

Actions to Address Risk and Opportunities

A look at Section 8.5 of ISO/IEC 17025:2017



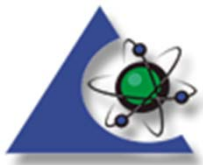
Presented by:

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Perry Johnson Laboratory Accreditation, Inc.

12-May-2020



Perry Johnson Laboratory Accreditation, Inc.

Actions to Address Risk and Opportunities

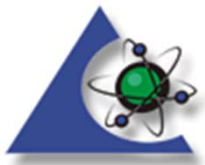
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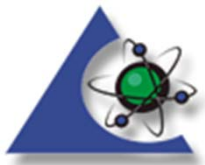


Actions to Address Risk and Opportunities

ISO/IEC 17025:2017 strongly emphasizes “risk based” thinking: ‘The word “risk appears over thirty times in the document compared to only four appearances in the 2005 Standard



As a result of this shift to risk-based thinking, there is no longer any reference to “preventive actions”; this is essentially replaced by the new clause on addressing risks and opportunities”

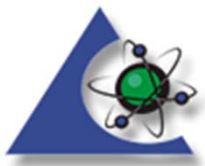


Actions to Address Risk and Opportunities

Even though a note within the 2017 Standard states that there is no requirement for formal risk assessment methodologies the fact that the new emphasis on the consideration of risk is in place, laboratories will need to produce evidence of compliance with the new clause.



Those laboratories who already undertake regular management reviews or staff meeting which stresses improvement opportunities may likely find that they already meet most of the requirements in the 2017 Standard in regards to Section 8.5.



Actions to Address Risk and Opportunities

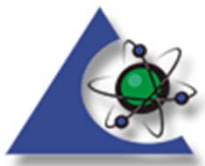
According to the Standard's Foreword Section, risk based thinking does enable reduction in prescriptive requirements and their replacement by performance requirements. Hopefully laboratories will be able to use this extra flexibility in practice

From ISO/IEC 17025:2005

Lab shall have policies and procedures to ensure protection of confidential information including :including electronic storage and transmission of results;

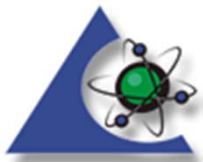
From ISO/IEC 17025:2017

Lab shall ensure the protection and confidential information including electronic storage and transmission of results.



Actions to Address Risk and Opportunities

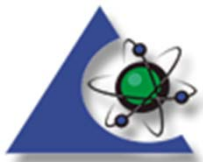
Addressing both risks and opportunities establishes a basis for increasing the effectiveness of the management system, achieving improved results and preventing negative effects. The laboratory is responsible for deciding which risks and opportunities need to be addressed.



Actions to Address Risk and Opportunities

We address risk everyday however probably never think about how we go about doing these:

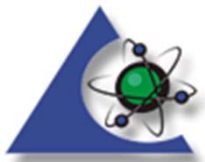
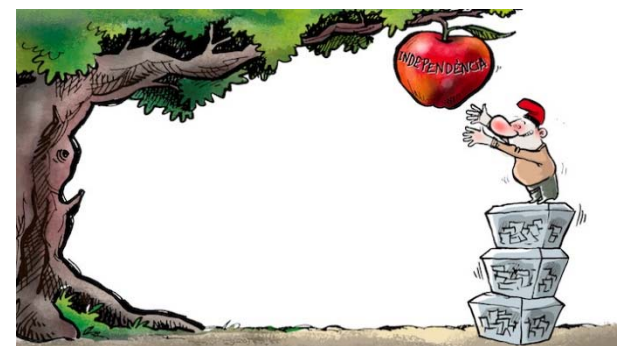
- Driving. Most of the time, we take this for granted. But staying off the cell phone, keeping basic systems in good order – and even replacing your wipers once in a while – can make a big difference and reduce the risk of having an accident.
- Food preparation. Keep surfaces clean, avoid transfer of bacteria from uncooked food to your hands, countertops, and utensils can greatly reduce the risk of getting ill from eating the prepared foods;



Actions to Address Risk and Opportunities

- Stairways. Simple, I know, but using the handrail can significantly reduce the likelihood of a fall.
- Non-routine tasks. Changing a light bulb in a ceiling fan? Get a good ladder or stepstool, not a chair. Using harsh chemicals to clean? Protect your hands.
- Yardwork. Substantial shoes are important in operating any power equipment. Good leather gloves for handling brush are a big plus.

Subconsciously we are aware of risk and take actions to reduce the adverse impact of a negative outcome.



Actions to Address Risk and Opportunities (Definitions)

Risk: what makes achieving an objective uncertain.

Level of Risk: an expression of the importance of the risk taking into account the consequences and the likelihood of situations.

Risk evaluation: comparison of the level of risk with an acceptance criterion

Risk treatment: Many options are possible and can be combined: avoiding the risk, taking the risk to seize an opportunity, eliminating the source of risk, changing the likelihood of occurrence or consequences, sharing risk or accept risk as it is and inform on it.

Residual risk: Risk remaining after risk treatment

Opportunity: an event with potential positive outcome for the organization



Actions to Address Risk and Opportunities (Definitions)

Risk management - appropriately optimizes success with minimal threat and maximal opportunity.

Risk mitigation - to reduce the extent of risk exposure, and the adverse effects of risk.

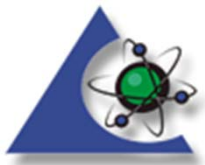
Risk mitigation plan

Step one, risk identification The risk needs to be identified.

Analysis and deliberation are needed to uncover, recognize and describe the risks that might affect your project or its outcomes;

Step two, risk evaluation - probability and impact;

Step three, risk treatment – Each risk treatment strategy can be described in terms of likelihood and impact;



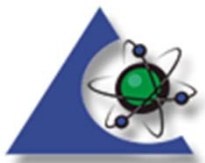
Risk mitigation plan

Risk acceptance: low likelihood, low impact

Risk avoidance: high likelihood, high impact

Risk transfer: medium likelihood, high impact

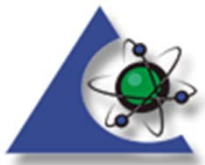
Risk mitigation: medium likelihood, high impact



Actions to Address Risk and Opportunities

8.5.1 The laboratory shall consider the risks and opportunities associated with the laboratory activities in order to:

- a) give assurance that the management system achieves its intended results;
- b) enhance opportunities to achieve the purpose and objectives of the laboratory;
- c) prevent, or reduce, undesired impacts and potential failures in the laboratory activities;
- d) achieve improvement



Actions to Address Risk and Opportunities

8.5.2 The laboratory shall plan:

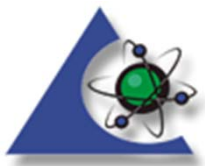
a) actions to address these risks and opportunities;

b) how to:

— integrate and implement these actions into its management system;

— evaluate the effectiveness of these actions.

NOTE Although this document specifies that the laboratory plans actions to address risks, there is no requirement for formal methods for risk management or a documented risk management process. Laboratories can decide whether or not to develop a more extensive risk management methodology than is required by this document, e.g. through the application of other guidance or standards.

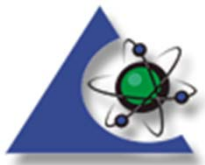


Actions to Address Risk and Opportunities

How to assess risks in a laboratory?

To identify risks, it is useful to consider both the internal context of the organization and its external context (risks related to the customer, the supplier, but also to the customer of the client and other stakeholders).

Risk identification methods range from common sense and brainstorming, the use of pre-established lists for a professional sector, to the use of standards setting good practices



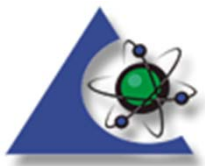
Actions to Address Risk and Opportunities

The assessment of risks can be addressed answering the following questions:

- What can happen and why (by risk identification)?
- What are the consequences?
- What is the probability of their future occurrence?
- Are there any factors that mitigate the consequence of the risk or that reduce the probability of the risk?

Shared Risk??

Create a record that this is taking place



Actions to Address Risk and Opportunities

Example - Impartiality Risk Management Matrix - Excel

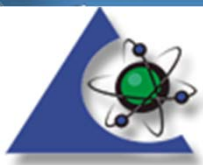
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RISK RATING KEY		LOW	MEDIUM	HIGH	EXTREME
		0 - ACCEPTABLE OK TO PROCEED	1 - ALARP (as low as reasonably) TAKE MITIGATION EFFORTS	2 - GENERALLY UNACCEPTABLE SEEK SUPPORT	3 - INTOLERABLE PLACE EVENT ON HOLD
		SEVERITY			
		ACCEPTABLE	TOLERABLE	UNDESIRABLE	INTOLERABLE
		LITTLE TO NO EFFECT ON EVENT	EFFECTS ARE FELT, BUT NOT CRITICAL TO OUTCOME	SERIOUS IMPACT TO THE COURSE OF ACTION AND OUTCOME	COULD RESULT IN DISASTER
LIKELIHOOD	IMPROBABLE	LOW	MEDIUM	MEDIUM	HIGH
	RISK IS UNLIKELY TO OCCUR	- 1 -	- 4 -	- 6 -	- 10 -
	POSSIBLE	LOW	MEDIUM	HIGH	EXTREME
	RISK WILL LIKELY OCCUR	- 2 -	- 5 -	- 8 -	- 11 -
PROBABLE	MEDIUM	HIGH	HIGH	EXTREME	
RISK WILL OCCUR	- 3 -	- 7 -	- 9 -	- 12 -	

Risk Management Matrix KEY - Risk Assessment Matrix

READY 60%

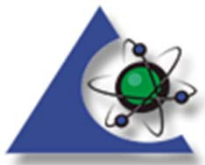


Actions to Address Risk and Opportunities

8.5.3 Actions taken to address risks and opportunities shall be proportional to the potential impact on the validity of laboratory results.

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

NOTE 2 Opportunities can lead to expanding the scope of the laboratory activities, addressing new customers, using new technology and other possibilities to address customer needs.



Examples of Risk Management Tools

FMEA – Failure Mode and Effects Analysis

HAZOP - Hazard and Operability Study

Risk Management Checklist

Pareto Chart

Fishbone

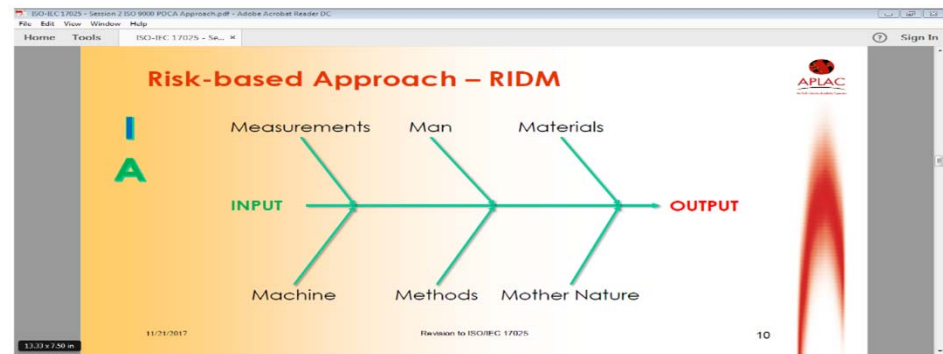
Fault Tree

SWOT Analysis

RIDM –Risk Informed Decision Making

Brain Storming

For further information: ISO 31000:2009 Risk management — Principles and guidelines ; IEC/ISO 31010:2009 Risk management – Risk assessment techniques



Risk Analysis Tools (SWOT)

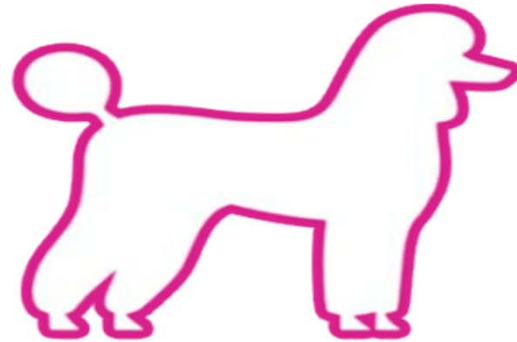
.S.W.O.T. is an acronym that stands for Strengths, Weaknesses, Opportunities, and Threats. A SWOT analysis is an organized list of your business's greatest strengths, weaknesses, opportunities, and threats

Strengths What do you do well? What unique resources can you draw on? What do others see as your strengths?	Weaknesses What could you improve? Where do you have fewer resources than others? What are others likely to see as weaknesses?
Opportunities What opportunities are open to you? What trends could you take advantage of? How can you turn your strengths into opportunities?	Threats What threats could harm you? What is your competition doing? What threats do your weaknesses expose to you?

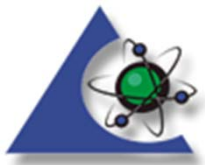
Risk Analysis Tools (SWOT)

SWOT Analysis Example for Delightful Dog Grooming

Purpose: To create a marketing action plan



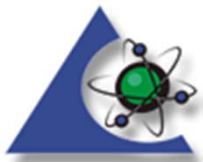
Delightful Dog Grooming



Risk Analysis Tools (SWOT)

Strengths

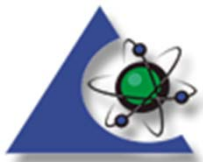
- Have many return customers
- Customer satisfaction - customers do say they like the service and give positive word of mouth by recommending grooming services to others
- Do get some walk-in business
- Mobile grooming van has eye-catching logo and gives some exposure when performing on-site services



Risk Analysis Tools (SWOT)

Weaknesses

- Don't pay much attention to marketing – dependent on word-of-mouth and website
- Website purely informational and static
- Don't have a marketing plan
- Don't have much of a marketing budget



Risk Analysis Tools (SWOT)

Opportunities

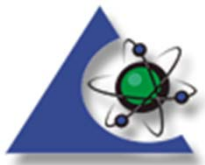
Take advantage of the increasing popularity of dogs

Increasing use of social media

Increase the amount of walk-in traffic

Local annual Pet Fair

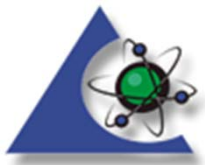
Kennel clubs, rescue societies, local SPCA



Risk Analysis Tools (SWOT)

Threats

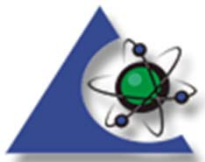
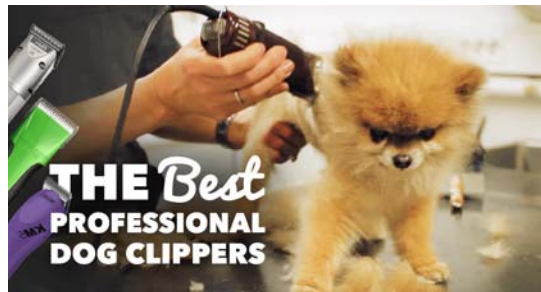
- Other dog grooming businesses in town, competition is increasing
- One dog grooming business has a series of radio ads running and is also running newspaper ads once a week
- Another competitor has partnered with the local SPCA to host a dog washing and grooming day every few months (by donation to the SPCA)
- Expense of running media ads



Risk Analysis Tools (SWOT)

Do Strengths Open Any Opportunities?

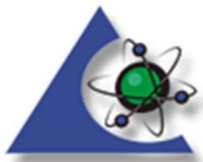
- As customers say they like services and are willing to recommend them, could create some type of referral reward program to actively encourage referrals.
- A loyalty program for repeat customers could be developed.
- Could try to increase walk-ins by having an eye-catching window display.
- Consider relocating business to a location that would get more walk-in traffic.
- Look into setting up a booth at the local annual Pet Fair.
- See if kennel clubs, rescue societies, etc. are interested in partnerships.
- Increase the use of social media and investigate other low-cost ways of promoting the business



Risk Analysis Tools (SWOT)

How Can We Convert Weaknesses to Strengths?

Looking at opportunities and listed weaknesses, looks like social media could be a real marketing opportunity. Instead of just having an informational website, our business could put up a Facebook page and open a Twitter account to try and reach out to old (and new) customers. (Because dogs are so popular, might be helpful to tweet as a dog, e.g. "Rover says regular grooming makes him happy and healthy"). Pinterest or Instagram might also be good options - pictures of cute pets are very popular.

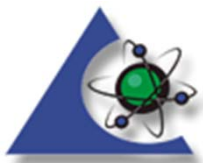


Risk Analysis Tools (SWOT)

What Do We Have to Do to Use Opportunities?

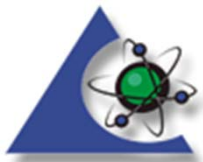
- Set up social media business accounts/pages. (Am already familiar with Facebook and Twitter through personal accounts.) Set aside time or assign staff person to update [Facebook](#)/Twitter accounts. Set up a Pinterest and/or Instagram account, purchase a camera, and train a staff person to take photos of animals and post images.
- Canvas staff for Facebook contest ideas.
- Find out details of annual Pet Fair, such as when it runs and how much a booth/table would cost there. (Remember will also have cost/logistics of manning the booth or table, too

Continue next slide



Risk Analysis Tools (SWOT)

- Scout out some possible new business locations. Contact a realtor and ask about a more centralized business location where many people walk their pets.
- Canvas kennel clubs and dog rescue groups for possible partnership opportunities.
- Contact window artists for quotes on a window display.
- Decide on referral discount and customer loyalty schemes and notify existing customers

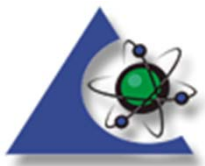


Risk Analysis Tools (SWOT)

How Do We Best Neutralize Threats?

Without a bigger marketing budget, we can't run competing radio and newspaper ad campaigns (although would be a good idea to run occasional newspaper ad). Might be able to off-set the competition's newspaper and radio campaigns through developing our online presence as above and running marketing campaigns on social media.

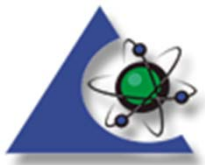
Results: As you see above, this SWOT analysis has created the seeds of an action marketing plan, providing clear direction for how this small business can counter their competitions' marketing efforts and increase their own customer base.



Risk Management Checklist

Creating a Risk Management Checklist

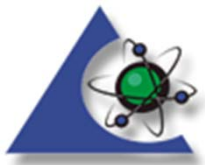
In any type of project planning, risk management is a necessary tool. Risk management identifies and prioritizes risks, measures how harmful they can be, and develops a plan to deal with risks that are a threat to the project. Beyond creating a risk management plan, you should also create a risk management checklist. As you develop your risk management plan, including the risks and how they will be dealt with, a risk checklist should quickly tell you from past experience and forecasting if a risk area will evolve.



Risk Management Checklist

Scope of Work - The first part of your risk checklist should include questions and answers such as: Has the work been done before or is it something new? In essence, has an area in the work been identified in prior projects as a risk? If a task is a new task within the project, what risks may occur?

Project Resources - The second part of the checklist should deal with your resources. Do you have the right number of resources? Do your resources have the experience they need or do they have to be trained? How experienced are they and do they work well together? Again, if a resource risk is a potential problem, it should be identified on your checklist.



Risk Management Checklist

Project Timeline - The third part of your risk management checklist should identify items like scheduling conflicts and if they are flexible. Will you and your team have enough time to complete all the tasks within the project? If any items are identified as a risk, list them here.

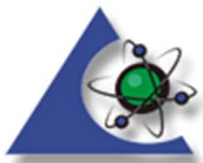
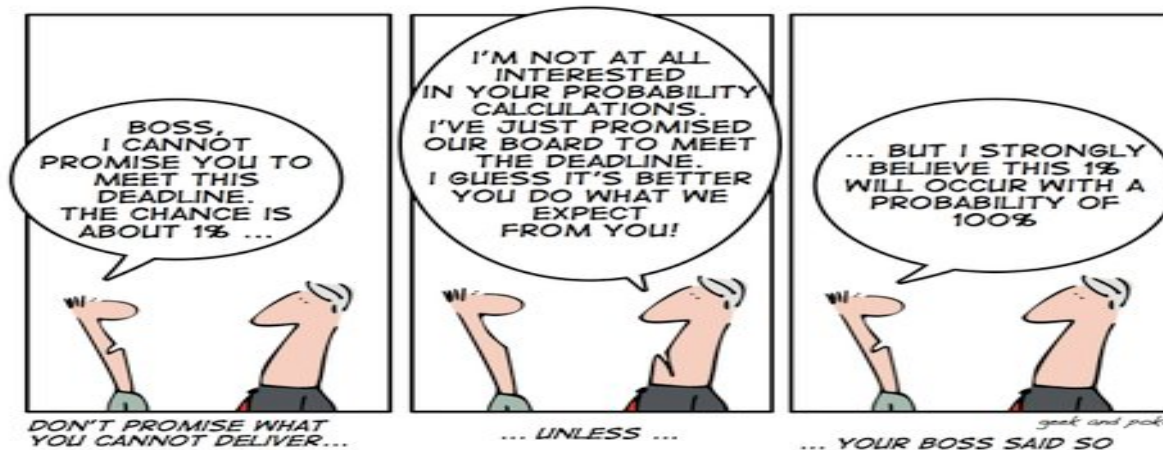
Project Cost - This fourth part should identify risks that have to do with project costs and project overrun costs. If you feel a project may overrun its budget, list this as a risk on your checklist.

Outside Sources - What outside sources are involved in the project that may cause a risk? They are the fifth part of your checklist. If you feel an outside source can't deliver on time or has other issues that are considered to be a risk, put them on your checklist.



Risk Management Checklist

Deliverables - Can you deliver the project? That means not just the goals of the project, but the project itself. A goal may be to analyze tools to change a process and the project may be to change a certain process. If you feel the project has risk in its deliverables, identify this as a risk

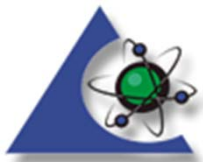


Actions to Address Risk and Opportunities

The requirements of ISO/IEC 17025:2017

The international standard ISO/IEC 17025:2017 states in its introduction:

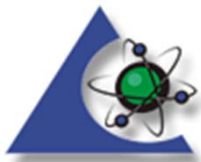
This document requires the laboratory to plan and implement actions to address risks and opportunities. Addressing both risks and opportunities establishes a basis for increasing the effectiveness of the management system, achieving improved results and preventing negative effects. The laboratory is responsible for deciding which risks and opportunities need to be addressed



Actions to Address Risk and Opportunities

The laboratory is responsible for deciding which risks and opportunities need to be addressed. The accreditation body, however, assesses whether the laboratory has established appropriate actions for dealing with risks and opportunities in accredited laboratories.

This may vary among laboratories in certain instances.



Actions to Address Risk and Opportunities

The requirement for impartiality is a good example of where the risk and measures necessary may vary among laboratories

A privately owned independent lab with many customers where the owner or lab personnel has no other activities or ownership is unlikely to need extensive measures to protect impartiality

Other situations may require alternate considerations

- A lab with only one customer
- A lab where the owner owns some of the customers
- A lab within a manufacturer also taking on third party work
- A lab with minimum wage staff in a culture known for corruption
- A lab where its ownership is complex and keeps changing as does that of related bodies within the structure

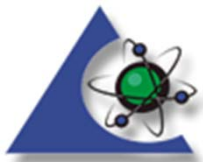
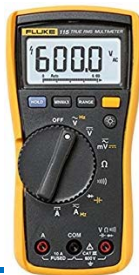


Actions to Address Risk and Opportunities

A Technical Example

6.4.10 When intermediate checks are necessary to maintain confidence in the performance of the equipment, these checks shall be carried out according to a procedure

The complexity of this will vary according to risk.. A gauge block or mass standard used as a reference may need little by way of intermediate checks. On the other hand sensitive electronic items exhibiting drift may need frequent checks, plotting and calculations from comparisons resulting in a drifting reference value being identified;



Actions to Address Risk and Opportunities

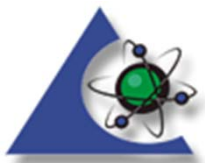
Other Area's of ISO/IEC 17025:2017 Were Risk Shall be Addressed

4.1.4 The laboratory shall identify **risks** to its impartiality on an on-going basis;

8.9.2 The inputs to management review shall be recorded and shall include information related to the following;

m) results of **risk** identification;

7.8.6.1 When a statement of conformity to a specification or standard is provided, the laboratory shall document the decision rule employed, taking into account the level of **risk** (such as false accept and false reject and statistical assumptions) associated with the decision rule employed, and apply the decision rule;



Actions to Address Risk and Opportunities

Nonconforming work

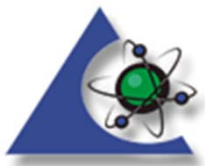
7.10.1 The procedure shall ensure that:

b) actions (including halting or repeating of work and withholding of reports, as necessary) are based upon the **risk** levels established by the laboratory;

Corrective actions

8.7.1 When a nonconformity occurs, the laboratory shall:

e) update **risks** and opportunities determined during planning, if necessary;

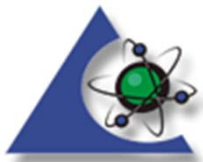


Actions to Address Risk and Opportunities

What will an accreditation body be looking for in regards to compliance with Section 8.5?



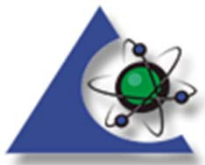
- Objective Evidence which would show that the organization has adopted a risk based approach: This may include a specific document (procedure or any other name) where risks and opportunities are identified, as well as a plan to implement action to minimize risks and maximize opportunities;
- Interview “ What opportunities for improvement have been identified, implemented, or rejected and what risk was identified? (8.6) Improvement;
- Inputs associated with the management review;



Actions to Address Risk and Opportunities

4.1.4 The laboratory **shall identify risks to its impartiality** on an on-going basis. This shall include those risks that arise from its activities, or from its relationships, or from the relationships of its personnel. However, such relationships do not necessarily present a laboratory with a risk to impartiality

NOTE A relationship that threatens the impartiality of the laboratory can be based on ownership, governance, management, personnel, shared resources, finances, contracts, marketing (including branding), and payment of a sales commission or other inducement for the referral of new customers, etc.



Actions to Address Risk and Opportunities

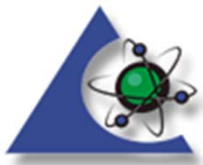


Thank You

Any Questions?

This time is allocated for questions. You should have a space provided for submitting questions.

If a question is unanswered please submit directly to webinar@pjlabs.com



Perry Johnson Laboratory Accreditation, Inc.

Save the Date

Next Scheduled Webinar

Option A and B as presented in ISO/IEC 17025:2017 along with the Management System Documentation (8.2)

June 2020						
S	M	T	W	T	F	S
	1	2	3	4	5	6
7	8	9	10	11	12	13
14	15	16	17	18	19	20
21	22	23	24	25	26	27
28	29	30				

Thursday, Jun 25th 2020

