Procedure: [Risk Management Proc. Title]

1. **SUMMARY**
   1. The company has established, implemented and maintained this procedure for managing risks and opportunities throughout the [Short Client Name].
   2. Responsibility and authority for this procedure are spread across various functions, and defined within this procedure.
   3. *Note: this procedure has adopted definitions for key terms developed specifically by [Short Client Name] and determined appropriate for its use within the unique requirements of its management system. It does not adopt current ISO definitions, which [Short Client Name] has determined are not sufficient for its use.*
   4. *Note: the QMS documentation occasionally uses the term “opportunity for improvement” when discussing internal audit findings or management review actions; that term does not have the same context as the term “opportunity” used herein.*
   5. The [who?] is responsible for implementation and management of this procedure.
2. **REVISION AND APPROVAL**

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| **Rev.** | **Date** | **Nature of Changes** | **Approved By** |
| [Rev Number] | [Date of Issue] | Original issue. | [Procedure Approver Name] |
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1. **DEFINITIONS**
   1. **Risk**: A negative effect of uncertainty.
   2. **Opportunity**: A positive effective of uncertainty.
   3. **Uncertainty**: A deficiency of information related to understanding or knowledge of an event, its consequence, or likelihood. (Not to be confused with measurement uncertainty.)
   4. **Risk Assessment:** a systematic investigation and analysis of potential risks, combined with the assignment of severities of probabilities and consequences. These are used to rate risks in order to prioritize the mitigation of high risks.
   5. **Risk Mitigation:** a plan developed with the intent of addressing all known or possible risks and preventing their occurrence.
   6. **FMEA (Failure Mode Effects Analysis):** a specific risk treatment method which ranks risks by probability and consequence.
2. **PROCEDURE: GENERAL**
   1. [Short Client Name] considers and manages risks and opportunities differently.
   2. Risks are managed with a focus on decreasing their likelihood, and minimizing their impact if they should occur.
   3. Opportunities are managed to increase their likelihood, and to maximize their benefits if they should occur.
   4. Where risks and opportunities overlap, the best appropriate method for managing them shall be ascertained, given the situation at hand. Elements of such “blended” uncertainties may require methods which both address the negative risk and positive opportunity.
3. **PROCEDURE: MANAGEMENT OF RISKS**
   1. Risks are identified as part of the “Context of the Organization Exercise” described in the procedure ***[Context of the Org Proc. Title].***
   2. Additional risks may be identified by any employee at any time.
   3. Each process is defined in detail through a ***[Process Definition Doc Title].*** This document includes the identification and mitigation plans for key risks associated with the defined process. [Short Client Name] management reviews these risks and takes action to minimize them.
   4. Risks identified as part of the Context of the Organization exercise defined in the procedure ***[Context of the Org Proc. Title]*** and logged within the COTO Log. This indicates a rough priority, as well as a selected risk treatment method.
   5. The methods for risk assessments vary, but should always include a means of identifying the risk under examination, and a description of the result of the risk assessment.
   6. Detailed methods may include FMEA (failure mode effects analysis), SWOT (strength, weakness, opportunity and threat) or other tools. No single method is used for all risk assessments; the tool selected should be the best tool applicable to that particular risk analysis.
   7. NOTE: ISO 31010 provides guidance on the selection of risk tools.
   8. Where FMEA style risk treatment is deemed optimal, an entry shall be made in the Risk Register tab of the COTO Log. When using the Risk Register, the following steps are to be followed:
      1. Identifying the risk.
      2. Identifying the process for which the risk most likely dominates.
      3. Assigning a probability rating to the identified risk; this probability is comprised of two elements: likelihood and previous occurrences. Each element is given a score from 1 (lowest risk) to 5 (highest risk). The final probability rating is the average of the elements.
      4. Assigning a consequence rating if the risk were to be encountered; this consequence is comprised of five elements: eventual loss of contract; negative impact on existing customers; inability to meet contract terms; any violation of statutory regulations or law; impact on [Short Client Name]’s reputation; and estimated cost of correction. Again, each element is given a score from 1 (lowest risk) to 5 (highest risk). The final consequence rating is the average of the elements.
      5. Calculating a final Risk Factor based on the equation:

**PROBABILITY RATING x CONSEQUENCE RATING = RISK FACTOR**

* + 1. For risks with a final Risk Factor rating equal to or greater than the threshold set in the Risk Register, management will decide whether to reject the subject due to the risk, or accept the risks after the development of a risk mitigation plan. The mitigation plan must be documented, either in the Risk Register or in another document which must be referenced on the form.
    2. Risks with a factor less than the risk threshold may be accepted without a mitigation plan, unless otherwise directed by management.
    3. The Risk Register also allows for setting a “warning” threshold range, where risks that have a Risk Factor within that range are flagged as suggesting the need for a mitigation plan, but such a plan is not mandatory.
    4. The final column allows for entry of an estimated risk factor after mitigation, which is an estimate on what the risk should be reduced to if the risk treatment is successful.
  1. If a risk includes a potential positive aspect, management may elect to conduct an opportunity pursuit assessment on the positive aspect, as defined below.

1. **PROCEDURE: MANAGEMENT OF OPPORTUNITIES**
   1. [Short Client Name] actively seek out opportunities which could enhance its financial viability and market position. For example:
      1. obtaining new contracts
      2. obtaining access to new markets
      3. identification of new industries which may be served by [Short Client Name]
      4. development of new offerings that are within the scope of capabilities of [Short Client Name]
      5. streamlining existing processes to improve efficiency and reduce costs
   2. Opportunities are identified as part of the “Context of the Organization Exercise” described in ***[Context of the Org Proc. Title]*** and as part of the corrective and preventive action program described in ***[Corrective Preventive Action Proc. Title].***
   3. Discussing and analyzing opportunities shall be done by top management. If made part of the management review activities, these shall be recorded in the management review records.
   4. To help determine which opportunities should be pursued, the Opportunity Register within the COTO Log may be used to conduct an “opportunity pursuit assessment.” This register is similar to the Risk Register, but ranks potential positive opportunities by their likelihood of success and potential benefit.
   5. The opportunity pursuit assessment is conducted by:
      1. Identifying the opportunity.
      2. Identifying the process for which the opportunity most likely falls under.
      3. Assigning a probability rating to the identified opportunity; this probability that the organization can achieve the opportunity. It is comprised of two elements: likelihood and previous occurrences. Each element is given a score from 1 (lowest probability) to 5 (highest probability). The final probability rating is the average of the elements.
      4. Assigning a benefit rating to assess potential benefits if the opportunity is won. This is comprised of six elements: potential for new business; potential expansion of current business; potential improvements in the organization’s ability to satisfy regulatory or statutory requirements; potential improvements to the quality management system; potential enhancements of [Short Client Name]’s reputation; and estimated cost of implementation. Again, each element is given a score from 1 (lowest benefit) to 5 (highest benefit). The final benefit rating is the average of the elements.
      5. Calculating a final Opportunity Factor based on the equation:

**PROBABILITY RATING x BENEFIT RATING = OPPORTUNITY FACTOR**

* + 1. For opportunities with a final Opportunity Factor rating equal to or greater than the threshold set in the Opportunity Register, management will decide whether to pursue the opportunity through an “opportunity pursuit plan” or to abandon the opportunity altogether. The opportunity pursuit plan must be documented, either in the Opportunity Register or in another document which must be referenced on the form.
    2. Opportunities with a factor less than the opportunity target rating may be abandoned outright, unless otherwise directed by management.
    3. The final column allows for entry of success result, once the opportunity has been closed; this includes entries for abandoning the opportunity, failing to win the opportunity, and three grades of success.
  1. Analysis of any opportunity will generally result in one of the following possible determinations:
     1. Pursue the opportunity
     2. Explore the opportunity in greater detail before proceeding
     3. Accept the opportunity, but under limited and controlled conditions
     4. Decline the opportunity, typically based on a high expected cost or low anticipated benefit
  2. If an opportunity includes a negative aspect, management may elect to conduct a risk assessment on the negative aspect, as defined above.