

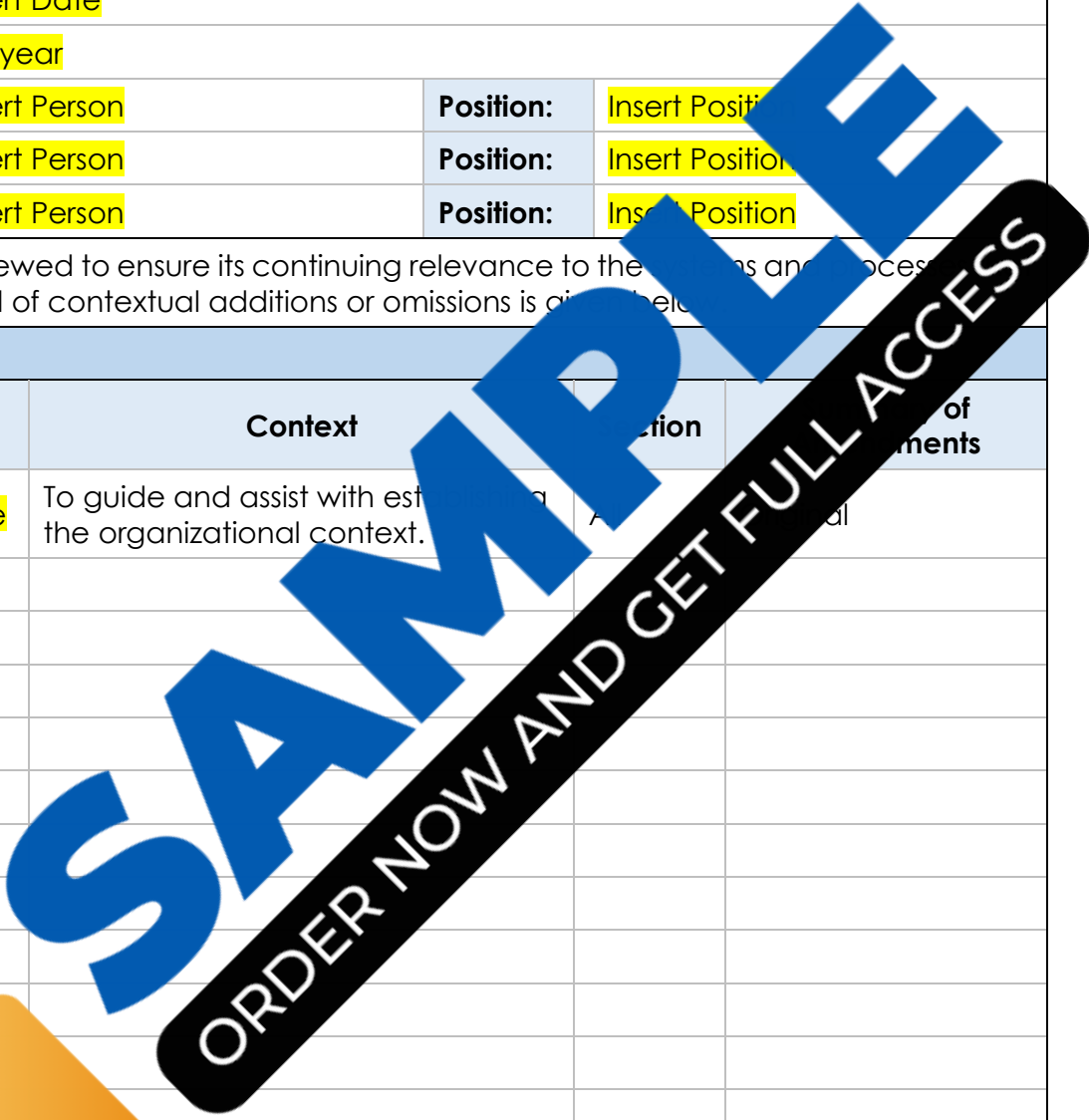
**QUALITY MANAGEMENT
PROCEDURE FOR THE
CONTEXT OF THE ORGANIZATION**

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1. APPROVAL

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This procedure is reviewed to ensure its continuing relevance to the conditions and processes it describes. A record of contextual additions or omissions is maintained below.			
Amendment Record			
Version	Date	Context	Reason for Amendments
1.0	Insert Date	To guide and assist with establishing the organizational context.	
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2. PURPOSE

The purpose of this procedure is to define the guidelines on how to establish the context of the organization and subsequent strategic objectives and direction of **Insert Your Company** through the:

- Identification of interested parties.
- Analysis of internal and external issues of concern.
- Identification of needs and expectations of interested parties.
- Relevant risks and opportunities.

3. SCOPE

This procedure applies to the processes of defining **Insert Your Company** in the marketplace and understanding how relevant factors coming from legal, economic, social and technological issues influence the strategic direction of **Insert Your Company** organizational context.

4. TERMS AND DEFINITIONS

Term	Definition
Inputs	Resources such as people, materials, energy, information or financial resources put into a process to seek a desired output.
Interested Parties	Stakeholders who use our products and services, or who may be impacted by them, or those parties who may otherwise have a significant interest in (or to) Insert Your Company .
Objectives	The results to be achieved. Objectives must be SMART – Specific, Measurable, Achievable, Realistic and Timely.
Opportunities	The positive effect of uncertainty.
Outputs	The result of a process.
Processes	A set of interrelated or interacting activities which use inputs to deliver outputs.
Threats	The likelihood of a negative effect.
Risk Management	Is the overall process of risk identification, risk analysis and risk evaluation.

5. ROLES AND RESPONSIBILITIES

Managers are responsible for:

- Understanding the needs of internal and external stakeholders to ensure that **Insert Your Company** quality management system is effective.

- Conducting a 'context of the organization assessment' to identify interested parties, their issues of concern, needs and expectations and the associated risks and opportunities.
- Developing the company's strategic direction based on the context of the organization.

Supervisors are responsible for:

- Supporting management with **Insert Your Company** quality management system.

6. PROCEDURES

6.1 Overview of the Context of the Organization Assessment

It is vitally important to fully understand the needs and expectations of internal and external parties to ensure that the quality management system is fully effective. To this end, senior management shall conduct a 'context of the organization assessment' to identify the 'interested parties' (stakeholders), their issues of concern, needs and expectations and the associated risks and opportunities derived from these matters.

The outputs of this assessment shall determine management's strategic development of the company's strategic objectives and actions.

Q-MF-1 –Organizational Context Register is the primary output of this assessment.

6.2 Determining the Context

In relation to ISO 9001:2015 *Quality Management System – Requirements*, there is no prescribed method of determining the context of the organization, however **Company X** will follow the generic framework approach:

1. Identify who are the interested parties and what are their requirements, needs and expectations.
2. Identify the internal issues that can affect our products, services, investments and interested parties.
3. Identify the external issues that can affect our organization's products, services, investments and interested parties.

Management shall monitor those internal issues, external issues and interested parties that have been identified.

6.3 Interested Parties

Interested parties are those stakeholders who receive our **products or services** or who may be impacted by them, or those parties who may otherwise have a significant interest in **Insert Your Company**.

The internal and external interested parties applicable to **Insert Your Company** shall be listed in Q-MF-1 – *Context of the Organization Register*, along with the reason for their inclusion.

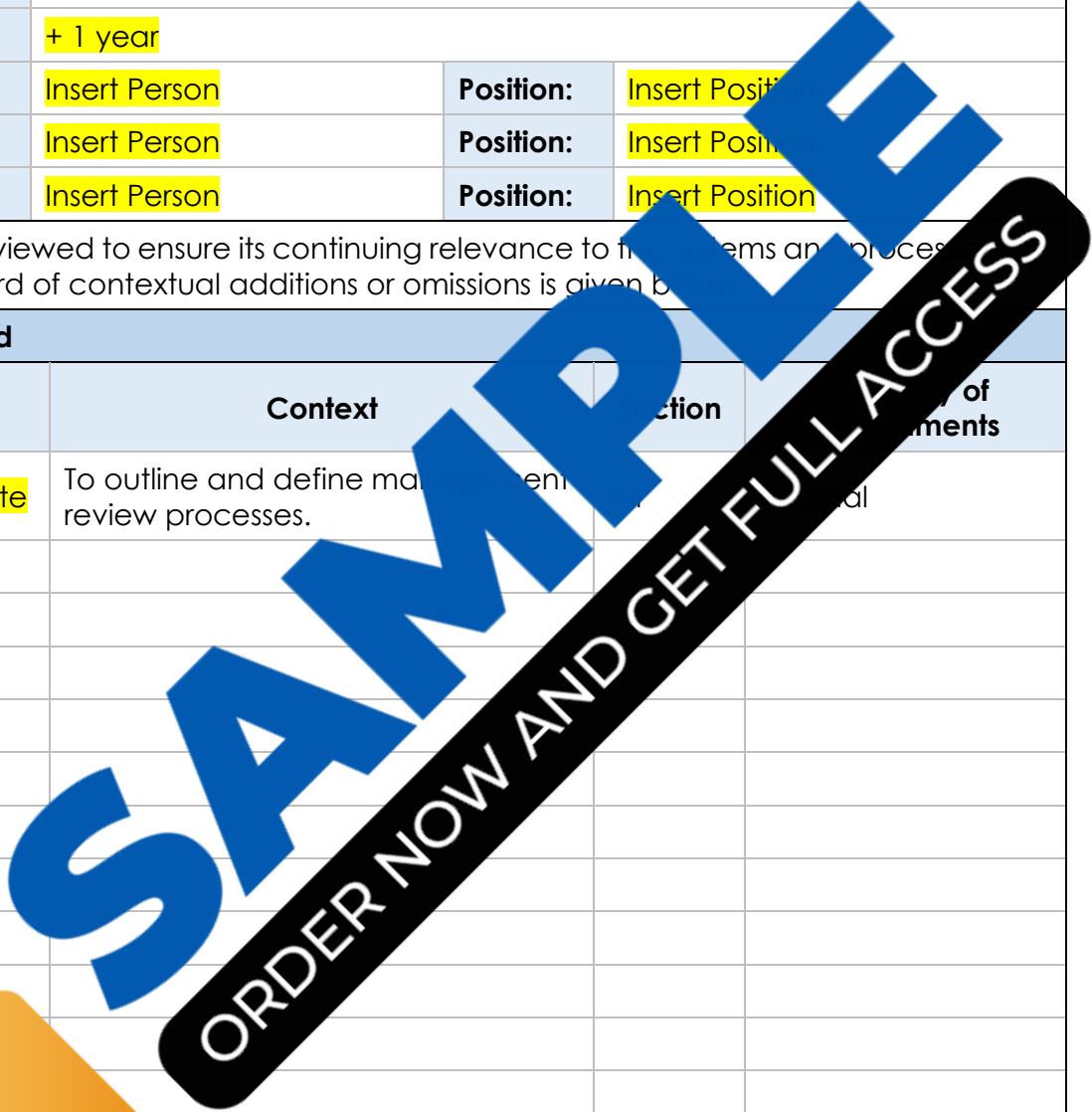
**QUALITY MANAGEMENT
PROCEDURE FOR
MANAGEMENT REVIEWS**

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1. APPROVAL

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1.0	Insert Date	To outline and define management review processes.	
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2. PURPOSE

The purpose of this procedure is to outline and define **Company X's** process for undertaking management reviews to assess the effectiveness of the quality management system and its compliance with *ISO 9001 Quality Management System – Requirements*.

3. SCOPE

This procedure applies to the methods of reviewing the quality management system to ensure that it is up to date, controlled and effective. The methods and processes enable the quality systems' continuing suitability and effectiveness in satisfying the requirements of *ISO 9001 Quality Management System – Requirements* and **Company X's** quality policy and objectives.

The 'strategic objectives and direction' management review is conducted **yearly**, at a minimum.

4. TERMS AND DEFINITIONS

Term	Definition
Continual Improvement	Recurring activity to enhance performance.
Corrective Action	An action to eliminate the cause of an identified non-conformance to the management system.
Non-Conformance Report (NCR)	A report that documents the details of a non-conformance and an action plan for further process review.
Objective	The result to be achieved. Objectives must be SMART – Specific, Measurable, Achievable, Realistic and Timely.
Record	Documentation that provides evidence of a process performed.

5. RESPONSIBILITIES

- Responsibilities for:
- Managing the management review agenda and ensuring minutes are recorded.
 - Ensuring management reviews are conducted at planned intervals.
 - Determining the review schedule and agenda, in coordination with participating attendees.
 - Ensuring that each management review includes the applicable quality management system data (e.g. results of internal audits, KPIs, opportunities for improvement, etc.).
 - Reviewing quality, environmental and health and safety objectives.

- Reporting and evaluating the cost of poor quality.

Supervisors are responsible for:

- Assisting management with collating data for management reviews.

Workers are responsible for:

- Reporting any relevant information that may contribute to the management review of products and services.

6. PROCEDURES

o Management Review Process Overview

The objective of the management review process is to confirm the continuing adequacy and effectiveness of the quality management system in line with **Your Company** objectives and strategies.

Action items from the last meeting

The senior manager shall report on the status of action items from the previous meeting. Items that have been completed are carried on and actions that are not completed are recorded as such in the meeting minutes.

Process performance and product conformance

The senior manager shall report on system performance data. This includes product conformity, on-time delivery performance and supplier performance and productivity data.

Internal and external audits

The senior manager shall present the results of internal and external audits. This includes summaries of results for the cycle, non-conformities, findings against particular elements of the quality system and a discussion of particularly important findings.

Corrective actions

The senior manager shall present the highest risk corrective actions implemented during the period and the status of pending actions.

Customer complaints

The senior manager shall present summaries of customer feedback and complaints, including an analysis of trends for particular categories.

Customer satisfaction

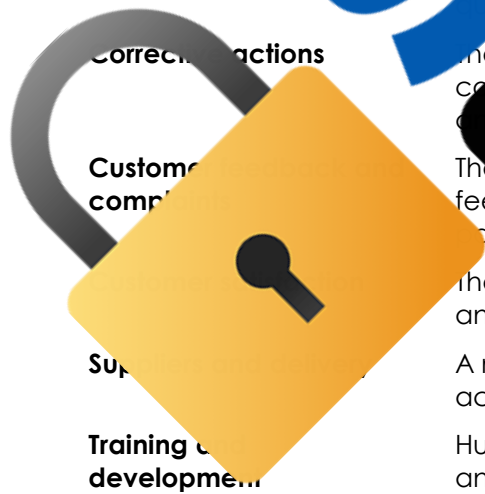
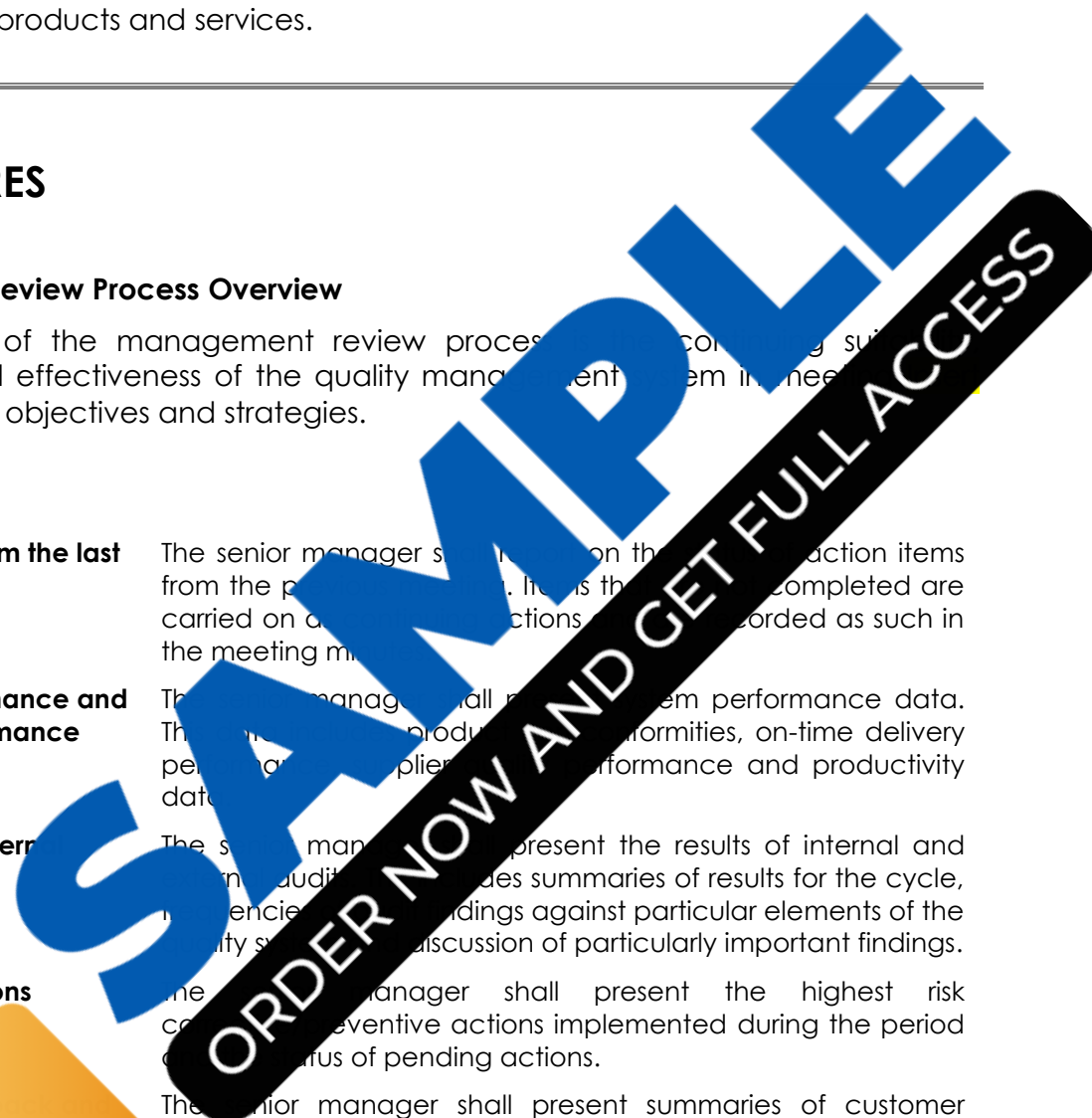
The senior manager shall present customer satisfaction data and trends.

Supplier performance

A management representative shall present supplier corrective action data and trends.

Training and development

Human resources shall report on the status of training programs and the effectiveness of training provided.



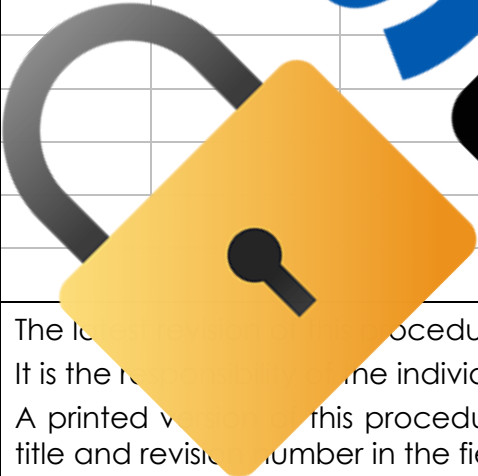
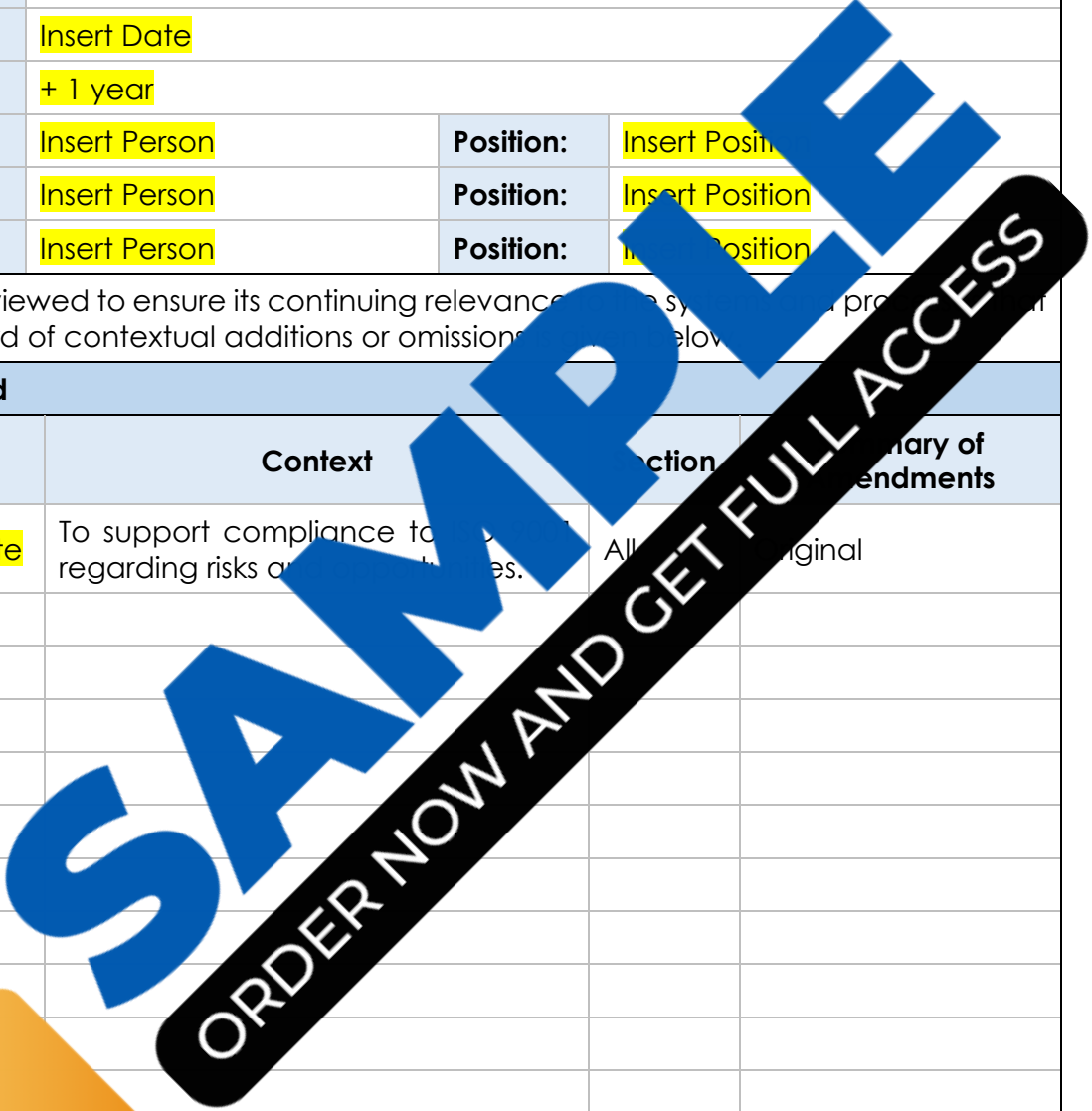
**QUALITY MANAGEMENT
PROCEDURE FOR THE MANAGEMENT
OF RISKS AND OPPORTUNITIES**

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1. APPROVAL

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1.0	Insert Date	To support compliance to... regarding risks and... es.	All... original
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2. PURPOSE

The purpose of this procedure is to ensure that the systematic identification and assessment of risks and opportunities associated with the workplace and work practices are consistent, relevant and applicable to **Insert Your Company** objectives and desired outcomes.

3. SCOPE

This procedure applies to the processes whereby management and **Insert Your Company** personnel assess the risks and opportunities attached to their activities, to achieve a sustained benefit or avoid an undesirable outcome.

4. TERMS AND DEFINITIONS

Term	Definition
Inputs	Resources such as people, materials, equipment, information or finance that are used in a system to produce a desired output.
Opportunity	The positive effect of a risk, given a level of uncertainty.
Outputs	The result of a process.
Process	A set of interrelated or interdependent activities which use inputs to deliver outputs.
Risk	The likelihood of a risk event occurring and its effect.
Risk Assessment	The overall process of risk identification, risk analysis and risk evaluation.
Risk Based Thinking	Planning objectives and actions with consideration to the known risks and their potential effects. The ideal situation is to minimize the likelihood or impact of unwanted outcomes.
Risk Control	Control measures developed with the intent of addressing all known or potential risks and preventing their occurrence.
Uncertainty	A deficiency of information related to understanding or knowledge of an event, its consequence, or likelihood. (Not to be confused with measurement uncertainty.)

5. ROLES AND RESPONSIBILITIES

Managers are responsible for:

- Considering all types of risk and opportunity, including processes, schedules, costs, quality, 3rd parties, etc.

- Ensuring that the scope of this procedure fully applies within their area(s) of authority.
- Ensuring that resources are provided to enable the management of risks and opportunities.
- Ensuring that all relevant parties and perspectives are appropriately engaged.
- Assisting with the maintenance of a risk and opportunity register for the scope and objectives for which they are accountable.

Supervisors are responsible for:

- Ensuring that this procedure is implemented in their area of responsibility.
- Ensuring that risk assessments are completed when required.
- Assisting with the control of risks and development of opportunities.

Workers are responsible for:

- Reporting new and existing hazards.
- Assisting with the development of risk control measures and opportunities.
- Complying with implemented risk control measures.

6. PROCEDURES

6.1 Risk and Opportunity Management Process Overview

Insert Your Company considers and manages risks and opportunities differently. Risks are managed with a focus on reducing their likelihood and minimizing their impact while opportunities are managed to increase their likelihood and maximize their benefits.

Where risks and opportunities overlap, an appropriate method for managing them shall be ascertained when the situation presents elements of such 'blended' uncertainties may require methods that both address negative risk and positive opportunity.



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