Risk-based thinking on calibration and testing laboratory: 
Current challenge in transition period

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Abstract. This research was conducted to discuss the application of risk-based thinking concept in calibration and testing laboratories. This research is motivated by the publication of the new edition of ISO/IEC 17025:2017 standard that applies the principle of risk-based thinking. From the results of the JCRB 39/3 resolution, full-implementation of ISO/IEC 17025:2017 standard by calibration and testing laboratories is no more than 3 years after publication. In addition, the National Accreditation Committee (KAN) as an accreditation body in Indonesia requires calibration laboratories and testing laboratories to switch their management system to ISO/IEC 17025:2017 standard starting at 2018. This research is carried out by identifying the risks found in calibration and testing activity. Clause 8.5 of ISO/IEC 17025:2017 is applied to take actions to minimize or eliminate risks that have been identified as preventive or corrective actions. In this research, 5x5 risk matrix is also used by considering the impact and frequency of risks in the calibration and testing laboratories.

1. Introduction
The application of risk management or what is known as risk-based thinking has been implemented in various aspects of work, especially those related to standardization of the process in order to produce consistent product and good quality. The ISO/IEC 17025:2017 standard as reference by the calibration/testing laboratory has also adopted risk-based thinking concept into its requirements. Even the main changes of the ISO/IEC 17025 standard from edition 2 (published in 2005) to edition 3 (published in 2017) was motivated by the application of the concept of Risk-Based Thinking. The concept of risk-based thinking is adopted by the ISO/IEC 17025:2017 standard, aimed to implement performance-based requirements method that replaces the prescriptive requirements method previously used [1]. The laboratory needs to identify the risks that can occur in the management system that can affect on the validity of the calibration/testing results. Therefore it is necessary to take action on the identified of risks to prevent unwanted impacts and the occurrence of errors in the laboratory management system.

Based on JCRB 39/3 resolution related to the issuance of the 3rd edition of the ISO/IEC 17025 standard, then the organizations, laboratories, or individuals implementing the standard are given a time limit of no more than 3 years to implement full-implementation of new edition of ISO/IEC 17025 [2]. It means that the end of 2020th year is the last deadline for full adoption, and the 2019th year is a transition period for the implementation of the 3rd edition of the ISO/IEC 17025 standard. This research discusses the application of the concept of risk-based thinking based on ISO /IEC 17025:2017 which was implemented in the calibration/testing laboratory. The purpose of this research is to provide real action related to the implementation of risk-based thinking or risk management for calibration/testing
laboratories in the transition period. Therefore, it is necessary to review the steps that need to be carried out related to the implementation of risk-based thinking concept to meet the requirements of the ISO/IEC 17025:2017 standard.

2. Study Literature

According to Coppola paper, risk is the interaction between consequences and likelihood and can be expressed by the following mathematical equations [3]:

\[\text{Risk} = \text{Likelihood} \times \text{Consequence}\]

From equation 1, risk is likelihood multiplied by consequences. That means, the total risk that can occur is influenced by the possibility and consequences of an event that can have a negative effect on the calibration/testing laboratory management system. If there are events that have a negative effect and have high probability of occurring on the management system of a calibration/testing laboratory, it can be said that the event has “high risk”. Likewise if there are events that have negative effect and have major consequences on the calibration/testing laboratory management system, it can be said that the event also has “high risk”. The examples of events that have negative effect on the calibration/testing laboratory are: errors on writing down the calibration/testing certificate, calibration standards have used when the recalibration due date has passed, and incorrect in calculating the measurement results. These events need to be anticipated so as not to occur in the management system of the calibration/testing laboratory. That is the role of the concept of risk-based thinking which can be used as proactive action of the laboratory to take preventive or corrective actions from the event that has a negative effect.

![The 5x5 risk matrix](image)

Figure 1. The 5x5 risk matrix

In this research, the 5x5 risk matrix is used to classify categories of risk. Some studies such as those carried out by Elmonstri [4] and by Guede [5] also use the 5x5 risk matrix with different classification categories. The 5x5 risk matrix used in this research is shown in figure 1. In the 5x5 matrix above, the risk can be categorized as “low risk” which is symbolized as green colour, “medium risk” which is represented by yellow colour and “high risk” which is represented by red colour. Included in the “low risk” category is matrix with a combination of consequences and likelihood such as the following: A-1,
A-2, A-3, B-1, B-2, and C-1. While for the “medium risk” category is matrix with a combination of consequences and likelihood such as the following: A-4, A-5, B-3, B-4, B-5, C-2, C-3, C-4, D-1, D-2, D-3, E-1, and E-2. For the category “high risk” is matrix with a combination of consequences and likelihood as follows: C-5, D-4, D-5, E-3, E-4, and E-5.

3. Methodology
In the ISO/IEC 17025:2017 standard, related to the discussion about risk-based thinking contained in clause 8.5. The flowchart of using the risk-based thinking concept in the calibration/testing laboratory in accordance with clause 8.5 of ISO/IEC 17025:2017 is stated in Figure 2.

![Risk-based thinking flowchart based on ISO/IEC 17025:2017](image)

Figure 2. Risk-based thinking flowchart based on ISO/IEC 17025:2017

The steps of implementing risk management in the calibration/testing laboratory are divided into 2 parts. The first part starts from the process of identifying the risks that might arise and determining the source of these risks. After the process of identifying and determining the source of risk, the ranking process is carried out against these risks. The ranking process is based on the possibility of events and consequences of risk based on the 5x5 risk matrix as discussed earlier. Then the risks that have been ranked are categorized into categories of “low risk”, “medium risk”, or “high risk”. The first process of risk management is carried out based on 8.5.1 subclause of ISO/IEC 17025:2017.

The second part of the risk-based thinking process is making actions (corrective or preventive) of the risks. The actions taken by the laboratory must be in accordance with the impact of the risks that will occur. After that, the next step is to evaluate the actions taken to see the effectiveness of risks handling. The actions carried out by a laboratory that can be said to be effective if the action succeeded in eliminating/minimizing the occurrence of risk in a calibration/testing laboratory that could have a negative effect on the quality of the calibration/testing results.
4. Results

According to 8.5.1 subclause of the ISO/IEC 17025:2017 standard, laboratories need to identify the risks that can arise in management system. Based on the risk-based thinking flowchart, the next step is to rank the risks that have been identified. The process of risk ranking is viewed from 2 aspects, these are the possibility of the occurrence of risks and consequences of these risks if they occur in the calibration/testing laboratory. Related to risk ranking associated with the likelihood aspect can be determined as in table 1 below.

**Table 1. Likelihood criteria**

| Likelihood Criteria: Probability (Parameter: % Chance of a risk may occur within a year) | Exposure of Likelihood | Likelihood Rating |
|-----------------------------------|------------------------|-------------------|
| 0 – 20%                           | Almost Never           | 1                 |
| 21 – 40%                          | Unlikely               | 2                 |
| 41 – 60%                          | Possible               | 3                 |
| 61 – 80%                          | Likely                 | 4                 |
| 81 – 100%                         | Almost Certain         | 5                 |

In table 1, the likelihood criterion can be divided into scale of 1 to 5, with parameter the probability of occurring risk in one-year. The “almost never” category means that the risks identified have the lowest probability of occurring with a percentage of 0 – 20%. Otherwise the category “almost certain” has the meaning that the identified risks are more likely to occur with a percentage of 81– 100%. Determination of the parameters of the likelihood criterion is seen from the data on the trend of the occurrence of these risks in the period of the last few years (e.g. the last 3 years data).

In addition to the likelihood aspect, the risk rating process is also viewed from the aspect of consequences. The consequence means the impact caused if the risk occurs in the calibration/testing laboratory management system so that it can affect the consistency, quality and validity of the results. Table 2 below is the consequences criteria on risk-based thinking concept based on ISO/IEC 17025:2017.

**Table 2. Consequence criteria**

| Consequence Criteria: Handling of calibration items (Parameter: Accident in Transportation of UUT) | Exposure of Consequence | Consequence Rating |
|---------------------------------------------------------------|-------------------------|-------------------|
| Minor accident (UUT does not suffer physical and functional damage) | Insignificant           | A                 |
| Minor accident (UUT is scratched, but does not suffer functional damage) | Minor                  | B                 |
| Moderate accident (UUT is scratched, some functions out of specification) | Moderate               | C                 |
| Serious accident (UUT is scratched and all functions out of specification) | Major                  | D                 |
| Fatal accident (UUT has suffered physical and functional damage) | Significant            | E                 |
In table 2 above, the consequence is regarding handling of Unit Under Test (UUT) with their parameters concerning about accident during the transportation process. In the aspect of consequence, it can also be emphasized about the impact or exposure of the risks caused when it occurs. Exposure from consequences is given scale from “Insignificant” with rating A to “Significant” with rating E. It means that if it is associated with transportation in the process of handling UUT, the rating A (Insignificant) indicate it has happened minor accident and UUT does not physically and function damage. In other words means UUT can still functionally and be used properly so that calibration activities can be carried out.

Whereas the E (Significant) rating if there has been a fatal accident against UUT during the transportation process which has resulted in physical and functional damage to the UUT, so that its calibration activities cannot be carried out. After the ranking is reviewed in terms of likelihood and consequence aspects, the 5x5 risk matrix is used to determine the level of risk. Until this step, the fulfillment of the implementation of subclause 8.5.1 has been done.

The next step is conducting subclause 8.5.2 from ISO/IEC 17025:2017. After the risk has been identified and determines the risk level, then the next step is to take action to minimize or eliminate the risk. The actions carried out by the laboratory can consist of “corrective action” if the non-conformity has been realized or “preventive action” if the non-conformity has not occurred, but if it is continuously allowed it will occur. According to subclause 8.5.3 of ISO/IEC 17025:2017, actions (corrective or preventive) carried out by the calibration/testing laboratory must be proportional to the risk level.

The next step in risk-based thinking implementation as indicated by the risk flowchart is to determine the level of effectiveness of actions that has been taken. Example of determining the effectiveness of actions as shown in the following table.

**Table 3. Control effectiveness criteria**

| Control Effectiveness Criteria: Corrective Action (Parameter: Outcome of Corrective Action) | Effectiveness Level | Effectiveness Rating |
|-----------------------------------------------|---------------------|---------------------|
| CA has been implemented, its properly as designed and consistently produces result as expected | Very Effective | 5 |
| CA has been implemented, its properly as designed, but not consistently produces result as expected | Effective | 4 |
| CA has been implemented, its properly as designed, but does not produces result as expected | Less Effective | 3 |
| CA has been implemented, but does not work properly as designed | Not Effective | 2 |
| CA does not implemented | Not Available | 1 |

In table 3 above, the effectiveness of actions taken can be seen from its impact to eliminate or minimize the risk and the results achieved. The actions is said to be “Very Effective” if it has been implemented consistently and produces results that are as expected. This means that these actions can prevent the occurrence of risks that can harm the calibration/testing laboratory. On the other hand, the actions that is not implemented or implemented but has no impact on handling of risk, it can be said that the action is “Not Effective”. The scale of the effectiveness of the actions in related with risk handling is from 1 (Not Available) to 5 (Very Effective).

From the risk-based thinking implementation steps that have been discussed, handling of risk process can be tabulated as shown in table 4 below.
| Identification of Risk | Source of Risk | Likelihood | Consequence | Risk Level | Action | Monitoring | Evaluation | Effectiveness Level |
|----------------------|---------------|------------|-------------|------------|--------|------------|------------|--------------------|
| Exchange of UUT in a calibrated package | Unfavorable UUT checking | Unlikely | Minor | Low | Making, establishing, and socialization UUT packaging procedures on a regular basis | Will be monitored in next management review and internal audit | UUT packaging procedures have been made and socialized. The procedure has been carried out consistently | Very Effective |
| Any deviations in calibration/testing room | The calibration/testing room maintenance routine is incorrect. | Possible | Major | Medium | Prioritizing in maintenance and monitoring work of the room condition | Will be monitored in next management review and internal audit | Monitoring the room condition along with maintenance has been carried out regularly | Effective |
| Error data in calibration certificate | Human error in inputting data in calibration certificate | Likely | Major | High | Verify the draft of calibration certificate before publication | Will be monitored in next management review and internal audit | Verification procedures have been carried out, although there are some work unit that have not been implemented them | Less Effective |
In table 4, there are some of the risks that can occur in the management system of the calibration/testing laboratory. Based on table 4, the risks handling process consist of: identification of risk step, determine source of risks, determine the risk levels, actions to eliminate/minimize the risk, evaluating of actions and determine the effectiveness level of the actions made. The risk-based thinking table above can be used to implement clause 8.5 ISO/IEC 17025:2017 as a whole. This table is filled in sequences according to the risk-based thinking flowchart that discussed in this paper. In a calibration/testing laboratory, the section that identifies the risk, makes & implements actions to eliminate/minimize the occurrence of risks, and evaluates the actions can be carried out by different individuals/teams.

5. Conclusions
From the results of this research, procedure or steps to implement risk-based thinking in a calibration/testing laboratory based on ISO/IEC 17025:2017 standard have been produced. Risks at the calibration/testing laboratory can occur in either the technical, administrative, top management or other related parts. Therefore the implementation of risk-based thinking is carried out on all section of management system in calibration/testing laboratory. The risk-based thinking process begins by identifying and looking for sources of risk. Then the identified risks are ranked based on the consequences and likelihood aspects, so that the level of risk can be determined.

The next step is proactive action from the laboratory through making actions (preventive or corrective) in the risk handling process. After that, the actions that has been implemented should be evaluate. The evaluation process is important to see the effectiveness of the overall risk handling process. This risk-based thinking concept are evidence of the implementation of risk-based thinking in the calibration/testing laboratory based on the ISO/IEC 17025:2017 standard. The effectiveness of the risk management process will have impact on achieving policies and objectives from the calibration/testing laboratory. In addition, this risk-based thinking concept are needed to serve as guide for calibration/testing laboratories which are new requirements for the latest edition of the ISO/IEC 17025:2017 standard.

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References
[1] International Organization for Standardization 2017 ISO/IEC 17025:2017 General Requirements for The Competence of Testing and Calibration Laboratories (Switzerland: ISO)
[2] Bureau International des Poids et Mesures 2018 Resolutions, Recommendations & Actions of the 39th JCRB Meeting (France: BIPM)
[3] Coppola D P 2007 Introduction to International Disaster Management (Oxford: Elsevier Inc) p 140
[4] Elmonstri M 2014 Review of the strength and weaknesses of risk matrices J. Risk Anal. Crisis Response 63 pp 444-461
[5] Guede F 2019 Risk-based structural integrity management for offshore jacket platforms Mar. Struct. 4(1) pp 149-57