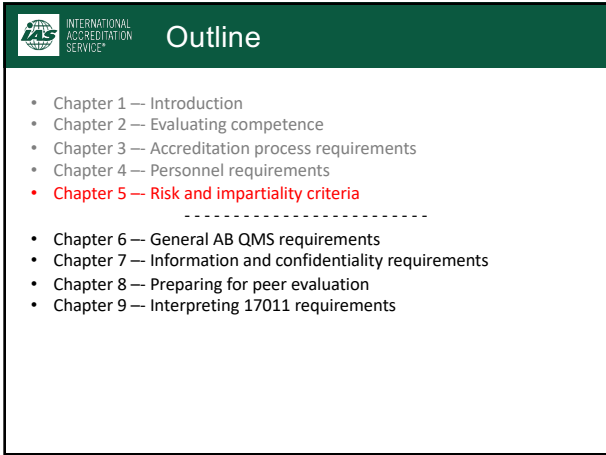
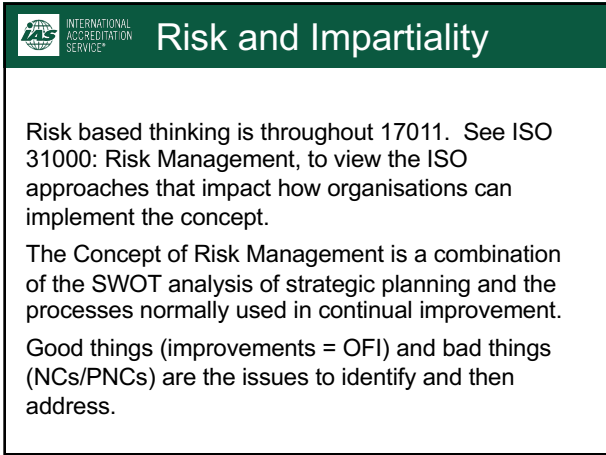


1



2



4



Risk and Impartiality

Risk based thinking involves three considerations and three actions. The considerations are:

- Risk is not only about things going bad (NC/PNC) – but includes doing things better (Opportunity/Benefit).
- We cannot ignore risks that have been identified.
- Risk analysis is not a complex task.

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SIMPLEST DEFINITION OF RISK

RISK/(BENEFIT) =

Probability of an occurrence

(could be a good occurrence or a bad one)

Multiplied by

Consequence/Impact of the occurrence

(Monetary/organisation/personal loss or benefit)

Risk(Benefit) = (σ x impact)

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SIMPLEST DEFINITION OF RISK

Case 1 (Adverse)

If probability = once per year
And consequence = injury of a person
Risk = injury of a person once every year.

Case 2 (Benefit)

If probability = once per day
And consequence = reduction of cost by \$10
Benefit = \$3,650 per year less cost.

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SIMPLEST DEFINITION OF RISK

Case 3 (Adverse)

If probability = every assessment of a lab
And consequence = complaint against assessor
Risk = Permanent loss of confidence in assessor.

Case 4 (Benefit)

If probability = every assessment of a lab
And consequence = satisfaction of lab staff
Benefit = Growth of program satisfaction

8



THREE ACTIONS

The three actions are:

- **Identify conditions** and circumstances from all sources that may impact our operations, our successes, our corporate objectives, and the integrity of our services.
- **Determine the impact** of these conditions and circumstances (risk analysis and evaluation) – the good and the not-so-good.
- **Take action** to address them:
 - Treat them (risk treatment).
 - Reduce (mitigate) adverse affects (and record it).
 - Enhance positive ones (and record it).

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RISK BASED THINKING

Simplest Approach

- Identify the condition
- Take immediate remediation action (where required)
- Determine the risk or benefit presented by the condition
 - Impact on accreditation
 - Impact on risk to business (reputation) or people (safety)
 - Impact of cost, efficiency, effectiveness, or impartiality
 - Amount of effort needed to address or mitigate the risk
- Determine any root cause
- Determine the permanent resolution (including those for any OFI)
- Document the permanent resolution and classify the remaining risk (low, medium, high, none?)

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RELEVANT CLAUSES IN 17011

- 4.4.6 to 4.4.9 – Impartialities risk
- 4.5.2 – Coverage for risk (insurance etc)
- 4.6 – Establishing schemes (but no risk)?*
- 6.1.2.4 – Assessment personnel knowledge of risk
- 6.1.3.4 – Competence of personnel to consider risk
- 7.4.6 – Assessment sampling to consider risk
- 7.9.3 – Assessment program to consider risk
- 9.6 – OFI risk
- 9.8.2i – Status of risk actions addressed in mgt review.

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Risk Management Requirements

“Impartiality requirements” is a significant expansion of the concept. It is now in clause 4.4 and is the result of the mandatory wording transferred to Section 5 of the Common Elements in CASCO standards (QAS/PROC-33) from ISO/PAS 17001 (Impartiality).

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Risk Management Requirements

“Impartiality requirements” in clause 4.4 contains the following considerations:

- (4.4.6) The “Related bodies” examination is now a full fledged risk assessment that includes risks from the relationships of AB personnel.
- (4.4.7) The AB is now required to document and demonstrate how it eliminates or minimizes such risks and document any residual risk. The demonstration shall cover all potential risks that are identified, whether they arise from within the accreditation body or from the activities of other persons, bodies or organizations.

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Risk Management Requirements

“Impartiality requirements” in clause 4.4 contains the following considerations regarding residual risk (following any risk assessment and mitigation):

- (4.4.8) Top management shall review any residual risk to determine if it is within the level of acceptable risk.
- (4.4.9) When an unacceptable risk to impartiality is identified and which cannot be mitigated to an acceptable level, then accreditation shall not be provided.

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Risk Management Requirements

1. There are 15 questions in this Chapter.
2. **What does the standard require?**
3. Participants select their own answers.
4. The whole group is balloted for the most appropriate response.
5. [Clapping indicates a correctly answered question.](#) [Buzzer indicates an incorrectly answered question.](#)
6. The citation from the standard is displayed next to the most correct answer.
7. The quiz then advances to the next question.

Press

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Risk Management Requirements

4.4 Impartiality Requirements

Impartiality requirements are heavily weighted by consideration of risk.

- A. [TRUE](#)
- B. [FALSE](#)
- C. [NOT APPLICABLE](#)

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Risk Management Requirements

4.4 Impartiality Requirements

Government ABs are deemed, by virtue of their governmental status, to deliver their services impartially:

- A. [TRUE](#)
- B. [FALSE](#)
- C. [NOT APPLICABLE](#)

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Risk Management Requirements

4.4 Impartiality Requirements

ABs must ensure that all interested parties contribute to the operation of accreditation programs.

- A. [TRUE](#)
- B. [FALSE](#)
- C. [NOT APPLICABLE](#)

20



Risk Management Requirements

4.4.6 Risks to Impartiality

The accreditation body must consult with appropriate interested parties to advise on matters affecting impartiality including openness and public perception.

- A. [TRUE](#)
- B. [FALSE](#)
- C. [NOT APPLICABLE](#)

22



4.4 Mitigating Risks to Impartiality

ISO/IEC 17011 requires ABs to completely eliminate **ALL** identified risks or cease the activity that causes it:

- A. [TRUE](#)
- B. [FALSE](#)
- C. [NOT APPLICABLE](#)

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4.4.9 Acceptable Risk to Impartiality

Whenever the accreditation determines that the residual risk to impartiality caused by an activity is not mitigated to an acceptable level, the accreditation body shall terminate the activity that provides such risk to impartiality.

- A. [TRUE](#)
- B. [FALSE](#)
- C. [NOT APPLICABLE](#)

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- Impartiality risk (4.4.6 - 4.4.9)
 - analysis of any risks to impartiality from sources such as ownership, governance, management, personnel, shared resources, finances, contracts, outsourcing, training, marketing and payment of a sales commission or other inducement for referral of new clients

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- The CEO of an Accreditation Body also holds a position as a board member for an association of laboratories, many of them accredited by the AB.

- Does this condition present risk?
 - If so, determine the risk level and impacts
- What is the remedial action? Root cause?
- What is the corrective/preventive action to take?
- What is the level of remaining risk?

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4.5.2 Risks arising from Activities

Accreditation bodies shall have insurance to cover all activities that provide risk.

- A. TRUE
- B. FALSE
- C. NOT APPLICABLE

30



Risk arising from AB Activities (4.5.2)

- Personnel used - staff and assessors (6.1.2.4 and 6.1.3.4)
- Content of the assessment program (7.9.3)
- Content of the assessment plan (7.4.6)
- Establishing new accreditation schemes (4.6)

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RISK BASED THINKING - EXERCISE

The Accreditation body has decided on a four year accreditation cycle for its medical testing laboratories with a remote assessment taking place at the end of year one, year two, and year 3 of the accreditation cycle.

- Does this condition present risk?
 - If so, determine the risk impacts
- What is the remedial action? Root cause?
- What is the corrective/preventive action to take?
- What is the level of remaining risk?

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RISK BASED THINKING - EXERCISE

The AB does not have any insurance to cover its liabilities.

- Does this condition present risk?
 - If so, determine the risk impacts
- What is the remedial action? Root cause?
- What is the corrective/preventive action to take?
- What is the level of remaining risk?

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Risk Management Requirements

4.6 Establishing Accreditation Schemes

Accreditation bodies shall determine the risks associated with the development and implementation of new accreditation schemes.

- A. [TRUE](#)
- B. [FALSE](#)
- C. [NOT APPLICABLE](#)

35



RISK BASED THINKING - EXERCISE

An Accreditation body is considering the launching of an inspection body accreditation scheme but the federal authority overseeing all food import inspection bodies requires these inspection bodies to be accredited to a government-developed scheme by a government agency .

- Does this condition present risk?
 - If so, determine the risk impacts
- What is the remedial action? Root cause?
- What is the corrective/preventive action to take?
- What is the level of remaining risk?

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RISK BASED THINKING - EXERCISE

A PTP is contracted by the AB to deliver specific PT under a regulatory accreditation scheme.

- Does this condition present risk?
 - If so, determine the risk impacts
- What is the remedial action? Root cause?
- What is the corrective/preventive action to take?
- What is the level of remaining risk?

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Risk Management Requirements

6.1.2.4 Personnel Competence in Risk

All accreditation body personnel must be certified in Risk Management.

- A. TRUE
- B. FALSE
- C. NOT APPLICABLE

39



Risk Management Requirements

6.1.3.4 Risk associated with Performance of Personnel

The level of risk associated with the competence and performance of personnel shall be based, in part, on the level of risk of the activities they undertake.

- A. [TRUE](#)
- B. [FALSE](#)
- C. [NOT APPLICABLE](#)

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RISK BASED THINKING - EXERCISE

Accreditation certificates are signed by a CEO who is not technically competent in any of the fields listed on the CABs scope of accreditation.

- Does this condition present risk?
 - If so, determine the risk impacts
- What is the remedial action? Root cause?
- What is the corrective/preventive action to take?
- What is the level of remaining risk?

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Risk Management Requirements

7.4.6 Risk associated with Sampling of Witnessed Conformity Assessment Activities

The level of risk associated with the competence and performance of personnel shall be based, in part, on the level of risk of the activities they undertake.

- A. [TRUE](#)
- B. [FALSE](#)
- C. [NOT APPLICABLE](#)

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Risk Management Requirements

7.9.3 Risk associated with Assessment Frequency and Scope of Assessment

The level of risk associated with the competence and performance of personnel shall be based, in part, on the level of risk of the activities they undertake.

- A. [TRUE](#)
- B. [FALSE](#)
- C. [NOT APPLICABLE](#)

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RISK BASED THINKING - EXERCISE

Because of the increasing number of complaints being received by the AB from its CABs, the AB has hired a new manager whose sole job is to handle all complaints.

- Does this condition present risk?
 - If so, determine the risk impacts
- What is the remedial action? Root cause?
- What is the corrective/preventive action to take?
- What is the level of remaining risk?

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Risk Management Requirements

9.6 Risk Tools in Continual Improvement

There is no requirement to consider risk in Continual Improvement.

- A. [TRUE](#)
- B. [FALSE](#)
- C. [NOT APPLICABLE](#)

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Risk Management Requirements

9.8 Risk Tools in Continual Improvement

Top Management must consider risk during its periodic review of its management system .

- A. [TRUE](#)
- B. [FALSE](#)
- C. [NOT APPLICABLE](#)

51



RISK BASED THINKING - EXERCISE

Risk analysis to accompany OFIs (9.6)

- Management review records to show that the status of actions to address risk and opportunities were reviewed

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RISK BASED THINKING – ADDITIONAL EXERCISE

Order the following identified conditions in descending risk (from most risk to least risk)

- Assessing the QC for an H1N1 test in a clinical lab
- Assessing the PT performance of a concrete testing lab
- Assessing traceability of measurement in a RMP
- Conducting document review for a pre-assessment of a CAB
- Reviewing the application for a lab that is part of a nuclear power station
- Assessing document control in a government product safety lab
- Assessing education and experience records for QA staff in an asphalt testing lab
- Assessing method validation for salt-spray testing of steel
- Assessing PCR methods in a forensic lab

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4.4 Impartiality Requirements

ABs must publish their impartiality policy:

- A. TRUE
- B. FALSE
- C. NOT APPLICABLE

55



Sample scenarios are included in Chapter 5 of the Course Handbook. They are to be discussed within the teams. Each team is to take 45 minutes to discuss the three scenarios and come to consensus on the answers to the questions posed at the end of each scenario.

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