Risk management in a testing laboratory using thermoluminescent detectors to determine absorbed dose to water for dosimetry audits of radiation therapy centers

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Laboratory accredited by the Polish Centre for Accreditation, accreditation No. AB 1499*
* an actual scope of accreditation No. AB 1499 is available on the PCA website: www.pca.gov.pl

Introduction

The Secondary Standards Dosimetry Laboratory (SSDL) in Warsaw in Poland has been accredited by the Polish Centre of Accreditation for the conformity with the **ISO/IEC 17025 standard „General requirements for the competence of testing and calibration laboratories"** [1].

The accreditation No. AB 1499 was granted on April 9, 2014. It covers the determination of absorbed dose to water for X-ray beams in the range of accelerating potentials of 4 MV to 25 MV and for electron beams in the energy range of 4 MeV to 22 MeV.

The Polish SSDL performs measurements in the aforementioned accreditation scope for the purposes of dosimetry audits of radiation therapy centers in Poland.

Introduction

In this work, the ways of implementing requirements of the ISO/IEC 17025:2017 standard [1] regarding **actions to address risk and opportunities associated with the laboratory activities** are presented.

These requirements (see section 8.5 of the ISO/IEC 17025:2017 standard) are as follows:

a. consideration of risks and opportunities associated with laboratory activities;

b. planning and taking actions in relation to risks and opportunities and assessing the effectiveness of these actions.

Methods

Risk can be defined as **effect of uncertainty on objectives** [2].

This effect is a deviation from the expected and it **can be positive**, **negative** or **both**, and can address, create or result in **opportunities** and **threats** [2].

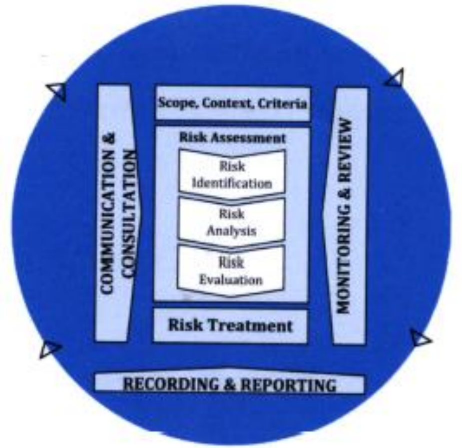
Managing risk considers the **external and internal context of the organization**, including human behaviour an cultural factor [2].

Methods

Due to the fact that the ISO/IEC 17025:2017 standard does not recommend the use of specific risk management methods, **each laboratory can define its own methodology**.

ISO 31000:2018 *Risk management – Guidelines* **can be a helpful standard in this regard**.

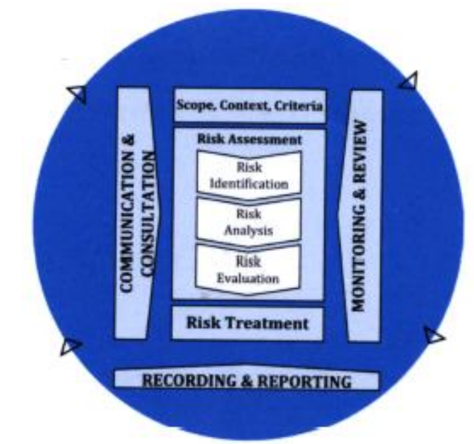
At the Polish SSDL,
it was assumed that **risk management is the overall process**,
as shown in the ISO 31000:2018 standard Risk management – Guidelines [2]
which standard can be applied to any organization and its context or activity.



The risk management process involves the systematic application of policies, procedures and practices to the activities of communicating, establishing the context and assessing, treating, monitoring, reviewing, recording and reporting risk.

Methods

Risk assessment is the overal process of **risk identification**, **risk analysis** and **risk evaluation** [2].



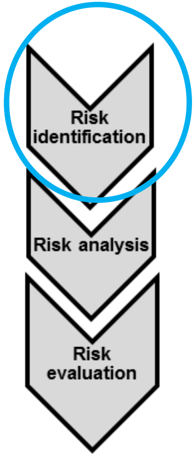
Risk identification
- **is conducted to find, recognize and describe risks that might help or prevent the Polish SSDL achieving its objectives.**

Risk analysis
- **is an activity aimed at determining the level of risk, taking into account the effectiveness of existing risk controls.**

Risk evaluation
- **involves comparing the results of the risk analysis with the criteria established at the Polish SSDL to determine where additional action is required.**

Note:
Risk assessment is conducted systematically, iteratively and collaraboratively, drawing on the knowledge and views of stakeholders of the Polish SSDL.

Methods



Risk identification in practice:

Subject of risk identification: goals and objectives (processes).

Main areas of risk identification: staff, equipment.

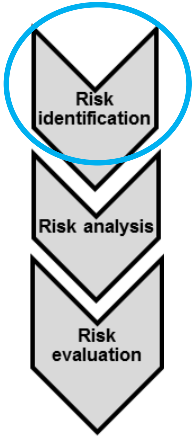
Risks are identified:
- during work planning - when goals are set, necessary resources are determined;
- on an ongoing basis - when the conditions for the performance of tasks change.

Risks are identified by:
- the same people who are involved in achieving goals and objectives;
- all levels of the organization (management and lower-level employees).

Main techniques for risk identification:
- "brainstorming„
- event lists;
- process analysis;
- threat scenarios ("black scenarios").

Recommended risk identification technique:
- mixed as a combination of all the techniques listed.

Methods



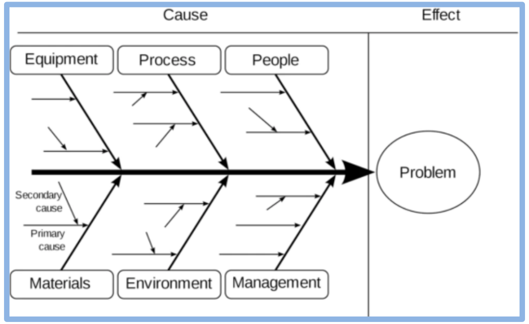
Risk identification in practice:

The next step in risk identification is <u>risk description</u>.

Description of the risk, i.e. indicating:

- the **source (cause)** of the potential risk;
- **effects (consequences)** that will occur after the risk materializes.

An example of a tool for determining the causes of potential risks: **the Ishikawa diagram**



Methods

Risk analysis in practice:

Risk analysis is an activity aimed at determining <u>the level of risk</u>, taking into account the effectiveness of existing <u>risk controls</u>.

The level of risk - the magnitude of risk (risk significance), combining the **likelihood of risk materialization** and **the effect of risk materialization.**

Risk control – measure that maintains and/or modifies risk.

The level of risk can be determined by following techniques, depending on the circumstances and intended use:

- **qualitative** - risks presented in a descriptive way, without using any numbers;
- **quantitative** - risks presented using numbers;
- **combination of aforementioned techniques**.

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Methods

Evaluation of the effectiveness of existing risk controls

Risk control – measure that maintains and/or modifies risk.

Control completely eliminates or reduces risk sufficiently → a strong control

Control partially eliminates or partially reduces risk → a moderate control

Control does not eliminate risk or does not sufficiently reduces risk → a weak control

Examples of risk control evaluation criteria:

- adequacy;
- efficacy;
- cost effectiveness.

If, for a given risk, **all three criteria for assessing the control of that risk are met** (if reasonable) → **control of that risk is strong.**

Methods

Evaluation of the effectiveness of existing risk controls

Risk control – measure that maintains and/or modifies risk.

Criteria adopted by the Polish SSDL:

Criterion	Definition	Scope of evaluation
Adequacy	The applied risk responses are the appropriate / accurate response to a given risk.	Do the applied risk responses: • affect the sources (causes) or consequences of the risk, or both; • have been structured in such a way that their proper application will protect against the respective risk.
Efficacy	The applied risk responses effectively deal with the risks for which they were established, work as planned.	Do the applied risk responses: • reduce risks to the desired degree (to an acceptable level); • completely protect against a given source (cause) of risk or limit the consequences, without the need for other actions.
Cost effectiveness	The applied risk responses effectively affect risk with the least possible expense associated with the operation of these responses.	Whether: • the costs of implementing and operating the response do not exceed the damage that would be caused if the risk materialized; • the expenses of the applied response are lower than the effects obtained as a result of the response.

Methods

Risk evaluation in practice:

Estimated level of risk ≤ established acceptable level of risk → identified risk is acceptable

Estimated level of risk > established acceptable level of risk → identified risk is UNACCETABLE

If the identified risk is on UNACCEPTABLE level, actions are taken to bring the risk to an acceptable level.

Acceptable level of risk can be established as:

- **common for the entire organization** (all processes / tasks);
- **separate for individual processes / tasks**.

Example of risk evaluation:

Score (score 25 is the highest score)	**Level of risk**	
from 15 to 25	**UNACCETABLE**	**Risk requires actions and management decision (risk management plan)**
from 5 to 14	**medium acceptable**	**Risk requires proceeding and ad hoc actions**
from 1 to 4	**low acceptable**	**Risk requires ongoing monitoring and ad hoc actions**

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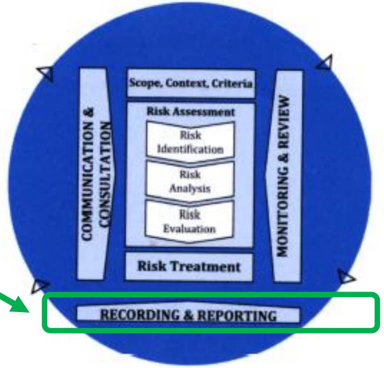
Methods

Recording and reporting risk in practice:



The risk management process and its outcomes should be documented and reported through appropriate mechanisms. [2]

At the Polish SSDL, meeting the requirements of the ISO/IEC 17025:2017 standard regarding activities related to risks and opportunities **is described in the established procedure: „Activities related to risks and opportunities in the Medical Physics Department"**.

This procedure includes the following forms for documenting risk and opportunity activities:

- ✓ **Form No. 1:** ***Register of risks and opportunities in the year …………;***
- ✓ **Form No. 2:** ***Criteria for evaluating the strength of risk control;***
- ✓ **Form No. 3:** ***Risk analysis principles;***
- ✓ **Form No. 4:** ***Acceptable risk levels.***

Practical examples of risk management

- several selected threats important from the point of view of the Polish SSDL were identified;
- for each threat:
  - ✓ an assessment of the strength of the controls currently applied was made;
  - ✓ likelihood and effect of the risk materialization were determined using the following tables:

Likelihood of risk materialization	Descriptive assessment of the likelihood of risk materialization	Scoring of the likelihood of risk materialization
< 15%	low	1
16 % - 45 %	moderate	2
46 % - 60 %	high	3
> 60 %	very high	4

Effect of the risk materialization	Descriptive assessment of the effect of the risk materialization	Scoring of the effect of risk materialization
Materialization of the risk will insignificantly affect the implementation of the task to which it relates	low	1
Materialization of the risk will complicate the implementation of the task to which it relates	moderate	2
Materialization of the risk will make it impossible to carry out the task to which it relates	high	3
Materialization of risk will disable the SSDL from functioning	very high	4

Note: If the risk responses used are rated as strong, then the likelihood or effect of risk materialization or both the likelihood and effect of risk materialization are rated lower, respectively (depending on what the strong risk responses are directed at).

- ✓ the level of risk was further determined using the following table:

Scoring of risk level	Descreptive assessment of risk level
1 - 4	low
5 - 8	moderate
9 - 12	high
13 - 16	very high

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Practical examples of risk management

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Identification of risk			Description of the risk or opportunity (potential cause and effect)	Applied control and evaluation of its strength	Risk analysis		Risk level	Risk level is acceptable?	The planned reaction
Purpose / Subprocess number	Task	Risk			Likelihood of risk materialization	Effect of risk materialization		Yes / No	
Providing customers with valid results / 22.8	Monitoring the validity of results and preventing invalid results from being included in certificate.	Low representativeness of confirmation of the validity of the results obtained throughout the scope of accreditation based on samples representing the PT programs selected and planned for participation.	**Potential cause:** limited access to PT. **Effect:** obtaining an invalid result.	**Control used**: review of the participation plan by the SSDL Head and ongoing monitoring of opportunities to participate in various PTs appropriate to one's scope of accreditation. **Strength evaluation:** strong control.	2	4	8	Yes	No reaction is required.
Providing customers with valid calibration results / 22.8	Monitoring the validity of results and preventing invalid results from being included in certificate.	Low effectiveness of monitoring and control of specific results.	**Potential cause:** incorrect dose determination for reference capsules, incorrect setting of irradiation time on the device with the Co-60 source. **Effect:** obtaining an invalid result.	**Control used:** checking dosimetric calculations by another PWWD employee, checking the correctness of the irradiation time setting on the device with the Co-60 source. **Strength evaluation:** strong control.	1	3	3	Yes	No reaction is required.
Providing customers with valid results obtained with impartiality / 22.8	Reliable preparation of certificate.	Pressure on SSDL personnel carrying out laboratory activities regarding test results.	**Potential cause:** personal/family/professional relationships of personnel performing laboratory activities with the client's personnel. **Effect:** issuing an unreliable certificate.	**Control used:** • commitment of the employee on the relevant Management System document to maintain impartiality, objectivity and independence from all pressures (commercial, financial and other) with regard to laboratory activities carried out by the employee; • control of proper assignment of tasks to employees. **Strength evaluation:** strong control.	1	2	2	Yes	No reaction is required.

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Practical examples of risk management

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Identification of risk			Description of the risk or opportunity (potential cause and effect)	Applied control and evaluation of its strength	Risk analysis		Risk level	Risk level is acceptable?	The planned reaction
Purpose / Subprocess number	Task	Risk			Likelihood of risk materialization	Effect of risk materialization		Yes / No	
Reliable preparation of the certificate of test results / 22.8	Correct determination of absorbed dose to water using TL detectors.	Incorrect data entry into the spreadsheet by SSDL personnel.	**Potential cause:** lack of an electronic data entry system by the client. **Effect:** incorrect determination of absorbed dose in water using TL detectors.	**Applied control:** check of entered data by another authorized SSDL employee. **Strength evaluation:** strong control.	1	3	3	Yes	No reaction is required.
Providing customers with valid test results / 22.8	Preparation of certificate of test results.	TL reader malfunction.	**Potential cause:** TL reader failure (including photomultiplier malfunction). **Effect:** lack of reliable data essential to calculate absorbed dose to water using TL detectors.	**Applied control:** inspection and maintenance of TL reader by authorized service, participation in Blind check. **Strength evaluation:** strong control.	1	3	3	Yes	No reaction is required.
Protection of customer data / 22.8	Preventing unauthorized access to customer data.	Customer data read by unauthorized persons.	**Potential cause:** failure to sufficiently secure customer records. **Effect:** The client's data records go to unauthorized persons.	**Applied control:** password-protected computers, client documentation not made available to unauthorized persons, PWWD room doors locked, "clean desk" policy. **Strength evaluation**: moderate control.	1	3	3	Yes	No reaction is required.
Performing dosimetry audits / 22.8	Irradiation of control and reference TL detectors in the absorbed dose range in water in a Co-60 gamma ray beam.	Failure of the device with the Co-60 source source.	**Potential cause:** radioactive source device in use for more than 15 years, no authorized service in the European Union (only service in Canada). **Effect:** inability to perform calibrations for absorbed dose to water in the Co-60 gamma beam.	**Applied control:** periodic checking of the device by the staff of the Dosimetry Laboratory in accordance with the current instruction; intermediate checking of the working standard by an employee of the PWWD ZFM NIO-PIB in Warsaw performed each day on which the client's dosimeter is calibrated using the given working standar**d.** **Strength evaluation: weak control.**	4	4	16	No	The reaction is required through the purchase of a new Co-60 source device with a source activity of about 550 TBq and maintenance service for about 10 years.

Conclusions

We hope that the practical examples of risk management presented in this work will help other testing laboratories manage risk in their routine activities.

References

1. INTERNATIONAL ORGANIZATION FOR STANDARDIZATION, General requirements for the competence of testing and calibration laboratories, ISO/IEC 17025:2017, ISO, Geneva (2017).
2. INTERNATIONAL ORGANIZATION FOR STANDARDIZATION, Risk management – Guidelines, ISO 31000:2018, ISO, Geneva (2018)

Thank you for your attention.