Procedure: [Context of the Org Proc. Title]

1. SUMMARY
   1. The purpose of this procedure is to define how the company’s Strategic Direction is developed by senior management through the identification of interested parties, issues of concerns, risks and opportunities.
   2. 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. OVERVIEW OF THE COTO EXERCISE
   1. It is important for [Short Client Name] to fully understand the needs of internal and external stakeholders in order to ensure its Quality Management System (QMS) is fully effective.
   2. To this end, the [Senior Management Team Name] conducts the following “Context of the Organization Exercise,” or “COTO Exercise,” to identify the appropriate stakeholders, their issues of concern, and then the associated risks and opportunities derived from those issues.
   3. Finally, the outputs of this exercise inform the [Senior Management Team Name] and [Senior Most Manager Title] so that the company’s Strategic Direction may be updated as necessary.
   4. The ***COTO Log*** is the primary record for this exercise.
2. INTERESTED PARTIES (STAKEHOLDERS)
   1. “Interested parties” are those stakeholders who receive our [Products or Services Plur.], who may be impacted by them, or those parties who may otherwise have a significant interest in our company. The interested parties applicable to [Short Client Name] are listed in the COTO Log, along with the reason for their inclusion. This includes both internal and external parties.
   2. The identification of an interested party does not necessarily bring that party into the scope of the QMS; for example, labor union leadership may be identified as an interested party, but that does not mean QMS documents and policies must be developed related to them.
3. ISSUES OF CONCERN
   1. For each interest party, the related issues of concern shall be identified in the COTO Log. These issues may reflect direct concerns of the party (for example, customers are concerned about quality of products or services they purchase) or they may be indirect concerns. Such concerns may impact on the interested party, or may be concerns derived from the party that impact on the company.
   2. Issues may be either internal or external, depending on whether the interested party is internal or external. In addition, a certain type of party may have both internal and external concerns.
   3. When attempting to identify internal concerns, it may be useful to consider technological concerns, employee concerns, etc.
   4. When attempting to identify external concerns, it may be useful to consider concerns arising from competition, society and culture, labor relations, statutory and regulatory issues, supply chain, economic issues, etc.
   5. Each identified issue is assigned a “bias” (risk, opportunity, or mixed) which will help in determining how to manage the issues, per the next section.
4. RISKS AND OPPORTUNITIES
   1. Each issue is assigned a bias as indicated above. The “bias” identifies if the issue is a risk, an opportunity, or a mix of the two.
   2. Management will then determine a “treatment method” for each risk or opportunity. Risks are managed to reduce their likelihood and consequence, while opportunities are managed to increase their likelihood and consequence. “Mixed” issues may require both – mitigation of their negative aspects (risks) and pursuit of their positive aspects (opportunities).
   3. Each issue may have any manner of treatment indicated; it may be a complex plan defined in a separate document, or may be a simple statement. The field for treatment method must indicate the plan, or reference a separate document if appropriate. The drop-down menu offers suggestions for treatment methods, but this is not comprehensive.
   4. Where a risk is determined to be treated via a Failure Mode Effects Analysis (FMEA) style treatment, these must then be entered into the Risk Register tag within the COTO Log. There may not be a one-for-one alignment of each issue with a risk register entry; a single issue may result in multiple risks entered, for example.
   5. Opportunities are managed via the Opportunity Register tab within the COTO Log.
   6. For more on the management of risks and opportunities, see [Risk Management Proc. Title].
5. STRATEGIC DIRECTION
   1. From the information above, the [Senior Management Team Name] devises a “strategic direction” which is documented in the records of management review. See the procedure ***[Management Review Proc. Title].***