditing. COPs in this context are small special micro-processes which are required only by specific customers. For instance a specific customer may want their corrective action format used or they may want their orders shipped

by FedEx only. These are important aspects of customer satisfaction and therefore deserve special attention during audits. (See Customer Oriented Process – Section 4 of this document)

- o Add notes on the identified COPs to your checklist as a reminder during the audit.

Plan Your Audit

- o Allocate time to the audit. If the audit is to cover multiple processes, create a formal audit plan and bias your time toward those processes with poorer performance (i.e.: those processes which present greater RISK to the organization.)
- o If your audit is to cover only one process, a formal audit plan is unnecessary but still bias your time toward those functions within the process which are most likely to be associated with the identified risk areas.

Conduct Your Audit

- o Follow your checklist questions referring to your notes as you go.

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3.0 THE AUDIT REPORT (Process Specific Assessment)

It is important that evidence from an audit is collected and reported fairly, accurately and effectively. That is to say that the evidence gathered and reported must be put into context. Therefore there should always be a summary of the audit findings attached to each audit.

Typical information on the summary report

1. Areas where evidence shows above average performance –
2. Areas where evidence shows that action **MUST** be taken to conform to the requirements of the standard, the customer or the organization –
3. Areas where evidence shows less than average performance and action should be considered to improve performance, subject to management direction
4. Areas other than those above where in the opinion of the assessor improvement should be a practical expectation –
5. A synopsis of the benefits that should be expected if the actions described in 2,3 and 4 were effectively addressed.

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4.0 DOCUMENTING EVIDENCE (CONFORMITY OR NONCONFORMITY)

One important aspect of audit reporting often overlooked is the need to report evidence. Usually evidence of nonconformity is easily available, but evidence of conformity is often overlooked. It may be that auditors believe that the rule of no information means that there is nothing wrong, but this isn't the only requirement.

It is important that auditors record evidence of both conformity and nonconformity, however it is NOT required that auditors keep copies of every (or for that matter) any documents or evidence gathered.

A simple note stating what evidence was looked at and sufficient information so that the information could be verified if necessary is sufficient. Rather than copy a report it is enough to note that 'The daily report for scrap in the warehouse area dated 3/4/12 was reviewed.' Should anyone need to verify your findings, they can easily retrieve the report for 3/4/12. Obviously records of nonconformity require additional detail of the specific nonconformity and the requirement which has not been achieved.

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5.0 IDENTIFICATION OF ACTIONS REQUIRED

The ISO standard uses the term 'NONCONFORMITY' which we have continued to use in this text up to this point, but now there is an important discussion to be had. Many organizations have struggled with the term non-conformity. Telling someone in the organization that they have a non-conformity is comparable to telling them that their baby is ugly. It rarely elicits a positive reaction. The problem is often simply the word. For over twenty- five years, the ISO community has worked to make the act of giving a non-conformity punishment at least and insulting and degrading punishment at worst. Interestingly there is no requirement for issue of a non-conformity in the ISO requirement. Or rather there is a need to issue a non-conformity but NOT to call it a non-conformity. You have the right to call issues requiring attention anything you want to call them. The point being, If in your organizations non-conformities are accepted with the same reaction as news of a tax assessment the maybe there is an opportunity to change what you call them and at the same time change the internal culture related to finding and improving problem areas.

Consider problem areas under three categories:

a. ACTION REQUIRED TO ACHIEVE PERFORMANCE

An issue found that has a direct or indirect effect on performance. If the issue were resolved there would be a noticeable positive improvement in performance.

b. ACTION REQUIRED TO ACHIEVE SYSTEM CONFORMITY

An issue found that has created a condition where a specific requirement of the applicable standard or the procedures of the organization or a specific requirement of the customer is not being met. If this issue is resolved we will be in conformity to the requirement. It may or may not have any influence on performance and it may or may not have any influence on customer satisfaction.

c. ACTION REQUIRED TO ACHIEVE CUSTOMER REQUIREMENT

An issue that has created a condition where a customer requirement has not been or may not be complied with. If not resolved customer satisfaction will probably be affected

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6.0 THE WORD PROCESS AS USED BY ISO

The many dictionary meanings of the word 'Process' are –

- A series of things that happen and have a particular result,
- A systematic series of actions directed to some end.
- A series of actions or steps taken in order to achieve a particular end.
- A series of actions that produce something or that lead to a particular result.

Yet none of these meanings are particularly helpful in understanding the use of the word in the context of quality management systems. The problem is that you can have processes within processes which exist within processes. So the question stands that when we use the word 'process', at what level and in what context are we using the word?

Consider three categories of 'Process'

Management System Processes

These are the processes referred to in the beginning of the ISO 9001 standard where it says to identify the organization's processes and in ISO 9000 where it states that a process has an owner, has documentation, is measured etc. The basic business Management System Processes in generic terms include:

Value Added Processes

The 'Get Work' Process – The process used to bring customers or clients to the organization and to sell them on your product or service.

The 'How Do We Do This' Process – The process used to plan how we will create or provide what the customer wants.

The 'Buy Stuff' Process – Procurement of the tools, equipment, materials, services, etc. needed in order to provide our customer with what we have promised.

The 'Make Stuff' or 'Do Stuff' Process – Creating or Providing our product or service.

I've intentionally used very generic names because these processes have many different names depending on the industry, profession or structure of an organization.

'Support Processes'.

The 'Facilities and Equipment' Process – We certainly need a roof over our head and maybe machinery, equipment, computers etc.

Maybe an 'IT' Process, a 'Quality' Process or a 'Transport' Process.

And finally there is one other process which is really more of a basket full of small processes. It is called 'Management' or 'Administration'

'Management Processes

- o The Management Process is actually a bucket of small processes that include: Management Review, Management Responsibility, Management System Design, Documentation Control, Internal Audit, Corrective Action and Continual Improvement, etc.

Virtually all businesses consist of these or a variation of these management system processes. There are of course countless variations in structure and many different names for the processes listed. In larger organizations one process listed could in reality be two or three different processes. The list above should not stop your organization from applying creativity and imagination in the development of your system.

Operational Processes

This word process can and often is used interchangeably with Procedures or Methods. This meaning applies when the standard says that these must be a process for a given requirement. In other words there must be a described way of getting from 'A' to 'B'. Depending on the requirement the process or procedure may not necessarily need to be documented. The need for a document is sometimes specified in the standard, but when it is not the organization should consider risks related to the lack of documentation and the most efficient and effective way of providing direction before simply writing another procedure.

Note that operational processes can exist at various levels in the system. Creating a work order is an operational process, but so is the process of reviewing that work order.

Manufacturing Processes

The term manufacturing process has been used for a very long time. Manufacturing processes are the processes for making things. Forging, casting, molding, stamping, milling, turning, sewing,

fabricating, etc. are all manufacturing processes. When the standard is referring to the act of product realization, it is referring to manufacturing processes.

Manufacturing Processes can also exist at various levels in the system. Manufacturing a car is a manufacturing process, but so is attaching the 'GT' logo on the side of the body.

Understanding that within the ISO standard the same word 'PROCESS' actually refers to three different sets of conditions may help in your understanding of the requirements and in the design and operation of your system.

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7.0 RISK BASED APPROACH

All systems, processes and activities have inherent risks. Risks are the effects of unexpected results acting upon a process. The concept of risk-based thinking which has always been implicit in ISO 9001 is in this new 2015 edition more explicit. Risk-based thinking is found in the requirements for the establishing, implementing, maintaining and improving the quality management system.

The level of risk in terms of the organization's ability to meet its objectives and customer expectations will vary considerably from organization to organization and within organizations from process to process. Consequently the robustness of the process for determination of risk and the product, service or system controls applied will vary. "Risk-based thinking" therefore means considering risk qualitatively (and, depending on the organization's context, quantitatively) when defining the degree of formality needed to plan and control the quality management systems, as well as its component processes and activities.

Rules Related to Risk Based Thinking

1. Risk management must be a priority and responsibility of leadership. (not delegated)
2. Don't shoot the messenger. (Employees will not identify risks if they do not perceive an open environment to share risk information – reward for identifying risks would be good)
3. Have a formal and repeatable risk management process.
4. Participants must be trained and competent in risk management practices and procedures.

5. Risks must be determined, assessed, and reviewed at planned intervals.
6. Risk considerations must be a central focus of management reviews.
7. Risk management working groups and review boards must be rescheduled when there are conflicts.
8. Risk mitigation activities must be assigned only to staff with authority to implement mitigation actions.
9. Risk management must never be outsourced.
10. Consider risks that extend beyond cost, schedule, and technical performance. (considered - cross-program, social, political and economic impacts).
11. Risks must be written clearly. Use 'Condition-If-Then' protocol.
12. Approaches to risk management
SARA for Share Avoid Reduce Accept,
A-CAT for "Avoid, Control, Accept, or Transfer")

A Risk Management Procedure

Process

Summarize the steps necessary for responding to project risk. .

Risk Identification

Is an evaluation of environmental factors, organizational factors, culture and, project management considerations and concerns when applied to project deliverables, assumptions, constraints, cost, resources planning and key documentation.

Risk Analysis

Is an assessment to identify the range of possible project outcomes and their associated risks. .

Qualitative Risk Analysis

The probability and impact of occurrence for each identified risk will be assessed.

Probability

High – Greater than X% probability of occurrence

Medium – Between Y% and X% probability of occurrence

Low – Below Z% probability of occurrence

Impact

High – May greatly impact project cost, project schedule or performance

Medium – May slightly impact project cost, project schedule or performance

Low – Little impact on cost, schedule or performance

Detailed Risk Analysis

Analysis of high priority risks using qualitative analysis..

Risk Response Planning

For each major risk apply monitoring plus a plan for one of:

Avoidance

Elimination of the threat.

Control

Identify ways to reduce the potential impact of the risk

Acceptance

Nothing will be done

Transfer

Make another party responsible for the risk (buy insurance, outsourcing, etc.)

For each risk describe the plan for achievement of the chosen approach

Risk Monitoring, Controlling, and Reporting

Maintain a “Top 10 Risk List” with constant monitoring until risks are eliminated or further information prompts additional controls.

(For further information on Risk based auditing refer to ISO 3100.)

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8.0 CUSTOMER ORIENTED PROCESSES (COPs)

COPs the Theory

Again in the ISO world we use the same term with multiple meaning. In this case only two, but it has been enough to create its own share of misunderstandings. In the ISO documentation we talk about COPs, MOPs and SOPS. The gist of the text is that everything an organization does, should be a requirement of the customer COP – Customer Oriented Process, something management needs done – MOP Management Oriented Process or something we need to do in order to support COPs or MOPs. These are support processes, but someone's idea of simplicity is to call them SOPS – Support Oriented Processes. "COPS and MOPs didn't sound ridiculous enough on their own."

The theory of COPs, MOPs and SOPS is relevant enough and an organization should ensure that they are not doing work that has no customer, but that really is as far as it goes.

My personal thinking is that organizations should probably do a COPs, MOPs, SOPS review occasionally, maybe once every five or ten years. It would take that long for an unneeded process to creep into the system.

COPs the Practical Requirement

The second COPs is an invention of the automotive sector who on occasion come up with some good ideas. The COPs concept except for the duplication of the ISO term is one of those good ideas. COPs in this context are unique customer requirements that require your organization to input 'Micro Processes' needed to comply with the unique needs of that one customer into your processes,

In the normal business relationship the customer orders a product and we provide it. But in modern business it isn't always that cut and dried. Often during the process of creating or providing the product the customer introduces specific requirements. They may want you to use their software portal for communications, their format for quotes, corrective action and labeling, etc., their engineering software or suppliers designated by them. During delivery operations they may ask for special labels, stamps or other identification for various internal reasons.

In service industries customers may ask for special delivery times or locations, special safety equipment to be worn or special procedures to be followed. All of these are examples of COPs in this context. In the business world today where systems run business and systems run faster and faster each day, it pays for an organization to focus attention on these COPs. Each COP if not identified, understood and effectively implemented is an opportunity to dissatisfy your customer. For this reason COPs as used here need to be identified in each process, have specific controls in place to ensure that customer requirements are met and must be included and specifically considered when auditing.

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9.0 THIS CHECKLIST

Structure of this Checklist

This checklist is designed to take a theoretical journey through your organization following a 'Turtle Diagram' methodology. The checklist starts with management and from there generally follows the route of a generic product through the organization. As the journey is taken, the checklist captures the appropriate requirements of the ISO 9001 standard. The questions are intentionally designed not to provide specifics as to what is acceptable and what is not. The questions simply ask in most cases whether there is evidence of conformity to a requirement. Or more importantly is there evidence of an effective efficient system.

Sufficient and appropriate evidence in one organization may or may not be sufficient in another. Complexity of the business, criticality of the product or service, the degree to which statutory or regulatory compliance exists can affect the amount and the formality of evidence required.

The Questions

Each question is numbered. In 'Part 1' the numbering system is from Q1 to QX. In 'Part 2' they carry a unique numbering format for each generic system process (ie. M1-MX is used for the 'Management Process'). At the end of each question the appropriate clause of the standard is referenced. For simplicity, the clause numbers are restricted to the first two digits of the standard requirement.

Some questions are followed by (BP) these questions denote best practice and therefore are over and above the general need and are optional as to whether an organization chooses to use them. Other

questions are denoted as AP, these questions are audit process questions. They are designed to help the auditor gather information for audit trails. The data gathered will be used further into the audit. This linking of information will provide an effective audit. Where there are AP questions, there will be places later on in the audit where notes will give the auditor direction in how and when to use information previously gathered.

PART 1

Approximately 210 questions that cover the complete requirements of the standard from a system design perspective. Part 1 uses the Turtle Diagram Audit approach to examine the complete system. It would be most useful in determining if the organization should be confident that the system as designed meets all ISO 9001:2015 requirements prior to the first registration audit and once every three years as re registration comes up. Part one consists primarily of evidence based questions which confirm the conformity of the system, There are some BP (best practice) questions which will help to better evaluate the level of effectiveness of the system and there are AP (audit process) questions designed to help the auditor the gather data which can be used later in the audit to make the audit more effective.

PART 2

Part 2 covers 13 selected generic processes each with its own list of questions. Each list has its own Alpha numeric numbering. The alpha letter is simply to help find specific lists when scrolling through the checklist. Part two also consists primarily of evidence based questions which confirm the conformity of the system. Evidence based questions show the specific clause of the standard which is being assessed at the end of the sentence.

(BP) best practice questions are provided to help the auditor to better evaluate the level of effectiveness of the system. (BP) questions should be seen as the basis for evaluation of the effectiveness of the system and possibly for continual improvement but not as requirements unless the organization specifically includes them. (AP) 'Audit Process' questions are designed to help the auditor in the process of data gathering and audit trails. AP questions prompt the auditor to either gather specific data to be used

later or to use data previously gathered in order to add effectiveness to the audit. (AP) questions are not included in the question numbering sequence.

NOTES – Notes provided are for guidance to the auditor.

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PART 1 SYSTEM OVERVIEW ASSESSMENT

INTRODUCTION

Every organization is a unique entity with its own history, culture and belief systems. To the extent that this culture does not negatively affect the organization's ability to satisfy its customers and achieve its objectives, the Quality Management System (QMS) should reflect that culture.

TOP MANAGEMENT

It is very important that the most senior management of the organization is active and takes a leadership role in the development and ongoing success of the QMS. Depending on the organization and its structure top management may be a single individual or a small group. But it is important that senior management is that person or group that has the power to delegate authority and provide resources for the development and leadership of the QMS (See General clause 1.1 of ISO 9001:2015)

SYSTEM ASSESSMENT

QUESTIONS FOR TOP MANAGEMENT

AP – During your interview with Top Management and members of Sr. Management if a document or record is mentioned – stop the auditee – ask for the document – review it for legibility, availability, proper use and completeness. Look for evidence of poor performance or customer issues. Once satisfied make notes of your evidence and return the document to its owner.

Leadership

1. Is there evidence that senior management has had a strong leadership role in the development of the QMS? (1.1, 5.1)

NOTE: If the organization is upgrading from ISO 9001:2008 it is equally important that senior management get actively involved. Many systems in the past have been developed by consultants, individual managers, or staff employees. These systems usually met the requirements of the standard, but often the system developed did not recognize the unique culture of the organization. As a result, the QMS conformed but was not efficient, nor effective in helping the organization achieve its goals. This Sr. Management involvement is one of the significant requirement changes in the 2015 version of the standard.

2. Is there evidence that 'Top Management' has taken ownership and responsibility for the Quality Policy and for ensuring that it is effectively communicated and understood? (5.1)

NOTE: In most cases, Top Management should be the single individual who commands the top management position as it relates to the operation of the complete QMS. This may be the Owner, The President, the General Manager or the Operations Manager. In non-typical management structures Top Management can be made up of a small group.

3. Is there evidence that 'Top Management' has taken ownership and responsibility for the operation and effectiveness of the QMS? (5.1)

4. Is there evidence that Top Management is seen by the organization to be committed to the effective operation of the QMS and to the stated Quality Policy? (5.1)

5. Is there evidence to show that the QMS has been effectively implemented throughout the organization and that the QMS is integrated into normal business practices of the organization? (5.1)

6. Has Top Management facilitated the development of departmental or process objectives that are consistent with the goals and objectives of the organization? Do objectives facilitate achievement of the requirements of customers and other interested parties? (5.1)

7. Is there evidence that the objectives identified are linked directly to performance measures that are effectively implemented, recorded, analyzed, and reported to Top Management? (BP)

8. Is there evidence that the performance measurement cycle above results ultimately in the two primary goals of customer satisfaction (including statutory and regulatory compliance) and continual improvement? (5.1)

9. Where statutory or regulatory compliance is pertinent to the achievement of the organization's goals, is there evidence of the effective tracking of compliance to statutory and regulatory requirements? (5.1)

10. Is there a formal regularly scheduled activity used by Top Management to promote the Policy and communicate the importance of achieving the objectives of good quality, high levels of customer satisfaction and good customer relations? (BP)

11. Is the structure of the QMS as a whole and as individual processes based upon a Process Approach?

12. Is there evidence that all managers are competent in the use of the Process Approach? (5.1)

NOTE: The Process Approach includes: PLAN – Establish performance objectives based upon customer as well as organizational expectations, RISK – Determine the risks associated with the organizations ability to achieve the performance objectives, DO – Implement the process steps with risk management steps included, CHECK – Review and analyze actual performance against the targets, ACT – Take action where objectives are not met and consider opportunities to improve where objectives are being met

13 Is there evidence of a process which encourages people at all levels of the organization to contribute to the effectiveness of the Quality Management System? (5.1)

14. If there are Suggestion Plans, Open Door policies, or other processes designed to elicit employee contribution, is there evidence that they are working effectively? (BP)

Context of the Organization

15. Is there evidence that shows that senior management has taken an active role in considering risks related to the following during the process of developing the organization's QMS? -

- legal exposure,
- technological issues,
- concerns related to competition,
- market issues,
- cultural considerations (consider employees, the community and customers),
- social and economic impacts,
- environmental concerns.
- risks associated with products and services that the organization currently provides or is planning to provide as well as risks associated with introduction (launch) of future offerings?

Consideration should include international, national, regional and local contexts to the extent that they apply. (4.1)

16. Has the organization identified its strategic goals?(4.1)

17. Have the Strategic Goals been prioritized?(4.1)

18. Has the organization considered internal and external constraints and resource limitations when determining their strategic goals? (4.1)

19. Have all interested parties who's needs may affect the development of strategic goals been identified? (4.1)

20. Have previous commitments, to customers, agents, employees, government or shareholders been considered during the development of strategic goals? (4.1)

21. Have developing technological, legislative or social changes been considered during development of strategic goals? (4.1)

22. Has senior management converted this analysis into a statement of mission, vision or values for the organization? (BP)

23. Has the mission, vision, values been effectively communicated to interested parties? (BP)

Expectations of Interested Parties

24. Has the organization specifically identified who they consider to be interested parties? (4.2)

NOTE: Consider Statutory or Regulatory agencies, Customers, The Local Community.

25. Have the specific requirements of interested parties been identified? (4.2)

26. Have the specific requirements been addressed in appropriate processes? (BP)

NOTE: When the Specific Requirements of interested parties are included within a process they are sometimes referred to as Customer Oriented Processes (COPs). These are typically sub processes included within a process to ensure that a specific requirement has been met. For example, there may be a requirement for a specific safety label to be affixed to shipments of certain materials and not others. The organization may need specific process steps to be applied to the shipping process to ensure that when these special labels are required, they are properly applied.

27. Is there evidence of a process to review changes or additions to the requirements of interested parties and to ensure that changes or additions are effectively implemented? (4.2)

28. Is there evidence of a process to measure the effectiveness of compliance to specific requirements of interested parties? (BP)

29. Has Senior Management identified the specific objectives for the Organization and the role that the QMS is intended to play in the achievement of those goals? (6.2)

30. Has the Management Team identified the risks associated with achievement of the organization's objectives?(6.2)

NOTE: Consider risks related to the size of the organization, the complexity of processes, process performance, interaction between processes, personnel competence and skills in performing specific tasks, lack of sufficient documentation (too much or too little), equipment availability and reliability, effective communications ((between supervision and functions, between management and staff, between one process and another (remember to consider top down and bottom up communications))

31. Has Senior Management evaluated and clearly articulated the needs and expectations of its customers? Has Senior Management determined and evaluated associated risks? (9.1.1)

32. Has Senior Management evaluated and clearly articulated the needs of other relevant interested parties? Has Senior Management determined and evaluated associated risks? (9.1.1)

Customer Satisfaction

33. Is there evidence of an effective process for determining customer perception as to the organization ability to meet customer expectations? (9.1.2)

NOTE: The purpose for determining customer perception is to find out and evaluate the customers views and opinions of the organization. Customer perception can be determined through the use of surveys, customer provided performance evaluations, market analysis, compliments, warranty claims, dealer reports, contact feedback sheets, secret shopper methodologies, etc. The essence of determining customer perception is to determine where your organization stands with respect to the three qualities.

Quality Policy

34. Has Top Management clearly defined documented and communicated a Quality Policy which is consistent with the goals and objectives and stated mission of the organization? (5.2.1)

35. Does the Quality Policy include a commitment to meet appropriate requirements of customers, stakeholders and ISO 9001: 2015? (5.2.1)

36. Does the Quality Policy contain a commitment to continual improvement? (5.2.1)

37. Is the Quality Policy documented and prominently located where it is easily seen by employees and visitors? Where management determines that it is appropriate, is it available to other interested parties or the public? (5.2.2)

38. Is there evidence that actions are taken to ensure that the employees of the organization understand the intent of the policy and how it should affect their functions? (5.2.2)

NOTE: It is neither required nor intended that employees be able to recite the Quality Policy. It is important that everyone in the organization is able, in their own words to describe what the Policy says and what it means to their job functions.

NOTE: From this analysis by management an outline can be developed that identifies specific clauses of the standard that should have extra attention in specific processes. This should become an important consideration in the design of the organization's QMS.

Determining the scope

39. Has the organization developed and documented the Scope of the QMS? (4.3)

NOTE: Scope includes, locations including remote sites, product lines covered by the system, Standards included, industry codes of

practice to which the organization subscribes and requirements of relevant interested parties.

40. Where the organization has determined that a clause or sub-clause of this standard does not apply and is not covered, has the organization specifically determined the justification for why the clauses concerned cannot be applied? (4.3)

NOTE: The requirement for documenting exclusions in the Scope no longer exists but Clauses can still only be excluded if they CANNOT be applied

Quality Management System

41. Has the organization identified the processes needed in order to achieve, organizational, customer and interested party requirements including processes that are outsourced? (4.4) (8.4)

42 Has the organization identified the sequence of the processes, from initial product or service development to the final delivery and post-delivery activities? (4.4)

43. Has the organization identified the interdependency of processes? (4.4)

NOTE: Often organizations use a Process Map to achieve the three questions above, however this is not a requirement and other means

can be used.

44. Has the Organization effectively identified the inputs and outputs required for the effective operation of each process? (4.4)

45. Has the Organization effectively identified the performance indicators, the measurement methods to be used, the targets to be achieved and the method of analysis and reporting on these measurements, for each process? (4.4) (9.1)

46. For each process, has the organization identified the human resources necessary, the number of persons, their required competency levels and the responsibilities, authorities and accountabilities necessary for effective operation and control of the processes? (4.4 , 7.1)

47. Has the organization identified the tools, materials and equipment necessary for the effective operation of each process? (4.4)

48. Has the organization put in place methods to ensure that tools, equipment and materials provided are adequate to do the function required, available when and where needed, and are effectively maintained? (4,4)

49. Is there evidence that the organization has effectively determined risks, opportunities and constraints related to the resources provided and to the operation of each process? Is the need for outside resources part of this analysis? (4.4, 6.1, 7.1, 8.4)

50. In evaluating the risks associated with each process has the organization effectively insured that the process can achieve its intended results? (6.1)

51. Has the organization included steps designed to prevent or reduce undesired results and to identify opportunities to improve results? (6.1)

52. Is there evidence of a process which monitors the effectiveness of the problem reduction actions and the improvement actions taken; and where actions are not effective does the process require additional steps as necessary? (6.1)

53. Has the organization determined what QMS information will be communicated internally and externally? To whom? When? How? (7.4)

Objectives

54. For each process, have objectives been identified that are consistent with the Mission of the organization, the strategic goals of the organization and the stated Quality Policy? (6.2)

55. Where there are functions of the system which require the effective coordination of combined processes, are there appropriate

processes, methods and measurable objectives identified? (6.2)

56. Are all objectives 'objective' in nature – not subjective? (BP)

57. Do all measurements have targets identified? (6.2, 9.1.1)

58. In determining targets for measurements have the following been considered? (6.2, 9.1.1)

- What needs to be accomplished? By when?
- Is success achievable?
- Have sufficient resources been applied?
- Have responsibilities been identified and communicated?
- How will performance be evaluated?

59. Are all process measurements monitored, reported to management and changed or replaced as the needs arise? (6.2)

60. Are all appropriate measurables and their status effectively communicated within the organization and where appropriate with other interested parties? (6.2)

NOTE: Some notes on effective performance measurement:

- Performance measurements work best when they work in pairs. Consider if there is only one measurable and it measured quality what would happen? Chances are the quality would be very good, but productivity may slow to a crawl. Hence we measure quality and productivity.

- Combining measurements into formulae is often ineffective. Because causal factors are hidden in the formula, deficiencies when they are identified will require further analysis in order to determine cause. Simple one activity-one measurement is much more effective. This usually means many more measurable, but in a modern software based world this is a simple problem to address

- Reading and analyzing measurements is often negatively affected by formats that are too complex. Where possible charts provide the best information, but complex charts and multiple random colors make analysis of charts more time consuming. Simple charts with one measurement with a simple RED (Bad)/YELLOW (Marginal)/GREEN (Good) color scheme makes analysis simple and quick.

- Spreadsheets are often less effective as performance measurements, because they don't show trends.

- Finally consider the difference between operational measurements ie: the measure of things and time vs business measurements ie: the measure of money. While measurements obviously have to monitor the financial wellbeing of the organization, this is best done by the finance department using business measurements. In an operational environment often direct measurement of activities, things and time is more effective.

61. Is there documented evidence that performance is monitored, data is gathered, data is analyzed, data is reported, data is reviewed, corrective, preventive and/or improvement actions are determined

and implemented and that the output of this cycle is evidence of customer satisfaction and improvement to the QMS? (9.1.1)

62. Is there evidence that measurements are performed effectively throughout the system? (9.1.1) Consider:

- What is measured
- Where measurements are made
- Measurement methods
- Frequency of measurements
- Sample sizes
- Documentation and Recording methods
- Analysis, evaluation and reporting

63. Does evidence show that there is sufficient and effective measurement information to effectively monitor and control: (9.1)

- Product Conformity?
- Process efficiency and effectiveness?
- Customer Satisfaction?
- Suppliers of goods or services to the organization?
- The overall effectiveness of the QMS?

64. Is there evidence that the performance information collected and analyzed is reported to top management through an effective management review process? (9.1)

65. Is there evidence that the output of analysis of the above performance data is used to drive corrective and improvement activities? (9.1)

Management Review

NOTE: There is no requirement for a meeting called 'Management Review'. Because of this misunderstanding many organizations have found themselves with a redundant, non-value adding meeting. The requirement is for a meeting that does management review. This meeting might be called a 'Monthly Performance Meeting' a 'Staff Meeting', a 'Key Performance Indicator' meeting, an 'Operations Meeting' etc. In addition the requirements of the management review meeting may be accomplished in multiple meetings provided that Senior Management is involved in the meetings and records are kept.

66. Do meetings determined to be used for management review actively involve top management? (9.3)

67. Are meetings determined to be used for management review scheduled on a regular bases and is their frequency sufficient to ensure that issues are identified to top management in a timely

manner so that negative trends can be addressed before they become serious issues? (9.3)

68. Does the meeting or multiple meetings determined to meet the requirements of management review collectively cover all of the following:

- Status of actions from previous meetings?
- Status of internal and external issues determined by management to be relevant to the organizations objectives or strategic direction?
- Information relate to performance trends
- Information related to product conformity?
- Information related to process performance and conformity?
- Information related to corrective action status?
- Information related to monitoring and measurement?
- Information relate to internal audit status and results?
- Information related to customer satisfaction and dissatisfaction?
- Information related to external providers (suppliers)?
- Information related to the adequacy of the QMS?
- Information related to adequacy of resources?
- Information related to the status of programs or projects under development?

NOTE: Not all activities have to be on the agenda of every meeting. Different activities listed may be handled on different frequencies. The important point is that each item is reviewed at a frequency that will effectively provide timely feedback to management

69. Is there evidence that over appropriate frequencies, all required activities are covered? (9.3)

70. Is there evidence that the output of management review provides for:

- Improved product quality?
- Improved process performance?
- Improvements in the function of the QMS?
- Provision of adequate resources to the various functions and processes of the QMS?

71. Is there adequate documentation to show that all required subjects are covered, (see 68) that appropriate corrective actions have been taken and that there is evidence of general product, process and systems improvement? (9.3)

Changes

72. When changes to the QMS have been made, is there evidence that; (6.3, 8.5.6)

- there was a defined and communicated plan for the implementation of the changes?
- the need for additional or different resources was considered?
- changes or revision of responsibilities, authority or accountability was considered?

73. Where documentation changes and additions made available at the time of the implementation of system changes? (BP)

74. Was an Internal Audit activity used to verify the effective implementation of the changes? (BP)

Responsibility, Authority, and Accountability

NOTE: Accountability is NOT included in the ISO 9001 2015 requirement. I have include it here for clarification. There is a great deal of literature stating that Responsibility and Accountability are interchangeable and that therefore there is no need for both words. This makes for a great discussion for academics and theorists, but for the purposes of this guidebook, I am going to take a much more pedestrian viewpoint. We take responsibility for actions and accountability for results. Everyone can be responsible for satisfying the customer, but if everyone is accountable for customer satisfaction, then no one is.

75. Has the organization's management clearly defined the responsibilities, levels of authority and specific accountability for

each job function? (5.3)

76. Are employees fully aware of their responsibilities, authority levels and accountability in the fulfillment of their jobs? (5.3)

77. Are there specific assignments for: (5.3)

- Assurance that the QMS conforms to requirements
- Monitoring the operation of the QMS and ensuring the integrity of the system when changes are planned or implemented?
- Ensuring that processes provide their intended output?
- Reporting the performance of the QMS to Top Management?
- Promoting customer focus?
- Effective operation of each specific process?
- Providing the intended output to customers?

Resources

78. For each QMS process, has the organization determined overall resource requirements needed in order to achieve customer requirements as well as requirements of other interested parties? (7.1.1, 7.1.3, 7.1.4)

Consider:

- Space
- Lighting
- Other utilities
- Temperature and Humidity
- Ergonomics and Fatigue
- Equipment (including; hardware and software)
- Tools
- Information
- Communication systems
- Direction and supervision
- Security and safety
- Employee interaction
- Transportation equipment
- Value added use of floor space (BP)
- Lean technologies and methods (BP)
- Integrated processes with customers or suppliers (BP)

79. For each QMS process, has the organization considered the work environment, such as cleanliness, noise, safety hazards, crowding, lighting etc. needed in order to achieve customer

requirements as well as requirements of other interested parties?
(7.1.4)

Human Resources

80. For each QMS process, has the organization determined manpower requirements needed in order to achieve customer requirements as well as requirements of other interested parties?
(7.1.2)

NOTE: Are there the right number of people with the right skills, competence and training?

81. Has the manpower analysis included the need for human resources from outside the organization? (7.1.2)

82. For each QMS process, has the organization determined the level of competence necessary for each person conducting work within the process? (7.2)

83. Upon entering the workforce of the QMS is the employee's level of competence specifically evaluated? (7.2)

84. Is there an established, documented process for introducing employees to new positions? (BP)

NOTE: This requirements applies both to employees starting work with the organization and for employees moving to a new function or a new department within the organization.

85. Where an Employee's competence level is less than desired in a specific function of their job, is there a process to: (7.2)

- determine what remedial training or development is required?
- provide the required training or development within an appropriate time frame?
- re-evaluate the employees competence after the training/development is complete?

86. Are records available of: (7.2)

- employee competence requirements and status?
- training/development planned and completed?

87. Are employees aware of: (7.3)

- the content and intent of the organization's quality policy?
- objectives related to their functions?
- their contribution to the achievement of organizational objectives, customer focus and achievement of customer satisfaction?
- the benefits of improved quality performance?

- the potential implications that could result from nonconformities in their work?

Support Equipment

88. For each QMS process, has the organization determined equipment and facility requirements needed in order to achieve customer requirements as well as requirements of other interested parties? (7.1.3)

89. Has the equipment analysis included the need for outside resources? (7.1.3)

90. Has the analysis considered as appropriate: (7.1.3)

- Buildings?
- Utilities?
- Hardware?
- Software?
- Transportation equipment?
- Communication equipment?
- Communication and IT technology?
- Value added use of floor space? (BP)

- Lean technologies and methods? (BP)
- Integrated processes with customers or suppliers? (BP)

91. Are there records available to show that equipment is effectively maintained and repaired? (BP)

92. Do records show that maintenance of equipment happens prior to breakdown events (Preventive Maintenance) not simply when equipment fails? (BP)

93. Does equipment maintenance include: (BP)

- processing equipment,
- software,
- IT equipment,
- Trucks, transportation and materials handling equipment

94. Is there evidence of a process to ensure capability of new equipment as part of the procurement process? Does evidence show that equipment can actually perform the functions required at or better than the claims of the supplier? (BP)

Measurement Equipment

95. Is there evidence of a process to ensure the availability of measuring equipment capable of ensuring valid and reliable measurement results? (7.1.5)

96. Where required either by the nature of the product or by customer expectation, does evidence show that measuring equipment is: (7.1.5)

- Identified with unique identification
- Shows calibration status
- Maintained in a good state of order, cleanliness and repair
- Is available when, and where needed

97. Are records of inspection equipment controls (calibration controls) complete and do they show that a valid and reliable measurement system has been maintained? (7.1.5)

Resources

Documentation

98. For each QMS process, has the organization determined the documentation requirements needed in order to achieve customer requirements as well as requirements of other interested parties? (7.4)

99. Do performance records for the process indicate that the amount and type of documentation available is sufficient for the effective operation and control of the process? (7.5)

Creation and Revision of Documents

100. Is there evidence of an effective method of identifying documents and records? (7.5)

NOTE: Identification may include a date, signature, reference number, file number, etc. The method must ensure that the document cannot be confused with a previous or subsequent version of the same document or record.

101. Where necessary is format controlled? (7.5)

NOTE: While any format or medium can be used (ie paper, electronic, audio, video etc.) where a specific format is required, by procedure or inherent need, the format must be controlled.

102. Is there evidence that shows that when documents are created or revised, there is an effective process for approval or re-approval? (7.5)

Control of Documents

103. Are documents needed during the process readily available to the people who need them? (7.5)

NOTE: Readily available is dependent upon the situation. Having a recipe readily available for a Master Chef has a different expectation than having a portable defibrillator readily available to a Paramedic.

104. Are documents and records effectively stored and protected from; loss, loss of confidentiality, improper use, water damage, or deterioration? (7.5)

105 Has the organization effectively addressed distribution, access, retrieval and use of documents? Does evidence show that current controls are effectively implemented and effective in practice? (7.5)

NOTE: Access can mean permission to view information or permission to have a document under personal control or authority to use or modify a document.

106 Were all documents that were verified during the assessment legible, stored effectively and available within a reasonable amount of time considering the type and use of the document? (7.5)

107. Is there evidence that documents verified during the assessment have been effectively managed for changes? (7.5)

108. Is there a process for disposal of records? Does it comply with Statutory, Regulatory Internal Organization and /or Customer requirements? Do records show that disposal is effectively implemented? (7.5)

109. Is there evidence of an effective process for identification of documents of external origin which need to be controlled? (7.5)

NOTE: If an undetected change to an external document could have a detrimental effect on the process then control of the revision of that document should be seriously considered.

110. Is there evidence that shows that documents of external origin determined to need control are in fact effectively controlled? (7.5)

NOTE: The organizations determines whether a document of external origin needs to be controlled, However the auditor must make an independent determination of risk associated with NOT controlling the document before acceptance of the organization's process.

Operations Planning

111. Has the organization defined at each processes the activities needed in order to achieve customer product requirements? (internal

and external customers) (4.4, 8.1)

112. Has the organization identified the interdependency of processes needed for effective product or service realization? (4.4, 8.1)

113. Has the Organization effectively identified the inputs and outputs required for the effective operation of each process? (4.4, 8.1)

114. Has the Organization effectively identified what performance indicators will be used and when, the measurement methods to be used, the targets to be achieved and the frequency and method of reporting on these measurements, for each process? (4.4, 8.1) (9.1)

115. For each process, has the organization identified the human resources necessary, the number of persons, their required competency levels and the responsibilities, authorities and accountabilities necessary for effective operation and control of the processes? (4.4 , 7.1, 8.1)

116. Has the organization identified the tools, materials and equipment necessary for the effective operation of each process? (4.4. 8.1)

117. Has the organization put in place methods to ensure that tools, equipment and materials provided are adequate to do the function

required, available when and where needed, and effectively maintained? (4.4, 8.1)

118. Is there evidence that the organization has effectively determined risks, opportunities and constraints related to the resources provided and to the operation of each process? Is the need for outside resources part of this analysis? (4.4, 6.1, 7.1, 8.1)

119. In evaluating the risks associated with each process has the organization effectively assured that the process can achieve its intended results? (6.1, 8.1)

120. Has the organization included steps designed to prevent or reduce undesired results and to identify opportunities to improve results? (6.1, 8.1)

121. Is there evidence of a process which monitors the effectiveness of the preventive actions, reduction actions and the improvement actions taken and where actions are not effective takes additional steps as necessary? (6.1, 8.1)

122. For each operation step in the product (service) realization process, has the organization identified; (8.1)

- the specific product (service) criteria associated with the process step?

- the risks related with the achievement of product (service) criteria at each process step?

- appropriate equipment for effective operation at each process step?
- appropriate controls to address each risk? (product conformity, process capability, equipment, calibration, protection, safety and security controls)
- appropriate records to provide evidence of product (service) conformity?

NOTE: Product requirements include customer specified requirements, statutory and regulatory requirements and other requirements identified by the organization in addition to customer designated or design related product requirements.

123. Is there a document (traveler, product /process plan, control plan, work flow, job order, formulary, etc.) that is the output of the above planning process which will ensure the positive control of the product (service) realization process? (8.1)

124. Is there evidence that the controlling document provides sufficient information and control to ensure products or services that conform to requirements? (8.1)

125. Is there evidence that an effective change process is applied should the requirements for the product (service) change? (8.1)

QUESTIONS FOR THE PRODUCT DESIGN MANAGER

Design of Product

NOTE: This section is applicable to organizations that create new products for offer to customers. New products can include the development of new hardware, new software, new services, new recipes, etc. An organization does not design products when the requirements of the product or service are wholly defined by the customer or other interested party. In some industries the customer and supplier cooperate in the development of new product. In these situations the organization should include Clause 8.3 in their Quality Management System, focusing on those aspects and functions within the requirements that are provided by the organization.

For organizations that only design the process for construction or production of product or delivery of a service go to 'Design of Process' (Question 138)

126. Is there a product design process described? (8.3)

NOTE: Depending on the complexity of the design process this process can be a simple process flow in bullet form or a process flow diagram, or a procedure or a manual or manuals of procedures.

127. Does the product design plan identify stages of the process that effectively takes the process from initial concept to a completed, defined, verified and validated product or service, ready for provision to the customer? (8.3)

128. Where the design process include prototype development is this activity fully planned? (8.3)

NOTE: Questions 116 – 124 should be considered as they apply to steps in the prototype development process where prototype development applies.

129. Does the process include: (8.3)

- A timeframe for each stage and for completion of the design?
- Interactions between various functions during the design process?
- Responsibilities, Authority and Accountability for functions and tasks included in the design process?
- Inputs, outputs and key deliverables for each stage?
- Necessary equipment to be used at each stage?
- Verification of outputs at each stage and for completion of the design process?
- Equipment to be used for verification and test processes to be used (where applicable)?
- Validation where applicable during the design process and at the conclusion of the design process?
- Review by upper management at prescribed intervals?

130. Do design inputs include: (8.3)

- Desired characteristics of the product,
 - oDimensional
 - oFunctional
- Functional performance requirements,
 - oExpectations related to target market
 - oAmount of functional control by the user
 - oExpectation related to functional environment
- Statutory and regulatory requirements,
- Codes of practice or other requirements to which the organization subscribes,

131. Are the input requirements adequate, complete, clear and unambiguous? (8.3)

132. Where conflict occurs between the input requirements, are they effectively resolved prior to moving to subsequent phases of the design process? (8.3)

133. Is there exit criteria identified for each stage of the design process? (8.3)

134. Is there evidence to show that exit requirements at each stage of design are verified and validated to meet the specified exit criteria

prior to the design process moving into the next stage including sufficient oversight by management prior to final release of product design? (8.3)

135. Where exit criteria are not met is there effective subsequent activities to ensure that criteria are ultimately achieved? (8.3)

136. Where there are changes to the design, is there evidence of an effective process for: (8.3)

- Review of the required change?

- oTo determine if the change requirements are fully understood?

- oTo ensure that resources including timeframe are sufficient to accommodate the change?

- oTo determine the risks associated with the change?

- oTo determine if the change is feasible?

- Determination of change feasibility and the ramifications and risks related to changing or not changing?

- Planning for the implementation of the change, including:

- oEffective documentation of the change?

- oEffective communication of the change to all necessary parties?

- Verification of the effective implementation of the change?

- Validation of the implementation of the change?

137. Is there documented evidence of the implementation of the change? (8.3)

QUESTIONS FOR THE PROCESS DESIGN MANAGER

Design of Process

138. Is there an effective process design process? (8.3)

NOTE: The process design activity is a process to determine how a product will be produced or how a service will be delivered. This activity can include everything from the design of a fully automated, computerized manufacturing line for semi-conductors, to determination of the layout and the number of check-out counters required in your grocery store. While not all organizations design product, the need for process design is almost universal.

139. Does the process design plan identify stages of the process that effectively cover all of the steps from initial concept to an implemented, verified and validated process ready to provide products or services to the customer? (8.3)

140. Does the process include: (8.3)

- A timeframe for each stage of the process design?
- Interactions between various functions during the design process?

- Responsibilities, Authority and Accountability for functions and tasks included in the process design?
- Inputs, outputs and key deliverables for each stage?
- Necessary equipment to be used at each stage?
- Verification of outputs at each stage verification for completion of the development process?
- Equipment to be used for verification and test (where applicable)?
- Validation where applicable during the design process and at the conclusion of the design process? such as; run-at-rate, test runs, dress rehearsals, etc.
- Review by upper management at prescribed intervals and at the conclusion of the design process?

141. Do process design inputs include: (8.3)

- Required methods needed to ensure that required characteristics of the product will be attained,
 - oDimensional
 - oFunctional
- Performance expectations for the process such as:
 - oQuality Standards,
 - oDelivery Timing,
 - oCycle times,
 - oprocess speeds,

o costs,

o error rates,

o FIFO expectations,

o 5S requirements,

o Lean Technology expectations

- Statutory and regulatory requirements,

- Codes of practice or other requirements to which the organization subscribes,

142. Are the input requirements adequate, complete, clear and unambiguous? (8.3)

143. Where conflict occurs between the input requirements, are they effectively resolved prior to moving to subsequent phases of the process? (8.3)

144. Is the customer involved in resolution of input conflicts as appropriate?

145. Is there exit criteria identified for each stage of the design process? (8.3)

146. Is there evidence to show that exit requirements at each stage of process design are verified and validated to meet the specified exit criteria prior to the design process moving into the next stage? (8.3)

147. Where exit criteria are not met is there effective subsequent activities to ensure that criteria are ultimately achieved? (8.3)

148. Is there a formal process with Sr. Management involvement and oversight to Validate the process design's ability to meet all customer as well as organizational and other interested party's requirements prior to first delivery to customers? (BP)

NOTE: This validation may be in the form of Beta Testing, Run at Rate, Rehearsal, Peer Review, etc. But the process for evaluation and acceptance should be determined by and approved by Sr. Management. In addition Sr. Management should sign off on the final approval.

149. Where there are changes to the design, is there evidence of an effective process for: (8.3)

- Review of the required change?
 - oTo determine if the change requirements are fully understood?
 - oTo ensure that resources including timeframe are sufficient to accommodate the change?
 - oTo determine the risks associated with the change?

oTo determine if the change is feasible?

- Determination of change feasibility and the ramifications of changing or not changing?

- Planning for the implementation of the change, including:

- oEffective documentation of the change?

- oEffective communication of the change to all necessary parties?.

- Verification of the effective implementation of the change?

- Validation of the implementation of the change?

150. Is there documented evidence of the implementation of the change? (8.3)

NOTE: In many cases it is advisable for the date and time of the implementation of the changes to be included in documentation. This is mandatory where product traceability is a requirement.

Requirements for products or services

151. Is there evidence of effective communication systems between the organization and the customer related to: (8.2)

- Product or service quality

- On-time delivery

- Customer service
- Customer Quality System requirements
- Customer identified special needs or special characteristics of the product
- Contract, order or product changes
- Handling of customer owned property
- Planning and handling of contingencies
- Solicitation of customer perceptions about the organization
- Customer feedback and corrective action

152. Is there evidence that product (service) requirements are effectively reviewed to ensure that: (8.2)

- All requirements specified by the customer can be met, including packaging, delivery and post delivery requirements
- Requirements not identified by the customer but necessary for the proper operation of the product (service) can be met.
- Statutory and Regulatory Requirements can be met.

153. Where there are no documented requirements provided by the customer, is there evidence of an effective process for the organization to ensure that they have all of the information necessary to evaluate their capability to achieve customer expectations? (8.2)

154. Is there an effective process to ensure that the organization can achieve new or changed requirements before the organization commits to the new requirements? (8.2)

155. Does evidence indicate that all issues related to product and order or contract requirements are resolved prior to acceptance by the organization? (8.2)

Understanding the needs of interested parties

156. Prior to producing product or providing services, has the organization specifically identified who they consider to be interested parties for that product? (4.2)

NOTE: Consider Statutory or Regulatory agencies, Customers, The Local Community.

157. Have the specific requirements of interested parties been identified? (4.2)

158. Have the specific requirements been addressed in appropriate processes? (BP)

NOTE: When the Specific Requirements of interested parties are included within a process they are sometimes referred to as Customer Oriented Processes (COPs). These are typically processes or sub processes needed to ensure that a specific requirement has been met. For example, there may be a requirement for a specific safety label to be affixed to shipments of

certain materials and not others. The organization may need specific process steps to be applied to the shipping process to ensure that when these special labels are required, they are properly applied.

159. Is there evidence of a process to review changes or additions to the requirements of interested parties and to ensure that changes or additions are effectively implemented? (4.2)

160. Is there evidence of a process to measure the effectiveness of compliance to specific requirements of interested parties? (BP)

QUESTIONS FOR THE MANAGER OF PURCHASING

Purchasing

156. Does the organization purchase: (8.4)

- Products or services that are integrated into the organization's products or services for delivery to their customer?
- All or part of a service which is provided to the customer on behalf of the organization?
- Delivery or post-delivery activities subsequent to the delivery of the organizations product that is part of the product or service that the organization agreed to provide?

Note: If any of the above apply then purchasing requirements as defined below apply.

157. Is there evidence of an effective process by the organization to evaluate and select suppliers for activities identified in 156? (8.4)

158. Where the customer specifies suppliers of product or service which will be integrated into their product by the organization, is there evidence that the organization; ? (8.4)

- Uses the required suppliers,
- Maintains effective control over those suppliers

159. Is there an effective process to monitor and measure the effectiveness of all suppliers' ability to provide products or services which consistently meet the expectations of both the organization and their customers? (8.4)

160. Is there evidence of a process to determine risks associated with the products or services provided by each supplier and are these risks taken into consideration when establishing supplier controls? (8.4)

161. Is there evidence that supplier controls include (as applicable): (8.4)

- Selection criteria?

- On-going performance related to quality of products or services provided?
- On-going performance related to scheduled delivery of products or services provided?
- Achievement of statutory or regulatory compliance?
- Other criteria specific to the organization's goals and objectives?

162. Do records show that suppliers as described above are currently achieving the organization's defined criteria? (8.4)

163. Where expectations are not being met by the supplier is there an effective process in place for taking appropriate action in order to achieve acceptable results? (8.4)

164. Do records show that actions taken have been effective? (8.4)

165. Is there evidence of effective verification that delivered products or services meet expectations as agreed upon between the supplier and the organization? (8.4)

166. Is there evidence that suppliers of products or services receive clear unambiguous and consistent information which describes the product or service requirements as well as system requirements, statutory and regulatory requirements? (8.4)

NOTE: System requirements are often contained in a customer provided supplier quality manual or similar document or by contract. These documents provide detailed requirements for required inspection, documentation, testing, statistical analysis, packaging, employee qualification expectations, quality systems or standards to which suppliers are expected to conform, supplier roles in corrective action processes, supplier roles in continual improvement processes and expectations for customer verification of product or verification of supplier systems at the supplier's premises,.

QUESTIONS FOR THE MANAGER(S) RESPONSIBLE FOR THE PRODUCT REALIZATION PROCESS

Provision of Products or Services

NOTE: Provision of products or services, also known as product or service realization is the process of transforming raw material and customer expectations into finished products. The standard requires documentation which describes the requirements of the product and documentation that describes the steps in the process required to transform input into output. The amount of documentation, the format of the documentation and the amount of detail required in the documentation should be determined by the complexity of the product, the complexity of the process and the competency levels of the people doing the work.

Product descriptions are generally in the form of drawing, blueprints, specifications, diagrams, agreements, contracts, etc.

Process descriptions are most often in the form of process flow diagrams, travelers, work instructions, or work orders.

167. Is there documentation that describes the steps in the process that transforms input into output? (8.5)

168. Does evidence show that the process description includes:

- all necessary process activities (process steps),
- documentation and communications from process step to process step
- inspections, checks or verifications,
- movement from process step to process step,
- storage between process steps,
- final packaging, storage and delivery

NOTE: The process description should trace the realization of the product from the start of the process such as initial receipt of the raw material or information through to final delivery of the product or service. Where there are post-delivery activities which must be done, they too should be included.

169. Is there evidence of documentation which describes the characteristics of the product? (8.5)

170. Is this information available to those persons who need the information? (8.5)

QUESTIONS FOR FRONT LINE SUPERVISORS

(Consider sampling two or three supervisors. Base your sample on evidence gathered when looking at process performance. In other words if a particular supervisors area was where the cause of a customer complaint was found, then you pick that supervisor's area for your audit)

For Each Step of the Realization Process

171. Is there evidence that the product information available to the process operator is sufficient to ensure that all expectations of the particular job will be met? (8.5)

172. Does the operator have sufficient information as to how the work is to be done? (8.5)

173. To the extent that they apply to the individual job, does the operator have sufficient information about: (8.5)

- Safety practices?
- Environmental controls and procedures?

- Quality controls and procedures? (8.6)
- Related statutory or regulatory controls or procedures?
- Material handling requirements?

174. Is there evidence available that shows that before starting the job, the operator had;

- All information necessary?
- All tools, instruments, gages necessary?
- All required training and qualifications necessary?

175. Is there evidence that before work was begun, the work area was purged of materials from previous jobs which could cause defects if it got mixed with current required materials?

NOTE: This requirement is not only a manufacturing or production issue. It included paperwork, documents or records from different jobs being mixed or misfiled. It can include ingredients for one recipe being inadvertently put into a different recipe. I.e.; using salt instead of sugar because someone left the salt in a bowl on the counter.

176. Is there evidence that the operator is following described process steps as defined? (8.5)

NOTE: The extent of operator instructions (Work Instructions) necessary is a function of employee competence, complexity of the task and risks associated with potential errors.

177. Is there evidence that the operator has completed all inspections, checks, or verifications defined in their instructions? (8.5) (8.6)

178. Is there evidence that the operator is competent to do all work included in their job, including, inspections, tests, verifications and documentation? (8.5)

NOTE: Have the operator check a part while you observe.

179. Do tests and inspections include verification of the process as well as verification of the product? (8.5) (8.6)

180. Where product verification cannot be conducted on finished product is there evidence of sufficient controls of the process to ensure conformance of the product? (8.5) (8.6)

NOTE: While the standard requires control of the process when control of the product cannot be done, best practice is to always control the process and use controls on product as a validation if necessary. Effective use of Statistical process control could in most cases negate the need for product control.

181. Is there evidence that the operator knows and follows steps to handle, identify and report, nonconforming material, when it is found? (8.5)

182. In situations where the organization produces various products and there is a possibility that products can be mixed, is there evidence of an effective process for identifying product? (8.5)

NOTE: Product can be identified by a part or serial number molded, etched into the part or on a label attached to the part. Identification can be on the container holding the product or identification can be inherently obvious through its location, packaging, or position in the production stream.

Potential nonconformities include: product left on tables which could be erroneously assumed to be an acceptable product. Boxes or containers of parts with no identification. Parts stored without identification. Parts left on or around machines, Unidentified files.

183. Is there evidence that material is clearly identified as to its level of completeness, its quality status (good or bad) and its status in relation to its acceptance for further processing or for shipment? (8.5)

NOTE: In many organizations lack of specific identification that material is not acceptable is accepted as identification that it is acceptable. For this reason material that is unknown to be

acceptable must be identified as unacceptable until such time as acceptability is verified.

184. Where contractually or otherwise required is there an effective process for tracing an individual product through the production process and through to delivery to the customer? (8.5)

185. Is there evidence that the organization has an effective process for the control of property belonging to customers or external suppliers? (8.5)

NOTE: Consider returnable packaging, tools and fixtures, raw materials, prototypes, drawings and specifications, buildings, other intellectual property and personal property. Controls should cover loss, damage, deterioration, loss of confidentiality and should include when and how to inform the owner of the property.

186. Is there evidence that the organization contacts the customer when customer owned property is lost, damaged or destroyed? (8.5)

187. Is there evidence of effective preservation and protection of product during processing, after final processing, during packaging shipping and delivery? (8.5)

END OF THE REQUIREMENTS FOR EACH STEP OF THE
REALIZATION PROCESS

QUESTIONS FOR THE PRODUCT REALIZATION MANAGER

188. Where there are post-delivery activities, are they effectively implemented and effective in practice? (8.5)

NOTE: Post-delivery activities can include warranty services, guarantees, return policies, rebate processes, environmental clean-up after construction, service contracts, recycling services or disposal services. Depending on the complexity of the post-delivery activity, any or all of the requirements of clause 8.5 could apply. Where post-delivery activities include compliance to statutory or regulatory requirements there should be steps to ensure that the applicable requirements are reviewed and understood and that there is a process to monitor changes to those requirements.

189. When there are changes to the process, is there evidence of a planned process? (8.5)

190. Is there evidence of formal approval of changes? (8.5)

191. Is there evidence of effective implementation of changes? (8.5)

192. Is there evidence of verification and validation that the changes was effectively implemented and that planned effects of those changes were achieved? (8.5)

QUESTIONS FOR THE QUALITY MANAGER

Final Approval

193. Is there evidence that all inspections, tests, reviews and qualifications have been completed and results of conformance documented and verified prior to shipment or delivery of products or services? (8.6)

194. Does documented evidence show who was responsible for release of product? (8.6)

Nonconforming Product

195. When nonconforming processes, products or services are identified, is: (8.7)

- The suspect material identified?
- The suspect product or material isolated, quarantined or removed from service such that it cannot be reintroduced into the process flow?
- Are services suspended until such time as nonconformities are corrected and verified to be conforming?

196. Is there documented evidence of an effective process for dispositions of nonconforming materials? (8.7)

NOTE: Disposition can include:

- Use-as-is – This disposition would generally require approval from the customer in the form of a waiver or deviation.
- Rework – This disposition requires a rework instruction that describes the work to be done and inspection after the rework is complete done by someone other than the person who did the rework.
- Repair – This disposition requires the conditions of both of the above dispositions – Customer approval, repair instructions and re-inspection.
- Scrap – The organization must ensure that scrapped material is mangled or mutilated such that it cannot be used for its original purpose.

NOTE: Repair vs Rework.

- Rework is a process which brings the material back to its original expected condition.
 - Repair is a process which modifies the material so that it simulates the original condition and does not deviate from the performance as intended.
- oEG. A hole drilled undersize can be REWORKED by re-drilling the hole to the correct size. A hole drilled oversize can be REPAIRED by plugging the hole with a similar material and re-drilling the hole to the correct size.

197. Is there documented evidence that all product identified as nonconforming is accounted for after disposition and actions are complete? I.e: If 100 parts were rejected, then was the total of parts used, parts repaired, part reworked and parts scrapped 100? (8.7)

Monitoring, Measurement and Evaluation

198. Is there evidence that measurement of product is conducted: (9.1)

- In accordance with proscribed direction
- Using measuring instruments that are under calibration control
- By qualified personnel
- Under controlled environmental and ergonomic conditions where necessary
- Using appropriate sampling techniques
- With appropriate verification and validation of results

Reaction to Nonconformity

199. Is there evidence of corrective action taken in cases of: (10.2)

- Internally identified product nonconformity?

- Internally identified process nonconformity?
- Internally identified QMS (System) nonconformity?
- Customer identified product process or system nonconformity>
- Statutory or regulatory nonconformity?

200. In cases where suspect or nonconforming material is identified is the material: (10.2)

- Identified immediately?
- Removed or segregated from other product such that suspect material cannot be inadvertently reintroduces into production?
- Reviewed to confirm the cause for reject and determine the risks associated with the defect?
- Dis-positioned according to the risks determined? ie.
 - oUse-as-is
 - oRework
 - oRepair
 - oSort
 - oScrap
- Actioned as per the disposition?
- Re-inspected after rework, repair of sort?
- Verified to ensure that all material identified as suspect has been accounted for and has been either returned to the product stream or

has been effectively disposed of?

201. In cases of product, process or system nonconformity: (10.2)

- Has the nonconformity been reviewed for severity?
- Has initial containment action been taken to protect the customer and the organization from the effects of the nonconformity while effective corrective action is taken?
- Has effective investigation taken place to determine the causes of the nonconformity?
- Has the investigation identified all three root causes?
 - oThe root cause of the symptom (The symptom is the condition identified)
 - oThe root cause of the problem
 - oThe systemic root cause
- Has the process implemented effective correction to each root cause?
- Has the corrective action considered mistake proofing techniques as appropriate?
- Has the process identified other situations where the same or a similar nonconformance could happen and considered applying the same actions to those situations?
- Has the process verified that document changes related to the corrective action have been completed and the replacement of outdated documents has been implemented effectively?

- Has Internal Audit been used to validate the full implementation of corrective actions?

202. Is there evidence of effective documentation that shows; the problem identified, the root causes identified, the actions taken, evidence of verification of corrective action and validation of the effectiveness of the corrective action? (10.2)

QUESTIONS FOR THE MANAGER RESPONSIBLE FOR INTERNAL AUDITS

Internal Audit

203. Is there evidence of a process which plans audits of the QMS at prescribed intervals? (9.2)

NOTE: For years organizations have relied on a pre-determined matrix to show their planned intervals. Almost inevitably these matrix based systems have been ineffective and usually deteriorate to a process used only to show external auditors that there is a system in place. A more effective system is possible.

204. Are the audit intervals sufficient to identify negative performance trends before they can deteriorate and become significant issues? (9.2)

205. Is there an audit process which controls the conduct of audits that includes:

- Audit frequency?
- Audit methods?
- Audit scope and objectives for individual audits?
- Audit Responsibilities, Authorities and Accountabilities?
- The type, content, distribution, storage, and access to documentation related to planning, conducting, and reporting of audits?

206. Is there evidence that auditors are selected based upon objectivity, impartiality and lack of conflicts of interest? (9.2)

207. Is there evidence that audits cover:

- Compliance to the organization's QMS?
- Conformity to this International Standard?
- Conformity to the requirements of customer and other interested parties – as determined by the organization?
- Activities and results related to the organization's objectives?
- Activities and results related to process performance to goals and objectives?

208. Is there evidence that effective corrective action is taken when audits identify nonconformities? (9.2)

QUESTIONS FOR THE MANAGER RESPONSIBLE FOR CONTINUAL IMPROVEMENT

Improvement

209. Is there evidence in the management review records of identification of potential improvement opportunities? (9.3)

210. Is there evidence of assignment of responsibility for improvement actions and the monitoring of improvement projects? (9.3)

211. Is there evidence that improvement projects are successfully completed, implemented and verified to have achieved the intended result? (9.3)

212. Is there evidence that when considering improvement opportunities the following are considered: (10.1)

- Improvement through reduction of errors, (Correction)?
- Improvement through incremental change (Kaisen)?
- Improvement through breakthrough (Task Teams)?

- Improvement through creativity (Innovation)?
- Improvement through re-organization (Transformation)?

213. Does improvement evidence show activities targeting:

- Improvement of product?
- Improvement of processes?
- Improvement of the QMS?

214. Is there evidence that as an output of analysis of data inside or outside of the management review process the organization has identified poor performing processes, underperforming processes or opportunities for improvement? (10.3)

215. Is there evidence that defined processes or projects have been initiated as a result of such analysis as described in 213? (10.3)

216. Is there evidence of monitoring of improvement projects by top management? (10.3)

217. Is there evidence of improvement in products, processes or systems as a result of these projects? (10.3)

NOTE: Improvement should show up on charts, databases, or reports as improved product quality, improved process performance, improved system performance, improved customer satisfaction, or improved business performance.

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PART 2 INDIVIDUAL PROCESS ASSESSMENTS

In part two of this checklist the questions in part one will be redistributed and often reworded for assessment of specific processes. This has been done to make the questions more appropriate to scheduled internal audits. In some cases where part one did not provide a specific question clear enough for a specific process a new question has been included. Process Questions are numbered with a specific Alfa prefix different from the 'Q' used in part one.

TOP MANAGEMENT

If the scope of the audit covers only part of an organization, then top management refers to those who direct and control that part of the organization – The Process Owner.

Part 2 Processes include:

'M' Management

"\$" Sales and Marketing

'P' Product Development

'S' Process Development

'H' Human Resources

'B' Purchasing

'I' Quality Assurance

'R' Maintenance

'W' Shipping and Receiving

'IT' Information Technology

'PR' Product Realization (Manufacturing or Production)

'SR' Product Realization (Services and Retail)

'IA' Internal Audit

With the exception of the Management Process, the questions for each process will be divided into two groups. The first group will be questions intended for the owner of the process, while the second set of questions are designed for the people actually doing the work. In smaller organizations of course the owner and the person doing the work may be the same person.

The questions for each process follow the six steps used when auditing to the Turtle Diagram.

Visit systemsthinking.works to get a 'Process Audit Toolkit' which includes the 6 Step Process Audit Turtle and to find other valuable articles related to the subjects covered in this book.

'M'-MANAGEMENT ASSESSMENT

QUESTIONS FOR TOP MANAGEMENT

AP – If a document or record is mentioned during your interview with Top Management and members of Sr. Management – ask immediately to see the document – review it for legibility, availability, proper use and completeness. Look for evidence of poor performance or customer issues. Once satisfied document your evidence and return the document to the manager.

M1. Have Senior Leadership positions within the process changed recently? Whether new or not, has the leader taken a strong leadership role in the maintenance and development of the QMS?
(1.1)

M2. Is there evidence that the Top Management has reviewed the objectives for the Organization and the role that the QMS is intended to play in the achievement of goals?

M3. Has the review considered new risks related to the achievement of the organization's objectives?

NOTE: Consider new risks related to the size of the organization, the complexity of processes, process performance, interaction between processes, personnel competence and skills in performing specific tasks, lack of sufficient documentation (too much or too little), equipment availability and reliability, effective communications (between supervision and functions, between management and staff, between one process and another (remember to consider top down and bottom up communications))

M4. Has Senior Management evaluated and clearly articulated the needs and expectations of the organization's customers? Has Senior Management determined and evaluated associated risks related to new or revised customer expectations?

M5. Has Senior Management evaluated and clearly enunciated the needs of other relevant interested parties? Has Senior Management determined and evaluated associated risks related to new or revised expectations of interested parties including statutory and regulatory bodies?

NOTE: Consider, statutory or regulatory agencies, stockholders, and members (in the case of associations, clubs, etc.),

M6. Has Senior Management evaluated risks associated with products and services that the organization currently provides or is planning to introduce?

M7. Is there evidence that shows that Senior Management has considered risks related to the following during the process of reviewing the organization's QMS? (4.1)

- legal exposure,
- technological issues,
- concerns related to competition,
- market issues,
- cultural considerations (consider employees, the community and customers),
- social and economic impacts,
- and environmental concerns.

NOTE: For the above, consideration should include international, national, regional and local conditions and risks to the extent that they apply.

M8. Has the organization reviewed its strategic goals in relation to the policy, objectives and scope of the QMS?(4.1)

M9. Has the organization considered changes to internal and external constraints and resources when reviewing their strategic goals?(4.1)

M10. Have commitments, to customers, agents, employees, government or shareholders been considered during the review of strategic goals? (4.1)

M11. Has developing technological, legislative or social changes been considered during review of strategic goals? (4.1)

M12. Has the mission, vision and values statements where applicable been considered for revision? (BP)

M13. Has the organization considered new entities that may be considered as interested parties? (4.2)

NOTE: Consider Statutory or Regulatory agencies, New Customers, the Local Community, Mergers and Acquisitions, New Partners, New Regional Markets.

M14. Have changes to the requirements of interested parties or requirements of new interested parties been identified? (4.2)

M15. Have the specific requirements been addressed in appropriate processes? (BP)

NOTE: When Specific Requirements of interested parties are included within a process they are sometimes referred to as Customer Oriented Processes (COPs). These are typically sub processes included within a process to ensure that a specific requirement has been met. For example, there may be a requirement for a specific safety label to be affixed to shipments of certain materials and not others. The organization may need specific process steps to be applied to the shipping process to ensure that when these special labels are required, they are properly applied.

M16. Is there evidence of an effective process to measure compliance and conformance to the specific requirements of interested parties? (BP)

M17. Is there evidence that changes to the Scope of the QMS have been made or should be made? (4.3)

NOTE: Consider new remote sites (warehouses, sales sites, design centers, etc.), new product lines covered by the system, revisions to standards, and changes to industry codes of practice that the organization subscribes to.

M18. Is there evidence that the exclusions to the standard have changed and has the scope been revised?

M19. Have any processes needed in order to achieve, organizational, customer and interested party requirements including processes that are outsourced been changed or revised? If so is there evidence that all associated changes to documentation, training, etc. have been made and the internal audit system has been revised to include the new processes? (4.4) (8.4)

M20. In evaluating the risks associated with each process has the organization effectively assured that the process can achieve its intended outputs? (6.1)

M21. Has the organization done a review to determine what QMS information will be communicated internally and externally? To whom? When? How? (7.4)

M22. Where Top Management or Process Owners have changed, is there evidence that the new 'Management' has taken ownership and responsibility for the operation and effectiveness of the QMS? (5.1)

M23. Is there evidence that Top Management is seen by the organization to be committed to the effective operation of the QMS and to the stated Quality Policy? (5.1)

M24. Is there a formal regularly scheduled activity used by Top Management to promote the Policy and communicate the importance of achieving the objectives of good quality, high levels of customer satisfaction and good customer relations? (BP)

NOTE: Consider 'State of the Union' type presentations, News Letters, 'Town Hall' meetings etc. where management talks directly to every employee rather than 'Chain of Command' communication.

M25. Has Top Management reviewed the Quality Policy to ensure that it remains consistent with the goals and objectives and stated mission of the organization? (5.2)

M26. Is the Quality Policy documented and prominently located where it is easily seen by employees and visitors? Where management determines that it is appropriate, is it available to other interested parties (5.2)

M27. Has the organization's management reviewed the responsibilities, levels of authority and specific accountability for each job function? (5.3)

M28. Has the review of responsibilities considered changes to specific assignments such as: (5.3)

- Monitoring the operation of the QMS and ensuring the integrity of the system when changes are planned or implemented?
- Reporting the performance of the QMS to Top Management?
- Promoting customer focus?
- Effective operation of each specific process?
- Providing the intended output to customers?

M29. Is there evidence that process objectives have been reviewed to ensure that they are consistent with the Mission of the organization, the strategic goals of the organization and the stated Quality Policy? Are there performance measurements applied to each process objective (6.2)

M30. Are all measurements of objectives objective in nature – not subjective? (BP)

M31. Do all measurements have targets identified? (6.2)

M32. In determining targets for measurements have the following been considered? (6.2)

- What needs to be accomplished?
- Is success achievable?

- Have sufficient resources been applied?

M33. Are all measures monitored, reported to management and changed or replaced as the needs arise? (6.2)

M34. Are all appropriate measurements and their status effectively communicated within the organization and where appropriate with other interested parties? (6.2)

AP. Audit Process: Make note of processes with marginal, intermittent or poor performance. Make note of the performance and ask Senior Management about their interpretation of what the reason for poor performance is. If performance results show no significant negative performance ask Top Management what performance they are least happy with and why. Take note.

M35. When changes to the QMS have been made, is there evidence that; (6.3)

- there was a defined and communicated plan for the implementation of the changes?
- the need for additional or different resources was considered?
- changes or revision of responsibilities, authority or accountability was considered?

M36. Were new or revised documents or information made available at the time of the implementation of system changes? (BP)

M37. Was an Internal Audit activity used to verify the effective implementation of the changes? (BP)

M38. Before implementing changes has the organization re-evaluated the risks associated with each process and assured that each process can achieve its intended results? (6.1, 8.1)

M39 Has the organization included steps designed to prevent or reduce undesired results and to identify opportunities to improve results? (6.1, 8.1)

M40. Do meetings determined to be used for management review actively involve top management? (9.3)

M41. Is there evidence that meetings determined to be used for management review happen on a regular bases and that their frequency is sufficient to ensure that issues are identified to top management in a timely manner so that they can be addressed before they become serious issues? (9.3)

NOTE: Remember that there is no requirement for meetings called 'Management Review', there are requirements for meetings that DO 'Management Review'.

M42. Is there evidence that the meeting or multiple meetings determined to meet the requirements of management review collectively cover all of the following:

- Status of actions from previous meetings?
- Status of internal and external issues determined by management to be relevant to the organizations objectives or strategic direction?
- Information relate to performance trends
- Information related to product conformity?
- Information related to process performance and conformity?
- Information related to corrective action status?
- Information related to monitoring and measurement?
- Information relate to Internal Audit status and results?
- Information related to customer satisfaction and dissatisfaction?
- Information related to external providers (suppliers)?
- Information related to the adequacy of the QMS?
- Information related to adequacy of resources?
- Information related to the status of programs or projects under development?

NOTE: Not all activities have to be on the agenda of every meeting. Different activities listed may be handled on different frequencies or in different meetings. The important point is that each item is reviewed at a frequency that will effectively provide timely feedback to management.

AP – Take note of product numbers related to customer complaints. Note performance measures with poor performance. Note equipment associated with poor performance. Note performance charts with marginal trends or performance. Identify people departments or areas of the facility associated with poor performance.

M43. Is there evidence that the output of management review provides for: (9.3)

- Improved product quality?
- Improved process performance?
- Improvements in the function of the QMS?
- Provision of adequate resources to the various functions and processes of the QMS?
- Corrective action to identified issues?

M44. Is there evidence of assignment of responsibility for improvement actions and the monitoring of improvement projects? (9.3, 10.3)

M45. Is there evidence that improvement projects are successfully completed, implemented and verified to have achieved the intended result? (9.3, 10.3)

AP (Audit Process) – Take note of Improvement Projects, specifically recently completed or in-process projects. Keep this data for review when auditing in those areas.

M46. Is there evidence of an effective process for determining customer perception as to whether the organization is meeting their expectations? (9.1)

NOTE: Information related to customer views can include customer satisfaction surveys, data on delivery, products or services quality, market-share, compliments, warranty claims or dealer reports.

M47. Is there evidence from current process performance of: (9.1)

- Conformity of products or services
- Enhanced customer perception
- Effective implementation and operation of the quality management system
- Effective operation of manufacturing processes
- Effective operation of outsourced processes
- Preventive and continual improvement activities
- Effective use of statistical tools and methodologies

M48. Is there evidence and records of an effective process for gathering, recording, maintaining and using organizational

knowledge? (7.1)

AP – Take note of this process. Investigate its effectiveness when auditing Product and Process Development processes.

NOTE: The concept of the learning organization has been popular for some years. With the aging of employees, the rapid changes in technology and rapid changes in the marketplace organizations do not have the time or the resources to learn the same lessons multiple times. Organizations must have systems for capturing best practices and lessons learned.

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‘\$’- SALES AND MARKETING ASSESSMENT

PROCESS SPECIFIC ASSESSMENT

QUESTIONS FOR THE PROCESS OWNER

AP – If a document or record is mentioned during your interview with the process owner – ask immediately to see the document – review it for legibility, availability, proper use and completeness. Look for evidence of poor performance or customer issues. Once satisfied document your evidence and return the document to the manager.

\$1. Has the Organization effectively identified the inputs and outputs required for the effective operation of this process? (4.4)

\$2. Has the Organization effectively identified the performance indicators, the measurement methods to be used, the targets to be achieved and the method of analysis and reporting on these measurements, for this process? (4.4) (9.1)

AP – Is performance evidence provided consistent with the data gathered in discussion with Top Management and in audit planning? Does the process owner's explanation of the causes and actions related to identified issues with performance consistent with those expressed by Top Management? Note if specific job functions or specific equipment is associated with identified issues.

\$3. Has the organization identified the human resources necessary, the number of persons, their required competency levels and the responsibilities, authorities and accountabilities necessary for effective operation and control of this process? (4.4 , 7.1)

AP – Make a Note of the various job titles and how many people work in each. Ask if there are any contract, part time or shared employees working within the process. Ask who the newest employee is who is working within the process. Note the answers.

\$4. Has the organization identified the tools, materials and equipment necessary (including software) for the effective operation of this process? (4.4)

AP – Look closely at equipment identified that may be associated with issues identified earlier. Look closely at maintenance records, repair records etc.

\$5. Is there evidence that the organization has effectively determined risks, opportunities and constraints related to the resources provided and to the operation of this process? Is the need for outside or contract resources part of this analysis? (4.4, 6.1, 7.1, 8.4)

\$6. In evaluating the risks associated with this process has the organization effectively assured that the process can achieve its intended performance? (6.1)

\$7. Has the organization included steps designed to prevent or reduce undesired results and to identify opportunities to improve results? (6.1)

\$8. Is there evidence that the process management monitors the effectiveness of the preventive actions, reduction actions and the improvement actions taken and where actions are not effective takes additional steps as necessary? (6.1)

AP – If improvement projects identified with Top Management or in audit planning are being applied in this process this is the time to investigate their value and effectiveness. Did they get implemented as planned? Are the benefits expected being realized?

\$9. Is QMS information (performance, status, data, information) communicated internally or externally? To whom? When? How? Is dissemination of information effectively controlled? (7.4)

\$10. Is there evidence that the process owner has taken ownership and responsibility for the operation and effectiveness of this process? (5.1)

\$11. Has the owner of the process taken responsibility for process objectives for this process as identified by 'Top Management'? (5.1)

\$12. Is there evidence that the objectives identified are linked directly to performance measures that are effectively implemented, recorded, analyzed, and reported to Top Management? (BP)

\$13. Are all measurements of objectives objective in nature – not subjective? (BP)

AP – Are measurable consistent with those reviewed with Top Management and/or during audit planning? Note that additional measures which feed into those reported to management are acceptable.

\$14. Do all measurements have targets identified? (6.2)

\$15. In determining targets for measurements have the following been considered? (6.2)

- What needs to be accomplished?
- Is success achievable?
- Have sufficient resources been applied?

\$16. Are all measurements monitored, reported to management and changed or revised as the needs arise? (6.2)

\$17. Is there evidence that the performance measurement cycle above results ultimately in continual improvement? (BP)

\$18. Is there evidence that the process owner is competent in the use of the Process Approach? (5.1)

NOTE: The Process Approach includes: PLAN – Establish performance objectives based upon customer as well as organizational expectations, RISK – Determine the risks associated with the organizations ability to achieve the performance objectives, DO – Implement the process steps with risk management steps included, CHECK – Review and analyze actual performance against the targets, ACT – Take action where objectives are not met and consider opportunities to improve where objectives are being met

\$19. Is there evidence of a process which encourages people to contribute to the effectiveness of the Quality Management System? (5.1)

\$20. Is there evidence in this process of the use of Suggestion Plans, Open Door policies, or other processes designed to elicit employee contribution? Is there evidence that they are working effectively? (BP)

\$22. Do employees working within this process understand the intent of the policy and how it should affect their functions? (5.2)

NOTE: It is neither required nor intended that employees be able to recite the Quality Policy. It is important that everyone in the organization can describe in their own words what the Policy says and what it means to their job functions.

An important auditor question is whether the employees believe that top management believes in the Quality Policy. For employer's, actions speak much louder than words.

\$23. Within this process, have responsibilities, levels of authority and specific accountability been defined for each job function? (5.3)

NOTE: Accountability is NOT included in the ISO 9001 2015 requirement. I have include it here for clarification. There is a great deal of literature stating that Responsibility and Accountability are interchangeable and that therefore there is no need for both words. This makes a great discussion for academics and theorists, but for the purposes of this guidebook, I am going to take a much more pedestrian viewpoint. We take responsibility for actions and accountability for results. Everyone can be responsible for satisfying the customer, but if everyone is accountable for customer satisfaction, then no one is.

S24. Are employees fully aware of their responsibilities, authority levels and accountability in the fulfillment of their jobs? (5.3)

\$25. For this process, have objectives been identified that are consistent with the Mission of the organization, the strategic goals of the organization and the stated Quality Policy? (6.2)

\$26. Where there are functions and levels which require the effective coordination of combined processes, are there appropriate measurable objectives identified? (6.2)

\$27. When changes to the process documentation have been made, is there evidence that; (6.3)

- there was a defined and communicated plan for the implementation of the changes?
- the need for additional or different resources was considered?
- changes or revision of responsibilities, authority or accountability was considered?

\$28. Were documentation changes and additions made available to those responsible for implementation at the time of the system change? (BP)

\$29. Was an Internal Audit activity used to verify the effective implementation of the changes? (BP)

\$30. For this process, has the organization determined manpower requirements needed in order to achieve customer requirements as well as requirements of other interested parties? (7.1)

\$31. Has manpower analysis included the need for additional resources from outside the organization? (7.1)

\$32. Has the organization determined the level of competence necessary for each person conducting work within this process? (7.2)

\$33. Upon entering the workforce of the process is the employee's level of competence specifically evaluated? (7.2)

\$34. Is there an established, documented process for introducing employees to new positions? (BP)

\$35. Where an Employees competence level is less than desired in a specific function of their job, is there a process to:

- determine what remedial training or development is required?
- provide the required training or development within an appropriate time frame?
- re-evaluate the employees competence after the training/development is complete?

\$36. Are records available of:

- employee competence requirements and status? (7.2)
- training/development planned and completed? (7.2)

\$37. Are employees aware of:

- the content and intent of the organization's quality policy? (7.3)
- objectives related to their functions? (7.3)
- their contribution to the achievement of organizational objectives, customer focus and achievement of customer satisfaction? (7.3)

- the benefits of improved quality performance? (7.3)
- The potential implications that could result from nonconformities in their work? (7.3)?

\$38. For this process, has the organization determined equipment and facility requirements needed in order to achieve customer requirements as well as requirements of the management and other interested parties? (7.1)

\$39. Has the equipment analysis included hardware and software? (7.1)

AP – Where software is involved , particularly software unique to this process, is there an effective backup system for protecting data? Is backup frequency adequate? Is backup data stored off site or in a safe place where damage to the main system will not also damage the backup?

\$40 Are there records available to show that equipment is effectively maintained and repaired? (7.1)

\$41. Do records show that maintenance of equipment happens prior to breakdown events (Preventive Maintenance) not simply when equipment fails? (7.1)

\$42. For this process, has the organization determined the documentation requirements needed in order to achieve customer requirements as well as requirements of management and other interested parties? (7.4)

\$43. Do performance records for the process indicate that the amount and type of documentation available is sufficient for the effective operation and control of the process? (7.5)

\$44. Is there evidence of an effective method of identifying documents and records? (7.5)

NOTE: Identification may include a date, signature, reference number, file number, etc. The method must ensure that the document cannot be confused with a previous or subsequent version of the same document or record.

\$45. Where necessary is format controlled? (7.5)

NOTE: While any format or medium can be used (ie paper, electronic, audio, video etc.) where a specific format is required, by procedure or inherent need, the format must be controlled.

\$46. Is there evidence that shows that when documents are created or revised, there is an effective process for approval or re-approval? (7.5)

\$47. Are documents needed during the process readily available to the people who need them?

NOTE: Readily available is dependent upon the situation. Having a recipe readily available for a cook has a different expectation than having a portable defibrillator readily available to a paramedic.

\$48. Are documents and records effectively stored and protected from; loss, loss of confidentiality, improper use, water damage, or deterioration? (7.5)

\$49. Has the organization effectively addressed distribution, access, retrieval and use of documents? Does evidence show that current controls are effectively implemented and effective in practice? (7.5)

NOTE: Access can mean permission to view information or permission to have a document under personal control or authority to use or modify a document.

\$50. Were all documents verified during the assessment legible and stored effectively? (7.5)

\$51. Is there evidence that documents verified during the assessment have been effectively managed for changes? (7.5)

\$52. Is there a process for disposal of records? Does it comply with Statutory, Regulatory and /or Customer requirements? Do records show that it is effectively implemented? (7.5)

\$53. Is there evidence of an effective process for identification of documents of external origin which need to be controlled? (7.5)

NOTE: If an undetected change to an external document could have a detrimental effect on the process then control of the revision of that document should be seriously considered?

\$54. Is there evidence that shows that documents of external origin determined to need control are in fact effectively controlled? (7.5)

\$55. Does the process owner have the methods and documentation needed to achieve process objectives requirements? (internal and external customers) (4.4, 8.1)

\$56. Does the process owner understand and support the interdependency of processes needed for effective product or service realization? (4.4, 8.1)

\$57. Does the process owner understand and support the interdependency of processes needed for effective product or service realization? (4.4, 8.1)

JOB SPECIFIC QUESTIONS

AP – Choose employees in each job category for interview. Go back to your notes from the process owner and choose the employees with the greatest risk (New Employees, Contract Employees, Part Time Employees). Ask employees what they are responsible for and what authority they have. Answers should be the same as described by the process owner. Ask employees about their training. Answers should be as described by the process owner.

AP – During interviews, if the employee mentions a document or record – stop him – ask for the document – review it for legibility, availability, proper use and completeness. Once satisfied document your evidence and return the document to the employee.

\$58. Is there evidence of an effective process for communication with the customer during initial stages of contracting work? (8.2)

\$59. Where the customer has specific communication requirements such as portals, web sites, etc., is there evidence that the organization is fully prepared and equipped and with people trained to meet customer expectations? (8.2)

\$60. Does the communication process include the capability to handle contracts or orders, enquiries, changes, customer feedback on the organization's performance? (8.2)

\$61. Is there evidence of a process for the efficient and effective handling of information regarding customer property? (8.2)

NOTE: Consider where applicable, information related to how customer property will be provided, handled, stored, maintained, tracked and ultimately returned.

\$62. Is there evidence of an effective process for definition of the product required by the customer and the product determined to be delivered by the organization? (8.2)

\$63. Where there are differences between the organization's and the customer's definition of the product to be delivered is there an effective process for resolution prior to the organization's final acceptance of the order? (8.2)

\$64. Where the customer provides a detailed requirement, is there evidence of an effective process for review and determination that ALL requirements can be met prior to acceptance of the order? (8.2)

NOTE: Consider systems requirements, inspections, part approval processes, sample submission requirements, special handling or delivery requirements, special documentation requirements, or expectations for customer meetings.

\$65. Is cost of additional requirements added by the customer considered prior to acceptance? (BP)

\$66. In addition to customer requirements, is there evidence that the organization has included in the total requirements specifics determined by the organization, to be necessary for effectively meeting the customer's expectations? (8.2)

NOTE: Consider packaging, handling, protective coatings, safety, statutory or regulatory requirements, industry norms, industry codes of practice.

\$67. Is there evidence that the organization has the ability to fully comply with customer requirements and all product or service claims made by the organization? (8.2)

\$68. Is there evidence of a formal, documented step in the process for the review and approval of proposed work by a responsible person prior to acceptance of the order or submission of a quote? (8.2)

\$69. Where customer requirements are not documented, is there a process which ensures that the organization clearly understands the customer's requirements? (8.2)

\$70. Is there evidence that ALL sales personnel are competent in the organization's product descriptions, capabilities, applications,

statutory and regulatory requirements, safety considerations, etc.?
(BP)

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‘P’- PRODUCT DEVELOPMENT ASSESSMENT

PROCESS SPECIFIC ASSESSMENT

QUESTIONS FOR THE PROCESS OWNER

Product Design and Development

AP – If a document or record is mentioned during your interview with the process owner – ask immediately to see the document – review it for legibility, availability, proper use and completeness. Look for evidence of poor performance or customer issues. Once satisfied document your evidence and return the document to the manager.

P1. Is there a product design or product development process defined? (8.3)

P2. Has the Organization effectively identified the inputs and outputs required for the effective operation of the Product Design Process? (4.4)

P3. Has the Organization effectively identified the performance indicators or measurement methods to be used, the targets to be achieved and the method of analysis and reporting on these measurements, for the Product Design Process? (4.4) (9.1)

AP – Is performance evidence provided consistent with the data gathered in discussion with Top Management and in audit planning? Is the process owner's explanation of the causes and actions related to identified issues with performance consistent with those expressed by Top Management? Note if specific job functions or specific equipment is associated with identified issues.

P4. Are the measurements consistent with the described output criteria? (BP)

P5. Does the product design plan identify stages of the process that effectively take the process from initial concept to a completed, defined, verified and validated product or service, ready for provision to the customer? (8.3)

P6. Where the design process include prototype development is this activity fully and effectively planned, implemented, and measured? (8.3)

P7. Has the organization identified the human resources necessary for the effective operation of Product Design? Does this include the number of persons, their required competency levels and the responsibilities, authorities and accountabilities necessary for effective operation and control of the process? (4.4, 5.3, 7.1)

AP – Make a Note of the various job titles and how many people work in each. Ask if there are any contract, part time or shared employees working within the process. Ask who the newest employee is who is working within the process. Note the answers.

P8. Has the organization identified the tools, materials and equipment necessary for the effective operation of this process? (4.4)

P9. Has the organization put in place methods to ensure that tools, equipment and materials provided are: adequate to do the function required, available when and where needed, and effectively maintained? (4,4)

NOTE: If the product design activities include prototype production, modelling, beta testing, etc. the equipment, materials and methods for those activities must be effectively applied in addition to tools, equipment and methods needed for product development, test, verification and validation. Tools required may include software as well as hardware.

P10. Is there evidence that the organization has effectively determined risks, opportunities and constraints related to the resources provided and to the operation of this process? Is the need for outside resources part of this analysis? (4.4, 6.1, 7.1, 8.4)

AP – Is there evidence of the effective use of lessons learned in previous design projects during the design process?

P11. In evaluating the risks associated with this process has the organization effectively insured, within reason, that the process can achieve its intended results? (6.1)

P12. Has the organization included steps designed to prevent or reduce undesired results and to identify opportunities to improve results? (6.1)

P13. Is there evidence of a process that monitors the effectiveness of corrective, preventive, risk reduction and improvement actions taken? Where actions taken are not sufficiently effective are additional steps taken as necessary? (6.1)

AP – Look for repetitive issues and make a note of what action was taken, by whom and where. Use this data when auditing those areas and look for causal factors for why actions taken have not been effective.

P14. Has the organization determined what Product Design information will be communicated internally and externally? To whom? When? How? (7.4)

P15. Is there evidence that the objectives identified for this process are linked directly to its performance measures? Are those measures effectively implemented, recorded, analyzed, and reported at a regular frequency to Top Management? (BP)

P16. Is there evidence that the performance measurements identified above results ultimately in continual improvement? (BP)

P17. Where statutory or regulatory compliance is pertinent to the achievement of Product Design goals, is there evidence of measurement and tracking of compliance to these statutory and regulatory requirements? (5.1)

P18. Is there evidence that the owner/manager of the Product Development process is competent in the use and application of the Process Approach? (5.1)

P19. Is there evidence in the Product Development process that people are encouraged to contribute to the effectiveness of the Quality Management System?(5.1)

P20. Is there evidence that employees working in the Product Development process understand the intent of the quality policy and how it affects their functions? (5.2)

P21. Are employees fully aware of their responsibilities, authority levels and accountability in the fulfillment of their jobs? (5.3)

P22. Have objectives been identified for this process that are consistent with the Mission of the organization, the strategic goals of the organization and the stated Quality Policy? (6.2)

P23. Has the Organization effectively identified what performance indicators will be used and when, the measurement methods to be used, the targets to be achieved and the frequency and method of reporting on these measurements, for each process? (4.4, 8.1, 9.1)
Are all measurements objective in nature – not subjective? (BP)

P24. Do all measurements have targets identified? (6.2)

P25. In determining targets for measurements have the following been considered? (6.2)

- What needs to be accomplished?
- Is success achievable?
- Have sufficient resources been applied?

P26. Are all measures monitored and reported to management regularly as specified by the procedures of the organization? Are measures changed, replaced or revised as the needs arise? (6.2)

P27. Are all appropriate measurements and their status effectively communicated to senior management, within the organization and where appropriate with other interested parties? (6.2)

P28. When changes are made to procedures, work instructions, etc., is there evidence that; (6.3)

- The changes are approved prior to the change being implemented
- There was a defined and communicated plan for the implementation of the changes?
- The need for additional or different resources was considered?
- Changes or revision of responsibilities, authority or accountability was considered?

- There is a process in place to verify the effective implementation of the change?
- There is verification that the changes achieved or met the intended outcomes of the changes?

P29. Is there evidence that the process owner has effectively determined risks, opportunities and constraints related to the resources provided and to the operation of each process? Is the need for outside resources part of this analysis? (4.4, 6.1, 7.1, 8.1)

P30. In evaluating the risks associated with each process has the organization effectively assured that the process can achieve its intended results? (6.1, 8.1)

P31. Have manpower requirements needed by this process in order to achieve customer requirements as well as requirements of other interested parties been determined and effectively applied? (7.1)

P32. For this process, has the organization identified the human resources necessary, the number of persons, their required competency levels and the responsibilities, authorities and accountabilities necessary for effective operation and control of the processes? (4.4 , 7.1, 8.1)

P33. Has the manpower analysis included the need for human resources from outside the organization? (Contracted Employees) (7.1)

P34. Has the current level of competence necessary for each person conducting work within the process been determined? (7.2)

P35. Is there evidence of an established and effective, process for introducing new employees or employees to new positions? (BP)

P36. Where an Employees competence level is less than desired in a specific function of their job, is there a process to:

- Determine what remedial training or development is required?
- Provide the required training or development within an appropriate time frame?
- Re-evaluate the employee's competence after the training/development is complete?

P37. Are records available of:

- employee competence requirements and status? (7.2)
- training/development planned and completed? (7.2)

P38. Are individual employees aware of: (consider sampling)

- Objectives related to their functions? (7.3)
- Their contribution to the achievement of organizational objectives, customer focus and achievement of customer satisfaction? (7.3)

- The potential implications that could result from nonconformities in their work? (7.3)

P39. Has the organization determined equipment and facility requirements needed by this process in order to achieve customer requirements as well as requirements of other interested parties? (7.1)

AP – Where software is involved , particularly software unique to this process, is there an effective backup system for protecting data? Is backup frequency adequate? Is backup data stored off site or in a safe place where damage to the main system will not also damage the backup?

P40. Has the organization identified the tools, materials and equipment necessary for the effective operation of each process? (4.4. 8.1)

P41. Has the organization put in place methods to ensure that tools, equipment and materials provided are adequate to do the function required, available when and where needed, and are effectively maintained? (4,4, 8.1)

P42. Does the equipment analysis included the need for outside resources? (7.1)

P43. Has the analysis considered as appropriate: (7.1)

- Hardware?
- Software?
- Communication and IT technology?

P44. Are there records available to show that equipment is effectively maintained and repaired? (7.1)

P45. Do records show that maintenance of equipment happens prior to breakdown events (Preventive Maintenance) not simply when equipment fails? (7.1)

P46. Does equipment maintenance include: (7.1)

- processing equipment,
- software,
- computers,
- IT equipment,
- Test and verification equipment

P47. Has the process owner determined that the documentation requirements needed for this process to achieve customer requirements as well as requirements of other interested parties is available to those people tasked with implementation of the process activities? (7.4)

P48. Do performance records for the process indicate that the amount and type of documentation available is sufficient for the effective operation and control of the process? (7.5)

P49. Have all documents and records reviewed been effectively identified? (7.5)

P50. Where necessary is the format of documents controlled? (7.5)

P51. Is there evidence that shows an effective process for approval or re-approval of documents? (7.5)

P52. Are documents needed during the process readily available to the people who need them?

P53. Are documents and records effectively stored and protected from; loss, loss of confidentiality, improper use, water damage, rodent damage, or deterioration? For documents stored electronically, is there effective control to segregate current revisions of documents from versions under development as well as obsolete versions? (7.5)

P58.(Q87) Is there effective control of distribution, access, retrieval and use of documents? Does evidence show that current controls are effectively implemented and effective in practice? (7.5)

P54. Were all documents verified during the assessment legible and stored effectively? (7.5)

P55. Is there evidence that documents verified during the assessment have been effectively managed for changes? (7.5)

P56. Is there evidence of an effective process for identification and control of documents of external origin where control is required? (7.5)

P57. Is there an effective process for review of documents of external origin to determine the need for controls? (7.5)

NOTE: If an undetected change to an external document could have a detrimental effect on the process then control of the revision of that document should be seriously considered.

P58. Has the organization defined and implemented the methods needed in order to achieve customer product requirements? (internal and external customers) (4.4, 8.1)

P59. Has the organization effectively identified the inputs and outputs of process steps required for the effective operation of the process? (4.4, 8.1)

P60. Are there steps in the process designed to prevent or reduce undesired results and to identify opportunities to improve results? (Tests, Modelling, Rehearsal, Statistical Analysis, Design of Experiments, etc.) (6.1, 8.1)

P61. Is there evidence of a process which monitors the effectiveness of the preventive actions, reduction actions and the improvement actions taken and where actions are not effective takes additional steps as necessary? (6.1, 8.1)

P62. For each operation step in the product design process, has the organization identified; (8.1)

- the specific criteria associated with the step?
- the risks related to the achievement of criteria at each step?
- appropriate equipment for effective operation at each step?
- appropriate controls to address risk? (product conformity, process capability, equipment, calibration, protection, safety and security controls)
- appropriate records to provide evidence of product (service) conformity?

NOTE: Product requirements include customer specified requirements, statutory and regulatory requirements and other requirements identified by the organization.

P63. Is there a document (traveler, product /process plan, control plan, work flow, job order, formulary, script or score, etc.) that is the output of the above planning process which will ensure the positive control of the process? (8.1)

P64. Is there evidence that the documents in P63 provide sufficient information and control to ensure products or services that conform to requirements? (8.1)

P65. Is there evidence that an effective change process is applied should the requirements for the product (service) change? (8.1)

P66. Is there evidence of effective communication systems between the organization and the customer related to: (8.2)

- Product
- Contract, order or product changes
- Handling of customer owned property
- Planning and handling of contingencies
- Solicitation of customer perceptions about the organization
- Customer feedback and corrective action

P67. Is there evidence that requirements are effectively reviewed to ensure that: (8.2)

- All requirements specified by the customer and design input requirements can be met, including packaging, delivery and post delivery requirements
- Requirements not identified by the customer but necessary for the proper operation of the product (service)
- Statutory and Regulatory Requirements

P68. Is there an effective process to ensure that the organization can achieve new or changed requirements before the organization commits to the new requirements? (8.2)

P69. Does evidence indicate that all issues related to product and design requirements are resolved prior to acceptance by the organization? (8.2)

AP- Asks the auditee to provide the documentation for their most recent best practice project. Ask that they pick a project that has just finished or is in its final stages. Once the client has chosen their project you should choose another project. The second project need not be recent but it should cover areas of the client's process not covered by their chosen project. In other words if the company makes brushes and combs and their choice is a comb, then your choice should be a brush etc. Sit down with the two project leaders. The reason for this approach is that if projects are chosen at random or in any other method and issues are identified, the auditee will simply say "Yes I see the problem but we have changed our process and that problem no longer exists with our latest process." If one of your samples is their most recent process and it exhibits the identified issue, there is no defense.

QUESTIONS FOR THE PROJECT LEADERS

P70. Is there evidence in each project that input criteria were fully developed? (8.3)

P71. Is there evidence in each project that gate reviews were conducted as described by management? (8.3)

P72. Is there evidence of a formal way of monitoring the process from start to finish. Is it as described in documentation? Is each activity described in the process phase done and verified prior to moving on to the next phase? (8.3)

P73. Is there evidence in each project of effective design verification and validation? (8.3)

NOTE: Verification is to determine if the product as designed meets the physical form as intended. Validation is to determine whether the final product performs its functional requirements as intended. In other words Verification is 'Does it look like it was supposed to look?' Validation is 'Does it work like it was supposed to work?'

P74. Is there evidence of effective change control throughout the project? (8.3)

P75. Is there evidence of control of inspection, measuring and test equipment including prototype work? (7.1)

P76. Is there evidence of effective output control to ensure that all input requirements have been met? (8.3)

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‘S’- PROCESS DEVELOPMENT ASSESSMENT

PROCESS SPECIFIC ASSESSMENT

QUESTIONS FOR THE PROCESS OWNER

AP – If a document or record is mentioned during your interview with the process owner – ask immediately to see the document – review it for legibility, availability, proper use and completeness. Look for evidence of poor performance or customer issues. Once satisfied document your evidence and return the document to the manager.

S1. Is there a defined process to develop and implement methods for taking customer requirements and developing methods, procedures, or protocols needed to effectively and efficiently provide a product or service which will fully and effectively meet those requirements? (8.3)

S2. Has the Organization effectively identified the inputs and outputs required for the effective operation of this process? (4.4)

S3. For this process, has the process owner effectively identified the performance indicators, the measurement methods to be used, the targets to be achieved and the method of analysis and reporting on these measurements to senior management? (4.4) (9.1)

AP – Is performance evidence provided consistent with the data gathered in discussion with Top Management and in audit planning? Is the process owner's explanation of the causes and actions related to identified issues with performance consistent with those

expressed by Top Management? Note specific job functions or specific equipment that are associated with identified issues.

S4. Does the process design plan identify stages of the process that effectively takes the process from initial definition to a completed, defined, verified and validated process or service, which effectively provides the planned product or service to the customer? (8.3)

S5. Has the process owner identified the human resources necessary for the effective operation of the process? Does this include the number of people required, their required competency levels and the responsibilities, authorities and accountabilities necessary for effective operation and control of the process? (4.4, 7.1)

AP – Make a Note of the various job titles and how many people work in each. Ask if there are any contract, part time or shared employees working within the process. Ask who the newest employee is who is working within the process. Note the answers.

S6. Has the process owner identified the tools, materials and equipment necessary for the effective operation of this process? (4.4)

NOTE: This is not equipment used to make the product but rather equipment used by the process designers to create the product or service realization process. It includes hardware, software, fixtures, gages, test equipment, etc.

S7. Has the organization put in place methods to ensure that tools, equipment and materials provided are adequate to do the function required, available when and where needed, and are effectively maintained? (4,4)

AP – Where software is involved, particularly software unique to this process, is there an effective backup system for protecting data? Is backup frequency adequate? Is backup data stored off site or in a safe place where damage to the main system will not also damage the backup?

S8. Is there evidence that the organization has effectively determined risks, opportunities and constraints related to the resources provided and to the success of this process? Is the need for outside resources part of this analysis? (4.4, 6.1, 7.1, 8.4)

S9. In evaluating the risks associated with this process has the organization effectively insured within reason that the process can achieve its intended results? (6.1)

AP – Is there evidence of the effective use of lessons learned from previous projects and during the product development process?

S10. Has the organization included steps designed to prevent or reduce undesired results and to identify opportunities to improve results? (6.1)

S11. Is there evidence of an effective process that monitors the effectiveness of corrective, preventive, risk reduction and improvement actions taken? Where actions taken are not sufficiently effective are additional steps taken as necessary? (6.1)

S12. Has the organization determined what process design information will be communicated internally and externally? To whom? When? How? (7.4)

S13. Is there evidence that the objectives identified for this process are linked directly to its performance measures and objectives? Are those measures effectively implemented, recorded, analyzed, and reported at a regular frequency to Top Management? (BP)

AP – Are measurement results consistent with those reviewed with Top Management and/or during audit planning? Note whether additional measures which feed into those reported to management are acceptable.

S14. Is there evidence that the performance measurements identified above will result ultimately in continual improvement? (BP)

S15. Where statutory or regulatory compliance is pertinent to the achievement of Process Design goals, is there evidence that processes are effectively implemented, recorded, analyzed, and reported at a regular frequency to top management for statutory and regulatory requirements? (5.1)

S16. Is there evidence that the owner/manager of the process is competent in the use and application of the Process Approach? (5.1)

S17. Is there evidence in the process that people are encouraged to contribute to the effectiveness of the Quality Management System? (5.1)

S18. Is there evidence that employees working in the Process Design process understand the intent of the quality policy and how it affects their functions? (5.2)

S19. Has the process management clearly defined the responsibilities, levels of authority and specific accountability for each job function? (5.3)

S20. Are employees fully aware of their responsibilities, authority levels and accountability in the fulfillment of their jobs? (5.3)

S21. Have objectives been identified for this process that are consistent with the mission of the organization, the strategic goals of the organization and the stated Quality Policy? (6.2)

S22. Are all measurements objective in nature – NOT subjective? (BP)

S23. Do all measurements have targets identified? (6.2)

S24. In determining targets for measurements have the following been considered? (6.2)

- What needs to be accomplished?
- Is success achievable?
- Have sufficient resources been applied?

S25. Are all process measures monitored and reported to management regularly as specified by the procedures of the organization? Are measurements changed, replaced or revised as the needs arise? (6.2)

S26. Are all appropriate process measures and their status effectively communicated within the organization and where appropriate with other interested parties? (6.2)

REVIEW OF SPECIFIC PROJECTS UNDER DEVELOPMENT

(IDENTIFY TWO PROCESS DEVELOPMENT PROJECT (S)
ASSESSED –)

AP- Asks the auditee to provide the documentation for their most recent best practice project. Ask that they pick a project that has just finished or is in its final stages. Once the client has chosen their project you should choose another project. The second project need not be recent but it should cover areas of the client's process not covered by their chosen project. In other words if the company makes brushes and combs and their choice is a comb, then your choice should be a brush etc. Sit down with the two project leaders. (for an explanation for this methodology see the Product Development Process.)

QUESTIONS FOR THE PROJECT LEADERS

S27. Is there evidence in each project that input criteria was fully defined? (8.3)

S28. Do process design inputs include: (8.3)

- Required characteristics of the product as defined by the product or service design, including:

- oDimensional

- oFunctional

- Performance expectations for the process such as:

- oCycle times,

- oprocess speeds,

- ocosts,

oerror rates,

- Statutory and regulatory requirements,
- Codes of practice or other requirements to which the organization subscribes,
- Required reviews by upper management at prescribed intervals?

S29. Are the input requirements adequate, complete, clear and unambiguous? (8.3)

S30. Where conflict occurs between the input requirements, are they effectively resolved prior to moving to subsequent phases of the process? (8.3)

S31. Is there evidence in each project that gate reviews were conducted as described by management and that all gate requirements were complete and verified prior to moving to the next phase of the project? (8.3)

S32. Is there evidence of a formal way of monitoring the process from start to finish, including the management of risks? Is it as described in documentation? (8.3)

S33. Is there evidence in each project of effective design verification, validation and risk management? (8.3)

S34. Is there evidence of effective change control throughout the project? (8.3)

S35. Is there evidence of control of inspection, measuring and test equipment including prototype work? (7.1)

S36. Is there evidence of effective output control to ensure that all input requirements have been met? (8.3)

S37. When changes are made to procedures, work instructions, etc., for the process is there evidence that; (6.3)

- The changes are approved prior to the change being applied
- The need for additional or different resources was considered?
- Changes or revision of responsibilities, authority or accountability was considered?
- There is a process in place to verify that the change was fully implemented into the process?
- There is verification that the change achieved or met the intended purpose of the change and did not introduce a new risk?

S38. Is there evidence that the organization has effectively determined risks, opportunities and constraints related to the resources provided and to each operation of the process? Is the need for outside resources (testing, auditing, transport, security, etc.) part of this analysis? (4.4, 6.1, 7.1, 8.1)

Note: The above applies to risks associated with the success of the process being developed, NOT risks related to the process development process.

S39. In evaluating the risks associated with the process has the process development team effectively assured that the process under development can achieve its intended results? (6.1, 8.1)

S40. For this process, has the organization identified the human resources necessary, the number of persons for each process step, their required competency levels, training needs and skills development? (4.4 , 7.1, 8.1)

S41. Are responsibilities, authorities and accountabilities necessary for effective operation and control of the process established for each process step? (4.4 , 7.1, 8.1)

S42. Has the manpower analysis included the need for human resources from outside the organization? (Contracted Employees) (7.1)

S43. Do records show that a plan has been developed for the maintenance of equipment? Does this process focus on Preventive Maintenance not simply repair when equipment fails? (7.1)

S44. Does equipment maintenance planning include: (7.1)

- processing equipment,
- software,
- computers,
- IT equipment,
- Test and verification equipment

S45. Has the organization determined the extent, format and control of documentation requirements needed for this process to achieve customer requirements as well as requirements of other interested parties? (7.4)

S46. Does a review of the planned documentation indicate that the amount and type of documentation is sufficient for the effective operation and control of the process? (7.5)

NOTE: Consider the planned documentation as it compares to current processes. What types of issues exist with current documentation and will the documentation of the new process provide improved performance where needed?

S47. Where necessary for effectiveness is there a requirement in the process design for format control? (7.5)

S48. Is there evidence that documents in the project under development have been effectively managed for changes? (7.5)

S49. Are there steps in the process being designed which will prevent or reduce undesired results and identify opportunities to improve results? (6.1, 8.1)

S50. For each operation step in the process design process, has the organization identified; (8.1)

- the specific criteria associated with the process step?
- the risks related to the achievement of criteria at each process step?
- appropriate equipment for effective operation at each process step?
- appropriate controls to address each risk? (product conformity, process capability, equipment, calibration, protection, safety and security controls)
- appropriate records to provide evidence of product (service) conformity?

NOTE: Product requirements include customer specified requirements, statutory and regulatory requirements and other requirements identified by the organization.

S51. Is there a document (traveler, product /process plan, control plan, work flow, job order, formulary, etc.) that is the output of the

planning process which will ensure the positive control of the process? (8.1)

S52. Is there evidence that the documents in S51 provide sufficient information and control to ensure products or services that conform to requirements? (8.1)

S53. Is there evidence that requirements for the process under development are effectively reviewed to ensure that: (8.2)

- All requirements specified by the customer and process design inputs are understood, including packaging, delivery and post delivery requirements?
- Requirements not identified by the customer but necessary for the proper operation of the product (service) can be met?
- Statutory and Regulatory Requirements can be met?

S54. Is there exit criteria identified and achieved for each stage in the development of the process? (8.3)

S55. Is there evidence to show that exit requirements at each stage of process are verified and validated that they meet the specified exit criteria prior to the development process moving into the next stage? (8.3)

S56. Where exit criteria are not met is there effective subsequent activities to ensure that criteria are ultimately achieved? (8.3)

S57. If the project being assessed is complete, is there evidence of effective validation that the developed process met its expectations? (8.4)

RETURN TO ASSESSMENT OF THE PROCESS DEVELOPMENT PROCESS

S58. When changes are made to process development procedures, work instructions, etc., is there evidence that; (6.3)

- The changes are approved prior to the change being implemented
- There was a defined and communicated plan for the implementation of the changes?
- The need for additional or different resources was considered?
- Changes or revision of responsibilities, authority or accountability were considered?
- There is a process in place to verify effective implementation of the change?
- There is verification that the change achieved or met the intended outcomes of the change?

S59. Is there evidence that the organization has effectively determined risks, opportunities and constraints related to the resources provided and to the operation of the process? Is the need for outside resources part of this analysis? (4.4, 6.1, 7.1, 8.1)

Note: The above applies to risks associated with the success of the Process Development Process, NOT risks related to the design being developed.

S60. In evaluating the risks associated with this process has the organization effectively assured that the development process can achieve its intended results? (6.1, 8.1)

S61. For this process, has the organization identified the human resources necessary, the number of persons, their required competency levels and the responsibilities, authorities and accountabilities necessary for effective operation and control of the process? (4.4 , 7.1, 8.1)

S62. Have manpower requirements needed to achieve customer requirements as well as requirements of other interested parties been determined and effectively applied? (7.1)

S63. Has the manpower analysis included the need for human resources from outside the organization? (Contracted Employees) Including competency levels and the responsibilities, authorities and accountabilities necessary? (7.1)

S64. For equipment (including computer hardware and software) used for this process, do records show that maintenance of equipment happens prior to breakdown events (Preventive Maintenance) not simply when equipment fails? (7.1)

S65. Does equipment maintenance include: (7.1)

- processing equipment,
- software,
- computers,
- IT equipment,
- Test and verification equipment

S66. Has the organization determined the documentation requirements needed for this process to achieve customer requirements as well as requirements of other interested parties? (7.4)

S67. Do performance records for the process indicate that the amount and type of documentation available is sufficient for the effective operation and control of the process? (7.5)

S68. Are documents and records effectively identified? (7.5)

S69. Where necessary is format controlled? (7.5)

S70. Is there evidence that shows an effective process for approval or re-approval of documents? (7.5)

S71. Are documents needed during the process readily available to the people who need them?

S72. Are documents and records effectively stored and protected from; loss, loss of confidentiality, improper use, water damage, or deterioration? If stored electronically, is there effective back up of data and is there effective control to segregate current revisions of documents from versions under development and/or obsolete versions? (7.5)

S73. Is there effective control of distribution, access, retrieval (consider backup systems for software) and use of documents? Does evidence show that current controls are effectively implemented and effective in practice? (7.5)

S74. Have all documents verified during the assessment been legible and stored effectively? (7.5)

S75. Is there evidence that documents verified during this assessment have been effectively managed for changes? (7.5)

S76. Is there evidence of an effective process for identification and control of documents of external origin where control is needed? (7.5)

NOTE: If an undetected change to an external document could have a detrimental effect on the process then control of the revision of that document should be seriously considered.

S77. Has the Organization effectively identified the inputs and outputs required for the effective operation of the process? (4.4, 8.1)

S78. Are there steps in the process designed to prevent or reduce undesired results and to identify opportunities to improve results? (6.1, 8.1)

S79. Is there evidence of a process which monitors the effectiveness of the preventive actions, reduction actions and the improvement actions taken and where actions are not effective takes additional steps as necessary? (6.1, 8.1)

S80. Is there a document (traveler, product /process plan, control plan, work flow, job order, formulary, etc.) that is used to effectively control the planning process? (8.1)

S81. Is there evidence that the documents in S80 provide sufficient information and control to ensure products or services that conform to requirements? (8.1)

S82. Is there evidence that an effective change process is applied should the requirements for the product (service) change? (8.1)

S83. Is there evidence of effective communication systems between the organization, the customer, and/or the product design function related to: (8.2)

- Product requirements
- Performance requirements
- Solicitation of customer perceptions about the product
- Customer feedback

S84. Is there evidence that requirements are effectively reviewed to ensure that: (8.2)

- All requirements specified by the customer and process design input requirements are understood, including packaging, delivery and post delivery requirements?
- Requirements not identified by the customer but necessary for the proper operation of the product (service) can be met?
- Statutory and Regulatory Requirements can be met?

S85. Is there an effective process to ensure that the organization can achieve new or changed requirements before the organization commits to the new requirements? (8.2)

S86. Does evidence indicate that all issues related to product and design requirements are resolved prior to acceptance by the organization or start of the process development process? (8.2)

S87. Is there documented evidence of the implementation of the change? (8.3)

S88. Is there exit criteria identified for each stage to the process? (8.3)

S89. Is there evidence to show that exit requirements at each stage of process are verified and validated to meet the specified exit criteria prior to the design process moving into the next stage? (8.3)

S90. Where exit criteria are not met is there effective subsequent activities to ensure that criteria are ultimately achieved? (8.3)

S91. Does the process design plan identify stages of the process that effectively cover all of the steps from initial input criteria to an implemented, verified and validated process ready to provide products or services that meet all applicable customer, organization and statutory and regulatory requirements? (8.3)

S92. Does the process include: (8.3)

- A timeframe for each stage of the process design?
- Interactions between various functions during the design process?
- Responsibilities, Authority and Accountability for functions and tasks included in the process design?

- Inputs, outputs and key deliverables for each stage?
- Necessary equipment to be used at each stage?
- Verification of outputs at each stage?
- Equipment to be used for verification and test (where applicable)?
- Validation where applicable during the design process and at the conclusion of the design process? such as; run-at-rate, test runs, dress rehearsals, etc.
- Review by upper management at prescribed intervals and at the conclusion of the design process?

S93. Are input requirements adequate, complete, clear and unambiguous? (8.3)

S94. Where conflict occurs between the input requirements and outputs, are they effectively resolved prior to moving to subsequent phases of the process? (8.3)

S95. Is the customer involved in resolution of input conflicts as appropriate?

S96. Is there exit criteria identified for each stage of the design process? (8.3)

S97. Is there evidence to show that exit requirements at each stage of design are verified and validated to meet the specified exit criteria prior to the development process moving into the next stage? (8.3)

S98. Where exit criteria for a specific phase of the development project are not met is there effective subsequent activities to ensure that criteria are ultimately achieved? (8.3)

S99. Is there evidence of a process to determine risks associated with the products or services provided by outside services and are these risks taken into consideration when establishing overall project risks? (8.4)

S100. Is there evidence of effective verification that the developed process meets expectations? (8.4)

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‘H’- HUMAN RESOURCES PROCESS ASSESSMENT

PROCESS SPECIFIC ASSESSMENT

QUESTIONS FOR THE PROCESS OWNER

AP – If a document or record is mentioned during your interview with the process owner – ask immediately to see the document – review it for legibility, availability, proper use and completeness. Look for evidence of poor performance or customer issues. Once satisfied document your evidence and return the document to the manager.

H1. Has the Organization effectively identified the inputs and outputs required for the effective operation of this process? (4.4)

H2. Has the Organization effectively identified the performance indicators, the measurement methods to be used, the targets to be achieved and the method of analysis and reporting on the measurements, for this process? (4.4) (9.1)

AP – Is performance evidence provided consistent with the data gathered in discussion with Top Management and in audit planning? Is the process owner's explanation of the causes and actions related to identified issues with performance consistent with those expressed by Top Management? Take note if specific job functions or specific equipment is associated with previously identified issues.

H3. Has the organization identified the human resources necessary, the number of persons, their required competency levels and the responsibilities, authorities and accountabilities necessary for effective operation and control of the processes? (4.4 , 7.1)

AP – Make a Note of the various job titles and how many people work in each. Ask if there are any contract, part time or shared employees working within the process. Ask who the newest employee is who is working within the process. Note the answers.

NOTE: This requirement applies to the human resource requirements for the Human Resource Management function NOT the human resources managed by the function.

H4. Has the organization identified the tools, materials and equipment necessary for the effective operation of each process? (4.4)

AP – Look closely at equipment identified as associated with issues. Look closely at maintenance records, repair records etc.

H5. Has the organization put in place methods to ensure that tools, equipment and materials provided for this process are adequate to do the function required, are available when and where needed, and are effectively maintained? (4,4)

H6. Is there evidence that the organization has effectively determined risks, opportunities and constraints related to the resources provided and to the operation of this process? Is the need for outside resources part of this analysis? (4.4, 6.1, 7.1, 8.4)

NOTE: Particularly with HR functions it is important that initial orientation of new employees is well done. Consider that if you don't do a good job of communicating to a new employee the values and culture of your organization, what you will be hiring will be their previous employer's worst habits.

H7. In evaluating the risks associated with this process has the organization effectively assured that the process can achieve its intended results? (6.1)

NOTE: Consider whether there is a mismatch between training plans and the organization's strategic plan.

H8. Has the organization included steps designed to prevent or reduce undesired results and to identify opportunities to improve results? (6.1)

H9. Is there evidence that the process management monitors the effectiveness of the preventive actions, reduction actions and the improvement actions taken and where actions are not effective takes additional steps as necessary? (6.1)

H10. Is QMS information (performance, status, data, information) communicated internally or externally? To whom? When? How? (7.4)

H11. Is there evidence that the process owner has taken ownership and responsibility for the operation and effectiveness of this

process? (5.1)

H12. Has the owner of the process taken responsibility for process objectives for this process as identified by 'Top Management'? (5.1)

H13. Is there evidence that the objectives identified are linked directly to performance measures that are effectively implemented, recorded, analyzed, and reported to Top Management? (BP)

AP – Are measurements consistent with those reviewed with Top Management and/or during audit planning? Note whether additional measures which feed into those reported to management are acceptable.

H14. Are all process performance measures objective in nature – not subjective? (BP)

H15. Do all measurements have targets identified? (6.2)

H16. In determining targets for measurements have the following been considered? (6.2)

- Is the achievement of the performance measures identified for this process within the control of the process owner of this process?
- What needs to be accomplished and within what defined time frame?

- Is success achievable?
- Have sufficient resources been applied?

H17. Are all measures monitored and reported to management and changed or replaced as the needs arise? (6.2)

H18. Is there evidence that the performance measurement cycle above results ultimately in continual improvement? (BP)

AP – If improvement projects identified with Top Management or in audit planning are being applied in this process this is the time to investigate their value and effectiveness. Did they get implemented as planned? Are the expected benefits being realized?

H19. Where statutory or regulatory compliance is pertinent to the achievement of the process goals, is there evidence of a similar tracking cycle for compliance to statutory and regulatory requirements? (5.1)

NOTE: Consider government subsidies for new hires, apprenticeship programs or specific skills requirements (licenses, certifications, professional designations etc.).

H20. Is there evidence that the process owner is competent in the use of the Process Approach? (5.1)

NOTE: The Process Approach includes: PLAN – Establish performance objectives based upon customer as well as organizational expectations, RISK – Determine the risks associated with the organizations ability to achieve the performance objectives, DO – Implement the process steps with risk management steps included, CHECK – Review and analyze actual performance against the targets, ACT – Take action where objectives are not met and consider opportunities to improve where objectives are being met

H21. Is there evidence of a process which encourages people to contribute to the effectiveness of the Quality Management System? (5.1)

H22. Is there evidence in this process of the use of Employee Surveys, Suggestion Plans, Open Door Policies, Employee Advocates or other processes designed to elicit employee involvement? Is there evidence that they are working effectively? (BP)

H23. Do employees working within this process understand the intent of the policy and how it should affect their functions? (5.2)

NOTE: It is neither required nor intended that employees be able to recite the Quality Policy. It is important that everyone in the organization, in their own words what the Policy says and what it means to their job functions.

An important auditor question is whether the employees believe that top management believes in the Quality Policy. For employees, actions speak much louder than words.

H24. Within this process, have responsibilities, levels of authority and specific accountability been defined for each job function? (5.3)

NOTE: Accountability is NOT included in the ISO 9001 2015 requirement. I have include it here for clarification. There is a great deal of literature stating that Responsibility and Accountability are interchangeable and that therefore there is no need for both words. This makes a great discussion for academics and theorists, but for the purposes of this guidebook, I am going to take a much more pedestrian viewpoint. We take responsibility for actions and accountability for results. Everyone can be responsible for satisfying the customer, but if everyone is accountable for customer satisfaction, then no one is.

H25. Are employees fully aware of their responsibilities, authority levels and accountability in the fulfillment of their jobs? (5.3)

H26. For each process, have objectives been identified that are consistent with the Mission of the organization, the strategic goals of the organization and the stated Quality Policy? (6.2)

H27. Where there are functions and levels which require the effective coordination of combined processes, are there appropriate measurable objectives identified? (6.2)

H28. When changes to the process documentation have been made, is there evidence that; (6.3)

- there was a defined and communicated plan for the implementation of the changes?
- the need for additional or different resources was considered?
- changes or revision of responsibilities, authority or accountability was considered?

H29. Were documentation changes and additions made available to those responsible for implementation at the time of a system change? (BP)

H30. Was an Internal Audit activity used to verify the effective implementation of changes? (BP)

H31. For this process, has the organization determined manpower requirements needed in order to achieve customer requirements as well as requirements of other interested parties? (7.1)

H32. Has manpower analysis included the need for additional resources from outside the organization? (7.1)

H33. Has the organization determined the level of competence necessary for each person conducting work within this process?

(7.2)

H34. Upon entering the workforce of the process is the employee's level of competence specifically evaluated? (7.2)

H35. Is there an established, documented process for introducing employees to new positions? (BP)

NOTE: This requirement should apply both to employees starting work in the process and for employees moving to a new function within the process.

H36. Where an employee's competence level is less than desired in a specific function of their job, is there a process to: (7.2)

- determine what remedial training or development is required?
- provide the required training or development within an appropriate time frame?
- re-evaluate the employees competence after the training/development is complete?

H37. Are records available of:

- employee competence requirements and status? (7.2)
- training/development planned and completed? (7.2)

H38. Are employees aware of:

- the content and intent of the organization's quality policy? (7.3)
- objectives related to their functions? (7.3)
- their contribution to the achievement of organizational objectives, customer focus and achievement of customer satisfaction? (7.3)
- the benefits of improved quality performance? (7.3)
- The potential implications that could result from nonconformities in their work? (7.3)?

H39. For this process, has the organization determined equipment and facility requirements needed in order to achieve customer requirements as well as requirements of the management and other interested parties? (7.1)

AP – Where software is involved , particularly software unique to this process, is there an effective backup system for protecting data? Is backup frequency adequate? Is backup data stored off site or in a safe place where damage to the main system will not also damage the backup?

H40. Has the equipment analysis included the need for outside resources? (7.1)

H41. Has the analysis considered as appropriate: (7.1)

- Building space?
- Hardware?
- Software?
- Communication and IT technology?

H42. Are there records available to show that equipment is effectively maintained and repaired? (7.1)

H43. Do records show that maintenance of equipment happens prior to breakdown events (Preventive Maintenance) not simply when equipment fails? (7.1)

H44. Does equipment maintenance include: (7.1)

- software,
- computers,
- IT equipment,

H45. For this process, has the organization determined the documentation requirements needed in order to achieve customer requirements as well as requirements of management and other interested parties? (7.4)

H46. Do performance records for the process indicate that the amount and type of documentation available is sufficient for the effective operation and control of the process? (7.5)

H47. Is there evidence of an effective method of identifying documents and records? (7.5)

NOTE: Identification may include a date, signature, reference number, file number, etc. The method must ensure that the document cannot be confused with a previous or subsequent version of the same document or record.

H48. Where necessary is format controlled? (7.5)

NOTE: While any format or medium can be used (ie paper, electronic, audio, video etc.) where a specific format is required, by procedure or inherent need, the format must be controlled.

H49. Is there evidence that shows that when documents are created or revised, there is an effective process for approval or re-approval? (7.5)

H50. Are documents needed during the process readily available to the people who need them?

NOTE: Readily available is dependent upon the situation. Having a recipe readily available for a cook has a different expectation than having a portable defibrillator readily available to a paramedic.

H51. Are documents and records effectively stored and protected from; loss, loss of confidentiality, improper use, water damage, or deterioration? (7.5)

H52. Has the organization effectively addressed distribution, access, retrieval and use of documents? Does evidence show that current controls are effectively implemented and effective in practice? (7.5)

NOTE: Access can mean permission to view information or permission to have a document under personal control or authority to use or modify a document.

H53. Where all documents verified during this assessment legible and stored effectively? (7.5)

H54. Is there evidence that documents verified during this assessment have been effectively managed for changes? (7.5)

H55. Is there a process for disposal of records? Does it comply with Statutory, Regulatory and /or Customer requirements? Do records show that it is effectively implemented? (7.5)

H56. Is there evidence of an effective process for identification of documents of external origin which need to be controlled? (7.5)

NOTE: If an undetected change to an external document could have a detrimental effect on the process then control of the revision of that document should be seriously considered?

H57. Is there evidence that shows that documents of external origin determined to need control are in fact effectively controlled? (7.5)

H58. Does the process owner have a processes needed to achieve process objectives requirements? (internal and external customers) (4.4, 8.1)

H59. Does the process owner understand and support the interdependency of processes needed for effective product or service realization? (4.4, 8.1)

PROCESS SPECIFIC QUESTIONS

AP – Choose employees in each job category for interview. Go back to your notes from the process owner and choose the employees with the greatest risk of nonconformity (New Employees, Contract Employees, Part Time Employees). Ask employees what they are responsible for and what authority they have. Answers should be the same as described by the process owner. Ask employees about their training. Answers should be as described by the process owner.

AP – During interviews, if the employee mentions a document or record – stop him – ask for the document – review it for legibility, availability, proper use and completeness. Once satisfied document your evidence and return the document to the employee.

H60. Has manpower analysis been completed that takes into consideration;

- Current manpower required to achieve customer and organizational requirements
- Future manpower requirements to achieve new technological requirements, growth, new product introduction, etc.
- Need for additional hires, or use of resources from outside the organization? (7.1)

H61. Is there evidence of an HR process to determine the level of competence necessary for each person conducting work within the organization? (7.2) Note: This includes technical and management personnel.

H62. Upon entering the workforce, is there an effective process for introducing the employee to the organization? (BP)

H63. Upon entering the workforce is there an effective process for establishing and evaluating the employee's level of competence? (7.2)

H64. Is there an established, documented process for introducing employees to new positions and ensuring that required levels of competence are achieved? (BP)

H65. Where an Employees competence level is less than desired in a specific function of their job, is there a process to: (7.2)

- determine what remedial training or development is required?
- provide the required training or development within an appropriate time frame?
- re-evaluate the employees competence after the training/development is complete?

H66. Is there a process for determining and planning training and development for all employees? (7.2)

H67. Do records show that planned training and development happens as planned? (7.2)

NOTE: Achievement of his requirement requires assessment by the auditor. Often training cannot happen as planned simply because the particular training course was not readily available, however this is different from training that is simply planned but not executed. The auditor must determine which situation is shown by the evidence.

H68. Are records available of:

- employee competence requirements and status for all employees? (7.2)
- training/development planned and completed? (7.2)

H69. Where training occurs is there a evidence of an effective process for determining the effectiveness of the training? (7.2)

H70. Is there an effective succession planning process for critical technical and management positions? (BP)

H71. Is the process for evaluation of training appropriate to the complexity, cost, time involved and importance to the organization? (7.2)

H72. Is there a process to make employees aware of:

- the content and intent of the organization's quality policy? (7.3)
- objectives related to their functions? (7.3)
- their contribution to the achievement of organizational objectives, customer focus and achievement of customer satisfaction? (7.3)
- the benefits of improved performance? (7.3)
- The potential implications that could result from nonconformities in their work? (7.3)?

H73. Where there is a process for cross training employees is it

- Effectively documented
- Effectively recorded
- Effectively implemented
- Are records of which employees are qualified on which job, readily available to front line supervisors

NOTE: Having training records visible to employees can have positive benefits for the organization

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‘B’- PURCHASING PROCESS ASSESSMENT

PROCESS SPECIFIC ASSESSMENT

QUESTIONS FOR THE PROCESS OWNER

AP – If a document or record is mentioned during your interview with the process owner – ask immediately to see the document – review it for legibility, availability, proper use and completeness. Look for evidence of poor performance or customer issues. Once satisfied document your evidence and return the document to the manager.

B1. Has the Organization effectively identified the inputs and outputs required for the effective operation of this process? (4.4)

B2. Has the Organization effectively identified the performance indicators, the measurement methods to be used, the targets to be achieved and the method of analysis and reporting on the measurements, for this process? (4.4) (9.1)

AP – Is performance evidence provided consistent with the data gathered in discussion with Top Management and in audit planning? Is the process owner's explanation of the causes and actions related to identified issues with performance consistent with those expressed by Top Management? Note if specific job functions or specific equipment is associated with identified issues.

B3. Has the organization identified the human resources necessary for the purchasing process to work effectively, including; the number of persons required, their required competency levels and the responsibilities, authorities and accountabilities necessary for each process function? (4.4 , 7.1)

AP – Make a Note of the various job titles and how many people work in each. Ask if there are any contract, part time or shared employees working within the process. Ask who the newest employee is who is working within the process. Note the answers.

B4. Has the organization identified the tools, materials and equipment necessary for the effective operation of each process? (4.4)

AP – Look closely at warehouse and loading dock equipment such as fork lifts, cranes, identified to be associated with issues. Look closely at maintenance records, repair records etc.

B5. Has the organization put in place methods to ensure that tools, equipment and materials (including software) provided for this process are adequate to do the function required, are available when and where needed, and are effectively maintained? (4,4)

B6. Is there evidence that the organization has effectively determined risks, opportunities and constraints related to the resources provided and to the operation of this process? Is the need for outside resources part of this analysis? (4.4, 6.1, 7.1, 8.4)

B7. In evaluating the risks associated with this process has the organization effectively assured that the process can achieve its intended results? (6.1)

B8. Has the organization included steps designed to prevent or reduce undesired results and to identify opportunities to improve results? (6.1)

B9. Is there evidence that the management of this process monitors the effectiveness of the preventive actions, reduction actions and the improvement actions taken and where actions are not effective takes additional steps as necessary? (6.1)

B10. Is QMS information related to the operation of this process (performance, status, data, information) communicated internally or externally? To whom? When? How? (7.4)

B11. Is there evidence that the process owner has taken ownership and responsibility for the operation and effectiveness of this process? (5.1)

B12. Has the owner of the process taken responsibility for process objectives for this process as identified by 'Top Management'? (5.1)

B13. Is there evidence that the objectives identified are linked directly to performance measures that are effectively implemented, recorded, analyzed, and reported to Top Management? (BP)

AP – Are measures consistent with those reviewed with Top Management and/or during audit planning? Note that additional

measures which feed into those reported to management are acceptable.

B14. Are all measures objective in nature – not subjective? (BP)

B15. Do all measurements have targets identified? (6.2)

B16. In determining targets for measurements have the following been considered? (6.2)

- What needs to be accomplished?
- Is success achievable?
- Have sufficient resources been applied?

B17. Are all measures monitored, reported to management and changed or replaced as the needs arise? (6.2)

B18. Is there evidence that the performance measurement cycle above results ultimately in continual improvement? (BP)

AP – If improvement projects were identified with Top Management or in audit planning are being applied in this process this is the time to investigate their value and effectiveness. Did they get implemented as planned? Are the benefits expected being realized?

B19. Where statutory or regulatory compliance is pertinent to the achievement of the process goals, is there evidence of a similar tracking cycle for compliance to statutory and regulatory requirements? (5.1) ie: Measures of status and compliance, reporting, analysis and actions.

B20. Is there evidence that the process owner is competent in the use of the Process Approach? (5.1)

NOTE: The Process Approach includes: PLAN – Establish performance objectives based upon customer as well as organizational expectations, RISK – Determine the risks associated with the organizations ability to achieve the performance objectives, DO – Implement the process steps with risk management steps included, CHECK – Review and analyze actual performance against the targets, ACT – Take action where objectives are not met and consider opportunities to improve where objectives are being met

B21. Is there evidence of a process which encourages people to contribute to the effectiveness of the Quality Management System? (5.1)

B22. If there evidence in this process of the use of Suggestion Plans, Open Door policies, or other processes designed to elicit employee contribution. Is there evidence that they are working effectively? (BP)

B23. Do employees working within this process understand the intent of the policy and how it should affect their functions? (5.2)

NOTE: It is neither required nor intended that employees be able to recite the Quality Policy. It is important that everyone in the organization, in their own words what the Policy says and what it means to their job functions.

An important auditor question is whether the employees believe that top management believes in the Quality Policy. For employees, actions speak much louder than words.

B24. Within this process, have responsibilities, levels of authority and specific accountability been defined for each job function? (5.3)

NOTE: Accountability is NOT included in the ISO 9001 2015 requirement. I have include it here for clarification. There is a great deal of literature stating that Responsibility and Accountability are interchangeable and that therefore there is no need for both words. This makes a great discussion for academics and theorists, but for the purposes of this guidebook, I am going to take a much more pedestrian viewpoint. We take responsibility for actions and accountability for results. Everyone can be responsible for satisfying the customer, but if everyone is accountable for customer satisfaction, then no one is.

B25. Are employees fully aware of their responsibilities, authority levels and accountability in the fulfillment of their jobs? (5.3)

B26. For this process, have objectives been identified that are consistent with the Mission of the organization, the strategic goals of the organization and the stated Quality Policy? (6.2)

B27. When changes to the process documentation have been made, is there evidence that; (6.3)

- there was a defined and communicated plan for the implementation of the changes?
- the need for additional or different resources was considered?
- changes or revision of responsibilities, authority or accountability was considered?

B28. Were documentation changes and additions made available to those responsible for implementation at the time of the system change? (BP)

B29. Was an Internal Audit activity used to verify the effective implementation of the changes? (BP)

B30. For this process, has the organization determined manpower requirements needed in order to achieve customer requirements as well as requirements of other interested parties? (7.1)

B31. Has manpower analysis included the need for additional resources from outside the organization? (7.1)

B32. Has the organization determined the level of competence necessary for each person conducting work within this process? (7.2)

B33. Upon entering the workforce of the process is the employee's level of competence specifically evaluated? (7.2)

B34. Is there an established, documented process for introducing new employees to their positions or current employees to new positions? (BP)

B35. Where an employee's competence level is less than desired in a specific function of their job, is there a process to:

- determine what remedial training or development is required?
- provide the required training or development within an appropriate time frame?
- re-evaluate the employees competence after the training/development is complete?

B36. Are records available of:

- employee competence requirements and status? (7.2)
- training/development planned and completed? (7.2)

B37. Are employees aware of:

- the content and intent of the organization's quality policy? (7.3)
- objectives related to their functions? (7.3)
- their contribution to the achievement of organizational objectives, customer focus and achievement of customer satisfaction? (7.3)
- the benefits of improved quality performance? (7.3)
- The potential implications that could result from nonconformities in their work? (7.3)?

B38. For this process, has the organization determined equipment and facility requirements needed in order to achieve customer requirements as well as requirements of the management and other interested parties? (7.1)

AP – Where particularly software unique to this process is used, is there an effective backup system for protecting data? Is backup frequency adequate? Is backup data stored off site or in a safe place where damage to the main system will not also damage the backup?

B39. Has the equipment analysis included the need for outside resources? (7.1)

B40. Has the analysis considered as appropriate: (7.1)

- Building space?

- Hardware?
- Software?
- Transportation equipment?
- Communication equipment?
- Communication and IT technology?
- Value added use of floor space? (BP)
- Lean technologies and methods? (BP)
- Integrated processes with customers or suppliers? (BP)

B41. Are there records available to show that equipment used within the purchasing process is effectively maintained and repaired? (7.1)

B42. Do records show that maintenance of equipment happens prior to breakdown events (Preventive Maintenance) not simply when equipment fails? (7.1)

B43. Does equipment maintenance include as appropriate: (7.1)

- processing equipment,
- software,
- computers,
- IT equipment,

- trucks and transportation equipment

B44. For this process, has the organization determined the documentation requirements needed in order to achieve customer requirements as well as requirements of management and other interested parties? (7.4)

B45. Do performance records for the process indicate that the amount and type of documentation available is sufficient for the effective operation and control of the process? (7.5)

B46. Is there evidence of an effective method of identifying documents and records? (7.5)

NOTE: Identification may include a date, signature, reference number, file number, etc. The method must ensure that the document cannot be confused with a previous or subsequent version of the same document or record.

B47. Where necessary is format of documents controlled? (7.5)

NOTE: While any format or medium can be used (ie paper, electronic, audio, video etc.) where a specific format is required, by procedure or inherent need, the format must be controlled.

B48. Is there evidence that shows that when documents are created or revised, there is an effective process for approval or re-approval? (7.5)

B49. Are documents needed during the process readily available to the people who need them?

NOTE: Readily available is dependent upon the situation. Having a recipe readily available for a cook has a different expectation than having a portable defibrillator readily available to a paramedic.

B50. Are documents and records effectively stored and protected from; loss, loss of confidentiality, improper use, water damage, or deterioration? (7.5)

B51. Has the organization effectively addressed distribution, access, retrieval and use of documents? Does evidence show that current controls are effectively implemented and effective in practice? (7.5)

NOTE: Access can mean permission to view information or permission to have a document under personal control or authority to use or modify a document.

B52. Where all documents verified during the assessment legible and stored effectively? (7.5)

B53. Is there evidence that documents verified during the assessment have been effectively managed for changes? (7.5)

B54. Is there a process for disposal of records? Does it comply with Statutory, Regulatory and /or Customer requirements? Do records show that it is effectively implemented? (7.5)

B55. Is there evidence of an effective process for identification of documents of external origin which need to be controlled? (7.5)

NOTE: If an undetected change to an external document could have a detrimental effect on the process then control of the revision of that document should be seriously considered?

B56. Is there evidence that shows that documents of external origin determined to need control are in fact effectively controlled? (7.5)

B57. Does the process owner have a processes needed in to achieve process objectives requirements? (internal and external customers) (4.4, 8.1)

B58. Does the process owner understand and support the interdependency of processes needed for effective product or service realization? (4.4, 8.1)

PROCESS SPECIFIC QUESTIONS – To be used for organizations where purchased material is;

- used or integrated into the organization's product
- provided to the organization's customer
- critical to the manufacture, production or creation of the organization's product.

AP – Choose employees in each job category for interview. Go back to your notes from the process owner and choose the employees with the greatest risk (New Employees, Contract Employees, Part Time Employees). Ask employees what they are responsible for and what authority they have. Answers should be the same as described by the process owner. Ask employees about their training. Answers should be as described by the process owner.

AP – During interviews, if the employee mentions a document or record – stop him – ask for the document – review it for legibility, availability, proper use and completeness. Once satisfied document your evidence and return the document to the employee.

B59. Is there a process for evaluation and acceptance of new suppliers? (8.4)

B60. Does the evaluation consider the potential impact on the organization and the customer of; (8.4)

- the supplier's quality system,

- The quality level of the supplier's product,
- the supplier's delivery performance, and the use of special or premium freight services in order to achieve delivery performance,
- the quality of services provided by the supplier,
- risks associated with supplier control of statutory and regulatory requirements
- price?

B61. Is there an effective way to identify and compare supplier performance so that good suppliers can be highlighted as well as poor suppliers? (8.4)

B62. Is there a process for on-going measurement of supplier performance which tracks quality, delivery and service appropriate to the risks associated with product supplied? (8.4)

B63. Do records show that preferred suppliers have the better performance? (8.4)

B64. Is supplier performance reported to management and to the suppliers on a regular basis? (8.4)

B65. When supplier product does not meet requirements for quality, delivery or service, is there an expectation that the supplier will implement corrective action? (8.4)

B66. Are the organization's expectations for corrective action communicated to the supplier? (8.4)

B67. Is there evidence of effective implementation of this process? (8.4)

B68. Is there evidence of regular planned reviews of supplier performance? (8.4)

B69. Is there a formal process which results in discontinued use of a supplier due to unacceptable performance? (8.4)

NOTE: Best practice would be to have a multilevel approach starting with a relatively simple corrective action requirement for a first issue to a high level significant corrective action expectation for continue poor performance. (8.4)

B70. Is there an effective process in place for verification (and validation as applicable) of supplied materials? (8.4) (Consider; inspection, statistical analysis, lab certification, source inspection, functional testing, etc.)

B71. If a certified supplier process is used is there an effective product quality tracking process integrated into the production or service application processes? Is there evidence that quality issues

found during production or service application generate changes to the supplier's certification status? (8.4)

B72. Is there evidence that the organization's purchase information provides the supplier with; (8.4)

- A clear unambiguous description of their product requirements?
- The organization's system requirements?
 - oThe organization's supplier performance expectations and controls
 - oCompetence and special training requirements for supplier personnel
 - oSupplier interaction with the organization's quality management system
 - oConditions related to customer or organization provided materials or equipment
- Inter-organization communication requirements?
- Information related to release of services, products, methods, processes or equipment

B73 Is there evidence that issues between the supplier and the organization related to product requirements are resolved prior to finalization of a purchase contract? (8.4)

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'I'-QUALITY ASSURANCE ASSESSMENT

PROCESS SPECIFIC ASSESSMENT

QUESTIONS FOR THE PROCESS OWNER

AP – If a document or record is mentioned during your interview with the process owner – ask immediately to see the document – review it for legibility, availability, proper use and completeness. Look for evidence of poor performance or customer issues. Once satisfied document your evidence and return the document to the manager.

I1. Has the Organization effectively identified the inputs and outputs required for the effective operation of this process? (4.4)

I2. Has the Organization effectively identified the performance indicators, the measurement methods to be used, the targets to be achieved and the method of analysis and reporting on these measurements, for this process? (4.4) (9.1)

AP – Is performance evidence provided consistent with the data gathered in discussion with Top Management and in audit planning? Is the process owner's explanation of the causes and actions related to identified issues with performance consistent with those expressed by Top Management? Note if specific job functions or specific equipment is associated with identified issues.

I3. Has the organization identified the human resources necessary, the number of persons, their required competency levels and the responsibilities, authorities and accountabilities necessary for effective operation and control of this process? (4.4 , 7.1)

AP – Make a Note of the various job titles and how many people work in each. Ask if there are any contract, part time or shared employees working within the process. Ask who the newest employee is who is working within the process. Note the answers.

14. Has the organization identified the tools, materials and equipment necessary for the effective operation of each process? (4.4)

AP – Look closely at equipment including gauges identified to be associated with issues. Look closely at maintenance records, repair records etc.

15. Has the organization put in place methods to ensure that tools, equipment and materials provided for this process are adequate to do the function required, are available when and where needed, and are effectively maintained? (4,4)

16. Is there evidence that the organization has effectively determined risks, opportunities and constraints related to the resources provided and to the operation of this process? Is the need for outside resources part of this analysis? (4.4, 6.1, 7.1, 8.4)

17. In evaluating the risks associated with this process has the organization effectively assured that the process can achieve its intended results? (6.1)

I8. Has the organization included steps designed to prevent or reduce undesired results and to identify opportunities to improve results? (6.1)

I9. Is there evidence that the process management monitors the effectiveness of the preventive actions, reduction actions and the improvement actions taken and where actions are not effective takes additional steps as necessary? (6.1)

I10. Is QMS information (performance, status, data, information) communicated internally or externally? To whom? When? How? (7.4)

I11. Is there evidence that the process owner has taken ownership and responsibility for the operation and effectiveness of this process? (5.1)

I12. Has the owner of the process taken responsibility for process objectives for this process as identified by 'Top Management'? (5.1)

I13. Is there evidence that the objectives identified are linked directly to performance measures that are effectively implemented, recorded, analyzed, and reported to Top Management? (BP)

AP – Are measurements consistent with those reviewed with Top Management and/or during audit planning? Note that additional measures which feed into those reported to management are acceptable.

I14. Are all measures objective in nature – not subjective? (BP)

I15. Do all measurements have targets identified? (6.2)

I16. In determining targets for measurements have the following been considered? (6.2)

- What needs to be accomplished?
- Is success achievable?
- Have sufficient resources been applied?

I17. Are all measurements monitored, reported to management and changed or replaced as the needs arise? (6.2)

I18. Is there evidence that the performance measurement cycle above results ultimately in continual improvement? (BP)

AP – If improvement projects identified with Top Management or in audit planning are being applied in this process this is the time to investigate their value and effectiveness. Did they get implemented as planned? Are the benefits expected being realized?

I19. Where statutory or regulatory compliance is pertinent to the achievement of the process goals, is there evidence of a similar measurement and a tracking cycle for compliance to statutory and regulatory requirements? (5.1)

I20. Is there evidence that the process owner is competent in the use of the Process Approach? (5.1)

NOTE: The Process Approach includes: PLAN – Establish performance objectives based upon customer as well as organizational expectations, RISK – Determine the risks associated with the organizations ability to achieve the performance objectives, DO – Implement the process steps with risk management steps included, CHECK – Review and analyze actual performance against the targets, ACT – Take action where objectives are not met and consider opportunities to improve where objectives are being met

I21. Is there evidence of a process which encourages people to contribute to the effectiveness of the Quality Management System? (5.1)

I22. If there evidence in this process of the use of Suggestion Plans, Open Door policies, or other processes designed to elicit employee contribution, is there evidence that they are working effectively? (BP)

I23. Do employees working within this process understand the intent of the policy and how it should affect their functions? (5.2)

NOTE: It is neither required nor intended that employees be able to recite the Quality Policy. It is important that everyone in the organization, in their own words what the Policy says and what it means to their job functions.

An important auditor question is whether the employees believe that top management believes in the Quality Policy. For employees, actions speak much louder than words.

I24. Within this process, have responsibilities, levels of authority and specific accountability been defined for each job function? (5.3)

NOTE: Accountability is NOT included in the ISO 9001 2015 requirement. I have include it here for clarification. There is a great deal of literature stating that Responsibility and Accountability are interchangeable and that therefore there is no need for both words. This makes a great discussion for academics and theorists, but for the purposes of this guidebook, I am going to take a much more pedestrian viewpoint. We take responsibility for actions and accountability for results. Everyone can be responsible for satisfying the customer, but if everyone is accountable for customer satisfaction, then no one is.

I25. Are employees fully aware of their responsibilities, authority levels and accountability in the fulfillment of their jobs? (5.3)

I26. For each process, have objectives been identified that are consistent with the Mission of the organization, the strategic goals of the organization and the stated Quality Policy? (6.2)

I27. Where there are functions and levels which require the effective coordination of combined processes, are there appropriate measurable objectives identified? (6.2)

I28. When changes to the process documentation have been made, is there evidence that; (6.3)

- there was a defined and communicated plan for the implementation of the changes?
- the need for additional or different resources was considered?

- changes or revision of responsibilities, authority or accountability was considered?

I29. Where documentation changes and additions made available to those responsible for implementation at the time of the system change? (BP)

I30. Was an Internal Audit activity used to verify the effective implementation of the changes? (BP)

I31. For this process, has the organization determined manpower requirements needed in order to achieve customer requirements as well as requirements of other interested parties? (7.1)

I32. Has manpower analysis included the need for additional resources from outside the organization? (7.1)

I33. Has the organization determined the level of competence necessary for each person conducting work within this process? (7.2)

I34. Upon entering the workforce of the process is the employee's level of competence specifically evaluated? (7.2)

I35. Is there an established, documented process for introducing employees to new positions? (BP)

NOTE: This requirement should apply both to employees starting work with the process and for employees moving to a new function within the process.

I36. Where an Employees competence level is less than desired in a specific function of their job, is there a process to:

- determine what remedial training or development is required?
- provide the required training or development within an appropriate time frame?
- re-evaluate the employees competence after the training/development is complete?

I37. Are records available of:

- employee competence requirements and status? (7.2)
- training/development planned and completed? (7.2)

I38. Where quality personnel require specific competencies for specific jobs such as 'Quality Technician', 'Quality Technologist', 'Quality Engineer', 'Laboratory Technician', 'Calibration Technician, records of these competencies must be maintained

NOTE; Records related to I38 are most useful when they are available in the 'Quality Office' or 'Laboratory'. They may also be maintained in HR. (BP)

I39. Are employees who work within the Quality Assurance process aware of:

- the content and intent of the organization's quality policy? (7.3)
- objectives related to their functions? (7.3)
- their contribution to the achievement of organizational objectives, customer focus and achievement of customer satisfaction? (7.3)
- the benefits of improved quality performance? (7.3)
- The potential implications that could result from nonconformities in their work? (7.3)?

I40. For this process, has the organization determined equipment and facility requirements needed in order to achieve customer requirements as well as requirements of the management and other interested parties? (7.1)

I41. Has the equipment analysis included the need for outside resources? (7.1)

I42. Has the analysis considered as appropriate: (7.1)

- Building space?
- Hardware (including gaging, test equipment, etc)?

- Software?
- Communication equipment?
- Communication and IT technology?
- Adequate Quarantine space
- Space for rework, repair, sort, etc.?

I43. Are there records available to show that equipment is effectively maintained and repaired? (Including calibration records) (7.1)?

I44. Do records show that maintenance of equipment happens prior to breakdown events (Preventive Maintenance) not simply when equipment fails? (7.1)

I45. Does equipment maintenance include: (7.1)

- software,
- computers,
- IT equipment,

I46. For this process, has the organization determined the documentation requirements needed in order to achieve customer requirements as well as requirements of management and other interested parties? (7.4)

I47. Do performance records for the process indicate that the amount and type of documentation available is sufficient for the effective operation and control of the process? (7.5)

I48. Is there evidence of an effective method of identifying documents and records? (7.5)

NOTE: Identification may include a date, signature, reference number, file number, etc. The method must ensure that the document cannot be confused with a previous or subsequent version of the same document or record.

I49. Where necessary is format controlled? (7.5)

NOTE: While any format or medium can be used (ie paper, electronic, audio, video etc.) where a specific format is required, by procedure or inherent need, the format must be controlled.

I50. Is there evidence that shows that when documents are created or revised, there is an effective process for approval or re-approval? (7.5)

I51. Are documents needed during the process readily available to the people who need them?

NOTE: Readily available is dependent upon the situation. Having a recipe readily available for a cook has a different expectation than having a portable defibrillator readily available to a paramedic.

I52. Are documents and records effectively stored and protected from; loss, loss of confidentiality, improper use, water damage, or deterioration? (7.5)

I53 Has the organization effectively addressed distribution, access, retrieval and use of documents? Does evidence show that current controls are effectively implemented and effective in practice? (7.5)

NOTE: Access can mean permission to view information or permission to have a document under personal control or authority to use or modify a document.

I54 Where all documents verified during the assessment legible and stored effectively? (7.5)

I55. Is there evidence that documents verified during the assessment have been effectively managed for changes? (7.5)

I56. Is there a process for disposal of records? Does it comply with Statutory, Regulatory and /or Customer requirements? Do records show that it is effectively implemented? (7.5)

I57. Is there evidence of an effective process for identification of documents of external origin which need to be controlled? (7.5)

NOTE: If an undetected change to an external document could have a detrimental effect on the process then control of the revision of that document should be seriously considered?

I58. Is there evidence that shows that documents of external origin determined to need control are in fact effectively controlled? (7.5)

I59. Does the process owner have a processes needed in to achieve process objectives requirements? (internal and external customers) (4.4, 8.1)

I60. Does the process owner understand and support the interdependency of processes needed for effective product or service realization? (4.4, 8.1)

PROCESS SPECIFIC QUESTIONS

AP – Choose employees in each job category for interview. Go back to your notes from the process owner and choose the employees with the greatest risk (New Employees, Contract Employees, Part Time Employees). Ask employees what they are responsible for and what authority they have. Answers should be the same as described by the process owner. Ask employees about their training. Answers should be as described by the process owner.

AP – During interviews, if the employee mentions a document or record – stop him – ask for the document – review it for legibility, availability, proper use and completeness. Once satisfied document your evidence and return the document to the employee.

I61. Is there sufficient documentation available at stages of the realization process which provides information necessary to verify and where necessary validate specific characteristics of the product or service? (8.5)

NOTE: Consider stages of the inspection/quality control or quality assurance process, not the production process.

I62. Where necessary is there sufficient documentation available at stages of the inspection process for verification that operations are conducted as intended by process development? (8.5)

I63. Do verification activities sufficiently cover both product and process characteristics? (8.5)

I64. Are there unique performance expectations defined for each product or service being provided? (8.5)

I65. Do performance measures cover both the expected performance of the product or service and the performance of the

process which produces the product or service? (8.5)

I66. Is there sufficient inspection and measuring equipment available to ensure that characteristics of the production or service product and the requirements of the process used to create or provide the product or service can be effectively verified? (7.1, 8.5)

AP – Where software is used to perform inspections, provide calculations or record data, is there an effective system for software verification and is there an effective backup system for protecting data? Is backup frequency adequate? Is backup data stored off site or in a safe place where damage to the main system will not also damage the backup?

I67. Is there an effective process for ensuring that inspection and test equipment is calibrated under controlled conditions and that calibrations are traceable to national standards when possible? (7.1, 8.5)

I68. Is there evidence that; where necessary verification activities are completed only by qualified personnel? (8.5)

I69. If product is moved further along the realization process prior to full verification, is there evidence of an effective positive recall system to ensure that material can be found and returned for verification? (8.5)

I70. Is product clearly identifiable throughout the product realization process? (8.5)

I71. Is the quality status (acceptable/unacceptable) clearly identifiable for all materials throughout the realization process? (8.5)

I72. Is the sequence or level of completion effectively identified throughout the realization process? (8.5)

I73. Is there evidence that product conformity and process set-up conformity are verified prior to starting the process (first-off) as well as any time the process is interrupted (material change, maintenance, shift change , etc.)? (8.5)

I74. Where product cannot be verified by inspection of product characteristics, is there effective control of process characteristics?

I75. Have all process steps verified during the assessment had positive identification that all conditions relating to the previous operation have been met? (8.6)

I76. Is there evidence of the effective use of Statistical Process Controls? (8.3)

177. Is there evidence that no product has been released to the customer until all required verification was completed and all requirements were met? (8.6)

178. Where nonconforming product is identified or suspected: (8.7)

- Is the product clearly identified as nonconforming?
- Is the product moved out of the normal product flow?
- Is material produced prior to or after the identification of the nonconformance re-verified to ensure that it meets all requirements?
- Is there an effective process for disposition of the suspect material?
- Does the disposition process clearly identify the person or persons with the authority to making dispositions?
- Is there evidence that the customer was informed of nonconformities where appropriate?
- Is suspect material controlled such that each suspect part is accounted for as scrapped, repaired, reworked, sorted and accepted or accepted per a waiver or deviation?
- Is sorted, repaired or reworked material re-inspected prior to release? NOTE: re-inspection cannot be completed by the person who did the sort or rework.
- Is there an effective link between the process of identification of nonconformities and a corrective action process for correction of the root cause of the nonconformity?
- Are records related to nonconformities documented, analyzed, and reported to top management?

- Is there evidence of effective activities designed to reduce the number of nonconformities?

NOTE: In most organizations the quality function takes a leadership role in the 'Corrective Action activity, therefore this section has been placed here. If this is not the case in your organization please move these questions to the appropriate location.

179. Is there a corrective action process which effectively works to control and reduce: (10.2)

- Customer complaints
- Internal product or service noncompliance
- Internal process noncompliance (for both manufacturing processes and system processes)
- Internal performance issues

180. Does the corrective action process: (10.2)

- Effectively identify the problem rather than the symptom of the problem
- Effectively describe the problem
- Effectively determine the root cause of the symptom, the root cause of the problem and the systemic root cause
- Effectively address each of the three root causes
- Effectively implement corrective actions

- Verify and validate the effectiveness of each corrective action

I81. When customers return product is there evidence of effective review of the returned product in order to effectively address the problem? (BP)

I82. Do records indicate that corrective actions are generally effective (limited numbers of repeat problems – overall reduction in corrective actions)? (10.2)

I83. When a problem is encountered and resolved in one process, is the corrective action implemented on similar processes where the problem is a potential problem? (BP)

I84. Where there is a specific quality laboratory, do laboratory documents including laboratory scope, lab procedures, lab technician training, lab material handling? Is lab documentation effectively implemented, and maintained?

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‘R’- MAINTENANCE PROCESS ASSESSMENT

PROCESS SPECIFIC ASSESSMENT

QUESTIONS FOR THE PROCESS OWNER

AP – If a document or record is mentioned during your interview with the process owner – ask immediately to see the document – review it for legibility, availability, proper use and completeness. Look for evidence of poor performance or customer issues. Once satisfied document your evidence and return the document to the manager.

R1. Has the Organization effectively identified the inputs and outputs required for the effective operation of this process? (4.4)

R2. Has the Organization effectively identified the performance indicators, the measurement methods to be used, the targets to be achieved and the method of analysis and reporting on these measurements, for this process? (4.4) (9.1)

AP – Is performance evidence provided consistent with the data gathered in discussion with Top Management and in audit planning? Does the process owner's explanation of the causes and actions related to identified issues with performance consistent with those expressed by Top Management? Note if specific job functions or specific equipment is associated with identified issues.

R3. Has the organization identified the human resources necessary, the number of persons, their required competency levels and the responsibilities, authorities and accountabilities necessary for effective operation and control of the processes? (4.4 , 7.1)

AP – Make a Note of the various job titles and how many people work in each. Ask if there are any contract, part time or shared employees working within the process. Ask who the newest employee is who is working within the process. Note the answers.

R4. Has the organization identified the tools, materials and equipment necessary for the effective operation of each process? (4.4)

AP – Look closely at equipment identified to be associated with issues. Look closely at maintenance records, repair records etc.

NOTE: This requirement is for equipment used by and owned by the maintenance department, NOT the equipment owned by other processes but maintained by the maintenance department.

R5. Has the organization put in place methods to ensure that tools, equipment and materials provided for this process are adequate to do the function required, are available when and where needed, and are effectively maintained? (4,4)

R6. Is there evidence that the organization has effectively determined risks, opportunities and constraints related to the resources provided and to the operation of this process? Is the need for outside resources part of this analysis? (4.4, 6.1, 7.1, 8.4)

R7. In evaluating the risks associated with this process has the organization effectively assured that the process can achieve its intended results? (6.1)

R8. Has the organization included steps designed to prevent or reduce undesired results and to identify opportunities to improve results? (6.1)

R9. Is there evidence that the process management monitors the effectiveness of the preventive actions, reduction actions and the improvement actions taken and where actions are not effective takes additional steps as necessary? (6.1)

R10. Is QMS information (performance, status, data, information) communicated internally or externally? To whom? When? How? (7.4)

R11. Is there evidence that the process owner has taken ownership and responsibility for the operation and effectiveness of this process? (5.1)

R12. Has the owner of the process taken responsibility for process objectives for this process as identified by 'Top Management'? (5.1)

R13. Is there evidence that the objectives identified are linked directly to performance measures that are effectively implemented, recorded, analyzed, and reported to Top Management? (BP)

AP – Are measurable consistent with those reviewed with Top Management and/or during audit planning? Note that additional measures which feed into those reported to management are acceptable.

R14. Are all measurable of objectives objective in nature – not subjective? (BP)

R15. Do all measurements have targets identified? (6.2)

R16. In determining targets for measurements have the following been considered? (6.2)

- What needs to be accomplished?
- Is success achievable?
- Have sufficient resources been applied?

R17. Are all measurable monitored, reported to management and changed or replaced as the needs arise? (6.2)

R18. Is there evidence that the performance measurement cycle above results ultimately in continual improvement? (BP)

AP – If improvement projects identified with Top Management or in audit planning are being applied in this process this is the time to investigate their value and effectiveness. Did they get implemented as planned? Are the benefits expected being realized?

R19. Where statutory or regulatory compliance is pertinent to the achievement of the process goals, is there evidence of a similar tracking cycle for compliance to statutory and regulatory requirements? (5.1)

R20. Is there evidence that the process owner is competent in the use of the Process Approach? (5.1)

NOTE: The Process Approach includes: PLAN – Establish performance objectives based upon customer as well as organizational expectations, RISK – Determine the risks associated with the organizations ability to achieve the performance objectives, DO – Implement the process steps with risk management steps included, CHECK – Review and analyze actual performance against the targets, ACT – Take action where objectives are not met and consider opportunities to improve where objectives are being met

R21. Is there evidence of a process which encourages people to contribute to the effectiveness of the Quality Management System? (5.1)

R22. Is there evidence in this process of the use of Suggestion Plans, Open Door policies, or other processes designed to elicit

employee contribution, is there evidence that they are working effectively? (BP)

R23. Do employees working within this process understand the intent of the policy and how it should affect their functions? (5.2)

NOTE: It is neither required nor intended that employees be able to recite the Quality Policy. It is important that everyone in the organization, in their own words what the Policy says and what it means to their job functions.

An important auditor question is whether the employees believe that top management believes in the Quality Policy. For employees, actions speak much louder than words.

R24. Within this process, have responsibilities, levels of authority and specific accountability been defined for each job function? (5.3)

NOTE: Accountability is NOT included in the ISO 9001 2015 requirement. I have include it here for clarification. There is a great deal of literature stating that Responsibility and Accountability are interchangeable and that therefore there is no need for both words. This makes a great discussion for academics and theorists, but for the purposes of this guidebook, I am going to take a much more pedestrian viewpoint. We take responsibility for actions and accountability for results. Everyone can be responsible for satisfying the customer, but if everyone is accountable for customer satisfaction, then no one is.

R25. Are employees fully aware of their responsibilities, authority levels and accountability in the fulfillment of their jobs? (5.3)

R26. For each process, have objectives been identified that are consistent with the Mission of the organization, the strategic goals of the organization and the stated Quality Policy? (6.2)

R27. Where there are functions and levels which require the effective coordination of combined processes, are there appropriate measurable objectives identified? (6.2)

R28. When changes to the process documentation have been made, is there evidence that; (6.3)

- there was a defined and communicated plan for the implementation of the changes?
- the need for additional or different resources was considered?
- changes or revision of responsibilities, authority or accountability was considered?

R29. Where documentation changes and additions made available to those responsible for implementation at the time of the system change? (BP)

R30. Was an Internal Audit activity used to verify the effective implementation of the changes? (BP)

R31. For this process, has the organization determined manpower requirements needed in order to achieve customer requirements as well as requirements of other interested parties? (7.1)

R32. Has manpower analysis included the need for additional resources from outside the organization? (7.1)

R33. Has the organization determined the level of competence necessary for each person conducting work within this process? (7.2)

R34. Upon entering the workforce of the process is the employee's level of competence specifically evaluated? (7.2)

R35. Is there an established, documented process for introducing employees to new positions? (BP)

NOTE: This requirements should apply both to employees starting work with the process and for employees moving to a new function within the process.

R36. Where an Employee's competence level is less than desired in a specific function of their job, is there a process to:

- determine what remedial training or development is required?

- provide the required training or development within an appropriate time frame?
- re-evaluate the employees competence after the training/development is complete?

R37. Are records available of:

- employee competence requirements and status? (7.2)
- training/development planned and completed? (7.2)

R38. Are employees aware of:

- the content and intent of the organization's quality policy? (7.3)
- objectives related to their functions? (7.3)
- their contribution to the achievement of organizational objectives, customer focus and achievement of customer satisfaction? (7.3)
- the benefits of improved quality performance? (7.3)
- The potential implications that could result from nonconformities in their work? (7.3)?

R39. For this process, has the organization determined equipment and facility requirements needed in order to achieve customer requirements as well as requirements of the management and other interested parties? (7.1)

AP – Where software is involved, particularly software unique to this process, is there an effective backup system for protecting data? Is backup frequency adequate? Is backup data stored off site or in a safe place where damage to the main system will not also damage the backup?

R40. Has the equipment analysis included the need for outside resources? (7.1)

R41. Has the analysis considered as appropriate: (7.1)

- Building space?
- Utilities?
- Hardware?
- Software?
- Transportation equipment?
- Communication equipment?
- Communication and IT technology?
- Value added use of floor space? (BP)
- Lean technologies and methods? (BP)
- Integrated processes with customers or suppliers? (BP)

R42. Are there records available to show that equipment is effectively maintained and repaired? (7.1)

R43. Do records show that maintenance of equipment happens prior to breakdown events (Preventive Maintenance) not simply when equipment fails? (7.1)

R44. Does equipment maintenance include: (7.1)

- processing equipment,
- software,
- computers,
- IT equipment,
- trucks and transportation equipment

R45. For this process, has the organization determined the documentation requirements needed in order to achieve customer requirements as well as requirements of management and other interested parties? (7.4)

R46. Do performance records for the process indicate that the amount and type of documentation available is sufficient for the effective operation and control of the process? (7.5)

R47. Is there evidence of an effective method of identifying documents and records? (7.5)

NOTE: Identification may include a date, signature, reference number, file number, etc. The method must ensure that the document cannot be confused with a previous or subsequent version of the same document or record.

R48. Where necessary is format controlled? (7.5)

NOTE: While any format or medium can be used (ie paper, electronic, audio, video etc.) where a specific format is required, by procedure or inherent need, the format must be controlled.

R49. Is there evidence that shows that when documents are created or revised, there is an effective process for approval or re-approval? (7.5)

R50. Are documents needed during the process readily available to the people who need them?

NOTE: Readily available is dependent upon the situation. Having a recipe readily available for a cook has a different expectation than having a portable defibrillator readily available to a paramedic.

R51. Are documents and records effectively stored and protected from; loss, loss of confidentiality, improper use, water damage, or deterioration? (7.5)

R52 Has the organization effectively addressed distribution, access, retrieval and use of documents? Does evidence show that current controls are effectively implemented and effective in practice? (7.5)

NOTE: Access can mean permission to view information or permission to have a document under personal control or authority to use or modify a document.

R53 Where all documents verified during the assessment legible and stored effectively? (7.5)

R54. Is there evidence that documents verified during the assessment have been effectively managed for changes? (7.5)

R55. Is there a process for disposal of records? Does it comply with Statutory, Regulatory and /or Customer requirements? Do records show that it is effectively implemented? (7.5)

R56. Is there evidence of an effective process for identification of documents of external origin which need to be controlled? (7.5)

NOTE: If an undetected change to an external document could have a detrimental effect on the process then control of the revision of that document should be seriously considered?

R57. Is there evidence that shows that documents of external origin determined to need control are in fact effectively controlled? (7.5)

R58. Does the process owner have a processes needed in to achieve process objectives requirements? (internal and external customers) (4.4, 8.1)

R59. Does the process owner understand and support the interdependency of processes needed for effective product or service realization? (4.4, 8.1)

PROCESS SPECIFIC QUESTIONS

AP – Choose employees in each job category for interview. Go back to your notes from the process owner and choose the employees with the greatest risk (New Employees, Contract Employees, Part Time Employees). Ask employees what they are responsible for and what authority they have. Answers should be the same as described by the process owner. Ask employees about their training. Answers should be as described by the process owner.

AP – During interviews, if the employee mentions a document or record – stop him – ask for the document – review it for legibility, availability, proper use and completeness. Once satisfied document your evidence and return the document to the employee.

R60. Is there evidence that the organization has the appropriate equipment required for the effective execution of their processes? (7.1)

NOTE: Consider (as applicable):

- Manufacturing / Production Equipment
- Material Handling Equipment
- Refrigeration and Temperature Control Equipment
- Transportation Equipment (Trucks and Cars)
- Storage and Racking
- Dedicated Software
- Telecommunications Equipment
- Testing, Analysis, Diagnostic Equipment
- Equipment associated with Utilities
- Equipment associated with Building Maintenance

R61. Is there evidence that the capabilities and limitations of equipment have been effectively considered? (7.1)

R62. Is there evidence and records to show that equipment maintenance is a planned activity? (7.1)

R63. Do records show that equipment maintenance is done per a planned schedule which is focused on prevention of breakdowns rather than reaction to them? (7.1)

R64. Are there records of equipment performance? (7.1)

NOTE: Popular performance measures are -Up Time and/or Down Time. More modern measures are MTBF (Mean Time Before Failure) and MTTR (Mean Time To Repair)

R65. Does performance suggest that through the result of current process, that equipment is effectively available and ready to provide the services required of it? (7.1, 8.1)

R66. Do records suggest that an effective process for dealing with equipment failures exists and is effectively used? (7.1, 8.1)

AP – Look closely at equipment identified to be associated with issues. Look closely at maintenance records, repair records etc.

R67. Do records show that the need to maintain spare parts for the equipment has been effectively evaluated? (7.1, 8.1)

R68. Where spare parts are required is there effective storage for spare parts that ensures that spare parts are not lost or misplaced and are available when needed? (7.1, 8.1)

R69. If there is sufficient spare parts inventory either by quantity or value to warrant effective inventory control is there evidence that there is an effective process in place? (7.1, 8.1)

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**‘W’- MATERIALS MANAGEMENT PROCESS ASSESMENT
(Includes Receiving and Shipping)**

PROCESS SPECIFIC ASSESSMENT

QUESTIONS FOR THE PROCESS OWNER

AP – If a document or record is mentioned during your interview with the process owner – ask immediately to see the document – review it for legibility, availability, proper use and completeness. Look for evidence of poor performance or customer issues. Once satisfied document your evidence and return the document to the manager.

W1. Has the Organization effectively identified the inputs and outputs required for the effective operation of this process? (4.4)

W2. Has the Organization effectively identified the performance indicators, the measurement methods to be used, the targets to be achieved and the method of analysis and reporting on these measurements, for this process? (4.4) (9.1)

AP – Is performance evidence provided consistent with the data gathered in discussion with Top Management and in audit planning? Does the process owner's explanation of the causes and actions related to identified issues with performance consistent with those expressed by Top Management? Note if specific job functions or specific equipment is associated with identified issues.

W3. Has the organization identified the human resources necessary, the number of persons, their required competency levels and the responsibilities, authorities and accountabilities necessary for effective operation and control of the processes? (4.4 , 7.1)

AP – Make a Note of the various job titles and how many people work in each. Ask if there are any contract, part time or shared employees working within the process. Ask who the newest employee is who is working within the process. Note the answers.

W4. Has the organization identified the tools, materials and equipment necessary for the effective operation of each process? (4.4)

AP – Look closely at equipment identified to be associated with issues. Look closely at maintenance records, repair records etc.

W5. Has the organization put in place methods to ensure that tools, equipment and materials provided for this process are adequate to do the function required, are available when and where needed, and are effectively maintained? (4,4)

W6. Is there evidence that the organization has effectively determined risks, opportunities and constraints related to the resources provided and to the operation of this process? Is the need for outside resources part of this analysis? (4.4, 6.1, 7.1, 8.4)

W7. In evaluating the risks associated with this process has the organization effectively assured that the process can achieve its intended results? (6.1)

W8. Has the organization included steps designed to prevent or reduce undesired results and to identify opportunities to improve results? (6.1)

W9. Is there evidence that the process management monitors the effectiveness of the preventive actions, reduction actions and the improvement actions taken and where actions are not effective takes additional steps as necessary? (6.1)

W10. Is QMS information (performance, status, data, information) communicated internally or externally? To whom? When? How? (7.4)

W12. Is there evidence that the process owner has taken ownership and responsibility for the operation and effectiveness of this process? (5.1)

W13. Has the owner of the process taken responsibility for process objectives for this process as identified by 'Top Management'? (5.1)

AP – Are measurable consistent with those reviewed with Top Management and/or during audit planning? Note that additional measures which feed into those reported to management are acceptable.

W14. Is there evidence that the objectives identified are linked directly to performance measures that are effectively implemented, recorded, analyzed, and reported to Top Management? (BP)

W15. Are all measurable of objectives objective in nature – not subjective? (BP)

W16. Do all measurements have targets identified? (6.2)

W17. In determining targets for measurements have the following been considered? (6.2)

- What needs to be accomplished?
- Is success achievable?
- Have sufficient resources been applied?

W18. Are all measurable monitored, reported to management and changed or replaced as the needs arise? (6.2)

W19. Is there evidence that the performance measurement cycle above results ultimately in continual improvement? (BP)

AP – If improvement projects identified with Top Management or in audit planning are being applied in this process this is the time to investigate their value and effectiveness. Did they get implemented as planned? Are the benefits expected being realized?

W20. Where statutory or regulatory compliance is pertinent to the achievement of the process goals, is there evidence of a similar tracking cycle for compliance to statutory and regulatory requirements? (5.1)

W21. Is there evidence that the process owner is competent in the use of the Process Approach? (5.1)

NOTE: The Process Approach includes: PLAN – Establish performance objectives based upon customer as well as organizational expectations, RISK – Determine the risks associated with the organizations ability to achieve the performance objectives, DO – Implement the process steps with risk management steps included, CHECK – Review and analyze actual performance against the targets, ACT – Take action where objectives are not met and consider opportunities to improve where objectives are being met

W22. Is there evidence of a process which encourages people to contribute to the effectiveness of the Quality Management System? (5.1)

W23. If there evidence in this process of the use of Suggestion Plans, Open Door policies, or other processes designed to elicit employee contribution, is there evidence that they are working effectively? (BP)

W24. Do employees working within this process understand the intent of the policy and how it should affect their functions? (5.2)

NOTE: It is neither required nor intended that employees be able to recite the Quality Policy. It is important that everyone in the organization, in their own words what the Policy says and what it means to their job functions.

An important auditor question is whether the employees believe that top management believes in the Quality Policy. For employees, actions speak much louder than words.

W25. Within this process, have responsibilities, levels of authority and specific accountability been defined for each job function? (5.3)

NOTE: Accountability is NOT included in the ISO 9001 2015 requirement. I have include it here for clarification. There is a great deal of literature stating that Responsibility and Accountability are interchangeable and that therefore there is no need for both words. This makes a great discussion for academics and theorists, but for the purposes of this guidebook, I am going to take a much more pedestrian viewpoint. We take responsibility for actions and accountability for results. Everyone can be responsible for satisfying the customer, but if everyone is accountable for customer satisfaction, then no one is.

W26. Are employees fully aware of their responsibilities, authority levels and accountability in the fulfillment of their jobs? (5.3)

W27. For each process, have objectives been identified that are consistent with the Mission of the organization, the strategic goals of

the organization and the stated Quality Policy? (6.2)

W28. Where there are functions and levels which require the effective coordination of combined processes, are there appropriate measurable objectives identified? (6.2)

W29. When changes to the process documentation have been made, is there evidence that; (6.3)

- there was a defined and communicated plan for the implementation of the changes?
- the need for additional or different resources was considered?
- changes or revision of responsibilities, authority or accountability was considered?

W30. Were documentation changes and additions made available to those responsible for implementation at the time of the system change? (BP)

W31. Was an Internal Audit activity used to verify the effective implementation of the changes? (BP)

W32. For this process, has the organization determined manpower requirements needed in order to achieve customer requirements as well as requirements of other interested parties? (7.1)

W33. Has manpower analysis included the need for additional resources from outside the organization? (7.1)

W34. Has the organization determined the level of competence necessary for each person conducting work within this process? (7.2)

W35. Upon entering the workforce of the process is the employee's level of competence specifically evaluated? (7.2)

W36. Is there an established, documented process for introducing employees to new positions? (BP)

NOTE: This requirement should apply both to employees starting work with the process and for employees moving to a new function within the process.

W37. Where an Employee's competence level is less than desired in a specific function of their job, is there a process to:

- determine what remedial training or development is required?
- provide the required training or development within an appropriate time frame?
- re-evaluate the employees competence after the training/development is complete?

W38. Are records available of:

- employee competence requirements and status? (7.2)
- training/development planned and completed? (7.2)

W39. Are employees aware of:

- the content and intent of the organization's quality policy? (7.3)
- objectives related to their functions? (7.3)
- their contribution to the achievement of organizational objectives, customer focus and achievement of customer satisfaction? (7.3)
- the benefits of improved quality performance? (7.3)
- The potential implications that could result from nonconformities in their work? (7.3)?

W40. For this process, has the organization determined equipment and facility requirements needed in order to achieve customer requirements as well as requirements of the management and other interested parties? (7.1)

AP – Where software is involved , particularly software unique to this process, is there an effective backup system for protecting data? Is backup frequency adequate? Is backup data stored off site or in a safe place where damage to the main system will not also damage the backup?

W41. Has the equipment analysis included the need for outside resources? (7.1)

W42. Has the analysis considered as appropriate: (7.1)

- Building space?
- Hardware?
- Software?
- Communication and IT technology?
- Lean technologies and methods? (BP)
- Integrated processes with customers or suppliers? (BP)

W43. Are there records available to show that equipment is effectively maintained and repaired? (7.1)

W44. Do records show that maintenance of equipment happens prior to breakdown events (Preventive Maintenance) not simply when equipment fails? (7.1)

W45. Does equipment maintenance include: (7.1)

- software,
- computers,
- IT equipment,

W46. For this process, has the organization determined the documentation requirements needed in order to achieve customer requirements as well as requirements of management and other interested parties? (7.4)

W47. Do performance records for the process indicate that the amount and type of documentation available is sufficient for the effective operation and control of the process? (7.5)

W48. Is there evidence of an effective method of identifying documents and records? (7.5)

NOTE: Identification may include a date, signature, reference number, file number, etc. The method must ensure that the document cannot be confused with a previous or subsequent version of the same document or record.

W49. Where necessary is format controlled? (7.5)

NOTE: While any format or medium can be used (ie paper, electronic, audio, video etc.) where a specific format is required, by procedure or inherent need, the format must be controlled.

W50. Is there evidence that shows that when documents are created or revised, there is an effective process for approval or re-approval?

(7.5)

W51. Are documents needed during the process readily available to the people who need them?

NOTE: Readily available is dependent upon the situation. Having a recipe readily available for a cook has a different expectation than having a portable defibrillator readily available to a paramedic.

W52. Are documents and records effectively stored and protected from; loss, loss of confidentiality, improper use, water damage, or deterioration? (7.5)

W53. Has the organization effectively addressed distribution, access, retrieval and use of documents? Does evidence show that current controls are effectively implemented and effective in practice? (7.5)

NOTE: Access can mean permission to view information or permission to have a document under personal control or authority to use or modify a document.

W54. Where all documents verified during the assessment legible and stored effectively? (7.5)

W55. Is there evidence that documents verified during the assessment have been effectively managed for changes? (7.5)

W56. Is there a process for disposal of records? Does it comply with Statutory, Regulatory and /or Customer requirements? Do records show that it is effectively implemented? (7.5)

W57. Is there evidence of an effective process for identification of documents of external origin which need to be controlled? (7.5)

NOTE: If an undetected change to an external document could have a detrimental effect on the process then control of the revision of that document should be seriously considered?

W58. Is there evidence that shows that documents of external origin determined to need control are in fact effectively controlled? (7.5)

W59. Does the process owner have a processes needed in to achieve process objectives requirements? (internal and external customers) (4.4, 8.1)

W60. Does the process owner understand and support the interdependency of processes needed for effective product or service realization? (4.4, 8.1)

PROCESS SPECIFIC QUESTIONS

AP – Choose employees in each job category for interview. Go back to your notes from the process owner and choose the employees with the greatest risk (New Employees, Contract Employees, Part Time Employees). Ask employees what they are responsible for and what authority they have. Answers should be the same as described by the process owner. Ask employees about their training. Answers should be as described by the process owner.

AP – During interviews, if the employee mentions a document or record – stop him – ask for the document – review it for legibility, availability, proper use and completeness. Once satisfied document your evidence and return the document to the employee.

W61. Does the receiving function have clear data describing the products or services being provided by outside suppliers? (8.4)

W62. Is there evidence of effective controls to ensure compliance with statutory and/or regulatory requirements related to materials received? (8.5)

W63. Is there a process for approval and release of products or for services to begin? (8.4)

W64. If the approval process includes inspection or physical verification of product, are there: (8.4, 8.5)

- Instructions for the inspections to be made?
- Records of inspections?
- Appropriate, calibrated and properly maintained inspection equipment?
- An effective process for handling materials that do not conform to requirements?
- Specified competency or qualification requirements for those doing verification?
- Handling instruction for the movement and storage of accepted material?

W65. Where product is verified at a source location, are there effective processes in place to ensure control? Including: (8.4)

- Procedures or instructions?
- Sufficient records?
- Competent personnel?

W66. Where a certified supplier process is used, is the acceptance of material linked to achievement of product performance once in process? (8.4)

W67. Is there evidence that material rejected during processing due to a failure with material as received has caused effective actions to be taken in the receiving process? (8.4)

W68. Where applicable is material identification available and maintained during and after the receiving process? (8.5)

W69. Is suspect or reject material clearly identified when found during the process?

NOTE: Material that is not known to be acceptable must be identified and non-conforming until such time as conformance can be verified.

W70. Is nonconforming material segregated from acceptable material in a timely manner such that nonconforming material cannot become re-integrated into the conforming material flow? (8.7)

W71. Is there evidence that material is effectively handled, packaged, stored and protected against dirt, water, contamination, damage or deterioration throughout receiving, movement, or storage activities? (8.5)

W72. Where materials have specific shelf life, Is there evidence of a process for monitoring and management of such materials? (8.5)

NOTE: Consider; for example- rubber or nylon belts or hoses, paper products, oils, paints, sealed bearings, food and the ingredients for foods, containers for foods, first aid and health care products.

W73. Where climate or environmental controls are required for storage of material is there: (8.5)

- Appropriate instructions for monitoring and measurement of controls?
- Appropriate monitoring and calibration of control equipment and gauging?
- Evidence of effective actions where climate or environmental controls fail?

W74. Is there an appropriate process for ensuring that all required process steps have been completed and that product complies with requirements prior to release for shipping? (8.6)

W75. Are there appropriate instructions for packaging and shipping methods? (8.5)

W76. Where there is a combination of product shipment and service provision; is there appropriate processes to ensure that: (8.6)

- All required materials and/or equipment will be available when and where needed?
- There is no ambiguity in understandings about the service to be provided?
- Service personnel have the competence and training to do the job?

- Service personnel are provided with all required information needed to ensure that they can provide for all stated customer requirements?
- That effective contingency processes are in place to provide service personnel with effective support should the information or materials turn out to be inadequate?

W77. Prior to shipping is there a process to ensure compliance with all statutory or regulatory requirements? (8.5)

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‘IT’- INFORMATION TECHNOLOGY PROCESS ASSESSMENT

PROCESS SPECIFIC ASSESSMENT

QUESTIONS FOR THE PROCESS OWNER

AP – If a document or record is mentioned during your interview with the process owner – ask immediately to see the document – review it for legibility, availability, proper use and completeness. Look for evidence of poor performance or customer issues. Once satisfied document your evidence and return the document to the manager.

IT1. Has the Organization effectively identified the inputs and outputs required for the effective operation of this process? (4.4)

IT2. Has the Organization effectively identified the performance indicators, the measurement methods to be used, the targets to be achieved and the method of analysis and reporting on these measurements, for this process? (4.4) (9.1)

AP – Is performance evidence provided consistent with the data gathered in discussion with Top Management and in audit planning? Does the process owner's explanation of the causes and actions related to identified issues with performance consistent with those expressed by Top Management? Note if specific job functions or specific equipment is associated with identified issues.

IT3. Has the organization identified the human resources necessary, the number of persons, their required competency levels and the responsibilities, authorities and accountabilities necessary for effective operation and control of the processes? (4.4 , 7.1)

AP – Make a Note of the various job titles and how many people work in each. Ask if there are any contract, part time or shared employees working within the process. Ask who the newest employee is who is working within the process. Note the answers.

IT4. Has the organization identified the tools, materials and equipment necessary for the effective operation of each process? (4.4)

AP – Look closely at software or hardware identified to be associated with issues.

IT5. Has the organization put in place methods to ensure that tools, equipment and materials provided for this process are adequate to do the function required, are available when and where needed, and are effectively maintained? (4,4)

IT6. Is there evidence that the organization has effectively determined risks, opportunities and constraints related to the resources provided and to the operation of this process? Is the need for outside resources part of this analysis? (4.4, 6.1, 7.1, 8.4)

IT7. In evaluating the risks associated with this process has the organization effectively assured that the process can achieve its intended results? (6.1)

IT8. Has the organization included steps designed to prevent or reduce undesired results and to identify opportunities to improve results? (6.1)

IT9. Is there evidence that the process management monitors the effectiveness of the preventive actions, reduction actions and the improvement actions taken and where actions are not effective takes additional steps as necessary? (6.1)

IT10. Is QMS information (performance, status, data, information) communicated internally or externally? To whom? When? How? (7.4)

IT11. Is there evidence that the process owner has taken ownership and responsibility for the operation and effectiveness of this process? (5.1)

IT12. Has the owner of the process taken responsibility for process objectives for this process as identified by 'Top Management'? (5.1)

IT13. Is there evidence that the objectives identified are linked directly to performance measures that are effectively implemented, recorded, analyzed, and reported to Top Management? (BP)

AP – Are measurable consistent with those reviewed with Top Management and/or during audit planning? Note that additional measures which feed into those reported to management are acceptable.

IT14. Are all measurable of objectives objective in nature – not subjective? (BP)

IT15. Do all measurements have targets identified? (6.2)

IT16. In determining targets for measurements have the following been considered? (6.2)

- What needs to be accomplished?
- Is success achievable?
- Have sufficient resources been applied?

IT17. Are all measurable monitored, reported to management and changed or replaced as the needs arise? (6.2)

IT18. Is there evidence that the performance measurement cycle above results ultimately in continual improvement? (BP)

IT19. Where statutory or regulatory compliance is pertinent to the achievement of the process goals, is there evidence of a similar tracking cycle for compliance to statutory and regulatory requirements? (5.1)

IT20. Is there evidence that the process owner is competent in the use of the Process Approach? (5.1)

NOTE: The Process Approach includes: PLAN – Establish performance objectives based upon customer as well as organizational expectations, RISK – Determine the risks associated with the organizations ability to achieve the performance objectives, DO – Implement the process steps with risk management steps included, CHECK – Review and analyze actual performance against the targets, ACT – Take action where objectives are not met and consider opportunities to improve where objectives are being met

IT21. Is there evidence of a process which encourages people to contribute to the effectiveness of the Quality Management System? (5.1)

IT22. If there evidence in this process of the use of Suggestion Plans, Open Door policies, or other processes designed to elicit employee contribution, is there evidence that they are working effectively? (BP)

IT23. Do employees working within this process understand the intent of the policy and how it should affect their functions? (5.2)

NOTE: It is neither required nor intended that employees be able to recite the Quality Policy. It is important that everyone in the organization, in their own words what the Policy says and what it means to their job functions.

An important auditor question is whether the employees believe that top management believes in the Quality Policy. For employees, actions speak much louder than words.

IT24. Within this process, have responsibilities, levels of authority and specific accountability been defined for each job function? (5.3)

NOTE: Accountability is NOT included in the ISO 9001 2015 requirement. I have include it here for clarification. There is a great deal of literature stating that Responsibility and Accountability are interchangeable and that therefore there is no need for both words. This makes a great discussion for academics and theorists, but for the purposes of this guidebook, I am going to take a much more pedestrian viewpoint. We take responsibility for actions and accountability for results. Everyone can be responsible for satisfying the customer, but if everyone is accountable for customer satisfaction, then no one is.

IT25. Are employees fully aware of their responsibilities, authority levels and accountability in the fulfillment of their jobs? (5.3)

IT26. For each process, have objectives been identified that are consistent with the Mission of the organization, the strategic goals of the organization and the stated Quality Policy? (6.2)

IT27. Where there are functions and levels which require the effective coordination of combined processes, are there appropriate measurable objectives identified? (6.2)

IT28. When changes to the process documentation have been made, is there evidence that; (6.3)

- there was a defined and communicated plan for the implementation of the changes?
- the need for additional or different resources was considered?
- changes or revision of responsibilities, authority or accountability was considered?

IT29. Where documentation changes and additions made available to those responsible for implementation at the time of the system change? (BP)

IT30. Was an Internal Audit activity used to verify the effective implementation of the changes? (BP)

IT31. For this process, has the organization determined manpower requirements needed in order to achieve customer requirements as well as requirements of other interested parties? (7.1)

IT34. Has manpower analysis included the need for additional resources from outside the organization? (7.1)

IT35. Has the organization determined the level of competence necessary for each person conducting work within this process?

(7.2)

IT36. Upon entering the workforce of the process is the employee's level of competence specifically evaluated? (7.2)

IT37. Is there an established, documented process for introducing employees to new positions? (BP)

NOTE: This requirement should apply both to employees starting work with the process and for employees moving to a new function within the process.

IT38. Where an Employee's competence level is less than desired in a specific function of their job, is there a process to:

- determine what remedial training or development is required?
- provide the required training or development within an appropriate time frame?
- re-evaluate the employees competence after the training/development is complete?

IT39. Are records available of:

- employee competence requirements and status? (7.2)
- training/development planned and completed? (7.2)

IT40. Are employees aware of:

- the content and intent of the organization's quality policy? (7.3)
- objectives related to their functions? (7.3)
- their contribution to the achievement of organizational objectives, customer focus and achievement of customer satisfaction? (7.3)
- the benefits of improved quality performance? (7.3)
- The potential implications that could result from nonconformities in their work? (7.3)?

IT41. For this process, has the organization determined equipment and facility requirements needed in order to achieve customer requirements as well as requirements of the management and other interested parties? (7.1)

IT42. Has the equipment analysis included the need for outside resources? (7.1)

IT43. Has the analysis considered as appropriate: (7.1)

- Building space?
- Hardware?
- Software?
- Communication and IT technology?

- Lean technologies and methods? (BP)
- Integrated processes with customers or suppliers? (BP)

IT44. Are there records available to show that equipment is effectively maintained and repaired? (7.1)

IT45. Do records show that maintenance of equipment happens prior to breakdown events (Preventive Maintenance) not simply when equipment fails? (7.1)

IT46. Does equipment maintenance include: (7.1)

- software,
- computers,
- IT equipment,

IT47. For this process, has the organization determined the documentation requirements needed in order to achieve customer requirements as well as requirements of management and other interested parties? (7.4)

IT48. Do performance records for the process indicate that the amount and type of documentation available is sufficient for the effective operation and control of the process? (7.5)

IT49. Is there evidence of an effective method of identifying documents and records? (7.5)

NOTE: Identification may include a date, signature, reference number, file number, etc. The method must ensure that the document cannot be confused with a previous or subsequent version of the same document or record.

IT50. Where necessary is format controlled? (7.5)

NOTE: While any format or medium can be used (ie paper, electronic, audio, video etc.) where a specific format is required, by procedure or inherent need, the format must be controlled.

IT51. Is there evidence that shows that when documents are created or revised, there is an effective process for approval or re-approval? (7.5)

IT52. Are documents needed during the process readily available to the people who need them?

NOTE: Readily available is dependent upon the situation. Having a recipe readily available for a cook has a different expectation than having a portable defibrillator readily available to a paramedic.

IT53. Are documents and records effectively stored and protected from; loss, loss of confidentiality, improper use, water damage, or deterioration? (7.5)

IT54. Has the organization effectively addressed distribution, access, retrieval and use of documents? Does evidence show that current controls are effectively implemented and effective in practice? (7.5)

NOTE: Access can mean permission to view information or permission to have a document under personal control or authority to use or modify a document.

IT55. Where all documents verified during the assessment legible and stored effectively? (7.5)

IT56. Is there evidence that documents verified during the assessment have been effectively managed for changes? (7.5)

IT57. Is there a process for disposal of records? Does it comply with Statutory, Regulatory and /or Customer requirements? Do records show that it is effectively implemented? (7.5)

IT58. Is there evidence of an effective process for identification of documents of external origin which need to be controlled? (7.5)

NOTE: If an undetected change to an external document could have a detrimental effect on the process then control of the revision of that document should be seriously considered?

IT59. Is there evidence that shows that documents of external origin determined to need control are in fact effectively controlled? (7.5)

IT60. Does the process owner have a processes needed in to achieve process objectives requirements? (internal and external customers) (4.4, 8.1)

PROCESS SPECIFIC QUESTIONS

AP – Choose employees in each job category for interview. Go back to your notes from the process owner and choose the employees with the greatest risk (New Employees, Contract Employees, Part Time Employees). Ask employees what they are responsible for and what authority they have. Answers should be the same as described by the process owner. Ask employees about their training. Answers should be as described by the process owner.

AP – During interviews, if the employee mentions a document or record – stop him – ask for the document – review it for legibility, availability, proper use and completeness. Once satisfied document your evidence and return the document to the employee.

IT61. Whether in house or contracted is IT identified and managed as an organization process? (7.1)

NOTE: There was a time when IT was considered an add-on to systems, but in today's modern organizations IT is an important integral activity. As a result, IT must have all of the components of a process in order to ensure effective operation and control.

IT62. Is there evidence that IT personnel are fully competent in the use and maintenance of unique or special software used by the organization? (7.1)

IT63. Is there evidence of an effective organizational approach to technology with regard to the development and use of software based technologies? (7.1)

IT64. Does evidence show that the level of technological development is sufficient to: (7.1)

- Ensure that customer expectations can be met?
- Meet stated organizational objectives?
- Support continual improvement?

IT65. Does evidence show that the IT areas of the organizations are effectively organized and equipped to ensure effective operations?

IT66. Where temperature, humidity or dust controls in IT areas, are needed, is there evidence of effective controls? (7.1)

IT67. Is there evidence of an effective process for monitoring of software and hardware breakdowns? (7.1)

IT68. Do performance records show that software and computer hardware is effectively available to system users when, where and as needed? (7.1)

IT69. Is there evidence of effective software version control? (7.5)

IT70. Where IT systems are used for specific customer required communication and information exchange systems, is the organization's system compatible and capable for performing the required activities? (7.4, 8.2)

IT71. Is there evidence that QMS documentation and records stored or used electronically are: effectively: (7.5)

- Effectively reviewed and approved?
- Maintained under revision control?
- Readily retrievable by personnel who require the documents or records as a component of their work?
- Protected from inadvertent revision or deletion?
- Prevented from loss of confidentiality?

IT72. Is there evidence of an effective process for disposal of electronic records? (7.5)

IT73. Where IT services are outsourced, are there effective performance measurement controls in place to ensure effective operations, availability, document controls and confidentiality controls? (8.4)

IT74. Does evidence show that acceptable levels of service performance are being provided? (8.4)

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‘PR’- PRODUCT REALIZATION PROCESS ASSESSMENT (Production and Manufacturing)

PROCESS SPECIFIC ASSESSMENT

QUESTIONS FOR THE PROCESS OWNER

AP – If a document or record is mentioned during your interview with the process owner – ask immediately to see the document – review it for legibility, availability, proper use and completeness. Look for evidence of poor performance or customer issues. Once satisfied document your evidence and return the document to the manager.

PR1. Has the Organization effectively identified the inputs and outputs required for the effective operation of this process? (4.4)

PR2. Has the Organization effectively identified the performance indicators, the measurement methods to be used, the targets to be achieved and the method of analysis and reporting on these measurements, for this process? (4.4) (9.1)

AP – Is performance evidence provided consistent with the data gathered in discussion with Top Management and in audit planning? Does the process owner's explanation of the causes and actions related to identified issues with performance consistent with those expressed by Top Management? Note if specific job functions or specific equipment is associated with identified issues.

PR3. Has the organization identified the human resources necessary, the number of persons, their required competency levels and the responsibilities, authorities and accountabilities necessary for effective operation and control of the processes? (4.4 , 7.1)

AP – Make a Note of the various job titles and how many people work in each. Ask if there are any contract, part time or shared employees working within the process. Ask who the newest employee is who is working within the process. Note the answers.

PR4. Has the organization identified the tools, materials and equipment necessary for the effective operation of each process? (4.4)

AP – Look closely at equipment identified to be associated with issues. Look closely at maintenance records, repair records etc.

PR5. Has the organization put in place methods to ensure that tools, equipment and materials provided for this process are adequate to do the function required, are available when and where needed, and are effectively maintained? (4,4)

PR6. Is there evidence that the organization has effectively determined risks, opportunities and constraints related to the resources provided and to the operation of this process? Is the need for outside resources part of this analysis? (4.4, 6.1, 7.1, 8.4)

PR7. In evaluating the risks associated with this process has the organization effectively assured that the process can achieve its intended results? (6.1)

PR8. Has the organization included steps designed to prevent or reduce undesired results and to identify opportunities to improve results? (6.1)

PR9. Is there evidence that the process management monitors the effectiveness of the preventive actions, reduction actions and the improvement actions taken and where actions are not effective takes additional steps as necessary? (6.1)

PR10. Is QMS information (performance, status, data, information) communicated internally or externally? To whom? When? How? (7.4)

PR11. Is there evidence that the process owner has taken ownership and responsibility for the operation and effectiveness of this process? (5.1)

PR12. Has the owner of the process taken responsibility for process objectives for this process as identified by 'Top Management'? (5.1)

PR13. Is there evidence that the objectives identified are linked directly to performance measures that are effectively implemented, recorded, analyzed, and reported to Top Management? (BP)

AP – Are measurable consistent with those reviewed with Top Management and/or during audit planning? Note that additional measures which feed into those reported to management are acceptable.

PR14. Are all measurable of objectives objective in nature – not subjective? (BP)

PR15. Do all measurements have targets identified? (6.2)

PR16. In determining targets for measurements have the following been considered? (6.2)

- What needs to be accomplished?
- Is success achievable?
- Have sufficient resources been applied?

PR17. Are all measurable monitored, reported to management and changed or replaced as the needs arise? (6.2)

PR18. Is there evidence that the performance measurement cycle above results ultimately in continual improvement? (BP)

AP – If improvement projects identified with Top Management or in audit planning are being applied in this process this is the time to investigate their value and effectiveness. Did they get implemented as planned? Are the benefits expected being realized?

PR19. Where statutory or regulatory compliance is pertinent to the achievement of the process goals, is there evidence of a similar tracking cycle for compliance to statutory and regulatory requirements? (5.1)

PR20. Is there evidence that the process owner is competent in the use of the Process Approach? (5.1)

NOTE: The Process Approach includes: PLAN – Establish performance objectives based upon customer as well as organizational expectations, RISK – Determine the risks associated with the organizations ability to achieve the performance objectives, DO – Implement the process steps with risk management steps included, CHECK – Review and analyze actual performance against the targets, ACT – Take action where objectives are not met and consider opportunities to improve where objectives are being met

PR21. Is there evidence of a process which encourages people to contribute to the effectiveness of the Quality Management System? (5.1)

PR22. If there evidence in this process of the use of Suggestion Plans, Open Door policies, or other processes designed to elicit employee contribution, is there evidence that they are working effectively? (BP)

PR23. Do employees working within this process understand the intent of the policy and how it should affect their functions? (5.2)

NOTE: It is neither required nor intended that employees be able to recite the Quality Policy. It is important that everyone in the organization, in their own words what the Policy says and what it means to their job functions.

An important auditor question is whether the employees believe that top management believes in the Quality Policy. For employees, actions speak much louder than words.

PR24. Within this process, have responsibilities, levels of authority and specific accountability been defined for each job function? (5.3)

NOTE: Accountability is NOT included in the ISO 9001 2015 requirement. I have include it here for clarification. There is a great deal of literature stating that Responsibility and Accountability are interchangeable and that therefore there is no need for both words. This makes a great discussion for academics and theorists, but for the purposes of this guidebook, I am going to take a much more pedestrian viewpoint. We take responsibility for actions and accountability for results. Everyone can be responsible for satisfying the customer, but if everyone is accountable for customer satisfaction, then no one is.

PR25. Are employees fully aware of their responsibilities, authority levels and accountability in the fulfillment of their jobs? (5.3)

PR26. For each process, have objectives been identified that are consistent with the Mission of the organization, the strategic goals of

the organization and the stated Quality Policy? (6.2)

PR27. Where there are functions and levels which require the effective coordination of combined processes, are there appropriate measurable objectives identified? (6.2)

PR28. When changes to the process documentation have been made, is there evidence that; (6.3)

- there was a defined and communicated plan for the implementation of the changes?
- the need for additional or different resources was considered?
- changes or revision of responsibilities, authority or accountability was considered?

PR29. Where documentation changes and additions made available to those responsible for implementation at the time of the system change? (BP)

PR30. Was an Internal Audit activity used to verify the effective implementation of the changes? (BP)

PR31. For this process, has the organization determined manpower requirements needed in order to achieve customer requirements as well as requirements of other interested parties? (7.1)

PR32. Has manpower analysis included the need for additional resources from outside the organization? (7.1)

PR33. Has the organization determined the level of competence necessary for each person conducting work within this process? (7.2)

PR34. Upon entering the workforce of the process is the employee's level of competence specifically evaluated? (7.2)

PR35. Is there an established, documented process for introducing employees to new positions? (BP)

NOTE: Requirements for introduction to jobs and for determining competence should apply both to employees starting work in the process and for employees moving to a new function within the process. Some organizations see benefit in cross training of employees in production processes. If this applies then the status of cross training for each employee should be readily available to supervisors. Evaluate how employees are determined to be competent at each specific job and how records are kept. ('see process specific questions')

PR36. Where employee's competence level is less than desired in a specific function of their job, is there a process to:

- determine what remedial training or development is required?

- provide the required training or development within an appropriate time frame?
- re-evaluate the employees competence after the training/development is complete?

PR37. Are records available of:

- employee competence requirements and status? (7.2)
- training/development planned and completed? (7.2)

PR38. Are employees aware of:

- the content and intent of the organization's quality policy? (7.3)
- objectives related to their functions? (7.3)
- their contribution to the achievement of organizational objectives, customer focus and achievement of customer satisfaction? (7.3)
- the benefits of improved quality performance? (7.3)
- The potential implications that could result from nonconformities in their work? (7.3)?

PR39. For this process, has the organization determined equipment and facility requirements needed in order to achieve customer requirements as well as requirements of the management and other interested parties? (7.1)

AP – Where software is involved , particularly software unique to this process, is there an effective backup system for protecting data? Is backup frequency adequate? Is backup data stored off site or in a safe place where damage to the main system will not also damage the backup?

PR40. Has the equipment analysis included the need for outside resources? (7.1)

PR41. Has the analysis considered as appropriate: (7.1)

- Building space?
- Utilities?
- Hardware?
- Software?
- Transportation equipment?
- Communication equipment?
- Communication and IT technology?
- Value added use of floor space? (BP)
- Lean technologies and methods? (BP)
- Integrated processes with customers or suppliers? (BP)

PR42. Are there records available to show that equipment is effectively maintained and repaired? (7.1)

PR43. Do records show that maintenance of equipment happens prior to breakdown events (Preventive Maintenance) not simply when equipment fails? (7.1)

PR44. Does equipment maintenance include: (7.1)

- processing equipment,
- software,
- computers,
- IT equipment,
- trucks and transportation equipment

PR45. For this process, has the organization determined the documentation requirements needed in order to achieve customer requirements as well as requirements of management and other interested parties? (7.4)

PR46. Do performance records for the process indicate that the amount and type of documentation available is sufficient for the effective operation and control of the process? (7.5)

PR47. Is there evidence of an effective method of identifying documents and records? (7.5)

NOTE: Identification may include a date, signature, reference number, file number, etc. The method must ensure that the document cannot be confused with a previous or subsequent version of the same document or record.

PR48. Where necessary is format controlled? (7.5)

NOTE: While any format or medium can be used (ie paper, electronic, audio, video etc.) where a specific format is required, by procedure or inherent need, the format must be controlled.

PR49. Is there evidence that shows that when documents are created or revised, there is an effective process for approval or re-approval? (7.5)

PR50. Are documents needed during the process readily available to the people who need them? (7.5)

NOTE: Readily available is dependent upon the situation. Having a recipe readily available for a cook has a different expectation than having a portable defibrillator readily available to a paramedic.

PR51. Are documents and records effectively stored and protected from; loss, loss of confidentiality, improper use, water damage, or deterioration? (7.5)

PR51. Has the organization effectively addressed distribution, access, retrieval and use of documents? Does evidence show that current controls are effectively implemented and effective in practice? (7.5)

NOTE: Access can mean permission to view information or permission to have a document under personal control or authority to use or modify a document.

PR52. Where all documents verified during the assessment legible and stored effectively? (7.5)

PR53. Is there evidence that documents verified during the assessment have been effectively managed for changes? (7.5)

PR54. Is there a process for disposal of records? Does it comply with Statutory, Regulatory and /or Customer requirements? Do records show that it is effectively implemented? (7.5)

PR55. Is there evidence of an effective process for identification of documents of external origin which need to be controlled? (7.5)

NOTE: If an undetected change to an external document could have a detrimental effect on the process then control of the revision of that document should be seriously considered?

PR56. Is there evidence that shows that documents of external origin determined to need control are in fact effectively controlled? (7.5)

PR57. Does the process owner have the organizational, documentation and system structure needed in to achieve process objectives requirements? (consider both internal and external customer requirements) (4.4, 8.1)

PR58. Does the process owner understand and support the interdependency of processes needed for effective product or service realization? (4.4, 8.1)

PROCESS SPECIFIC QUESTIONS

Verify conformance with the following questions for each step of the process from receipt of materials needed for the product to final shipping of the product. Follow the flow of manufacturing or production as closely as is practicable. Where there are multiple production lines, pick one line based upon history of customer complaints, internal part failures, negative performance (scrap, productivity), process changes etc.

PR59. Can the employee running the operation clearly describe their role and responsibilities? (5.3)

PR60. Is there evidence that the employees operating equipment of providing the function are trained and competent to do the job? (7.1,

7.2)

PR61. Is there evidence that the language of written instructions etc. is appropriate for the operator doing the work? (7.5)

PR62. Can the employee explain how customer focus applies to their function? (5.3, 7.3)

PR63. Can the employee explain in their own words the purpose and benefits of continual improvement in achieving customer satisfaction? (6.1, 7.3)

PR64. Is there an effective method for communicating changes to the job function to the employees involved? (7.5)

PR65. Is there documentation that describes the input requirements for the job function? (7.1, 8.1, 9.1)

NOTE: Consider incoming materials, tools, gages, instructions, packaging, labels, cleaning supplies (5S), sample boards, nonconforming material storage, first-off sample storage, proper sensor function.

PR66. Where part traceability is a requirement is it a component of in-input information and set-up? (7.1, 8.1)

PR67. Where there are specific special process steps or methods required by specific customers are these COPs (Customer Oriented Processes) uniquely identified, documented and monitored for completeness and effectiveness? Are personnel trained, competent and aware of these unique requirements? (8.2)

PR68. Where environmental conditions are a function of the process, are they effectively defined as in-put requirements? (7.1, 8.1)

NOTE: Consider lighting, temperature, humidity, noise, protection from climatic conditions (rain, snow, dust, dirt, etc.).

PR69. Is there evidence that all in-put requirements are or were in place prior to the start of the process? (7.1, 8.1)

PR70. Is there evidence that all materials in the work area are needed for the process? (BP)

NOTE: Unwanted materials such as parts from previous production runs whether scrap or production materials, fasteners, screws, bolts, labels, packaging, instructions, records, samples, dirty rags, etc. should not be in the work area.(BP)

PR71. Is there evidence that shows that all measuring instruments at the work area are: (7.1, 8.5)

- Those required for the job and only those required for the job
- Calibrated within its prescribed cycle
- Identified with its calibration date and calibration due date
- Identified as calibrated by qualified personnel
- Void of excess dirt or grime
- Undamaged and protected from damage
- Functioning properly
- Safeguarded from adjustment or tampering

PR72. Are there defined requirements for product and/or process monitoring during production? (7.5)

PR73. Do records indicate that all required checks have been conducted as specified? (7.5)

PR74. Do records provide variables data (specific measurements) as compared to check marks? (BP)

PR75. Where requirements have not been met is there an effective process to stop production and to segregate all suspect materials including materials which may have been produced and or moved to subsequent process steps prior to the identification of the problem?

PR76. Is there evidence of an effective corrective action process which investigates the cause of defective materials, fixes the problem, ensures that no defective material remains in the production stream, and re-verifies the production process prior to re-start of production?

PR77. Verify that Sensors, Poke Yoke, Mistake Proofing, Error Proofing, Failure Detection Systems, etc. are working properly and are effective?

PR78. Verify that product outside the normal process flow is:

- *properly identified as to its quality status?
- segregated from the material flow?
- cannot be inadvertently reintroduced to production?

NOTE: *Suspect material must be marked as nonconforming until such time as suitability has been confirmed.

PR79. Are all materials in the work area including components, sub-assemblies and hardware clearly identified through tags, labels part marking, etc. such that product can be readily identified? (8.5)

PR80. Verify that only labels used in the process are in the work area? (8.5)

PR81. Verify that labels are stored in such a way that sequence, right vs left, top vs bottom and color or style choices cannot be mixed? (8.5)

PR82. Is there evidence that only the required packaging materials are in the work area? (8.5)

PR83. Is there evidence that packaging is conducted as specified or required?

PR84. Is there evidence that all required processing is complete as required prior to material moving out of the work area unless such material is fully identified including description of the variance and approval by responsible authority?

VERIFICATION – Where operators and/or inspectors are responsible for product verification apply the following for each person responsible. Have the operator complete the required checks in front of the auditor. Once complete and the following three questions are answered, follow the same process with other operators or inspectors who do verifications.

PR85. Has the operator/inspector shown competence in doing the appropriate verifications? (9.1)

PR86. Does the operator have all required documentation for recording results and is the operator competent in the requirements

for completing the documentation? (9.1)

PR87. Does the evidence show that the inspection method will effectively discriminate between acceptable product and defective product? (9.1)

PR88. Is product currently in production in conformance with all criteria verified in the inspections? (9.1)

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‘SR’-SERVICE REALIZATION PROCESS ASSESSMENT (Service and Retail)

PROCESS SPECIFIC ASSESSMENT

QUESTIONS FOR THE PROCESS OWNER

AP – If a document or record is mentioned during your interview with the process owner – ask immediately to see the document – review it for legibility, availability, proper use and completeness. Look for evidence of poor performance or customer issues. Once satisfied document your evidence and return the document to the manager.

SR1. Has the Organization effectively identified the inputs and outputs required for the effective operation of this process? (4.4)

SR2. Has the Organization effectively identified the performance indicators, the measurement methods to be used, the targets to be achieved and the method of analysis and reporting on these measurements, for this process? (4.4) (9.1)

AP – Is performance evidence provided consistent with the data gathered in discussion with Top Management and in audit planning? Does the process owner's explanation of the causes and actions related to identified issues with performance consistent with those expressed by Top Management? Note if specific job functions or specific equipment is associated with identified issues.

SR3. Has the organization identified the human resources necessary, the number of persons, their required competency levels and the responsibilities, authorities and accountabilities necessary for effective operation and control of this process? (4.4 , 7.1)

AP – Make a Note of the various job titles and how many people work in each. Ask if there are any contract, part time or shared employees working within the process. Ask who the newest employee is who is working within the process. Note the answers.

SR4. Has the organization identified the tools, materials and equipment necessary for the effective operation of this process? (4.4)

AP – Look closely at equipment identified to be associated with issues. Look closely at maintenance records, repair records etc.

SR5. Has the organization put in place methods to ensure that tools, equipment and materials provided for this process are adequate to do the function required, are available when and where needed, and are effectively maintained? (4,4)

SR6. Is there evidence that the organization has effectively determined risks, opportunities and constraints related to the resources provided and to the operation of this process? Is the need for outside resources part of this analysis? (4.4, 6.1, 7.1, 8.4)

SR7. In evaluating the risks associated with this process has the organization effectively assured that the process can achieve its intended results? (6.1)

SR8. Has the organization included steSR designed to prevent or reduce undesired results and to identify opportunities to improve results? (6.1)

SR9. Is there evidence that the process owner monitors the effectiveness of the corrective actions, and the improvement actions taken and where actions are not effective takes additional steps as necessary? (6.1)

SR10. Is QMS information (performance, status, data, information) communicated internally and/or externally? To whom? When? How? (7.4)

SR11. Is there evidence that the process owner has taken ownership and responsibility for the operation and effectiveness of this process? (5.1)

SR12. Has the owner of the process taken responsibility for process objectives for this process as identified by 'Top Management'? (5.1)

SR13. Is there evidence that the objectives identified are linked directly to performance measures that are effectively implemented, recorded, analyzed, and reported to Top Management? (BP)

AP – Are measurable consistent with those reviewed with Top Management and/or during audit planning? Note that additional

measures which feed into those reported to management are acceptable.

SR14. Are all measurable of objectives objective in nature – not subjective? (BP)

SR15. Do all measurements have targets identified? (6.2)

SR16. In determining targets for measurements have the following been considered? (6.2)

- What needs to be accomplished?
- Is success achievable?
- Have sufficient resources been applied?

SR17. Are all measurables monitored, reported to management and changed or replaced as the needs arise? (6.2)

SR18. Is there evidence that the performance measurement cycle above results ultimately in continual improvement? (BP)

AP – If improvement projects identified with Top Management or in audit planning are being applied in this process this is the time to investigate their value and effectiveness. Did they get implemented as planned? Are the benefits expected being realized?

SR19. Where statutory or regulatory compliance is pertinent to the achievement of the process goals, is there evidence of a similar tracking cycle for compliance to statutory and regulatory requirements? (5.1)

SR20. Is there evidence that the process owner is competent in the use of the Process Approach? (5.1)

NOTE: The Process Approach includes: PLAN – Establish performance objectives based upon customer as well as organizational expectations, RISK – Determine the risks associated with the organizations ability to achieve the performance objectives, DO – Implement the process with risk management included, CHECK – Review and analyze actual performance against the targets, ACT – Take action where objectives are not met and consider opportunities to improve where objectives are being met

SR21. Is there evidence of a process which encourages people to contribute to the effectiveness of the Quality Management System? (5.1)

SR22. If there evidence in this process of the use of Suggestion Plans, Open Door policies, or other processes designed to elicit employee contribution, is there evidence that they are working effectively? (BP)

SR23. Do employees working within this process understand the intent of the quality policy and how it should affect their functions? (5.2)

NOTE: It is neither required nor intended that employees be able to recite the Quality Policy. It is important that everyone in the organization, in their own words what the Policy says and what it means to their job functions.

An important auditor question is whether the employees believe that top management believes in the Quality Policy. For employees, actions speak much louder than words.

SR24. Within this process, have responsibilities, levels of authority and specific accountability been defined for each job function? (5.3)

NOTE: Accountability is NOT included in the ISO 9001 2015 requirement. I have include it here for clarification. There is a great deal of literature stating that Responsibility and Accountability are interchangeable and that therefore there is no need for both words. This makes a great discussion for academics and theorists, but for the purposes of this guidebook, I am going to take a much more pedestrian viewpoint. We take responsibility for actions and accountability for results. Everyone can be responsible for satisfying the customer, but if everyone is accountable for customer satisfaction, then no one is.

SR25. Are employees fully aware of their responsibilities, authority levels and accountability in the fulfillment of their jobs? (5.3)

SR26. Have objectives been identified for this process that are consistent with the Mission of the organization, the strategic goals of the organization and the stated Quality Policy? (6.2)

SR27. Where there are functions and levels which require the effective coordination of combined processes, are there appropriate measurable objectives identified? (6.2)

SR28. When changes to the process documentation have been made, is there evidence that; (6.3)

- there was a defined and communicated plan for the implementation of the changes?
- the need for additional or different resources was considered?
- changes or revision of responsibilities, authority or accountability was considered?

SR29. Where documentation changes and additions made available to those responsible for implementation at the time of the system change? (BP)

SR30. Was an Internal Audit activity used to verify the effective implementation of the changes? (BP)

SR31. For this process, has the organization determined manpower requirements needed in order to achieve customer requirements as well as requirements of other interested parties? (7.1)

SR32. Has manpower analysis included the need for additional resources from outside the organization? (7.1)

SR33. Has the organization determined the level of competence necessary for each person conducting work within this process? (7.2)

SR34. Upon entering the workforce of the process is the employee's level of competence specifically evaluated? (7.2)

SR35. Is there an established, documented process for introducing employees to new positions? (BP)

NOTE: This requirement should apply both to employees starting work in the process and for employees moving to a new function within the process.

SR36. Where an employee's competence level is less than desired in a specific function of their job, is there a process to:

- determine what remedial training or development is required?

- provide the required training or development within an appropriate time frame?
- re-evaluate the employees' competence after the training/development is complete?

SR37. Are records available of:

- employee competency requirements and status? (7.2)
- training/development planned and completed? (7.2)

SR38. Are employees aware of:

- the content and intent of the organization's quality policy? (7.3)
- objectives related to their functions? (7.3)
- their contribution to the achievement of organizational objectives, customer focus and achievement of customer satisfaction? (7.3)
- the benefits of improved quality performance? (7.3)
- the potential implications that could result from nonconformities in their work? (7.3)?

SR39. For this process, has the organization determined equipment and facility requirements needed in order to achieve customer requirements as well as requirements of the management and other interested parties? (7.1)

AP – Where software is involved, particularly software unique to this process, is there an effective backup system for protecting data? Is backup frequency adequate? Is backup data stored off site or in a safe place where damage to the main system will not also damage the backup?

SR40. Has the equipment analysis included the need for outside resources? (7.1)

SR41. Has the analysis considered as appropriate: (7.1)

- Building space?
- Utilities?
- Hardware?
- Software?
- Display and merchandizing equipment
- Transportation equipment?
- Communication equipment?
- Communication and IT technology?
- Machinery and tools
- Value added use of floor space? (BP)

SR43. Are there records available to show that equipment is effectively maintained and repaired? (7.1)

SR44. Do records show that maintenance of equipment happens prior to breakdown events (Preventive Maintenance) not simply when equipment fails? (7.1)

SR45. Does equipment maintenance include: (7.1)

- Display and merchandizing equipment
- software,
- computers,
- IT equipment,
- trucks and transportation equipment
- machinery and tools

SR46. For this process, has the organization determined the documentation requirements needed in order to achieve customer requirements as well as requirements of management and other interested parties? (7.4)

SR47. Do performance records for the process indicate that the amount and type of documentation available is sufficient for the effective operation and control of the process? (7.5)

SR48. Is there evidence of an effective method of identifying documents and records? (7.5)

NOTE: Identification may include a date, signature, reference number, file number, etc. The method must ensure that the document cannot be confused with a previous or subsequent version of the same document or record.

SR49. Where necessary is format of documents controlled? (7.5)

NOTE: While any format or medium can be used (ie paper, electronic, audio, video etc.) where a specific format is required, by procedure or inherent need, the format must be controlled.

SR50. Is there evidence that shows that when documents are created or revised, there is an effective process for approval or re-approval? (7.5)

SR51. Are documents needed during the process readily available to the people who need them? (7.5)

NOTE: Readily available is dependent upon the situation. Having a recipe readily available for a cook has a different expectation than having a portable defibrillator readily available to a paramedic.

SR52. Are documents and records effectively stored and protected from; loss, loss of confidentiality, improper use, water damage, or deterioration? (7.5)

SR53. Has the organization effectively addressed distribution, access, retrieval and use of documents? Does evidence show that current controls are effectively implemented and effective in practice? (7.5)

NOTE: Access can mean permission to view information or permission to have a document under personal control or authority to use or modify a document.

SR54. Where all documents verified during the assessment legible and stored effectively? (7.5)

SR55. Is there evidence that documents verified during the assessment have been effectively managed for changes? (7.5)

SR56. Is there a process for disposal of records? Does it comply with Statutory, Regulatory and /or Customer requirements? Do records show that it is effectively implemented? (7.5)

SR57. Is there evidence of an effective process for identification of documents of external origin which need to be controlled? (7.5)

NOTE: If an undetected change to an external document could have a detrimental effect on the process then control of the revision of that document should be seriously considered?

SR58. Is there evidence that shows that documents of external origin determined to need control are in fact effectively controlled? (7.5)

SR59. Does the process owner have the organizational, documentation and system structure needed in to achieve process objectives requirements? (consider both internal and external customer requirements) (4.4, 8.1)

SR60. Does the process owner understand and support the interdependency of processes needed for effective product or service realization? (4.4, 8.1)

SR61. Does the process owner understand and support the interdependency of processes needed for effective product or service realization? (4.4, 8.1)

PROCESS SPECIFIC QUESTIONS

AP – Choose employees in each job category for interview. Go back to your notes from the process owner and choose the employees with the greatest risk (New Employees, Contract Employees, Part Time Employees). Ask employees what they are responsible for and what authority they have. Answers should be the same as described by the process owner. Ask employees about their training. Answers should be as described by the process owner.

AP – During interviews, if the employee mentions a document or record – stop him – ask for the document – review it for legibility, availability, proper use and completeness. Once satisfied document your evidence and return the document to the employee.

Verify conformance with the following questions for each step of the process from receipt of materials needed to final installation, sale or delivery of service. Follow the flow of the product realization process as closely as is practicable.

SR62. Can the employee running the operation clearly describe their role and responsibilities? (5.3)

SR63. Is there evidence that the employees providing a function are trained and competent to do the job? (7.1, 7.2)

SR64. Is there evidence that the language of written instructions etc. is appropriate for the operator doing the work? (7.5)

SR65. Can the employee explain how customer focus applies to their function? (5.3, 7.3)

SR66. Can the employee explain in their own words the purpose and benefits of continual improvement in achieving customer satisfaction? (6.1, 7.3)

SR67. Is there an effective method for communicating changes to the job function to the employees involved? (7.5)

SR68. Is there documentation that describes the input requirements for the job function? (7.1, 8.1, 9.1)

NOTE: Consider incoming materials, tools, gages, information and instructions, packaging, labels, cleaning supplies (5S), sample boards, nonconforming material storage, sales and marketing materials, required clothing, protective gear, etc.

SR69. Where part traceability is a requirement is it a component of in-put information and set-up? (7.1, 8.1)

SR70. Where there are specific special process steps or methods required by specific customers are these COPS (Customer Oriented Processes) uniquely identified, documented and monitored for completeness and effectiveness? Are personnel trained, competent and aware of these unique requirements? (8.2)

SR71. Where environmental conditions are a function of the process, are they effectively defined as in-put requirements? (7.1, 8.1)

NOTE: Consider lighting, temperature, humidity, noise, protection from climatic conditions (rain, snow, dust, dirt, etc.).

SR72. Is there evidence that all in-put requirements are or were in place prior to the start of the process? (7.1, 8.1)

SR73. Is there evidence that all materials in the work area are needed for the process? (BP)

NOTE: Unwanted materials such as product from previous jobs whether scrap or good material, labels, packaging, unneeded instructions, signage, records, samples, dirty rags, etc. should not be in the work area.(BP)

SR74. Is there evidence that shows that all measuring instruments at the work area are: (7.1, 8.5)

- As required for the job
- Calibrated within its prescribed cycle
- Identified with its calibration date and calibration due date
- Identified as calibrated by qualified personnel
- Void of excess dirt or grime
- Undamaged and protected from damage
- Functioning properly
- Safeguarded from adjustment or tampering

NOTE: If a measuring instrument is used to make value judgments as to the acceptability of product, then calibration requirements apply.

SR75. Are there defined requirements for product and/or process monitoring during processing? What checks? By whom? How often? (7.5)

SR76. Do records indicate that all required checks have been conducted as specified? (7.5)

SR77. Do records provide variables data (specific measurements) as compared to check marks? (BP)

SR78. Where statutory or regulatory checks are mandated is there evidence of compliance? (7.5)

SR79. Where requirements have not been met is there an effective process contain inadequate material where necessary and to correct the identified issue?(10.2)

SR80. Is there evidence of an effective corrective action process which stops the process, investigates the cause of issues, fixes the problem, ensures that the defect does not remain, and re-verifies the process prior to re-start?

SR81. Verify that product outside the normal process flow is:

- *properly identified as to its quality status?
- segregated from the material flow?
- cannot be inadvertently reintroduced to production?

NOTE: Consider material not required for the current activity, defective suspect or noncompliant material, excess material, out of date materials, etc.

*Suspect material must be marked as nonconforming until such time as suitability has been confirmed.

SR82. Are all materials in the work area including components, sub-assemblies and hardware clearly identified through tags, labels, part marking, etc. such that product can be readily identified? (8.5)

NOTE: Identification is not required where it is self-evident or evident due to its location.

SR83. Verify that only labels used for the job in progress are in the work area? (8.5)

SR84. Verify that labels are stored in such a way that sequence, right vs left, top vs bottom and color, size or style choices cannot be mixed? (8.5)

SR85. Is there evidence that only the required packaging materials are in the work area? (8.5)

SR86. Is there evidence that packaging is conducted as specified or required? (8.5)

VERIFICATION – Where retail customer interface is a requirement:

SR87. Through observation have employees shown competence in customer interface activities? (7.2)

SR88. Is there evidence that employees have been trained in appropriate customer communication skills and any statutory, regulatory or industry standards for which the organizations subscribes? (7.2)

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‘IA’- INTERNAL AUDIT PROCESS ASSESSMENT

PROCESS SPECIFIC ASSESSMENT

QUESTIONS FOR THE PROCESS OWNER

AP – If a document or record is mentioned during your interview with the process owner – ask immediately to see the document – review it for legibility, availability, proper use and completeness. Look for evidence of poor performance or customer issues. Once satisfied document your evidence and return the document to the manager.

IA1. Is there evidence of a process which plans audits of the QMS at prescribed intervals? (9.2)

NOTE: For years organizations have relied on a pre-determined matrix to show their planned intervals. Almost inevitably these matrix based systems have been ineffective and usually deteriorate to a process used only to show external auditors that there is a system in place. A more effective system is described at www.systemsthinking.works for your consideration

IA2. Are the audit intervals sufficient to identify negative performance trends before they can deteriorate and become significant issues? (9.2)

IA3. Is there a documented audit process which controls the conduct of audits that includes:

- Audit frequency?
- Audit methods?

- Audit scope and objectives for individual audits?
- Audit Responsibilities, Authorities and Accountabilities?
- The type, content, distribution, storage, and access to documentation related to planning, conducting, and reporting of audits?

IA4. Is there evidence that auditors are selected based upon objectivity, impartiality and lack of conflicts of interest? (9.2)

IA5. Is there evidence that all auditors have been effectively trained and are competent to perform audits. (9.2, ISO 19011)

NOTE: Auditors should be have an understanding of auditing as described in ISO 19011, auditing processes and recording information per the organization's process requirements. (BP)

IA6. Is there evidence that audits cover: (9.2)

- Compliance to the organization's QMS?
- Conformity to this International Standard?
- Conformity to the requirements of customer and other interested parties – as determined by the organization?
- Activities and results related to the organization's objectives?
- Activities and results related to process performance to goals and objectives?

IA7. Is there evidence that effective corrective action is taken when audits identify nonconformities? (9.2)

IA8. Do audit records show evidence of conformity and nonconformity? (ISO 19011)

IA9. Is there evidence that audit results are reported to appropriate senior management? (9.2)

IA10. Do records of specific audits include a summary of results, evidence of conformity and details of nonconformities when they are found? (ISO 19011)

IA11. Is there evidence that appropriate and effective corrective action is taken on reported audit nonconformities? (9.2)

IA12. Are audit nonconformities resolved in a timely manner? (9.2)

IA13. Are audit records maintained and show evidence of the effective operation of the QMS? (9.2)

Visit systemsthinking.works for opportunities to use this guide and checklist to even greater advantage. For a discount on the electronic copy of this checklist offered in PDF and Word and formatted with tables to easily print, edit and electronically manage questions and responses, please enter K0864 as your Coupon Code when purchasing.

Thank you for your purchase of this book. I sincerely hope that it provides you and your organization with the tools and resources to help make your organization its very best.

Sincerely – Pat Ambrose

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