

White Paper: Dekra Certification (Pty) Ltd.

Title-Risks and Opportunities. No:1

Reference document-ISO 9001:2015.

Extracts taken from the standard ISO 9001:2015

0.3.3

Risk- based thinking is essential for achieving an effective quality management system.

The concept of risk- based thinking has been implicit in previous editions of this International Standard including, for example, carrying out preventive action to eliminate potential nonconformities, analyzing any nonconformities that do occur and taking action to prevent recurrence that is appropriate for the effects on nonconformity.

To conform to the requirements of this International Standard, an organization needs to plan and implement actions to address risks and opportunities. Addressing both risks and opportunities establishes a basis for increasing the effectiveness of the quality management system, achieving improved results and preventing negative effects.

Opportunities can arise as a result of a situation favourable to achieving an intended result, for example, a set of circumstances that allow the organization to attract customers, develop new products and services, reduce waste or improve

productivity. Risk is the effect of uncertainty and any such uncertainty can have positive or negative effects. A positive deviation arising from a risk can provide an opportunity, but not all positive effects of risks result in opportunities.

6 Planning

6.1 Actions to address risks and opportunities.

6.1.1 When planning for the quality management system, the organization shall consider the issues referred to in 4.1 (Understanding the organization and its context) and the requirements referred to in 4.2 and determine the risks and opportunities that need to be addressed to:

- a) Give assurance that the quality management system can achieve its intended result(s);
- b) Enhance desirable effects
- c) Prevent, or reduce undesirable effects
- d) achieve improvement

6.1.2 The organization shall plan:

- a) actions to address these risks and opportunities;

b) how to:

1) integrate and implement the actions into its quality management system processes (refer to 4.4):

2) evaluate the effectiveness of these actions.

Actions taken to address risks and opportunities shall be proportionate to the potential impact on the conformity of products and services.

Note 1 Options to address risks can include avoiding risk, taking risk in order to pursue an opportunity, eliminating the risk source, changing the likelihood of consequences sharing the risk, or retaining risk by informed decision.

Note 2 Opportunities can lead to the adoption of new practices, launching new products, opening new markets, addressing new customers, building partnerships, using new technology and other desirable and viable possibilities to address the organization's or its customer's needs.

Risk based thinking

Adequate consideration should be given to risk based thinking as not all processes represent the same level of risk in terms of the organizations ability to fulfil its objectives.

The requirements of item number 6.1 point out that the organization is responsible for its application of risk based thinking and actions taken to address the risks, in addition to

deciding whether or not to retain documented information as evidence of derivation of risks.

One of the key purposes of a quality management system is to act as a preventive tool. Consequently, this international standard does not have a separate clause or sub-clause on preventive action. The concept of preventive action is expressed through the use of risk-based thinking in formulating quality management system requirements.

Although 6.1(Actions to address risks and opportunities) specifies that the organization shall plan actions to address risks, there is no requirement for formal methods for risk management or a documented risk management process. Organizations can decide whether or not to develop a more extensive risk management methodology than is required by this International Standard, for example, through consulting other guidance documents.

Not all processes of a quality management system represent the same level of risk in terms of the organizations ability to meet its objectives and the effects of uncertainty are not the same for all organizations. Under the requirements of 6.1(Actions to address risks and opportunities), the organization is responsible for its application of risk- based thinking and the actions it takes to address risk, including whether or not to retain documented information as evidence of its determination of risks.

How is risk based thinking applied to your organization?

As a starting point, review the processes adopted in the organizations quality management system and determine where risk based thinking can be applied effectively. For example;

-determining risks and opportunities associated with the organizations context and objectives.

It is recommended that this activity is not completed in isolation, rather involve all interested parties, especially top management.

The following suggested examples provide clarification ;

1. A company providing financial assistance to small businesses is asked to finance a prospect preparing and selling meals to the public.
Suggested initial risk process,
 - a) Request the prospect to provide copies of their last three bank accounts
 - b) Obtain credit worthiness reports from banks or other institutions who have provided loans in the past.
 - c) Provide the address of the premises where the company will operate from and carry out a due diligence audit on the location and facilities.
 - d) Determine what catering equipment/stores and furniture is available.

- e) Has the company operated previously, carrying out the same service.
- f) Has a certificate of acceptance to operate a food service facility been obtained previously.
- g) Has the company been involved in any litigation.
- h) Obtain an organogram and a curriculum vitae for each member of staff.
- i) Request a business plan
- j) Has the prospect ever held any certification, for example, HACCP or ISO 22000.

Are there any opportunities for the organization if a decision is given to provide financial assistance?

One opportunity could be to gain a good reputation in the market which would allow future business to be generated, based on positive customer feedback.

What evidence would the auditor be looking for?

Typically, referring to the example above;

Items A through to J. Apply a scoring mechanism to determine the risk classification, any mechanism can be used, however, in this example we are using 1-5.

1 is totally unacceptable (Do not pursue) unless timeous mitigation measures are put in place.

2 is poor (Do not pursue) unless timeous mitigation measures

are put in place,

3 Possible (with the proviso that extra information required is provided without delay)

4 Can pursue (with the proviso that the prospect seeks additional professional help to establish the operational controls required).

5 The loan can be granted.

Item	Evidence	Risk rating	Remarks
Are three bank statements (for the past three months available).	Three bank statements provided for the last three months, January-March 2017	5	The bank statements provided show the prospect is solvent.
Obtain credit worthiness reports from banks or other institutions who have provided loans in the past.	Two credit worthiness reports have been provided, however, one is still awaited	3	The two statements provided show the company has a good credit rating. However, one additional credit worthiness report is still outstanding.
Provide the address of the premises where the company will operate from and carry out a due diligence audit on the location and facilities.	The address for the premises has been provided, however, the area is considered to be a very high risk as numerous robberies have occurred in the vicinity.	3	Due diligence audit has been completed. The prospect is required to contract a security firm and fit cameras and alarms at the premises.
Determine what catering equipment/stores and furniture is available.	The catering equipment available is not fit for further use.	3	Provide a costing for new equipment and include as part of the loan required.

Has the company operated previously, carrying out the same service.	The prospect has operated previously from a mobile kitchen carrying out the same service.	4	Provide details of a consultant who can assist with respect to planning items such as menus, kitchen layout, food storage and fire equipment required.
Has a certificate of acceptance to operate a food service facility been obtained previously.	The prospect has never sought a certificate of acceptance to operate previously.	1	This is a legal requirement and must be sought and put in place before the business can operate.
Has the prospect been involved in any litigation.	The prospect has not been involved with litigation to date.	4	Contact an attorney to ensure all legal criteria can be established.
Obtain an organogram and a curriculum vitae for each member of staff.	Organogram available showing the owner/Chef, front of house manager, kitchen hand, one waiter, one waitress and cleaner. Curriculum vitae available for all staff,	5	Acceptable.
Request a business plan	The business plan is 90% complete.	4	Seek assistance from a consultant.
Has the prospect ever held any certification, for example, HACCP or ISO 22000.	No certification has been provided in the past.	4	The prospect is in consultation with Messrs Dekra to provide ISO 22000 certification.

2. Example;

A company providing security services comprising:

- Rapid response
- Security complex guarding and monitoring
- Construction site access control and guarding

- Security system(s) installation.

The company decided to utilize SWOT analysis methodology as a basis for identifying;

- Strengths
- Weakness
- Opportunities
- Threats

STRENGTHS	WEAKNESSES	OPPORTUNITIES	THREATS
The company is well established and has received numerous compliments for good service.	Shortage of suitably qualified guards with good character references	An active drive is in place to recruit interested persons with a military background.	Our staff are poached from competitor offering higher wages.
Security system installation has increased significantly due to the ability to utilize real time data used with security cameras.	Installation crews are in very short supply.	The installation crews are provided by outsourced organizations and our own training facility can provide the necessary training.	Biometric installation has a significant problem in some areas as individual(s) finger prints cannot always be provided.
	Our surveillance equipment is procured from overseas suppliers and the lead time for spares is very unpredictable and installation manuals are not readily available.	Develop a relationship with suppliers to provide a more structured spares availability	Loss of business due to un-availability of equipment.

The example shown above is not exhaustive, however, it can be clearly seen that weaknesses and threats pose a

risk and require addressing. The opportunities mentioned can be used as mitigation measures to address the risks

What evidence can an auditor request;

- The SWAT analysis

- Information used as inputs and outputs associated with the SWAT analysis.

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