EURAMET Webinar on changes to ISO/IEC 17025
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Practical issues in risk assessment & management

Dr. Dionysios Kyriakidis
Hellenic Institute of Metrology (EIM)
Director of Quality & Scientific Support

The aim of this presentation is to see:

- How EIM implemented risk assessment in the context of ISO 17025:2017
- Practical issues of the risk assessment conducted
- The main issues, difficulties & problems encountered
- The solutions found to face difficulties & problems

The practical steps taken in EIM to conduct risk assessment

Step1: Assigning a Risk Management Team (coordinator & risk owners) with responsibilities & tasks described in new procedure GP1-06 (prepared earlier in 2018 and approved in Oct.2018).

- This procedure specifies the methodology to assess risks (Severity – Probability Matrix method combined with a brainstorming method).
- The Coordinator (Quality Manager) has a critical role
- The members should be aware and familiar with operational issues

The practical steps taken in EIM to conduct risk assessment

Step2: The Coordinator did preliminary work for preparation

Before the meetings, a layout was prepared with preliminary risk scenarios as a basis for discussions and brainstorming within the Team.

Preparation of this layout started earlier in 2018 and was completed in Jan.2019.

Remark: Starting an open discussion based on a preliminary layout as a basis for discussion saves a lot of time and energy.

The practical steps taken in EIM to conduct risk assessment

Step3: Conducting 3 meetings of the Risk Management Team.

- 31 Jan., 4 & 7 Febr.2019 (total ~12 hours) with the participation of 8 people (Directors and Laboratory Heads)
- Based on preliminary layout prepared by the Coordinator
- To discuss and analyze the objectives, risk issues, evaluate & assess risks and propose risk treatment.

OUTCOME: Excel file of next slide and List of Actions for risk treatment.

Important Remark: Short presentation with definitions and basic principles for risk assessment before 1st meeting.

The practical steps taken in EIM to conduct risk assessment

Step4: Presenting outcome in Annual Report and to Management

- Overall results of risk assessment on Annual Report for 2018
- Submitted to Management
- Approval of risk treatment plan

Step5: Implementing Risk Treatment actions and monitoring implementation

Step6: To repeat previous steps 2-5 in a new cycle starting in Jan.2020.

Practical details of Risk Assessment

Objectives at risk:

Objective 1: MS effectiveness & consistent operation (i.e. customer satisfaction, meeting requirements & agreements, achieving stable & consistent operation)

Objective 2: Valid results of work (quality of work & services, technical competence, validity of results & work)

Objective 3: Impartiality (objectivity, integrity, independence)

Objective 4: Good image and prestige

Practical details of Risk Assessment

Look at Processes and how the achievement of Objectives is put at risk:

Process 1: Review of requests, contracts and offers

Process 2: Products and services provided by external parties

Process 3: Handling items to be calibrated/tested (in calibration & ILCs)

Process 4: Implementing work (SI realization, calibration, ILCs, services)

Process 5: Processing of Measurement Data and Issue of Results

Process 6: Release of Certificates, Reports (service deliverables)

Process 7: Information Management

Process 8: Promotion of the activities of EIM and support of Stakeholders

Practical details of Risk Assessment

To identify risks with the associated objectives:

a) Go through each process (1-8)
b) Identify risk scenarios and express each as a combination of threat and weaknesses
c) See what would be the probability, P, of the scenario to take place (occurrence probability) in a scale 1-5.
d) See how the scenario affects, severity S, each one of the objectives in a scale 1-5
e) See at the risk level as = PxS
f) Based on risk level (=PxS), consider risks as acceptable or not
g) Depending on risk level determine measures and actions to reduce risks (probability and/or severity)

Practical details of Risk Assessment

Just an example:

Objective 2: Validity of results in Mass calibrations

Risk: Mishandling weight standards leading to changes of mass values

Severity: very high (5 in scale 1-5)

Probability (P):

Case 1: very low (P=1) if experienced staff is involved , Risk Level=5

Case 2: very high (P=5) if inexperienced staff is involved, Risk Level=25

Risk evaluation: case 1: risk acceptable, case 2: risk unacceptable

Risk Treatment: only for case 2 actions such as:

1) Restrictions & authorizations for staff involvement in E2 calibrations

2) Training to raise awareness for handling sensitive standards/items

Practical details of Risk Assessment

Probability		Consequence/Severity				
		1	2	3	4	5
Rare	1	1	2	3	4	5
Unlikely	2	2	4	6	8	10
Possible	3	3	6	9	12	15
Probable	4	4	8	12	16	20
Very likely	5	5	10	15	20	25

Practical details of Risk Assessment

						Objective 1: MS effectiveness and consistent operation		Objective 2: Competence & quality of services		Objective 3: Impartiality (objectivity, integrity, independence)		Objective 4: Prestige and image of EIM				
Ref. Nr.	**Description of risk scenario (RED=unacceptable, GREEN=needs monitoring, BLACK=acceptable, BLUE=opportunity**	**Field (ISO 17025, 17043, 9001, Common)**	**Date of registr.**	**Any actions before?**	**Probability (P)**	**Severity (S)**	**Risk Level (PxS)**	**Severity (S)**	**Risk Level (PxS)**	**Severity (S)**	**Risk Level (PxS)**	**Severity (S)**	**Risk Level (PxS)**	**Total Risk Level**	**ACCEPTABLE (YES/NO)**	**Remarks (justification of actions, interpretations and comments - proposed actions to be included in a Risk Treatment Plan)**
Process 1: Review of requests,m contracts and offers																
1.3	Pressure by customer to accelate the process of offer review and also completing the services in combination with lack of personnel and the high volume of work	Common	7 Feb. 2019	NO	3	5	15	3	9	0	0	1	3	27	NO	Objective 1 (All services): we may have: a) incoplete offers (key terms/conditions and details to be followed by customers), b) not clear and unrealistic timeshedule, Objective 2: It is normally not affected: a) Cal Serviceρεσίες (confirmation for technical & other requirements by the Labs), b) ILCs and training (sililarly), c) Consulting projects (need care regarding deviations in meeting deadlines due to lack of staff) - an individual risk assessment is needed before submitting offers for these projects
1.5	OPPORTUNITY - Pressure by Customers to accelerate work of offer review may work as a motive to improve the planning of the operations of EIM, including the services, making the system faster and more efficient	Common	7 Feb. 2019	NO	3	5	15	1	3	0	0	0	0	18	**ACCEPTABLE Opportunity**	The pressure of the customers may provide a strong motive to improve the efficienty of the operation of services in EIM - EXAMINE possible measures: a) adopting digital calibration certificates for calibrations and tests (with digital signiture), b) deliverables of other services (training certificates, Reports of ILCs, etc.) only in electronic form, c) cancel the use of fax for hard copies (incoming and outgoing documents)

Practical details of Risk Assessment

Actions for Risk Treatment were specified to:

- Reduce risk level of unacceptable risks
- Monitor other risks
- Exploit opportunities

Actions for risk treatment are registered in the **List of Actions** together with actions arising from complaints, NCs, Management Reviews, etc.

Implementation of Risk Treatment Actions are monitored on continuous basis together with all other actions through the **List of Actions.**

Practical details of Risk Assessment

The outcome of the risk assessment conducted in EIM:

48 risk scenarios identified in total (ISO 17025, ISO 9001, ISO 17043)

a) 41 of them related to ISO 17025 (some common to other standards)

b) 11 of them unacceptable

c) 8 of them need monitoring

Risk treatment in progress and monitored through intermediate management reviews, making use of the List of Actions

Risk re-assessment in Jan.2020 unless there are some special cases

Problems and difficulties encountered

1. Volume of work and time (more than one meetings required with strong preparation, needs patience and positive thinking from the participants)

2. Difficulties in adopting common rules and criteria (a clear presentation of key aspects and issues helps to establish common rules, criteria and standards)

3. Get trapped and lost in scores and levels of risks (try to focus on the real problems and avoid too much quantifications)

4. Who should participate? Definitely Laboratory Heads with understanding of the processes and not necessarily top management

Problems and difficulties encountered

5. Handling large volume of information (try to group objectives and scenarios, what counts is the actions taken to reduce risks)

6. Should we see each lab individually? Group scenarios, processes are normally common

7. Approval of outcome risk assessment & risk treatment actions by Top Management (don't provide too much details to get them lost)

8. Don't forget that Risk Management is a dynamic system

Thank you for your Attention

My e-mail: sakis@eim.gr