6.1 ACTIONS TO ADDRESS RISKS AND OPPORTUNITIES

6.1.1 Risks

6.1.1.1 Risks are determined to prevent or reduce undesired effects, and to give assurance that quality management system can achieve its intended results.

6.1.1.2 Following types and categories of risks are determined and addressed:

In ISO 9001 does not define specific types of risks that need to be determined and addressed. In determining the scope of risk management, remember that risk related requirements replace the requirements for preventive actions that were required in the previous editions of the standard. The list below is probably the most minimalist scope acceptable:

- **Processes:** risks of nonconforming output, process breakdown, process inefficiency, excessive variability, etc.
- **Quality:** risk of defects and non attainment of specified requirements
- **Suppliers:** risk of defects and non attainment of specified requirements
- **Business:** risks to business continuity, data loss, public relations, etc.;

6.1.1.3 Risk levels are evaluated using appropriate risk evaluation and analysis methods. When risk levels are high, appropriate risks reduction actions are implemented and integrated into quality system processes. Risk reduction actions are proportionate to the potential impact on the conformity of products and services.

6.1.1.4 Processes related to determination and evaluation of risks, and to the implementation of risk reduction actions are defined in process procedures ***QPP-061-1 Risks and Opportunities*** and ***QPP-061-2 Risk Reduction Actions and Controls***.

6.1.2 Opportunities

The concept of an 'Opportunity' is tied in ISO 9001:2015 to Risk, but the standard fails to adequately explain the relationship between the two. The only 'official' explanation is given in a paper published by ISO titled 'Risk-based thinking in ISO 9001:2015'. In this paper, the opportunity is defined mostly as a 'positive effect of risk' -- a silver lining of having to mitigate or counteract risks. It makes a good sense philosophically, but doesn't offer a clue how to actually comply with the 'Opportunities' requirements in ISO 9001:2015. Should opportunities be identified independently and then analyzed for their own risks? Or, should risk reduction measures be identified as opportunities? Or both?

6.1.2.1 An opportunity is a set of circumstances which makes it possible to do positive things, for example:

- Develop new products and services
- Develop new markets and/or increase market share
- Improve work environment
- Improve productivity

- Improve operational efficiency (reduction of resource use, reduction of waste, etc.)

6.1.2.2 Opportunities may be identified as positive effects of risks; as in a risk forcing implementation of a risk reduction measure that is beneficial in a broader context than just reducing this particular risk. For example, health risks may require measures to improve working environment. However, these measure also create opportunities to attract better qualified employees, improve morale and job satisfaction, and reduce turnover; and so the health risk creates opportunities to improve the overall job satisfaction.

6.1.2.3 Taking or not taking an opportunity presents different levels of risk. To evaluate these risks, taking (or not taking) the opportunity is defined as a risk management project, and the associated risks are evaluated as for any other project, i.e., following process procedure ***QPP-061-1 Risks and Opportunities***.

6.2 QUALITY OBJECTIVES AND PLANNING TO ACHIEVE THEM

In ISO 9001 quality planning is addressed in several clauses. This section responds to Clauses 6.2.1 and 6.2.2, and thus addresses only planning of the overall quality system and for achieving quality objectives. Requirements for planning of processes for provision of products and services (manufacturing) are included in Clause 8.1.

6.2.1 Quality objectives

6.2.1.1 Quality objectives are established throughout the organization to implement the quality policy, to meet requirements for products and processes, and to improve quality system and quality performance.

6.2.1.2 Quality objectives are established at the management reviews of the quality system. Processes for establishing, implementing and monitoring quality objectives are defined in process procedures ***QPP-062-1 Quality Objectives*** and ***QPP-093-1 Management Review***.

6.2.1.3 Quality objectives define the direction and priorities for continual improvement.

6.2.2 Planning for achieving quality objectives

6.2.2.1 Plans for achieving quality objectives include determination of methods, resources, responsibilities, completion due dates, and evaluation criteria. The process for planning and implementing quality objectives is defined in process procedures ***QPP-062-1 Quality Objectives***.

6.3 PLANNING OF CHANGES

Planning of quality management system changes is implemented through management reviews,

6.3.1 Changes to the quality management system are determined and planned within the framework of management reviews, as defined in process procedure ***QPP-093-1 Management Review***. Planning of changes may be in response to changing circumstances, such as product, process, capacity, or other operational or organizational changes; or to improve the effectiveness and efficiency of the quality management system.

6.3.2 When planning for changes, the management review considers the purpose and

consequences of the change, and its impact on the integrity of the quality management system; as well as availability of resources and allocation responsibilities and authorities.

6.3.3 Actions to implement changes may be defined in Management Review Actions (review output actions), actions to implement Quality Objectives, Corrective Actions (CAPAs), and Risk Reduction Actions.