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Experience of the calibration and testing laboratory in establishing and maintaining a management system in accordance with the ISO/IEC 17025 standard

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Laboratory accredited by the Polish Centre for Accreditation, accreditation No. AP 155 *

Laboratory accredited by the Polish Centre for Accreditation, accreditation No. AB 1499 *

- an actual scope of accreditation No. AP 155 is available on the PCA website: www.pca.gov.pl

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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***.

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Introduction

The first accreditation (No. AB 1499) was granted on April 9, 2014. This accreditation concerns **the measurement of the dose absorbed in water, by thermoluminescent dosimetry method**.

The second accreditation (No. AP 155) obtained on May 28, 2014 covers the **calibration of ionizing radiation dosimeters*** in a ^{60}Co gamma ray beam in terms of dose absorbed to water and calibration of well chambers with a ^{192}Ir source in terms of air kerma.

The Polish SSDL performs laboratory activities in both of the aforementioned accreditation scopes for the needs of all radiotherapy centers in Poland.

Note: The status of accreditation and validity of the scope of accreditation can be confirmed at PCA website: www.pca.gov.pl.

* ionizing radiation dosimeter is set of electrometer and ionization chamber

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Introduction

This work will discuss **those requirements of the ISO/IEC 17025:2017 standard** [1] that caused the most difficulties in adapting the management system in accordance with the requirements of the ISO/IEC 17025:2005 to the requirements of the ISO/IEC 17025:2017 standard.

This work will also present **ways of implementing selected requirements of the ISO/IEC 17025:2017**, which may be helpful for other calibration and testing laboratories that plan to join the process of obtaining accreditation for compliance with the requirements of the ISO/IEC 17025:2017 or for such laboratories that would like to improve their management system.

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Material

The material of this work was **the system and technical documentation** necessary to establish, document, implement and maintain a management system in the Polish SSDL that was:

- capable of supporting and demonstrating the consistent achievements of the requirements of the ISO/IEC 17025:2017 standard;
- assuring the quality of the Polish SSDL results.

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Methods

In addition to meeting the general, structural, resource and process requirements (Clauses 4 to 7 of the ISO/IEC 17025:2017 standard) **a management system in accordance with Option A** was implemented in the Polish SSDL.

This management system includes:

- management system documentation (see section 8.2 of the ISO/IEC 17025:2017 standard);
- control of management system documents (see section 8.3 of the ISO/IEC 17025:2017 standard);
- control of records (see section 8.4 of the ISO/IEC 17025:2017 standard);
- acctions to address risks and opportunities (see section 8.5 of the ISO/IEC 17025:2017 standard);
- improvement (see section 8.6 of the ISO/IEC 17025:2017 standard);
- corrective actions (see section 8.7 of the ISO/IEC 17025:2017 standard);
- internal audits (see section 8.8 of the ISO/IEC 17025:2017 standard);
- management reviews (see section 8.9 of the ISO/IEC 17025:2017 standard).

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Requirements of the ISO/IEC 17025:2017 standard

that **caused the most difficulties**

in adapting the management system in accordance with the requirements

of the ISO/IEC 17025:2005 to the requirements of the ISO/IEC 17025:2017 standard:

7. Process requirements

8.5 Actions to address risks and opportunities

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7. Process requirements

One of the basic noticeable changes in the ISO/IEC 17025:2017 standard is the **implementation of the process approach** which is:

- one of the seven principles of quality management described in ISO 9000;
- typical of the management system according to ISO 9001.

According to the ISO 9000 standard, a **process** is a set of interrelated or interacting activities that use **process inputs** to deliver an **intended result**.

Process inputs are usually outputs from other processes, and **process outputs** are usually inputs from other processes.

In the remarks to the definition it is also indicated that the "**intended result**" is called **output, product or service**, depending on the context reference.

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7. Process requirements

Requirements for processes, given in Clause 7 of the ISO/IEC standard 17025:2017, indicate the following **11 processes**:

7.1 review of requests, tenders and contracts;
7.2 selection, verification and validation of methods;
7.3 sampling;
7.4 handling of test or calibration items;
7.5 technical records;
7.6 evaluation of measurement uncertainty;
7.7 ensuring the validity of results;
7.8 reporting of results;
7.9 complaints;
7.10 nonconforming work
7.11 control data and information management.

The application of the process approach in the management system in the current activities of the laboratory is facilitated by the Figure in Annex B to the standard.

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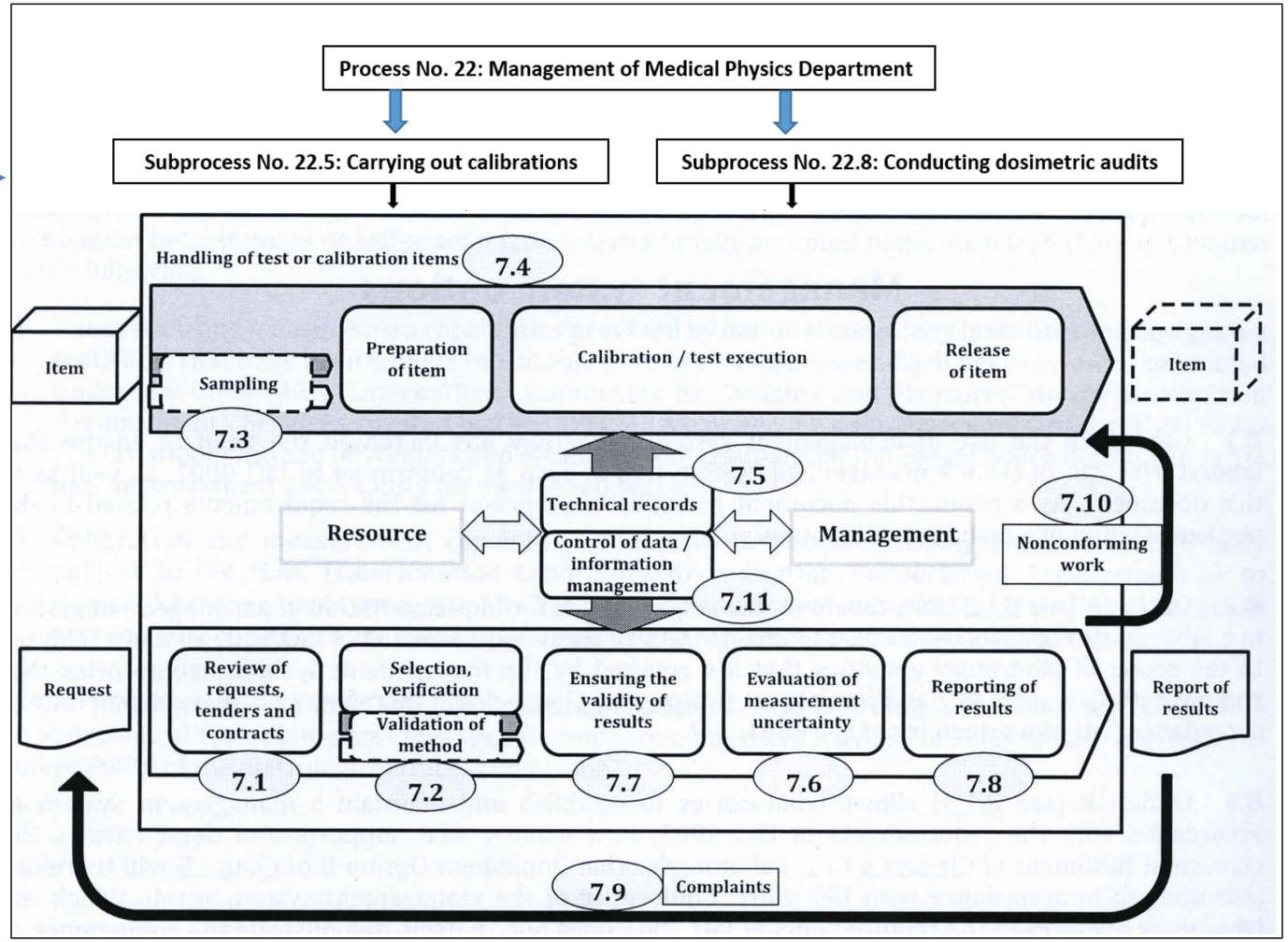
7. Process requirements

Schematic representation of two operational processes of the Polish SSDL

This diagram is included in Attachment No. 5 to the **Book of the Medical Physics Department's Management System**

Such a book is not strictly required by the standard. At the Polish SSDL it **was decided to issue this document to serve as a guide for the Polish SSDL personnel on the Medical Physics Department's Management System**.



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Book of the Medical Physics Department's Management System:

- was first released on June 16, 2020;
- **the 3rd edition of November 21, 2022** is currently in force;
- its layout corresponds to the layout of the ISO/IEC 17025:2027 standard, i.e. there are following parts:
  - **Introduction**
  - **Chapter 1: Scope of the Medical Physics Department's Management System Book**
  - **Chapter 2: Normative references**
  - **Chapter 3: Terms and definitions**
  - **Chapter 4: General requirements**
  - **Chapter 5: Structural requirements**
  - **Chapter 6: Resource requirements**
  - **Chapter 7: Process requirements**
  - **Chapter 8: Management system requirements**

  and
  - **additional Chapter 9: Attachments and related documents.**

This part is now 19 pages long.

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Book of the Medical Physics Department's Management System

- **Chapter 9: Attachments and related documents**

Attachment No.	Attachment title
1	Scope of Medical Physics Department 's laboratory activities
2	Organizational and management structure of the Medical Physics Department
3	List of documents applicable in the Medical Physics Department's Management System
4	List of management and technical personnel of the Medical Physics Department
5	Scheme of processes in the Medical Physics Department
6	Policies and goals

Related documents:

- **Documentation of process No. 22;**
- **Documentation of subprocess No. 22.5;**
- **Documentation of subprocess No. 22.8.**

This documentation **contains**, among others, **procedures** documented to the extent necessary to ensure the consistent implementation of the Polish SSDL activities and the validity of the results of these activities.

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Documentation of process No. 22:

- common to all activities of the Polish SSDL;
- includes **Book of the Medical Physics Department's Management System** and **16 procedures with instructions and forms, where necessary;**
- **total number of documents is 93.**

Documentation of subprocess No. 22.5:

- applies only to the calibration of ionizing radiation dosimeters in a ^{60}Co gamma ray beam in terms of dose absorbed to water and calibration of well chambers with a ^{192}Ir source in terms of air kerma;
- includes **4 procedures with instructions and forms, where necessary;**
- **total number of documents is 38.**

Documentation of subprocess No. 22.8:

- applies only to the measurement of the dose absorbed in water, by thermoluminescent dosimetry method;
- includes **2 procedures with instructions and forms, where necessary;**
- **total number of documents is 34.**

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8.5 Actions to address risks and opportunities

The individual requirements of the ISO/IEC 17025:2017 standard that **directly relate to taking action related to risk** are presented in the following table:

Point of standard	Title	Requirement
4.1	Impartiality	Identification and minimization of risks related to impartiality
7.8.6	Reporting statement conformity	Including the level of risk associated with the decision rule in the declarations of compliance
7.10	Nonconforming work	Setting risk levels for actions to be taken when nonconforming work is identified
8.5	Actions to address risks and opportunities	Consideration of risks and opportunities associated with laboratory activities. Planning and taking actions in relation to risks and opportunities and assessing the effectiveness of these actions
8.7	Corrective actions	Update of the identified risk as a result of the corrective actions taken
8.9	Management reviews	Analysis of risk identification results during management reviews

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8.5 Actions to address risks and opportunities

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..

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8.5 Actions to address risks and opportunities

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”.

Some guidelines of the ISO 31000:2018 standard <u>have been implemented</u> in this procedure.

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.***

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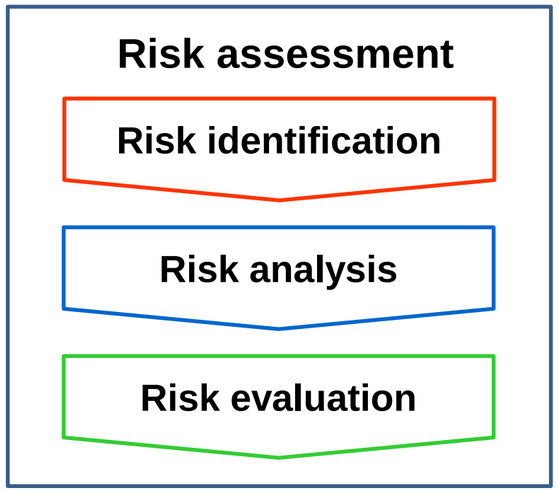
8.5 Actions to address risks and opportunities

At the Polish SSDL, it was assumed that **risk assessment is the overall process**, as shown in the diagram below - in accordance with the guidelines in the ISO 31000:2018 standard.



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

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 withe the criteria established at the Polish SSDL to determine where additional action is required.

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8.5 Actions to address risks and opportunities

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.

The outcome of risk is recorded on the form No. 1 of the **procedure *Activities related to risks and opportunities in the Medical Physics Department*** and then communicated to the Polish SSDL personel.

The current number of risks identified in subprocess 22.5 is 9.
The current number of risks identified in subprocess 22.8 is 6.
All identified risks are at an acceptable level and do not require any action.

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Conclusions

Adapting the management system in accordance with the requirements of the ISO/IEC 17025:2005 standard to the requirements of the ISO/IEC 17025:2017 standard **required a lot of thought and work**, especially by the person responsible for the management system in the Polish SSDL.

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Conclusions

Presented ways of implementing selected requirements of the ISO/IEC 17025:2017 standard may be helpful for other calibration and testing laboratories that plan to join the process of obtaining accreditation for compliance with the requirements of the ISO/IEC 17025:2017 standard or for such laboratories that would like to improve their management system.

The maintenance and continuous improvement of the management system in the Polish SSDL **requires the involvement of the entire laboratory personnel**.

References:

[1] INTERNATIONAL ORGANIZATION FOR STANDARDIZATION, *General requirements for the competence of testing and calibration laboratories*, ISO/IEC 17025:2017, ISO, Geneva (2017)

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Thank you for your attention.