


Risk and Opportunity Management Control Procedures

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1. Purpose

In order to establish countermeasures for risks and opportunities, Clarify the operational requirements including risk avoidance, risk reduction and risk acceptance, establish comprehensive risk and opportunity management measures and the construction of internal control, enhance the ability to resist risks, and provide operational guidance for incorporating and applying these measures in the quality management system and evaluating the effectiveness of these measures.

2. Range

This procedure is applicable to provide operational basis for the control of methods and requirements to deal with risks and opportunities in the Company's quality management system activities, including:

- 2.1 Risk and opportunity management in business development, market research and customer satisfaction survey process;
- 2.2 Risk and opportunity management in supplier review and procurement control process;
- 2.3 Risk and opportunity management in production process;
- 2.4 Process inspection and monitoring of measuring equipment management process risk and opportunity management;
- 2.5 Maintenance of equipment and fixtures and risk and opportunity management in the process of maintenance management;
- 2.6 Risk and opportunity management during the disposal of nonconforming products and the implementation and verification of corrective and preventive measures;
- 2.7 Risk and opportunity management of continuous improvement process;
- 2.8 When applicable, it can also be used to provide operational guidelines for the control of risks and opportunities in the process of company management.

3. Responsibilities

- 3.1 The general manager or management representative is responsible for providing resources required for risk management, including personnel qualifications, necessary training,

information acquisition, etc.; Be responsible for the determination of risk acceptable criteria and guidelines.

3.2 The Quality Department is responsible for establishing and maintaining this procedure, organizing and implementing risk and opportunity review according to the cycle required by the document, implementing and following up the completion and effectiveness of the measures taken in risk and opportunity assessment, and summarizing the 《Risk and Opportunity Assessment Analysis and Action Table》.

3.3 Each department is responsible for the risk and opportunity assessment of its own department, and formulating corresponding measures to avoid or reduce risks and implement them.

4. Definitions

4.1 Risk: All kinds of uncertain events that exist objectively under a certain environment and within a certain period of time and affect the realization of enterprise goals.

4.2 Opportunity: Conditions and events that have a positive impact on enterprises, including some unexpected events.

4.3 Risk assessment: Quantitative assessment of the impact and potential loss of a risk event before or after the event (but not yet concluded). That is, risk assessment is to quantify and evaluate the possible degree of impact or loss brought by an event or thing.

4.4 Risk avoidance: It is a method of risk response, which means to eliminate risks or conditions of risk occurrence through planned changes, and protect the target from the impact of risks. Risk aversion does not mean to eliminate risks completely, but what we want to avoid is the loss that risks may cause us. First, it is necessary to reduce the probability of losses, which is mainly to take prior control measures; The second is to reduce the degree of loss, which mainly includes two aspects: control in advance and remedy afterwards.

4.5 Risk reduction: By taking measures to achieve the effect of risk reduction. Under normal circumstances, if the measures taken can effectively reduce the risks suffered, the records of the measures taken should be kept or written into files for archiving, so as to be used as the basis for improvement when repeated in the later period.

- 4.6 Risk acceptance: refers to the loss caused by the enterprise taking risks. Risk acceptance is generally applicable to those risks that cause less loss and high repeatability, and is most suitable for self-retained risk events.
- 4.7 Internal risks: Risks formed within an enterprise, such as strategic decision-making risks, environmental risks, financial risks, management risks, operational risks, etc.
- 4.8 External risks: Risks caused by external factors, such as policy risks, market demand risks and business risks.
- 4.9 Risk severity: The severity of the impact of a risk after its occurrence.
- 4.10 Frequency of risk occurrence: the frequency or probability of risk occurrence.
- 4.11 The risk factor is used to assess whether measures have been taken against the identified risks, and the risk factor = risk severity * risk occurrence frequency.

5. Operation contents

5.1 Risk and opportunity management planning

In order to comprehensively identify and deal with the risks and opportunities existing in the production and management activities of various departments, All departments should establish identification and response methods, Confirm the risks existing in the department. In the process of identifying and coping with risks and opportunities, each department should screen and identify the processes, production processes and personnel that may have risks, and the risks existing inside and outside the enterprise one by one. In the process of risk identification, risks including but not limited to the following aspects should be identified:

5.1.1 The risks to be considered are:

1. Quality risk
 - a. Direct quality risk: Product quality problems, resulting in return, replacement, repair and other risks.
 - b. Indirect quality risk: If the use of the product damages other property rights or personal rights of the customer, it shall bear civil liability for compensation.
2. Organizational environmental risks

- a. The off-season and peak season of product sales affect customers' purchase and indirectly affect the company's product production, so consider inventory.
 - b. Humanistic environment: It is mainly reflected in the different consumption habits of people in different times, different regions and different nationalities.
 - c. Policy environment: National macroeconomic policies, changes in economic environment, and changes in relevant local policies will indirectly affect the financial integration of enterprises and the necessary conditions for enterprise operation.
 - d. Economic environment: Changes in interest rates, changes in exchange rates, inflation or deflation, etc.
3. Operational risk
- a. Supply of raw materials: mainly includes changes in the price, quality and delivery time of raw materials, fraud in the procurement process, negligence of procurement personnel, resulting in substandard quantity and quality of raw materials, etc.
 - b. Employee risks: risks caused by the negligence of purchasing personnel, service personnel, technical personnel and other production management personnel, as well as risks such as the departure of key personnel in various positions.
 - c. Equipment: Unexpected failure or even damage of production equipment.
 - d. Supply and marketing chain risks: mainly include risks such as default of suppliers and customers, and unsmooth supply or sales channels.
 - e. Legal disputes: Potential legal disputes such as consumer complaints.

4. Market risk

- a. Market capacity: The method used in the investigation of market capacity is inappropriate, and it does not accurately find out the amount of products used by market objects, which makes the output of products exceed the actual demand and increases the investment risk of the company.
- b. Market Competitiveness: An incorrect analysis of our competitors may lead to an overestimation or underestimation of the competitiveness of our product market, triggering expectation risk.
- c. Price risk: The price risk of a product is affected by the cost, quality and reputation of the product, customer consumption, etc.
- d. Promotion risk: Promotion risk includes cost control of promotion activities, error in effect prediction and doubt on quality.

5. Financial risk

- a. Financing/Risks in the financing process: For example, risky financing is costly and subject to more policy constraints, increasing uncertainty in financing.
- b. Risk in the process of repayment of funds: It is mainly affected by interest rates, which is extremely unstable and increases the repayment risk.
- c. Risks in the use of funds: mainly manifested as short-term capital risks and long-term capital investment risks.
- d. Risk in fund recovery: Receivables are not available in a timely manner, increasing the occurrence of bad debts.
- e. Risks in the process of income distribution: mainly manifested in the risks arising from the confirmation of risks and improper

income distribution to investors.

5.2 Establish a risk/opportunity management team

5.2.1 Establishment of risk and opportunity assessment teams

Risk identification activities shall be carried out as a group activity. Each department shall conduct risk identification and assessment through brainstorming and effective analysis and judgment. Before this, a "Risk and Opportunity Assessment Team" shall be established. The General Manager shall, through authorization, entrust the "Risk and Opportunity Assessment Team" with the following responsibilities:

- a. Organize and implement risk and opportunity analysis and evaluation;
- b. Formulate risk and opportunity response measures and implement them;
- c. Prepare risk management plan;
- d. Organize the implementation of risk response measures to verify the implementation effect.

In the "Risk and Opportunity Assessment Team", the General Manager shall appoint a person as the team leader, responsible for planning and arranging the identification of risks and opportunities and the control of response, and entrust the team leader with the following responsibilities:

- a) Plan and implement risk and opportunity management, and prepare the 《Risk and Opportunity Assessment Analysis and Action Table》.
- b) Follow up and coordinate the work of each member.
- c) Communicate with superiors to ensure effective work.

5.2.2 Job requirements for risk management team personnel

In order to ensure that the personnel involved in risk and opportunity identification and assessment meet the requirements, can be competent and participate in the identification of risks and opportunities of the department and formulate corresponding response measures, the personnel of the risk and opportunity assessment team shall have the following abilities:

- a. Familiar with all processes of his department;

- b. Have certain organization and coordination ability;
- c. Familiar with the requirements of this standard, and plan risk analysis and assessment according to the contents of this standard.

5.3 Risk management plan

The leader of the assessment team shall organize the planning of risk management and prepare the 《Risk and Opportunity Assessment Analysis and Measures Table》 to guide operational risk identification and risk assessment, as well as the criteria for risk acceptability. When preparing the 《Risk and Opportunity Assessment Analysis and Measures Table》, it shall include but not be limited to the following contents:

- 5.3.1 Scope of planning;
- 5.3.2 Allocation of duties and powers;
- 5.3.3 Requirements for the review of risk management activities;
- 5.3.4 Risk acceptability criteria, including when the probability of hazard cannot be estimated;
- 5.3.5 Validation activities;
- 5.3.6 Activities related to production and post-production information collection and review.

5.4 Risk assessment

To evaluate the severity and frequency of identified risks, the evaluation requirements shall be confirmed according to the evaluation criteria specified in this procedure. The confirmation of severity and frequency of risks shall be used to determine the risk coefficient, and then the measures to be taken for risks shall be determined according to the risk coefficient.

5.4.1 Criteria for evaluating the severity of risks

Risk severity is used to evaluate the possible damage degree caused by potential risks. According to the assessment and quantification of potential risks, if potential risks occur, they will cause various impacts and harm degree, including but not limited to the harm caused after risks occur:

- a. Laws and regulations, product and customer requirements;

- b. Personal injury caused by the occurrence of risks;
- c. The amount of property losses;
- d. Whether it will lead to shutdown/production suspension;
- e. Degree of damage to corporate image.

Note: When judging the severity of risks, it is recommended to expand the hazard level brought by the analysis of risks, so as to take more effective measures against potential risks and achieve the purpose of reducing or partially eliminating risks or even completely eliminating them.

In order to identify the degree of harm caused by risks, the severity of risks is distinguished, and the severity of risks is divided into the following five categories:

- a. Very serious
- b. Serious
- c. More serious
- d. General
- e. Slight

The following table quantifies the defined risk impact and its degree. When evaluating the severity of risk, the following table serves as the criterion for evaluating the severity of risk:

Severity	Describe					Severity grade
	Laws, regulations, products and other requirements	Personal injury	Property loss (Ten thousand yuan)	Stop work/production	Corporate image	

Severity	Describe					Severity grade
	Laws, regulations, products and other requirements	Personal injury	Property loss (Ten thousand yuan)	Stop work/producti on	Corporate image	
Very serious	Violation of laws and regulations, international/natio nal standards, customer standards	Death, amputation, fracture, hearing loss, chronic diseases, etc.	Property loss ≥ 10	Irrecoverable	Significant internationa l and domestic impacts	5
Serious	Provincial standards, industry standard	Injury requires shutdown for recuperation, and the shutdown time is ≥ 3 months	$10 < \text{property loss} \geq 5$	It takes a long time to adjust before it can be restored	Provincial, industry impact	4
More serious	Regional standard	Injury requires shutdown for recuperation, and the shutdown time is less than 3 months	$5 < \text{Property loss} \geq 0.5$	Intermittent recovery	Regional influence	3

Severity	Describe					Severity grade
	Laws, regulations, products and other requirements	Personal injury	Property loss (Ten thousand yuan)	Stop work/producti on	Corporate image	
General	Enterprise standard	Slight injury, just bandage	Property loss <0.5	Can be recovered in a short time	Enterprise and its surrounding areas	2
Slight	Do not violate	No casualties	No loss	No shutdown	Do not affect	1

In the process of severity judgment, when the severity of multiple factors is inconsistent, the principle of strictness should be followed, that is, when only one or part of multiple factors have higher severity level, the factors with higher severity level should be used as risk severity. After determining the severity of risks according to the above table, fill in the severity level figures in the Risk and Opportunity Assessment and Analysis Table.

5.4.2 Risk frequency evaluation criteria

Risk frequency refers to the frequency of potential risks. For convenience of identification and definition, the risk frequency is defined as 5 levels, as follows:

- Rarely;
- Seldom;
- Occasionally;
- Sometimes;
- Frequent;

By evaluating the frequency of risk occurrence through the above uncertain factors, the evaluation of risk occurrence frequency takes the quantitative confirmation of its possible occurrence frequency as the evaluation criterion of risk occurrence frequency:

Frequency of occurrence	Definition	Grades
Rarely	Occurrence probability $\leq 0.001\%$	1
Seldom	$0.001\% < \text{probability of occurrence} \leq 0.1\%$	2
Occasionally	$0.1\% < \text{occurrence probability} \leq 1\%$	3
Sometimes	$1\% < \text{occurrence probability} \leq 10\%$	4
Frequent	Occurrence probability $\geq 10\%$	5

In the process of judging the occurrence frequency, when the occurrence frequency of one or more factors is inconsistent in the judging process, the strict principle should be followed to judge, that is, when only one or part of the factors occur frequently, the risk occurrence degree should be judged according to the factors with higher occurrence frequency. After determining the severity of risks according to the above table, fill in the severity level figures in the Risk and Opportunity Assessment and Analysis Table.

5.4.3 Acceptable criteria for risk

The risk acceptability criterion is to determine whether the risk is acceptable by calculating the risk coefficient. After evaluating the severity and frequency of the risk, it determines whether to take measures against the risk by calculating the risk coefficient.

The risk factor is calculated as follows:

$$\text{Risk Factor} = \text{Risk Severity Rating} * \text{Risk Frequency Rating}$$

The size of the risk factor determines whether the measures should be taken for risks, as required in the following table:

Frequency of occurrence Severity	Rarely	Seldom	Occasional ly	Sometimes	Frequent
Very serious	5	10	15	20	25
Serious	4	8	12	16	20
More serious	3	6	9	12	15

Frequency of occurrence Severity					
	Rarely	Seldom	Occasional ly	Sometimes	Frequent
General	2	4	6	8	10
Slight	1	2	3	4	5

Using the risk factor as the reference value, the following table shows the range of risk factor and the measures to be taken when the risk factor reaches a certain value:

Risk coefficient	Risk level and measures to be taken	
	Risk level	Risk measures
15-25	High risk	Measures should be taken immediately to avoid or reduce risks
5-15	General risk	Measures need to be taken to reduce risks
1-5	Low risk	The risk is low. When the cost caused by taking measures to eliminate the risk is greater than the loss caused by the risk itself, accept the risk

Risk response should be screened according to the actual situation. When potential risks can be effectively avoided by taking evasive measures, risk avoidance schemes should be formulated, risk avoidance measures should be confirmed and implemented until risks are partially or completely eliminated. When there is no feasible scheme to avoid risks, effective risk reduction measures should be taken to reduce the impact of potential risks. The following table is a comparison table of risk response measures to be taken for emergency determination of risk level after identifying risk factors:

Frequency of occurrence Severity	Rarely	Seldom	Occasionally	Sometimes	Frequent
Very serious	General risk	General risk	High risk	High risk	High risk
Serious	Low risk	General risk	General risk	High risk	High risk
More serious	Low risk	General risk	General risk	General risk	High risk
General	Low risk	Low risk	General risk	General risk	General risk
Slight	Low risk	Low risk	Low risk	Low risk	General risk

In the process of risk analysis and risk response, the follow-up of the plan and implementation results of risk measures shall be recorded, and the records shall be kept for a specified time. The detailed contents of risk analysis and risk response measures shall be recorded in the Risk and Opportunity Assessment Analysis Table for subsequent reference and follow-up.

5.5 Risk Response

Each implementing department shall evaluate the identified risks and take measures according to the evaluation results, so as to achieve the purpose of reducing or eliminating risks. The methods of risk response include:

- Risk acceptance;
- Risk reduction;
- Risk aversion.

The measures taken for risks should consider eliminating risks as much as possible. When it is impossible to eliminate or there is no effective method for the time being, or when the cost of adopting the method of eliminating risks is higher than the loss caused by the existence of risks, the risk response methods of reducing risks or accepting risks should be selected.

5.5.1 Risk acceptance

It refers to the loss caused by the risk borne by the enterprise itself. Risk acceptance is generally applicable to those risks that cause less losses and high repeatability. The

method of risk acceptance can be adopted when the following situations occur:

- a. When the cost of taking risk avoidance measures far exceeds the loss caused by potential risks;
- b. The risk of less loss and high repeatability;
- c. When there are neither effective measures to reduce risks nor effective methods to avoid risks;
- d. Low risk with a risk factor less than 5 calculated according to the risk assessment criteria required in this document.

5.5.2 Risk reduction

Risk reduction means taking measures to reduce the damage or loss caused by potential risks. The risk assessment implementation unit shall formulate detailed risk reduction measures to reduce risks. Risk reduction methods can be taken when the following situations occur:

- a. When the cost of taking risk avoidance measures far exceeds the loss caused by potential risks;
- b. When the risk cannot be eliminated or there is no effective avoidance measure to avoid the risk;
- c. Generic risks with a risk factor of between 5 and 15 are calculated according to the risk assessment criteria required in this document.

5.5.3 Risk aversion

Risk aversion refers to eliminating risks or conditions under which risks occur through planned changes, and protecting targets from risks. Risk aversion does not mean to eliminate risks completely, but what we want to avoid is the loss that risks may cause us. First, it is necessary to reduce the probability of losses, which is mainly to take prior control measures; The second is to reduce the degree of loss, which mainly includes two aspects: control in advance and remedy afterwards.

5.5.4 Supervision and improvement of risk management

Risk identification and assessment activities are used to identify risks and consider the effective measures to be taken. When the risk coefficient is too high, risks should be avoided or reduced to reduce the harm or loss caused by risks. The risk assessment

implementation department shall formulate detailed and effective measures and implement them. When formulating measures, the following aspects shall be considered:

- a. The measures formulated should be enforceable and enforceable under the existing conditions;
- b. The measures formulated should be implemented to individuals, and the contents that each person should complete should be clear;
- c. A responsible person should be assigned to follow up the implementation progress and effect of the measures to ensure that the measures taken are effectively implemented.

5.6 Review of risks and opportunities

The Quality Department shall organize and implement the review cycle of risks and opportunities according to the established cycle to verify its effectiveness. The review of risks and opportunities should include the following aspects:

- a. Whether the identification of risks and opportunities is effective and perfect;
- b. Completion and progress of risk response measures;
- c. Potential impact on product and service conformity and customer satisfaction.

5.6.1 Planning of risk and opportunity review

Risk and opportunity reviews should be conducted at least once a year before management reviews to verify their effectiveness. When the following situations occur, the number of risks and risk reviews should be appropriately increased:

- a. When there are changes in laws, regulations, standards and other requirements related to the quality management system;
- b. When major adjustments have taken place in organizational structure, product scope and resource allocation;
- c. When major quality accidents occur or complaints from related parties occur continuously;
- d. Before the third-party certification audit or when it is considered necessary for management review;
- e. When other circumstances require it.

5.6.2 Implementation of Risk and Opportunity Review

a. Preparation before implementation

Before the risk and opportunity review meeting, each department shall collate the data of risk and opportunity analysis of its own department, including the contents of risk identification, risk assessment and risk response, and the results of measures taken in risk response, and make summary analysis, and fill in the Table of Risk and Opportunity Assessment, Analysis and Measures.

b. Implementation of risk and opportunity response

Quality Department shall organize all departments to conduct risk and opportunity reviews as required by the plan. Quality Department shall keep records of the reviews and the decisions made by the reviews, including subsequent improvement opportunities. The review of risks and opportunities shall form contents including but not limited to the following aspects:

- a) Risk assessment report;
- b) Opportunities for continuous improvement;
- c) Residual risk analysis and improvement measures.

6. Related documents

6.1 ISO9001: 2015 Quality Management System Standard

7. Related records

7.1 WII/QR01-19 《Risk and Opportunity Assessment Analysis and Action Sheet》