RISK ASSESSMENT FOR STEAM STERILIZER

RISK ASSESSMENT

EQUIPMENT: STEAM STERILIZER

EQUIPMENT ID: .....

PROTOCOL No.: .....

RISK ASSESSMENT FOR STEAM STERILIZER

Protocol Approval:

This is a specific protocol for ASSESSMENT of Autoclave, which is located in the Ground floor of the ..... Signing of this Approval page of Risk Assessment Protocol indicates the agreement with the risk assessment approach described in this document.

The following have been approved this protocol

Functional Area	Name	Signature	Date
Prepared by			
Quality Assurance Department			
Reviewed & Approved by			
Production Department			
Quality Control Department			
Engineering Department			
Quality Assurance Department			

RISK ASSESSMENT FOR STEAM STERILIZER

TABLE OF CONTENTS

RISK ASSESSMENT FOR STEAM STERILIZER

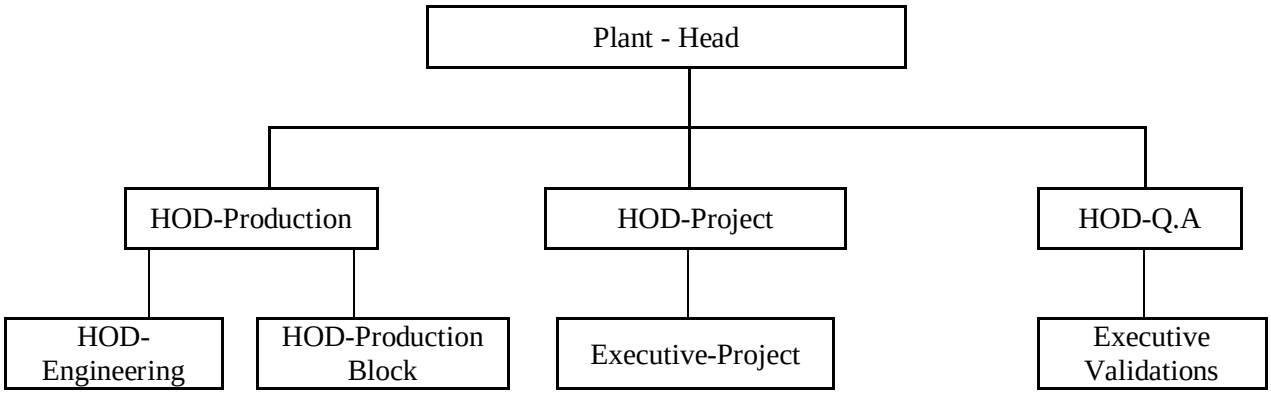
1.0 OBJECTIVE

A systematic, highly structured risk assessment can rely upon evaluation of component/functional failure and to generate a comprehensive review to ensure that appropriate safeguard /control procedures.

This document provides a basic overview of the failure modes and effect analysis and includes step by step control procedure of the system components.

2.0 RESPONSIBILITY

To conduct the equipment qualification study, a team shall be formed. The team shall contain the members from the, Project, Engineering, Manufacturing and Quality Assurance departments. The Validation team is described through the following responsibility hierarchy.



3.0 REANALYSIS

The Risk Analysis to be reanalysed on:

⇒ Replacement of major component of the equipment with a new component.

⇒ Any major modification in the existing equipment.

⇒ Shifting of the equipment from one location to another.

⇒ Consistently OSS in obtained results.

⇒ Equipment has shown any abnormal operations.

4.0 METHODOLOGY

The methodology states by asking following five very simple questions. The information can be derived from Design qualification Protocol, User requirement specification and suppliers technical documents.

4.1 **What are the major functions and associated performance requirements of the system?**

RISK ASSESSMENT FOR STEAM STERILIZER

4.2 **From the major functions, what are the sub-functions and their associated performance requirements?**

4.3 **What are the failure events?** From the list of sub-functions, look at the different types of failures that may exist in operating environment.

4.4 **What is the effect of each failure event?** From the list of failures event, look at all the likely effects of each type of failure in the production environment.

4.5 **What modifications to the design can be made to reduce risks?** Review findings and modify the design to eliminate the high risk/high probability of its happening and/or control the system by taking preventive measures through Standard Operating Procedures.

5.0 SYSTEM IDENTIFICATION

Equipment / System	:	Steam Sterilizer (Autoclave)
Equipment ID	:	
Stage of Risk Assessment	:	During Installation of the Equipment

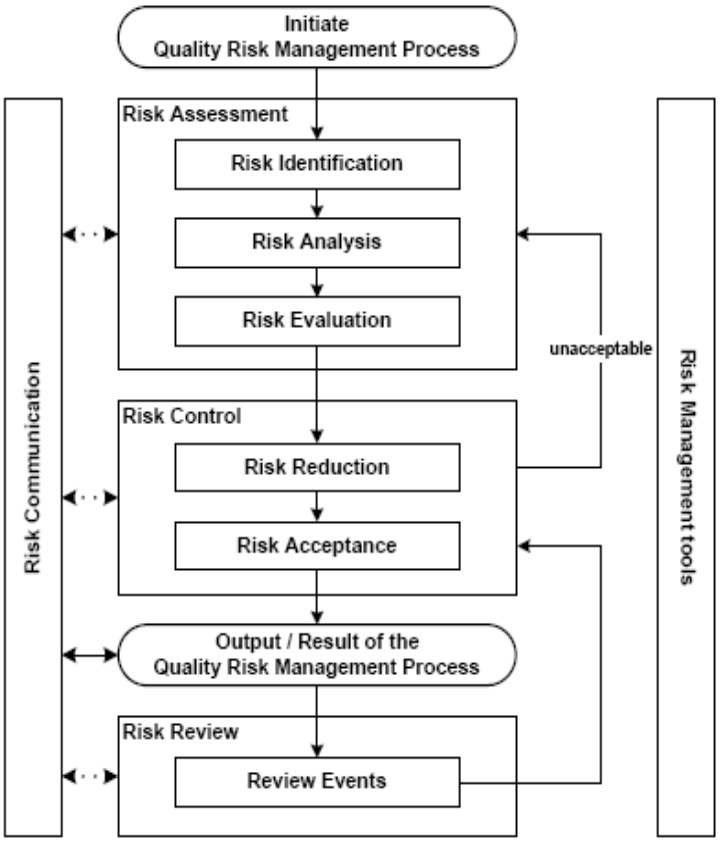
RISK ASSESSMENT FOR STEAM STERILIZER

6.0 PROCEDURE

6.1 The quality risk management is a systematic process for the assessment, control, communication and review of the risks to the quality of the drug product across the product life cycle. A model for quality risk management is given below.

6.2 The team including the expert from the appropriate areas in addition to individual who are knowledgeable about the risk management process should carry out quality risk management activities.

FLOW CHART FOR TYPICAL QUALITY RISK MANAGEMENT



6.3 Decision makers should take responsibility for coordinating quality risk management across various functions and departments of their organization and assure that a quality risk management process is defined, deployed and reviewed and that adequate resources are available.

6.4 **Risk Communication:**

6.4.1 It is sharing of information about risk and risk management between the decision makers and others.

6.4.2 Initiate the Risk Management by using risk management tools given below.

6.4.3 Risk management tools are primary tools that can be used in quality Risk Management, below given are few of them

⇒ Failure Mode Effects Analysis (FMEA).

⇒ Failure Mode, Effects and Criticality Analysis (FMECA).

⇒ Fault Tree Analysis (FTA).

⇒ Hazard Analysis and Critical Control Points (HACCP).

⇒ Hazard Operability Analysis (HAZOP).

⇒ Preliminary Hazard Analysis (PHA).

6.5 **Selection of Tools:**

6.5.1 FMEA / FMECA and HACCP are the widely used tools to mitigate the risk in pharmaceutical industries.

6.5.2 FMEA / FMECA can be used to assessing, controlling, communicating and reviewing risks related to products, equipment, utilities, system and environment.

6.5.3 HACCP can be used to identify the hazard and reduce the risk that may occur in the drug products manufacturing process.

6.5.4 HACCP can be applied to understand the risk that exists in controls over the raw materials, processes, environment, personnel, storage and distribution of finished drug products.

6.6 **FMEA / FMECA (Failure Mode Effects Analysis / Failure Mode, Effects and Criticality Analysis):**

6.6.1 FMEA provides for an evaluation of potential failure modes for processes and their likely effect on outcomes and / or product performance. Once failure modes are established, risk reduction can be used to eliminate, contain, reduce or control the potential failures.

6.6.2 FMEA relies on product and process understanding. FMEA methodically breaks down the analysis of complex processes into manageable steps. It is a powerful tool for summarizing the important modes of failure, factors causing these failures and the likely effects of these failures.

6.6.3 FMEA can be applied to equipment and facilities and might be used to analyze a manufacturing operation and its effect on product or process. It identifies elements/operations within the system that render it vulnerable.

6.6.4 Following are the basic steps to conduct the FMEA (Refer FMEA table Template below).

RISK ASSESSMENT FOR STEAM STERILIZER

6.7 **Describe the Equipment / Process:**

6.7.1 A clear and specific description of the equipment / process undergoing FMEA must first be articulated. The creation of this description ensures that the responsible engineer fully understands the 'form, fit, and function' of the product or process.

6.8 **Draw a Block Diagram of the Product or Process:**

6.8.1 A block diagram of the product/process needs to be developed to show the logical relationships between the components of the product or the steps/stages of the process. A block diagram may be in the form of boxes connected by lines, with each box corresponding to a major component of the product or a major step of the process. The lines correspond to how the product components or process steps are related to each other.

6.9 **Enumerate the Items (Components, Functions, steps, etc.) that make up the Product or Process:**

6.9.1 Break down the equipment / process being subjected to FMEA into its major components or steps. List down each of these components or steps in the FMEA table. The items must be listed down in a logical manner.

6.10 **Identify all Potential Failure Modes Associated with the Equipment / Process:**

6.10.1 A failure mode is defined as how a system or process is failing.

6.10.2 Potential Failure Mode is defined as a manner in which equipment/process fails to meet their specified conditions, which they are intended to perform. It describes the ways through which a failure can happen. All the known Potential Failure Modes are listed in the column according to their occurrence in their system, subsystem of the equipment/process. Failure modes in the column are ranked in a downstream manner. Failure modes are listed assuming that they could ‘occur’ and not necessarily ‘occur’.

6.11 **List down each Failure Mode using its technical term:**

6.11.1 Using an official technical term for listing the failure mode prevents confusion. All potential failure modes should be listed down for each item.

6.12 **Describe the effects of each of the failure modes listed and assess the severity of each of these effects:**

6.12.1 A failure effect is what the customer will experience or perceive once the failure occurs. A customer may be either internal or external, so effects to both must be included. Examples of effects include inoperability or performance degradation of the product or process, injury to the user, damage to equipment, etc.

6.12.2 Assign a **SEVERITY** rating to each effect. Each company may develop its own severity rating system, depending on the nature of its business. A common industry standard is to use a 1-to-10 scale system, with the '1' corresponding to 'no effect' and the '10' corresponding to maximum

severity, such as the occurrence of personal injury or death with no warning or a very costly breakdown of an enormous system.

Effect	Scale	Description of 'System Impact'
No	1	No effect on output
Very Slight	2	Stakeholder /customer not annoyed
Slight	3	Slight
Minor	4	Minor effect on performance
Moderate	5	Moderate Effect on performance
Significant	6	Partial Failure but operable
Major	7	Product performance severely affected, but some operability and safe
Extreme	8	Very dissatisfied, product Inoperable but safe.
Serious	9	Potentially hazardous effect, time - dependent failure
Hazardous	10	Hazardous Effect, Safety related sudden failure

6.13 **Identify the Possible Cause(s) of each Failure Mode:**

6.13.1 Aside from its effect(s), the potential cause(s) of every listed failure mode must also be enumerated. A potential cause should be something that can actually trigger the failure to occur. Examples of failure causes include improper equipment set-up, operator error, use of worn-out tools, use of incorrect software revision, contamination, etc.

6.14 **Quantify the probability of OCCURRENCE of Each of the Failure Mode Causes:**

6.14.1 The likelihood of each of the potential failure cause occurring must be quantified. Every failure cause will then be assigned a number indicating this likelihood or probability of occurrence. A common industry standard for this is to assign a '1' to a cause that is very unlikely to occur and a '10' to a cause that is frequently encountered.

Occurrence	Scale	Description of 'occurrence'
Never	1	Failure Unlikely :history shows no failures
Remote	2	Rare number of historical failure
Very slight	3	Very few failures likely
Slight	4	Few Failures likely
Low	5	Occasional number of failures likely
Medium	6	Medium number of failures likely
Moderately High	7	Moderately high number of failures likely
High	8	High number of failures likely
Very high	9	Very high number of failures likely.

RISK ASSESSMENT FOR STEAM STERILIZER

Almost certain	10	Failure almost certain

6.14.2 Identify all existing controls (Current Controls) that contribute to the prevention of the occurrence of each of these failure mode causes.

6.14.3 Existing controls that prevent the cause of the failure mode from occurring or detect the failure before it reaches the customer must be identified and evaluated for its effectiveness in performing its intended function.

6.15 **Determine the Ability of Each Control in Preventing or Detecting the Failure Mode or its Cause:**

6.15.1 The effectiveness of each of the listed controls must then be assessed in terms of its likelihood of preventing or detecting the occurrence of the failure mode or its failure cause. As usual, a number must be assigned to indicate the detection effectiveness of each control.

6.15.2 Detection capability is defined as the ability of the equipment to detect failures before occurring. Higher the detection capability lower is the Probability of occurrence of a failure. There has always been confusion about where to consider detection controls during Risk Assessment.

6.15.3 If detection controls serve to prevent the failure from occurring then it should be considered while estimating the risk during Risk Assessment as detection capability reduces the Probability of occurrence.

6.15.4 However if detection controls serve only to detect the failure from occurring, then detection controls should not be used to estimate risk during Risk Assessment process, should be considered only as a risk control measure. Detection control is evaluated on a scale of '1' to '10'.

Probability of detection	Scale	Description of 'Detection'
Almost certain	1	Proven detection methods with high reliability
Very high	2	Proven detection methods available
High	3	Detection tools have high chance of detecting methods.
Moderately high	4	Almost certain not to detect failures
Medium	5	Detection tools have moderate chance of detecting defect.
Low	6	Detection tools have a low chance of detecting failure
Slight	7	Detection tools may not detect failure
Very slight	8	Detection tools will probably not detect failure
Remote	9	Detection tools most likely will not detect failure
Impossible	10	Failure not detected

6.16 **Calculate the Risk Priority Numbers (RPN):**

RISK ASSESSMENT FOR STEAM STERILIZER

6.16.1 The Risk Priority Number (RPN) is simply the product the Failure Mode Severity, Occurrence and Control Detection Effectiveness ratings.

Thus, RPN = S x O x D.

RPN = S x O x D.
= 5 x 5 x 5 = 125.

6.17 **Acceptance Criteria:**

6.17.1 In case the calculated RPN rating is greater than 27 that particular, failures are not acceptable.

Sr. No.	RPN Rating	RPN Category	Action Status
01	≥76	Critical	CAPA is required
02	51 to 75	Major	CAPA is required
03	28 to 50	Moderate	CAPA is required
04	Up to 27	Minor	No action required

6.17.2 For RPN rating ≤ 27, no action plan is required.

6.17.3 Action plan is required if any of individual severity, occurrence and detection is ≥8 (even if RPN is within acceptance criteria).

6.18 **Identify Action(s) to Address Potential Failure Modes that have a high RPN:**

6.19 A high RPN needs the immediate attention of the user department/engineer since it indicates that the failure mode can result in an enormous negative effect, its failure cause has a high likelihood of occurring, and there are insufficient controls to catch it. Thus, action items must be defined to address failure modes that have high RPNs (especially unacceptable and intolerable), These actions include but should not be limited to the following:

⇒ Inspection,

⇒ Testing,

⇒ Monitoring,

⇒ Redesign,

⇒ De-rating,

⇒ Conduct of preventative maintenance,

⇒ Redundancy,

⇒ Process evaluation / optimization, etc.

RISK ASSESSMENT FOR STEAM STERILIZER

6.20 **Review the Results of the Actions taken and Reassess the RPN's:**

6.20.1 After the defined actions have been completed, their over-all effect on the failure mode they are supposed to address must be reassessed. The respective person must update the Severity, Occurrence and Detectability numbers accordingly.

6.20.2 The new RPN must be recalculated once the new Severity, Occurrence and Detectability numbers have been established. The new RPN should help the engineer decide if more actions are needed or if the actions are sufficient.

6.21 For Detailed Risk Analysis is described in Attachment #01.

7.0 SUMMARY AND CONCLUSION

Based on the Failure assessment, effect analysis it is concluded that the reliability on the system performance is appropriate by following the recommendations of Control procedures and safeguards.

8.0 CERTIFICATION FOR RISK ASSESSMENT

This risk assessment Protocol is studied, executed and approved by the Undersigned Authorized Personnel.

The following have been approved this protocol

Functional Area	Name	Signature	Date
Prepared by			
Quality Assurance Department			
Reviewed & Approved by			
Production Department			
Quality Control Department			
Engineering Department			
Quality Assurance Department			