RISK ASSESSMENT & MITIGATION FOR SAMPLING POINTS OF PURIFIED WATER USED IN WASHING ROOM AT GROUND FLOOR ON THE WEEKLY BASIS

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QUALITY ASSURANCE DEPARTMENT

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1. Report Approval

Signing of this approval page for risk analysis indicates agreement with approach described in this risk assessment sampling point of purified water

Prepared By:

Name	Designation	Department	Signature	Date

Checked By:

Name	Designation	Department	Signature	Date

Approved By:

Name	Designation	Department	Signature	Date

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2.0 Overview

2.1 Objective:

The Objective of this report is to describe in detail about the decision taken by adopting a systematic process for the assessment, control, communication and review of risk associated with Risk Assessment for the sampling point of purified water.

2.2 Purpose and Scope:

The purpose of this report is to outline a scientific and practical approach for decision making process by applying a suitable tool of risk assessment covering all aspects of risk associated with Risk Assessment for the sampling point of purified water.

2.3 Risk Assessment Team:

- Quality Assurance Executive/Officer/Manager
- Production Executive/Officer/Manager

2.4 Responsibility

S.No.	Department	Designation	Responsibility
1.	Microbiology	Executive/Officer/ Manager	Facilitate to Identify, analyse and evaluate the risk Execute the risk mitigation exercise Compile the supporting data
2.	Quality Assurance	Executive/Officer/ Manager	Review & approval of Risk Assessment document Identify, analyse and evaluate the risk Review the supporting documents

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3. Introduction

Risk analysis of sampling point of purified water shall be done by considering the below mentioned factors

- The Risk Impact on the Process
- The Risk impact on the Product Quality
- The Risk impact on the environment
- The Risk impact on the person
- The Risk impact on the regulatory compliance

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4. Quality Risk Management Process:

Risk assessment is a systematic process of organizing information to support a risk decision to be made within a risk management process. Its consists Identification of hazards and the analysis and evaluation of risks associated with exposure to those hazards

Quality risk assessment begins with a well defined problem description or risk question.

For risk assessment process three fundamental questions are considered

— What might go wrong?

— What is likely hood **(Occurrence)** it will go wrong?

— What are the consequences **(severity)?**

- **Risk Identification**

  Risk Identification is systematic use of information to identify hazards referring to risk questions or problem description. Information may include historical data theoretical analysis, informed opinions and concerns of stakeholders. risk Identification will be conducted by reviewing the types of events that might occur in both normal and unusual situations. This may be done by challenging the normal presumptions, and considering the possibilities of unanticipated situations. For each risk event, the underlying (root) cause should be determined that will create the potential risk occurrence.

  Risk Identification addresses the “what might go wrong” question including identifying the possible consequences. This provides the basis for the further steps in quality risk management process.

- **Risk Analysis**

  Risk analysis is the estimation of risk associated with the identified hazards.

  It is the quantitative or qualitative process of linking the likelihood of occurrence and severity of harm and sometime the detectability of harm is also consider during estimation of risk.

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- **Risk Evaluation**

  Risk Evaluation compares the identified and analyzed risk against the given risk criteria. Risk evaluation considers the strength of evidence for all three of fundamental questions.

  Risks are ranked by scoring various criteria with appropriate numerical ratings, adding to scores to determine the overall score of each risk, and sorting the risks into descending order based on each score. A risk scoring threshold is established, over which risks must be mitigated using adequate design and/ or process controls that will protect the system. Those risks that fall below the threshold are either unmitigated or scheduled for later mitigation. An additional threshold or characteristic of risk can be used to determine the differentiation of non- mitigation versus postponed mitigation.

- **Risk Control**

  Risk control includes decision making to reduce or mitigate risk. The purpose of risk control is to reduce the risk to the acceptance level

  The risk control is done by considering the following question

  — Is the risk above an acceptable level?

  — What can be done to reduce or eliminate risk?

  — What is appropriate balance among benefits, risks and resources?

  — Are new risk is introduced as a result identified risk being controlled?

- **Risk Reduction**

  Risk reduction focuses on processes the mitigation or avoidance of quality risk when it exceeds the acceptable level. Risk reduction includes action taken to mitigate the severity, occurrence or probability of harm and the processes that improve the detectability of harm. It is the part of risk control strategy and involves

  — Engineering Control

  — Procedural Control

  — Manual control etc.

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5. Risk Assessment for the for Sampling Point of Purified Water in Washing Room

5.1 Risk Assessment Legend

A. Severity

Ranking	Effect	Criteria
10	Hazardous	Hazardous effect without warning. Safety related. Regulatory non-compliant.
9	Serious	Potential hazardous effect. Able to stop without mishap. Regulatory compliance in jeopardy.
8	Extreme	Item inoperable but safe. Customer very dissatisfied.
7	Major	Performance severely affected but functional and safe. Customer dissatisfied.
6	Significant	Performance degraded but operable and safe. Non-vital part inoperable. Customer experiences discomfort.
5	Moderate	Performance moderately affected. Fault on non-vital part requires repair. Customer experiences some dissatisfaction.
4	Minor	Minor effect on performance. Fault does not require repair. Non-vital fault always noticed. Customer experiences minor nuisance.
3	Slight	Slight effect on performance. Non-vital fault notice most of the time. Customer is slightly annoyed.
2	Very Slight	Very slight effect on performance. Non-vital fault may be noticed. Customer is not annoyed.
1	None	No effect.

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B. Probability or Occurrence

Ranking	Possible Failure	Probability of Failure
10	≥ 1 in 2	Almost certain.
9	1 in 3	Very high.
8	1 in 8	High.
7	1 in 20	Moderately high.
6	1 in 80	Medium
5	1 in 400	Low
4	1 in 2,000	Slight
3	1 in 15,000	Very slight.
2	1 in 150,000	Remote.
1	1 in 1,500,000	Almost impossible.

C. Detection

Ranking	Detection	Likelihood of Detection by design control
10	Absolute Uncertainty	No design control or design control will not detect potential cause
9	Very Remote	Very remote chance design control will detect potential cause.
8	Remote	Remote chance design control will detect potential cause.
7	Very Low	Very low chance design control will detect potential cause.
6	Low	Low chance design control will detect potential cause.
5	Moderate	Moderate chance design control will detect potential cause.
4	Moderately High	Moderately high chance design control will detect potential cause.
3	High	High chance design control will detect potential cause.
2	Very High	Very high chance design control will detect potential cause.
1	Almost Certain	Almost certain that the design control will detect potential cause.

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5.2 Risk Assessment Tool– Failure Mode effect Analysis (FMEA)

5.2.1 Risk Identification

S.No.	Failure Mode {What can go wrong}	Potential cause of Failure	What are the Consequences	Justification
	Risk Identification			
1.	Sampling	Human error was identified during investigation. Analyst was not aware of the sampling point.	During investigation it was found that water from sampling point is used for cleaning and washing purpose, hence the threat to the product quality can be ruled out.	With respect to the investigational study it can be stated that as the sampling point is used only for washing purpose, so does not have any adverse impact on the product quality.

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5.2.2 Risk Analysis

S.No.	Failure Mode {What can go wrong}	Potential cause of Failure	Existing Design Control	Severity	Probability	Detection	Risk Priority Number
				(S)	(P)	(D)	RPN=S x P x D
	Risk Analysis						Risk valuation
1.	Sampling	According to the schedule the frequency of sampling for the user point is weekly.	To maintain the quality of the water, supportive analytical data for supply and return end points are available which are being tested daily.	2	3	3	=2×3×3=18

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5.2.3 Risk Reduction or Mitigation

S.No.	Failure Mode {What can go wrong}	Existing Design Control	Severity (S)	Probability (P)	Detection (D)	Risk Priority Number (RPN)	Additional Design Control	Severity (S)	Probability (P)	Detection (D)	Risk Priority Number (RPN)
	Risk Mitigation										
1	Sampling	To maintain the quality of the water, supportive analytical data for supply and return end points are available which are being tested daily	2	3	3	**=2×3×3 =18**	The existing design control made the risk at the acceptable level .	2	3	3	**=2×3×3=18**

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6. Acceptance Criteria

The Risk Priority Number shall be within the range 0<RPN<125

7. Risk Control Strategy

S.No.	Risk Priority Number	Risk Decision	Risk control strategy
1.	0<RPN<125	Risk Acceptable	No control is required
2.	125<RPN<500	Risk Reduction	Additional Procedural Control
			Manual Control
			Documentary Evidence
3.	500<RPN<1000	Risk Reduction	Rugged Procedural control
			Additional Manual Control
			Auditing
			Engineering controls (if Possible)

8. Summary

With respect to the sampling point ……, It can be summarized that First Phase and Second Phase validations had been performed successfully for all the user points. After the completion of the third phase, some points were reduced and being performed weekly. Frequency of sampling point was reduced to weekly after evaluating the results of first and second phase, which conformed that the results were within the acceptable limits and meeting the specifications.

Conclusion

Based on the Risk assessment study, it can be summarized that the sampling of the user point ……..is performed on weekly basis. The Risk Priority Number is 18 which is below the acceptance criteria, that is 125. Hence it is concluded that the sampling point ……shall be used as per schedule. There is no direct impact on the product quality as water is only used for cleaning of gowns.

9. References:

1. Risk Management Master Plan
2. ICH Q9