Implementation of ISO 9001:2008 standards in an Environmental, Health and Safety program for a Manufacturing Industry

Edgardo E. Torres Menéndez
Manufacturing Engineering
Rafael Nieves, PharmD
Industrial Engineering Department
Polytechnic University of Puerto Rico

Abstract *— Environmental, Health and Safety (EH&S) is a multidisciplinary area that concerned with the protecting the safety, health and welfare of people in their workplace. This project aims to create a guide to audit an EH&S department to determine the strength and weaknesses in terms of quality control and standardization. This project will describe the methodology used for an ISO 9001:2008 assessments, the area of investigation and the research instruments used for the implementation of the quality system. ISO 9001:2008 standards will be used as the principal guide for corrective actions and preventive actions method in conjunction with audit programs to ensure the implementation of the quality system program.*

Key Terms *— Audit Program, Corrective and Preventive Action Plans (CAPA), Environmental, Health and Safety (EH&S), ISO 9001:2008*

INTRODUCTION

In every worldwide industry environmental, health and safety (EH&S) work together to obtain a common goal, which is to provide every employee a safe working environment.

With many Occupational Safety and Health Administration (OSHA) and Environmental Protection Agency (EPA) regulations is hard to accomplish quality control standards in EH&S programs. However, there are quality programs like International Organization for Standardization, (ISO) 9001:2008 that includes EH&S in their platforms. ISO 9001:2008 will give all the necessary tools to achieve quality standards in an EH&S program.

RESEARCH DESCRIPTION

Quality control standards can be implemented in all areas of an industry. The area of interest is EHS due of the high importance part in every manufacturing industry.

This research is being conducted to find how ISO 9001:2008 standards will fortify the structure of an EHS programs. The use of ISO 9001:2008 will provide with standards that will pursue quality in the program.

RESEARCH OBJECTIVE

The main objective of this design project is to implement ISO 9001:2008 in an EH&S Department in a manufacturing industry. This will help to standardize the EH&S programs of the company and will promote compliance with all regulatory agencies mainly OSHA and EPA.

RESEARCH CONTRIBUTIONS

This research will provide support to the company goal of 100% compliance with regulatory agencies, which will avoid governmental fines and will generate monetary savings in long and short terms. Promoting standardization in the EH&S programs can lead to the preservation of a safety environment to all the employees and to the community. This can be accomplished by the implementation of ISO 9001:2008 standards that will provide tools to standardize EH&S processes and procedures in all the system.

RESEARCH BACKGROUND

Since the great demand of manpower and exponential increase of injuries due to the harsh workplace environment in the 1960s, the Congress approved the Occupational Safety and Health Act (OSH ACT). This Act was sign as law by President Richard M. Nixon in December 29, 1970 and had the proposed to ensure the live and health of ever man and woman in all industries nationwide. As OSHA, 1970 describes:

"To assure safe and healthful working conditions for working men and women; by authorizing enforcement of the standards developed under the Act; by assisting and encouraging the States in their efforts to assure safe and healthful working conditions; by providing for research, information, education, and training in the field of occupational safety and health; and for other purposes".

This Act applies to all governmental, federal and private industries that employ manpower in their facilities. This opened the way for what is call today Environmental, Health and Safety (EH&S) departments and professionals. EH&S departments implement standard operation procedures (SOP) that target to comply all the laws of the Occupational Safety and Health Agency (OSHA) and Environmental Protection Agency (EPA) for a safety workplace environment. This department as any other department targets the same goal, the implementation of quality in all their procedures. Targeting quality in an EH&S program is essential in an everyday basis for any type of industry because this will ensure the live and health of any individual in the company. Also, EH&S departments help to comply with all laws and regulation and keep away industry fines and demands.

Occupational Safety and Health Agency

Occupational Safety and Health Agency (OSHA) is the federal agency responsible to ensure that each employer have a secure, healthy and risk free workplace environment for their employees. OSHA motives all employers and employees to reduce risk in their workplace and to promote investigation measures to resolve safety and occupational problems. The Code of Federal Regulations (CFR) that contains 50 chapters, which chapter 29 corresponds to OSHA, governs this agency [1]. The 29 CFR contains norms that are based in a series of sources that includes: census standards, property standards and existing federal standards. OSHA is also responsible for the enforcements of ever law and regulations in the 29 CFR. Not complying with these norms may lead to fines and possible closure of the company depending on the severity of the case.

Environmental Protection Agency

Environmental Protection Agency (EPA) is the federal agency responsible for the enforcement and compliance of environmental laws in the nation. It also ensures that every company follows all the regulations and laws for the conservation of the environment. The Code of Federal Regulations (CFR) that contains 50 chapters, which chapter 40 corresponds to EPA, governs this agency [2]. The CFR 40 contains and the laws and regulations that EPA use to audit all companies nationwide. Not complying with these norms may lead to fines and possible closure of the company depending on the severity of the case.

Environmental, Health and Safety

Environmental, Health and Safety (EH&S) is a multidisciplinary area that concerned with the protecting the safety, health and welfare of people in their workplace. There are there main reasons for the creation of this multidisciplinary area, which are:

- Moral: reasonable care for employees; intolerance for putting health and safety of people at risk; attitude towards moral obligations to employees; making the moral case to senior management.
- Legal: enforce to comply with all laws and regulation and prevent fines and demands.
- Economic: impacts on unhealthy workplace costs.

EH&S area is responsible for making a hazard and risk assessment in the company for the benefit the all employees. These assessments need to cover the following:

- Identification of hazards environments and duties.
- Identification of all areas that are being or were affected by hazards.
- Identify and evaluate all the risks that are involved.
- Identify and prioritized measurements for risks and hazards control**.**

ISO 9001:2008

International Organization for Standardization (ISO), are a group of standards that includes the main requirements to ensure standardization and quality controls in any company. For a company to be certified by ISO 9001:2008, it has to comply with every standard and show complete fulfillment. These standards can be used in any area of the company to research standardization and for quality control purposes.

The ISO 9001:2008 standards diagram [3] (see Figure 1) shows that the company needs to identify the requirements that their customer wants. The requirements for the customer should be converted into product or service requirements. Those product or service requirements will be converted into design requirements. The design requirements should communicate and specify the acceptance, release criteria and production requirements, product measurements. Customer requirements must be the input in the quality management systems that should be stipulated in the design requirements. The output is the final product or service delivered to the customer. Customer satisfaction should be gathered by surveys or complaints. The information collected must be measured to improve the company's capability in a corrective or preventive action report (CAPA).

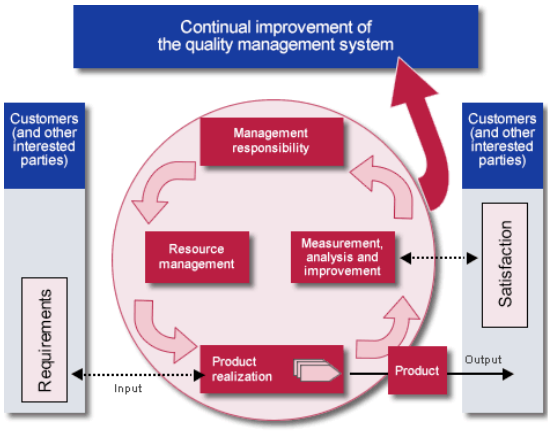

Figure 1

ISO 9001:2008 Diagram (Blog ISO 9001 Consultant)

RESEARCH METHODOLOGY

This project aims to audit an EH&S department to determine the strength and weaknesses in terms of quality control and standardization. The methodology used for the project assessment, the area of investigation and the research instruments used. ISO 9001:2008 standards are used as the principal guide.

Operational Procedure

The principal purpose of this project is to develop a corrective action plan under the standard of ISO 9001:2008 for an EH&S department. The initial audit will be the basis to design the corrective plan based on ISO 9001:2008. By this process the EH&S department will be evaluated and validated in conformance with the standards.

In order to start the process of implementing ISO 9001:2008, the EH&S department needs to establish their goals and objectives. Once the department has established their objectives will proceed to revise all the processes of the EH&S department to evaluate all the areas of impact. Then responsibilities are assigned to carry out the required training and staff training. To carry out this process within the requirements of the standard all training functions will be documented properly and will be conducted by competent personnel. Through internal audits, follow up of non-conformities and corrective actions the compliance

of the quality system in the department will be evaluated as shown in Figure 2.

Figure 2

ISO 9001:2008 Compliance Diagram

Requirements for ISO 9001:2008

The documentation of the implementation of the standards should include [4]:

- The policy, objectives and goals of the department
- Description of the scope of the system.
- Description of the principal elements of the systems and their interactions.
- Documents, including the records of the standards of ISO 9001:2008
- The documents included must be controlled and approved before their distribution; they should be legible and readily identifiable.
- The department should establish, implement and maintain one or more procedures to identify potential situation of emergency and accidents that could have an environment, health or safety impact and how to respond to them.
- The department should implement procedures to evaluate periodically the functions that could have and significant environment, health or safety impact.
- The audits plan should be performed in planned intervals with audit criterions, the scope, frequency and methods.

Methodological Design

To do an assessment of the actual conduction of the department an evaluation form will be created. This form will be created using the ISO 9001:2008 standards. This qualitative analysis will explore all the sections established in the ISO 9001:2008 standard. This evaluating form will be used as a guide to determine the non-compliances that are present. Also, a logbook will be developed to identify all the non-conformances of the department.

The first step of the project will consist of an internal audit using the evaluation form with all the ISO 9001:2008 standards as a guide for the implementation of the quality system. (See Table 1) As Fight, 2002 expounds in his book [5]:

‘‘Internal auditing is an independent, objective assurance and consulting activity designed to add value and improve an organization’s operations. It helps an organization accomplish its objectives by bringing a systematic, disciplined approach to evaluate and improve the effectiveness of risk management, control, and governance processes. Institute of Internal Auditors, June 1999.’’

The second step will be the creation of a logbook that will register all the findings of the internal audit through the entire department in terms of non-conformances. In both steps, the ISO 9001:2008 standards will be used as evaluation criteria.

Results and Discussion

With the purpose of evaluating the actual condition of the EH&S Department and to be able to comply with the requirements of ISO 9001:2008 standards, the Standard Operational Procedures of the EH&S Department needs to be evaluated by internal auditors. This evaluation allows the department to identify its status and guide its strategies. This auditory needs to be perform using the he evaluation sheet prepared for this purpose (see Table 1), which is based on the requirements of ISO 9001:2008. All non-conformance findings shall be documented in a corrective and preventive action plan. (See Table 2)

Standard Operational Procedures

All operational procedures of the EH&S Department shall be documented and establish, section 4.2.3 of ISO 9001:2008 states. These

operational procedures shall be established to define the controls needed to implement the quality system. The Standard Operational Procedures [6] or SOP's shall included the following sections:

- Purpose-The purpose of the Operational Procedure. The main purpose of an EH&S SOP is to comply with an EPA or OSHA regulation. However, EPA and OSHA do not required specific type of operational procedures as the ISO 9001:2008 requires.
- Scope- The scope will illustrate to which specific area or persons the standard operational procedure applies.
- Related Documents- All instructions of additional documents if needed will be specify in this part. Additional documentation can be:
- EPA Regulations
- OSHA Regulations or Protocols
- Human Resources (HR) Documentation
- General Information- The objective of the standard operational procedure can be explained in this section in more detail.
- Definitions- Definitions of non-common words. The SOP should be a document that any employee no matter the level of education of the employee can interpret and follow.
- Responsibilities- This sections states all employees that need to follow the SOP and the responsible person of maintaining the document updated.
- EH&S Equipment- This section states all the safety equipment needed to perform the operational procedure.
- Procedure- This section states all the steps that are needed to perform in a responsible and safety way the operational procedure. The procedure shall be written in a simple way avoiding misinterpretation and it shall be validated.
- Approvals-In compliance with section 4.2.3 of the ISO 9001:2008 requirements all documents shall be controlled. This section will include:
- The author name
- The author signature.
- The author job position.
- Date
- Document History- This section will include the following:
- Revision
- Effective Date
- Reason for Change

Absence of any procedure can cause deviations to the policy, objectives of the department and legal consequences. All roles and responsibilities must be property defined and commitment with continuous improvement must be present.

All the EH&S department team have to be sensitized of the importance of the compliance with ISO 9001:2008. Also, all the employees that are impact in the EH&S Department SOP's shall be trained to obtain the necessary tools to perform their functions in a safety and responsible manner following the standard operational procedures.

EH&S Department Audits

The audit system needs to be property establish with all ISO 9001:2008 requirements. The internal auditors shall have the necessary training and capability to execute the audits. An ISO 9001:2008 auditor shall train all internal auditors.

Internal auditors will audit the EH&S Departments based on their standard operational procedures. The audits frequency for the EH&S Department will be determine after the initial audit. However, ISO 9001:2008 does not state a specific number of internal audits.

The EH&S Department shall show evidence of compliance with ISO 9001:2008 requirements. The internal auditor will use the evaluation sheet as the baseline to perform the audit of the department. All non-conformance findings shall be documented in a corrective and preventive action plan (CAPA). This plan will explained in detail the non-conformance finding and will indicate the responsible for the implementation of the corrective plan. The internal auditor will give the CAPA document to the responsible person in the EH&S Department to give solution to the non-conformance. This person will

document in the CAPA all the steps and the methodology use to change the non-conformance to a conformance finding [7].

Internal Auditors will show commitment to follow up all corrective actions. Internal audits have to track down all non-conformities and auditors must document all corrective actions to eliminate non-conformities findings. Depending on the severity of the non-conformance the internal auditor will do weekly or monthly meetings with the EH&S Department to see how the CAPA is developing. These meetings will end up in metrics that will help the internal auditor to validate the tracking of all non-conformities. These metrics shall be documented discussed with the EH&S Departments as part of the preparation for the ISO 9001:2008 final auditory.

The department has to show if required, substantial evidence to the external ISO auditor that all non-conformances were track and manage in conformance to the standards. Not being able to show this evidence can cause a mayor finding in the final ISO audit and possible failure of the certification.

After the EH&S Department representative conclude the CAPA report (see Table 2), it will be evaluated by the originator which is the internal auditor. The internal auditor will validated the corrective action created by the EH&S Department representative. If the non-conformance is properly resolved, the CAPA repot will be closed satisfactory and conforming with the requirements. Otherwise, if the CAPA report was not properly resolved, the internal auditor in conjunction with the EH&S Department representative will analyzed the non-conformance using a root cause analysis (RCA). Some RCA techniques are 5 Why's, Fishbone and Logic Tree. This RCA will show the exact deviation that is causing the non-conformance. The internal auditor will give the audit a certain period of time to conclude the corrective action plan. The period of time that the internal auditor will give the audited will depend on several factors like complexity of the corrective or preventing plan. Working to eliminate the deviation will validate this analysis. Substantial evidence to the internal auditor needs to be present to show the effectiveness of the corrective action plan to the non-conformance. If the corrective action plan is satisfactory evaluated by the internal auditor, the action plan is properly documented and closed.

CONCLUSIONS

The purpose of this project was to provide a guide to implement ISO 9001:2008 in an EH&S Department in a manufacturing company. The guide of implementation in this project is based in the ISO 9001:2008 standards. Following this guide will promote total compliance with regulatory agencies such as EPA and OSHA, which will avoid governmental and federal fines. Also, this guide is a key element to help monitor the status of the EH&S program in the company. The guide provides standardization in the EH&S programs that will provide a safety environment to all the employees and to the community.

This guide can be modified depending on the needs of the EH&S Department and the type of manufacturing industry. This program has the advantage to comply with all governmental and federal regulation using ISO 9001:2008 standards as guide. However, all the modifications must be in conformance with ISO 9001:2008 standards, EPA and OSHA updates.

Limitations

The implementation of an ISO 9001:2008 to an EH&S department is an implementation process that must go through and approval process that includes top management, managers and supervisors in all levels.

This program guide must be revising every year due to continuous changes in EH&S regulations from agencies like EPA and OSHA. The owner of this program must be in constant awareness of the continuous changes previously mentioned.

Table 1

ISO 9001:2008 System Certification Audit Checklist

Client Identification:	Location:	
Auditor:	Number Report:	
	Date:	

Actual Revision of the System in the EH&S Department		
Manual ISO 9001:2008		Revision Date:
Requirements	Reference	Non-Conformity
4.0 QUALITY MANAGEMENT SYSTEM 4.1 General Requirement Has the organization established, documented, implemented and maintained a quality management system in accordance with the requirements of ISO 9001? Is the effectiveness of the quality management system continually improved? Has the organization; a. Identified the processes needed for the quality management system including their applications throughout the organization. b. Determined the sequence and interaction of these processes. c. Determine the criteria and methods needed to ensure that both the operation and control of these processes are effective. d. Ensure the availability of resources and information is necessary to support the operation and monitoring of these processes. e. Measured, monitored and analyzed these processes f. Implemented actions needed to achieve planned results and continual improvement? Does the organization manage the processes in accordance with the requirement of ISO 9001? Where processes that affect product conformity with requirements are outsourced, are the controls for these processes identified within the quality management system?		
4.2 Documentation Requirements 4.2.1 General Does the quality management system documentation include; a. Documented statements of quality policy and quality objectives? b. Quality Manual? c. Documented procedures and records required by ISO 9001? d. Documents and records needed by the organization to ensure the effective planning, operation and control of its processes?		
4.2.2 Quality Manual Has a quality manual been established and maintained that includes; a. the scope of the quality management system including details of and justification for any exclusions? b. Documented procedures established for the quality management system, or reference to them? c. Description of the interaction between the processes of the quality management system?		
4.2.3 Control of documents Are documents required for the quality management system controlled? Has documented procedure been establish identifying the following controls needed? a. Approval of documents for a adequacy prior to issue? b. Review, update as necessary and re-approval of documents? c. Ensure that changes and the current revision status of documents are identified? d. Ensure that relevant versions of applicable documents are available at points of use? e. Ensure that documents remain legible and readily identifiable? f. Ensure that documents of external origin are identified and their distribution controlled? g. Preventing the unintended use of obsolete documents, and to apply suitable identification to them if they are retained?		
4.2.4 Control of Records Have records been establish and maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system? Has a documented procedure been established to define the following controls needed? a. Identification? b. Storage? c. Retrieval? d. Protection? e. Retention Time? f. Disposition?		
5. MANAGEMENT RESPONSIBILITY **5.1** Management Commitment Has top management provide evidence of its commitments to the development and implementation of the quality management system and for the continual improvement of its effectiveness by; a. Communicating to the organization the importance of meeting customer as well as regularly and legal requirements? b. Establishing the quality policy? c. Ensuring that quality objectives are established? d. Conducting management reviews? e. Ensuring the availability of resources?		
5.2 Customer Focus Has top management ensured that customer requirements are determined and met with the aim of enhancing customer satisfaction?		
5.3 Quality Policy Has top management ensured that the quality policy: a. is appropriate to the purpose of the organization. b. Includes a commitment to comply with requirements and to continually improve the effectiveness of the quality management system. c. Provides a framework for establishing and reviewing quality objectives. d. Is communicated and understood within the organization? e. Is reviewed for continuing suitability?		
5.4 Planning 5.4.1 Quality Objectives Has top management ensured that quality objectives are established at relevant functions and levels within the organization? Have quality objectives needed to meet the requirements of the product been established? Are quality objectives measurable and consistent with the quality policy? 5.4.2 Quality Management System Planning Has top management ensured that the resources needed to achieve the quality objectives are identified and planned? Is the output of the planning documented? (e.g. : quality manual, procedures, works instructions, quality plans, etc.) Does top management ensure that the integrity of the quality management system is maintained when changes are planned and implemented?		
5.5 Responsibility, Authority and Communication 5.5.1 Responsibility and Authority Has top management ensured that responsibilities, authorities are defined and communicated within the organization? 5.5.2 Management Representative Has top management appointed member(s) of management who have responsibility and authority for: a. Ensuring that processes are established implemented and maintained? b. Reporting to top management on the performance of the quality management system, including needs for improvement? c. Promoting awareness of customer requirements throughout the organization.		
5.5.3 Internal Communication Has top management ensured that appropriate communication processes have been established within the organization? Does communication take place regarding the effectiveness of the quality management system?		
5.6 Management Review 5.6.1 General Does the top management review the quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness? Are opportunities for improvement and the need for changes to the quality management system, including quality policy and objectives, reviewed during the review? Are records of management reviews maintained as quality records?		
5.6.2 Review Input Do the inputs to management review include information on: a. Results of audits? b. Customer feedback? c. Process performance and product conformity? d. Status of preventive and corrective actions? e. Follow-up actions from previous managements reviews? f. Planned changes that could affect the quality management system? g. Recommendations for improvement?		
5.6.3 Review Output Do the outputs from management review include the		

decisions and actions related to: a. Improvement of the effectiveness of the quality management system and its processes? Improvement of the product related to customer requirements? Resources needed?		
Resource Management 6.1 Provision of Resources Have the resources been determined and provided for: a. Implementing and maintaining quality management system and continually improving its effectiveness? b. Enhancing customer satisfaction by meeting customer requirements?		
2 Human Resources 6.2.1 General Is competency for personnel who perform work affecting product quality based on appropriate education, training, skills, and experience?		
6.2.2 Competency, awareness and training Has the organization: a. Determined the necessary competency for personnel performing work affecting product quality? b. Provided training or take other actions to satisfy these needs? c. Evaluated the effectiveness of the actions taken? d. Ensured that employees are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives Maintained appropriate records of education, training, skills and experience.		
6.3 Infrastructure To achieve conformity of product, does the organization identity, provide, and maintain the facilities including: a. Building, workshops and associated utilities? b. Process equipment, hardware and software? c. Supporting services?		
6.4 Work Environment Has the environment needed to achieve conformity of product requirements been determined and managed?		
7. Product Realization 7. Product Realization 7.1 Planning of Realization Process Is planning of the organization's product realization consistent with the requirements of the other processes of the quality management system? Are the following being determined when planning the product realization: a. Quality objectives and requirements for the product? b. The need to establish processes, documents, and provide resources specific to the product? c. Required verification, validation, monitoring, inspection and test activities specific to the product and criteria for product acceptance? d. Records needed to provide evidence that the realization processes and resulting product fulfill requirements? Is the planning output in a form that is suitable for the organization's method of operation?		
7.2. Customer-Related Processes 7.2.1 Determination of Requirements Related to the Product Has the organization determined: a. Requirements specified by the customer, including the requirements for delivery and post delivery activities? b. Requirements not stated by the customer but necessary for specified or intended use, where known? c. Statutory and regulatory requirements related to the product? d. Any additional requirements determined by the organization?		
7.2.2 Review of Requirements Related to the Product Prior to the commitment to the customer (e.g. submission of tenders, acceptance of contracts or orders or acceptance of change orders) are requirements reviewed to ensure that: a. Product requirements are defined? b. Contract or order requirements differing from those previously expressed or resolved? c. The organization has the ability to meet defined requirements? Are the results of reviews and actions arising from these reviews recorded and maintained as records? Where the customer has not provided a documented statement of requirements, are customer requirements confirmed by the organization before acceptance? Where product requirements are changed, does the organization ensure that relevant documentation is amended and relevant personnel are made aware of the changed requirements?		
7.2.3 Customer Communication Has the organization determined and implemented effective arrangements for communicating with customers relating to: a. Product information?		
b. Inquiries, contracts, amendments or order handling? c. Customer feedback, including customer complaints?		
7.3 Design and Development 7.3.1 Design and Development Planning Are product design and development activities planned and controlled? During design and development planning has the organization determined: a. Stages of design and development? b. Review, verification and validation that are appropriate to each design and development stage? c. Responsibilities and authorities for design and development? Are interfaces between different groups involved in design and development managed to ensure effective communication and clear assignment of responsibilities? Is planning output updated as the design and development progresses?		
7.3.2 Design and Development Inputs Are inputs relating to product requirements defined, documented and maintained as a record? Does design and development input include: a. Functional and performance requirements? b. Applicable statutory and regulatory requirements? c. Applicable information derived from previous similar designs? d. Other requirements essentials for designs and development? Are design and development inputs reviewed for adequacy? Are incomplete, unambiguous or conflicting requirements resolved?		
7.3.3 Design and Development Outputs Are outputs of the design and development provided in a form that enables verification against the design and development inputs? Are design outputs approved prior releases? Does the design and development output: a. Meet the design and development input requirements? b. Provide appropriate information for purchasing, production and for service provision? c. Contain or reference product acceptance criteria? Specify the product characteristics that are essential to its safe and proper use?		
7.3.4 Design and Development Review Are systematic reviews performed in accordance with planned arrangements at suitable stages of the design and development? Do design and developments review: a. Evaluate the ability of the results of design and development to meet requirements? b. Identify problems and propose necessary actions? Do review participants include representatives of functions concerned with the design and development stage(s) being reviewed? Are results of reviews and any actions necessary maintained as records?		
7.3.5 Design and Development Verification Is design and development verification performed in accordance with planned arrangements to ensure that the design outputs have met the design and development input requirements? Are results of the verification and actions maintained as records?		
7.3.6 Design and Development Validation Is design and development validation performed in accordance with planned arrangements? Is design and development validation performed to confirm that the product is capable of meeting the requirements for the specified application or intended use, where known? Is validation completed prior to delivery or implementation of the product wherever applicable? Are results of the validation and actions maintained as records?		
7.3.7 Control of Design and Development Changes Are design and/ or development changes identified and recorded? Do reviews of design and development changes include evaluation of the effect of the changes on constituent parts and product already delivered? Are design and development changes reviewed, verified, validated as appropriate and approved before implementation? Are results of the review of changes and necessary actions maintained as records?		
7.4 Purchasing 7.4.1 Purchasing control Are the purchasing processes controlled to ensure purchased product (or service) conforms to requirements? Is the type and extent of control applied to the supplier and purchased product dependent upon the effect of the purchased product on subsequent product realization or the final product.		

Are supplies selected and evaluated based on their ability to supply product in accordance with the organization's requirements? Has the organization established criteria for selection evaluation and re-evaluation of suppliers? Are results of the evaluations and any necessary actions maintained as records?		
7.4.2 Purchasing Information Does purchasing information describe the product to be purchased? Including are appropriate: a. Requirements for approval of product, procedures, processes and equipment? b. Requirements for qualification of personnel? c. Quality management system requirements? Is the adequacy of specified purchased requirements ensured prior to their communication to the supplier?		
7.4.3 Verification of Purchased Product Have the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements been established and implemented? Are verification arrangements and method of product release specified in the purchasing information where the organization or its customer intends to perform verification at supplier's premises?		
7.5 Product and Service Provision 7.5.1 Control of Production and Service Provision Are the production and service provision planned and carried out under controlled conditions including: a. Availability of information that describes the product characteristics? b. Availability of work instructions, as necessary? c. Use of suitable equipment? d. Availability and use of monitoring and measuring devices? e. Implementation of monitoring and measurement? f. Implementation of release, delivery and post delivery activities?		
7.5.2 Validation of Processes for Production and Service Provision Have processes where deficiencies may become apparent only after the product is in use or the service has been delivered been validated? Do the results of validation demonstrate the ability of the processes to achieve planned results? Where applicable, have the arrangements been established for: a. Defining criteria for review and approval of processes? b. Approval of equipment and qualification of personnel? c. Use of specific methods and procedures? d. Requirements for records? e. Re- validation?		
7.5.3 Identification and Traceability Is the product identified by suitable means throughout product realization? Is the product status identified with respect to monitoring and measurement requirements? When traceability is a requirement, is the product uniquely identified and controlled? Is the unique identification maintained as a record?		
7.5.4 Customer Property Does the organization exercise care with customer property while it is under the organization's control or being used by the organization? Is customer property identified, verified, protected, and safeguard? If lost, damaged or otherwise found to be unsuitable for use, is condition recorded, reported to the customer and maintained as a record?		
7.5.5 Preservation of Product Is conformity of product preserved during internal processing and delivery to the intended destination? Does preservation activities include: a. Identification? b. Handling? c. Packaging? d. Storage? e. Protection? Are preservation activities applied to constituent parts of a product?		
7.6 Control of Measuring and Monitoring Devices Has the organization determined the monitoring and measurement to be undertaken and the monitoring and measurement devices needed to provide evidence of conformity of product to determined requirements? Have processes been established to ensure that monitoring and measurement can be carried out in a manner consistent with the monitoring and measurement requirements? Where necessary to ensure valid results, are measuring equipment: a. Calibrated or verified at specified intervals, or prior to use, against measurements standards traceable to international or national measurements standards; where no such standards exist, is the basis used for calibration or verification recorded?		
b. Adjusted or re-adjusted as necessary? c. Identified to enable the calibration status to be determined? d. Safeguarded from adjustments that would invalidate the measurement result? e. Protected from damage and deterioration during handling, maintenance and storage? Has the organization assessed and recorded the validity of the previous measuring results when the equipment is found not to conform to requirements and taken the appropriate action on the equipment and any product affected? Are records of the calibration and verification results maintained? Where computer software is used in the monitoring and measurement of specified requirements is the ability of the computer software to satisfy the intended application confirmed prior to initial use? Is the ability of computer software to satisfy the intended application reconfirmed as necessary?		
8 Measurement, analysis and improvement 8.1 General Have the monitoring, measurement, analysis and improvement processes been planned, and implement to: a. Demonstrate conformity of the product? b. Ensure conformity of the quality management system? c. Continually improve the effectiveness of the quality management system? Have the applicable methods including statistical techniques and their extent to use been determined?		
8.2 Monitoring and Measurement 8.2.1 Customer satisfaction Is information relating to customer perception monitored by the organization as to whether customer requirements have been met? Have the methodologies for obtaining and using information related to customer perception been determined?		
8.2.2 Internal Audit Are internal audits conducted at planned intervals to determine whether the quality management system: a. Conforms to planned arrangements, requirements of ISO 9001 and the quality management system? b. Is effectively implemented and maintained? Are the audit programs planned taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits? Is the audit criteria, scope, frequency and method defined? Do auditor selection and conduct of audits ensure objectivity and impartiality of the audit process? Is it ensured that auditors do not audit their own work? Has a documented procedure been established to define responsibilities and requirements for planning and conducting audits, reporting results, and maintaining records? Have management responsibilities for the area being audited ensured that actions have been taken without undue delay to eliminate detected nonconformities and their causes? Do follow-up activities include the verification of the actions taken, and the reporting of the verification results?		
8.2.3 Monitoring and Measurement of Processes Are suitable methods applied for monitoring and where applicable, measurement of the quality management system processes necessary to meet customer requirements? Do these methods demonstrate the ability of the processes to achieve planned results? Are correction and corrective actions taken when planned results are not achieved?		
8.3 Control of Nonconforming Product Is nonconforming product identified and controlled to prevent unintended use or delivery? Has a documented procedure been established to define controls and related responsibilities and authorities for dealing with nonconforming product? Are nonconforming product dealt with by one or more of the following ways: a. Action taken to eliminate the detected nonconformity? b. Authorized use, release or acceptance under concession by a relevant authority and, where applicable, by the customer. c. Action taken to preclude its original intended use or application. Are records maintained identifying the nature of nonconformities and any subsequent actions taken, including any concessions? When nonconforming product is corrected, is it subject to re-verification to demonstrate conformity to the requirements? When nonconforming product is detected after delivery, or use has started, is appropriate action taken by the organization to the effect or potential effect?		
8.4 Analysis of Data Is appropriate data determined, collected and analyzed to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the effectiveness of the quality management system can be made? Does this data include data generated from monitoring, measurement and other relevant sources? Does the analysis of this data provide information related to: a. Customer satisfaction? b. Conformance to product requirement?		

c. Characteristics and trends of processes and product including, opportunities for preventive action? d. Suppliers?		
8.5 Improvement 8.5.1 Continual Improvement Does the organization continually improve the effectiveness of the quality managements system? Are results of audits, analysis of data, corrective and preventive actions, management reviews, and quality Policy and quality objectives used for continual improvement		
8.5.2 Corrective Action Are corrective actions taken to eliminate the cause of nonconformities and to prevent recurrence? Are corrective actions appropriate to the effects of the nonconformities encountered? Has documented procedure been established to define the requirements for: a. Reviewing nonconformities, including customer complaints? b. Determining the causes of nonconformity? c. Evaluating the need for action to ensure that nonconformities do not recur? d. Determining and implementing action needed? e. Recording and maintaining the results of action taken? f. Reviewing corrective action taken?		
8.5.3 Preventive Action Has the organization determined actions to eliminate the causes of potential nonconformities in order to prevent occurrence? Are preventive actions appropriate to the effects of the potential problems? Has documented procedure been established to define the requirements for: a. Determining potential nonconformities and their causes? b. Evaluating the need for action to prevent occurrence of nonconformities? c. Determining and implementing actions needed? d. Recording and maintain the results of action taken? e. Reviewing of preventive action?		
Number of Non- Conformities:		
Comments:		
Name y Signature of Auditor:		

Table 2

Corrective and Preventive Action Report

Report No: Date Assigned:
Part 1: Notification of incidences and quality discrepancies:
Name of client, area or department:
Audit clause or purchase order:
Date of incident or discrepancy:
Notification received on:
Origen of the corrective/preventive action:
Internal audit:
Product non-conformance: ___
Idea for improvement: __
External audit: ___
Other:
Part 2: Description of Incident:
Part 3: Possible causes of failure:
Part 4: Analysis of the problem:
Part 5: Results of the investigation:
Part 6: Conclusion:
Part 7: Corrective Action:
Part 8: Preventive Action:
Part 9: Final disposition and revision:
Investigation stage: ( ) Completed ( ) Follow-up required
Comments:
Investigated by: _____ Date: _____
Approved by: _____ Date: _____
Part 10: Verification of Corrective and Preventive Action:
Verified by: _____ Date: _____
Approved by: _____ Date: _____

Recommendations

Recommend to EH& S Departments that need to comply with ISO 9001:2008 requirements through the standardization of the department programs. This research provides support to the EH&S Department supporting their goal of full compliance with regulatory agencies, to avoid federal and governmental fines and promote a safe workplace environment.

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