Risks and opportunities

in ISO/IEC 17025:2017 and ISO 15189:2012

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Some questions to be addressed

- What do we mean with risks?
- What could be considered as opportunity?
- Are relevant requirements in ISO/IEC 17025:2017 quite new?
- How are risks and opportunities addressed in ISO/IEC 17025:2017 and ISO 15189:2012?
- Reference to other standards and documents
- Some examples

Definitions – Risk is...

- the effect of uncertainty on the achievements
  (Guide ISO 73:2010, definition 1.1), **ή**
- the combination of the probability of occurrence of harm and severity of the harm
  (ISO/IEC Guide 51:2014, definition 3.9)

ISO 9000:2015 defines risk as…

the effect of uncertainty (clause 3.7.9)

Further to this...

Note 3 mentions that “risk is often characterized by reference to potential events* and consequences** ”, or a combination of these”

** ISO Guide 73:2009, 3.5.1.3*

*** ISO Guide 73:2009, 3.6.1.1*

Other notes to clause 3.7.9*

Note 4: Risk is often expressed in terms of a combination of the consequences of an event (including changes in circumstances) and the associated likelihood* of occurence

Note 5: “Risk” is sometimes used when there is the possibility of only negative consequences (see also Note 1 referring to “a deviation from the expected –positive or negative”

** ISO Guide 73:2009 , 3.6.1.1*

Standards on risk management

- **ISO 31000:2018** Risk management – Guidelines
- **ISO Guide 73:2009** Risk management – Vocabulary
- **ISO/IEC 31010:2009** Risk management – Risk assessment techniques
- **ISO/TS 22367:2008** Medical laboratories – Reduction of error through risk management and continual improvement

When dealing with risks…

reference is made to

- risk assessment
- risk management
- risk-based thinking – this is what is introduced by ISO/IEC 17025:2017

According to ISO 9000:2015…

opportunities are related to audit findings. According to **Note 2** to clause 3.13.9, these findings can lead to the identification of opportunities for improvement or recording good practices.

Improvement is defined as an activity, either recurring or singular, to enhance performance (clause 3.3.1) .

Performance is defined as a measureable result (clause 3.7.8 - **Note 1**: Performance can relate either to quantitative or qualitative findings

Note 2: It the management of activities, processes, products, services, systems or organizations

Some more definitions*

Level of risk

An expression of the importance of the risk taking into account the consequences and the likelihood of situations

Residual risk

Risk remaining after risk treatment

Opportunity

An event with potential positive consequences for the organization

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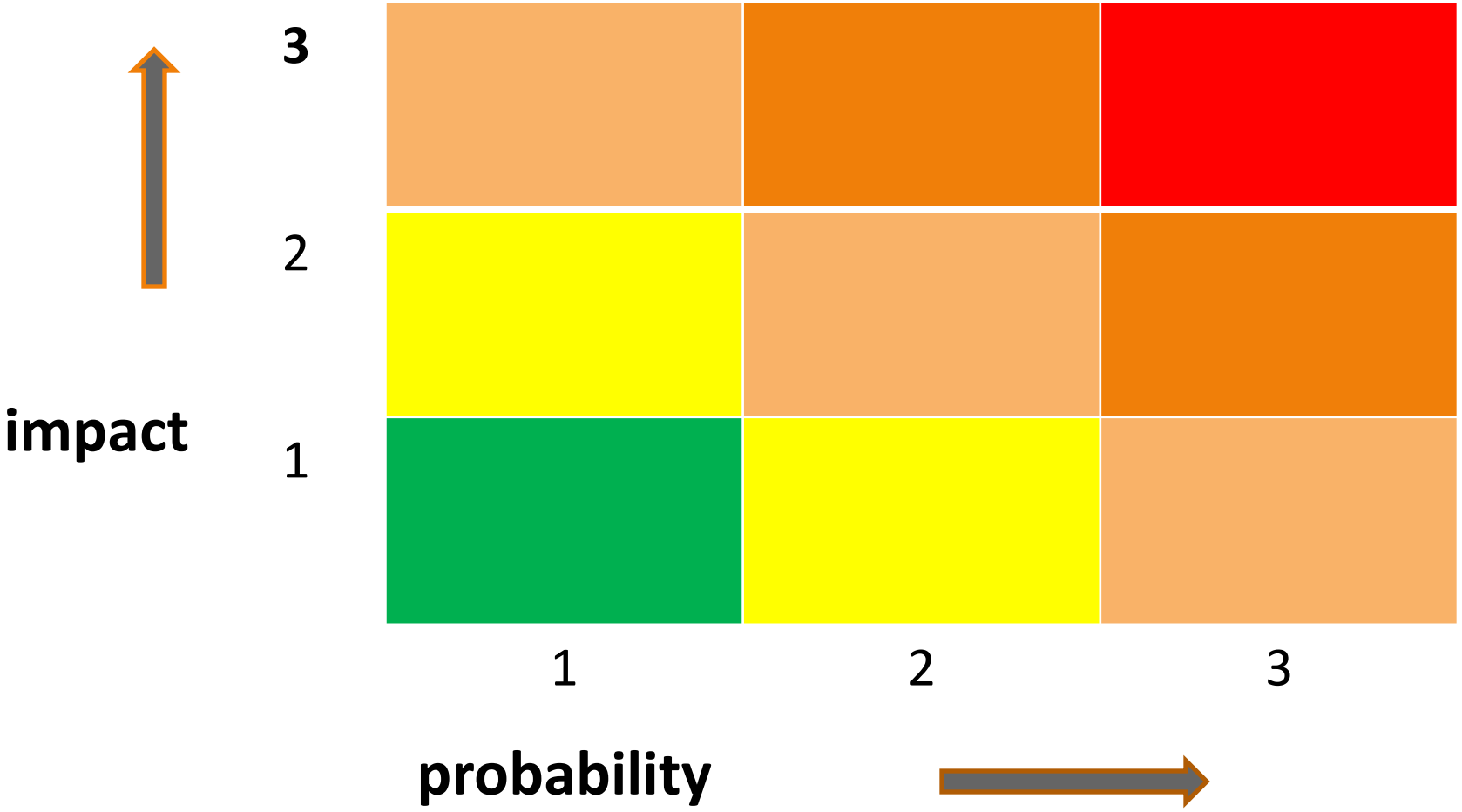
Impact vs probability – a combination



Can the risk be eliminated?

Not always!

Note 1 to clause 8.5.3 (ISO/IEC 17025:2017) refers to more than one options to address risks, namely

- 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

Failure Mode and Effects Analysis (FMEA)

Classification of possible failures based on

- the probability
- how easy is it to detect
- the severity of impact of the results

➔ evaluation of each factor (scoring 1-5 or 1-10)

When considering risks…

all factors, both internal and external, should be taken into account

➔ Internal factors refer to the management system and all technical aspects…

➔ External factors refer to customers, suppliers and authorities.

SWOT analysis*

List of **S**trengths (internal positive factors)	List of **W**eaknesses Internal negative factors)
List of **O**pportunities (external positive factors)	List of **T**hreats (external negative factors)

Are these issues entirely new?

Not at all! They appear in the 2005 version as well, although sometimes in a “hidden” way!

They really appear in a number of clauses and notes, even without the same terms and not in such detail, with reference to their importance, considering their importance and consequences and the possibility of recurrence.

In all accreditation standards…

reference is made to risks and opportunities;

namely in

- ISO 15189:2012
- ISO/IEC 17043:2010
- ISO 17034:2016
- ISO/IEC 17025:2005

=> ISO/IEC 17025:2017 (in a broader sense)

To this end, it is interesting…

to make some reference to the previous version and relevant requirements which are already being implemented; to this end, laboratories can further elaborate on the issue in order to comply with the risk-based thinking of the new standard.

Clause 4.9 of the 2005 version…

refers to nonconformities specifying the need to have a policy and procedures to handle them (4.9.1).

Where it is evaluated that the nonconforming work could recur or that there is doubt about the compliance of the operations with policies and procedures, then appropriate corrective actions has to be taken according to clause 4.11 (4.9.2).

Cause analysis

Clause 4.11.2 specifies that the first step for corrective action is an investigation to determine the root cause(s) of the problem.

Note: This is the main and often the most difficult part! In case the root cause is not obvious, a careful analysis of all potential causes is required:

Customer requirements, the samples, the samples specifications, methods and procedures, staff skills and training, consumables or equipment

Selection and implementation of corrective actions

Clause 4.11.3 specifies that

- where a corrective action is needed, the laboratory shall identify potential corrective actions and shall select and implement those most likely to eliminate the problem and prevent recurrence.
- Corrective actions shall be to a degree appropriate to the magnitude and the **risk** of the problem.

Further to this, clause 4.11.5

is related to risk as well. It specifies that where the identification of nonconformities casts doubts on the compliance with the laboratory's policies and procedures or the Standard, the laboratory shall ensure the appropriate areas of activities are audited as soon as possible.

Note: Additional audit should be necessary only when a serious issue or **risk** to the business is identified

Preventive actions

Clause 4.12 refers to preventive actions which are required when needed improvement opportunities and potential sources of nonconformities are identified; appropriate action plans shall be developed, implemented and monitored to reduce the likelihood of occurrence of these nonconformities and take advantage of the opportunities for improvement.

Note 2: Preventive action might involve analysis of data including trend and **risk** analyses and PT results.

With regard to validation…

Note 3 to clause 5.4.3 mentions that Validation is always a balance between costs, risks and technical possibilities. There are many cases in which the range and uncertainty of the values (e.g. accuracy, detection limit, selectivity, linearity, repeatability, reproducibility, robustness and cross-sensitivity) can only be given in a simplified way due to lack of information.

Risk-based thinking in the new Standard

According to a statement in the Introduction, the laboratory is required to plan and implement actions to address risks and opportunities

➔Addressing risks and opportunities, the laboratory establishes the basis for increasing the effectiveness of the management systems, achieving improved results and preventing negative effects.

➔The laboratory is responsible for deciding which risks and opportunities need to be addressed

Risks and opportunities…

are referred to in the Forward and the Introduction and a number of clauses:

- impartiality (4.1.4 and 4.1.5)
- statements of conformity (7.8.6.1)
- nonconforming work (7.10)
- management system (8.1.2)
- improvement (8.6.1)
- corrective actions (8.7.1),
- management reviews (8.9.2).

➔ Clause 8.5 is devoted to **risks and opportunities**

General requirements

4.1 Impartiality

- Laboratory committed to impartiality
- Shall identify risks to its impartiality on an on-going basis
- If a risk is identified, the laboratory shall be able to demonstrate how it eliminates or minimizes such risk

Actions to address risks and opportunities

Clause 8.5 refers to points which are known from the 2005 version of ISO/IEC 17025 under

- improvement (4.10) and
- preventive actions (4.12).

However, the approach is much wider; the text does not refer to IS0 31000 which is included in the Bibliography.

The best use of opportunities is now described in clause 8.6 (improvement).

The laboratory shall consider...

the risks and opportunities associated with lab activities in order to:

- Give assurance that management system achieves its intended results
- Enhance opportunities to achieve the purpose and objectives of the lab
- Prevent or reduce undesired impacts and potential failures in the lab activities
- Achieve improvement

(8.5.1)

The laboratory shall plan...

- Actions to address these risks and opportunities
- How to integrate and implement these actions into its management system and evaluate its effectiveness of these actions

Note: There is no requirement for formal methods for risk management. Labs can decide whether or not to develop a more extensive methodology of other guidance or standard.

(8.5.2)

Actions to address risks and opportunities...

shall be proportional to the potential impact on validity of lab results

Note 1: These can include identifying and avoiding threads, taking risk in order to pursue and opportunity, eliminating the risk source, changing the likelihood, sharing the risk or retaining risk by informed decision

Note 2: Opportunities can lead to expend scope of accreditation, addressing new customers, using new technology, and other possibilities to address customer needs.

(8.5.3)

Identification of opportunities

Clause 8.6.1 specifies that the laboratory shall identify and select opportunities for improvement and implement any necessary actions

Note: They can be identified through the review of operational procedures, the use of policies, overall objectives, audit results, corrective actions, management reviews, risk assessment, analysis of data, proficiency testing results

Feedback

Clause 8.6.2 specifies that the laboratory shall seek feedback, both positive and negative from its customers. The feedback shall be analysed and used to improve the management system, laboratory activities and customer service

Note: Examples include

- Customer satisfaction surveys
- Communication records
- Review of reports with customers

Management review

Some of the topics relevant to risks and opportunities

- changes in internal and external issues
- fulfilment of objectives
- status of actions from previous reviews
- results of **risk** identification
- effectiveness of any implemented **improvements**
- outcome of internal audits, external assessments
- customer and personnel feedback (8.9.2)

Statement of conformity

According to clause 7.8.6.1, when statement of conformity to a specification/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).

Nonconforming work

Clause 7.10.1(b) specifies that
"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

According to clause 8.7.1 (e)

“the laboratory shall update **risks and opportunities** determined during planning, if necessary”

Some words* give a hint…

- ensure *(clause 5.5.c)*
- prevent *(clauses 5.6.c, 6.3.4, 6.4.3, 6.4.9, 6.4.12, 7.7.3, 8.3.2, 8.5.1.c)*
- suitable *(clauses 6.3.1, 8.3.2)*
- sufficient *(clauses 7.2.1.2, 7.5.1)*
- critical *(clauses 7.6.3, 7.8.2.1)*

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In medical laboratories…

The consideration is similar but not identical.

This is illustrated with the following

Address risks* Vs Risk management**

* ISO/IEC 17025

** ISO 15189

Clause 4.14.6

requires that the laboratory shall evaluate the impact of work processes and potential failures on examination results which affect patient safety. Based on this, it shall modify processes to reduce or eliminate the risks and document decisions and actions taken.

This is related to clause 4.9…

where it is required that

"…When it is determined that nonconformities in any pre-examination, examination and post-examination processes could recur or that there is doubt about the laboratory's compliance with its own procedures, the laboratory shall take action to identify, document and eliminate the cause(s)...".

Despite the brief reference…

to risks, this issue is of great importance in medical laboratories. In the meaning of clause 4.14.6, “weak” points can exist in most of the activities of the laboratory and its management system

Continual improvement

Clause 4.12 provides for activities covering opportunities. It provides for “the use of management reviews to compare the laboratory’s actual performance in its evaluation, corrective and preventive actions with its intentions, as stated in the quality policy and quality indicators. Improvement activities shall be directed at areas of highest priority based on risk assessments…”.

Management review

According to clause 4.15.2 both risks and improvement are addressed during the meetings, both directly (subclauses (e) and (l) respectively).

The laboratory 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.*

The laboratory should consider the history…

- Impartiality
- Complaints
- Quality control
- Calibrations
- Control of consumables
- Personnel
- Test reports and calibration certificates
- Management review
- Internal and external control
- Data and information management

The assessor will not go deeply…

to check whether all aspects relating to risks and opportunities have been taken into consideration but mainly whether the laboratory has managed adequately.

The task is.

to increase the effectiveness of the management system, achieving improved results and preventing negative effects.

Thank you for your attention

….and your questions