

Procedure: Context of the Organization

1. SUMMARY

- 1.1. 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.
- 1.2. The Director is responsible for implementation and management of this procedure.

2. REVISION AND APPROVAL

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3. SCOPE OF PRODUCTS AND SERVICES

- 3.1. ICAH provides the following service:
 - Intensive Care At Home Nursing Services

4. INTERESTED PARTIES

- 4.1. "Interested parties" are those stakeholders who receive our service, who may be impacted by them, or those parties who may otherwise have a significant interest in our company. The interested parties applicable to ICAH are listed in the COTO Log, along with the reason for their inclusion. This includes both internal and external parties.
- 4.2. 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.

5. ISSUES OF CONCERN

- 5.1. 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.
- 5.2. 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.
- 5.3. When attempting to identify internal concerns, it may be useful to consider technological concerns, employee concerns, etc.
- 5.4. 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.

6. RISKS AND OPPORTUNITIES

- 6.1. Management will then identify risks and opportunities related to the issues of concern within the COTO Log.
- 6.2. Within the COTO Log, each risk and opportunity will be noted, along with the primary process involved, priority, and a bias. The “bias” identifies if the issue is a risk, an opportunity, or some blending of the two.
- 6.3. 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. Blended issues may require more complex treatment.
- 6.4. 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.
- 6.5. Opportunities are managed via the Opportunity Register tab within the COTO Log.
- 6.6. For more on the management of risks and opportunities, see Risk and Opportunity Management.

7. STRATEGIC DIRECTION

- 7.1. From the information above, the Senior Management Team devises a “strategic direction” which is documented in the records of management review. See the procedure ***Management Review***.