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POZEMNÍCH STAVEB  
CERTIFIKAČNÍ SPOLEČNOST



CZECH REPUBLIC  
DEVELOPMENT COOPERATION

CHISINAU 054/2019

## Czech Development Cooperation Project Implementation of Eurocodes in the Republic of Moldova

# Key changes between the 2005 and 2017 versions of the ISO/IEC 17025 standard

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Using the thesis by dissertation,  
Ing. Jan Šutka ČVUT Prague:2018



## Building Research Institute – Certification Company, Ltd.

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## Content

1. Development of testing laboratory requirements
2. Analysis of changes EN ISO/IEC 17025:2017
3. Theory .....
4. Practice



## Part 1

# Development of testing laboratory requirements

**EN 45001:1989**

**EN ISO/IEC 17025:2005**

**EN ISO /IEC 17025:2017**

Development of testing laboratory requirements

EN 45001:1989

**EN 45001:1989 General criteria for the operation of testing laboratories**

3	Legal identity . . . . .	8
4	Impartiality, independence and integrity . . . . .	8
5	Technical competence . . . . .	8
5.1	Management and organization . . . . .	8
5.2	Personnel . . . . .	9
5.3	Premises and equipment . . . . .	9
5.3.1	Availability . . . . .	9
5.3.2	Premises and environment . . . . .	9
5.3.3	Equipment . . . . .	9
5.4	Working procedures . . . . .	11
5.4.1	Test methods and procedures . . . . .	11
5.4.2	Quality System . . . . .	11
5.4.3	Test reports . . . . .	12
5.4.4	Records . . . . .	13
5.4.5	Handling of test samples or items . . . . .	14
5.4.6	Confidentiality and security . . . . .	14
5.4.7	Subcontracting . . . . .	14

6	Cooperation . . . . .	15
6.1	Cooperation with clients . . . . .	15
6.2	Cooperation with bodies granting accreditation . . . . .	15
6.3	Cooperation with other laboratories and with bodies producing standards and regulations . . . . .	15
7	Duties resulting from the use of accreditation . . . . .	16

**1 Object and field of application**

This European Standard specifies general criteria for the technical competence of testing laboratories including calibration laboratories, irrespective of the sector involved.

It is intended for the use of testing laboratories and their accreditation bodies as well as other bodies concerned with recognizing the competence of testing laboratories.

This set of criteria may have to be supplemented when applied to a particular sector.

## Development of testing laboratory requirements

## EN ISO 17025:2005

### General requirements for the competence of testing and calibration laboratories

4	Management requirements.....	11	4.12	Preventive action.....	21
4.1	Organization.....	11	4.13	Control of records.....	21
4.2	Management system.....	13	4.13.1	General.....	21
4.3	Document control.....	15	4.13.2	Technical records.....	22
4.3.1	General.....	15	4.14	Internal audits.....	23
4.3.2	Document approval and issue.....	15	4.15	Management reviews.....	23
4.3.3	Document changes.....	16	5	Technical requirements.....	24
4.4	Review of requests, tenders and contracts...	16	5.1	General.....	24
4.5	Subcontracting of tests and calibrations.....	17	5.2	Personnel.....	24
4.6	Purchasing services and supplies.....	18	5.3	Accommodation and environmental conditions.....	26
4.7	Service to the customer.....	18	5.4	Test and calibration methods and method validation.....	27
4.8	Complaints and/or calibration work.....	19	5.4.1	General.....	27
4.9	Control of nonconforming testing and/or calibration work.....	19	5.4.2	Selection of methods.....	27
4.10	Improvement.....	20			
4.11	Corrective action.....	20			
4.11.1	General.....	20			
4.11.2	Cause analysis.....	20			
4.11.3	Selection and implementation of corrective actions.....	20			
4.11.4	Monitoring of corrective actions.....	21			
4.11.5	Additional audits.....	21			

## Development of testing laboratory requirements

## EN ISO 17025:2017

### General requirements for the competence of testing and calibration laboratories

#### 4 General requirements

##### 4.1 Impartiality

##### 4.2 Confidentiality

#### 5 Structural requirements

### 6 Resource requirements

##### 6.1 General

##### 6.2 Personnel

##### 6.3 Facilities and environmental conditions

##### 6.4 Equipment

##### 6.5 Metrological traceability

##### 6.6 Externally provided products and services

### 7 Process requirements

##### 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

##### 7.8.1 General

##### 7.8.2 Common requirements for reports (test, calibration or sampling)

##### 7.8.3 Specific requirements for test reports

##### 7.8.4 Specific requirements for calibration certificates

##### 7.8.5 Reporting sampling – specific requirements

##### 7.8.6 Reporting statements of conformity

##### 7.8.7 Reporting opinions and interpretations

##### 7.8.8 Amendments to reports

### 7.9 Complaints

#### 7.10 Nonconforming work

#### 7.11 Control of data and information management

### 8 Management system requirements

#### 8.1 Options

#### 8.2 Management system documentation

#### 8.3 Control of management system documents

#### 8.4 Control of records

#### 8.5 Actions to address risks and opportunities

.....



## Development of testing laboratory requirements

### **The role of ISO 9001** Quality management systems – Requirements

**ISO / IEC 17025: 2005 referred to ISO 9001: 1995 and ISO 9002: 1995, following the change to ISO 9001: 2000 - standards for quality management system requirements. Article 6.1 of the Standard stated:**

**1.6** If testing and calibration laboratories comply with the requirements of this International Standard, they will operate a quality management system for their testing and calibration activities that also meets the principles of ISO 9001.

**ISO / IEC 17025: 2018 directly uses ISO 9001: 2015 standard. Article 8.1.3 „Option B“, Chapter 8, Management System Requirements.**





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## Part 2

# Analysis of changes EN ISO/IEC 17025:2017

## Part 2

# Analysis of changes EN ISO/IEC 17025:2017

17025:2005	17025:2017
1. Scope	1. Scope
2. Normative references	2. Terms and definitions
3. Terms and definition	3. Termíny a definice
4. Management requirements	4. General requirements
5. Technical requirements	5. Structural requirements
	6. Resource requirements
	<b>7. Process requirements</b>
	8. Management system requirements

- The first major change is the very approach to standard setting
- Supports process management and process analysis
- In many cases, requirements for setting objectives and policies have been deleted

## Part 2

# Transfer of requirements

17025:2017	17025:2005
4. General requirements	4. Management requirements
5. Structural requirements	4. Management requirements
6. Resource requirements	5. Technical requirements 4. Management requirements
<b>7. Process requirements</b>	5. Technical requirements 4. Management requirements
8. Management system requirements	4. Management requirements



## Part 3 - Theory

# Theory

## Functional management

## Process management

## Theory

### Functional management

Functional management is based on the management of departments (production, purchasing, marketing, etc.). The layout of the departments is determined by the organization chart. Division into departments and departments causes barriers to cooperation within the organization. Here usually the know-how holders are employees, head of departments.

### Process management

Process management is based on process identification and management. Know-how is stored in processes. The superiority and subordination of workers is defined within each process.

## Theory

### Process management

Every process has its objectives.

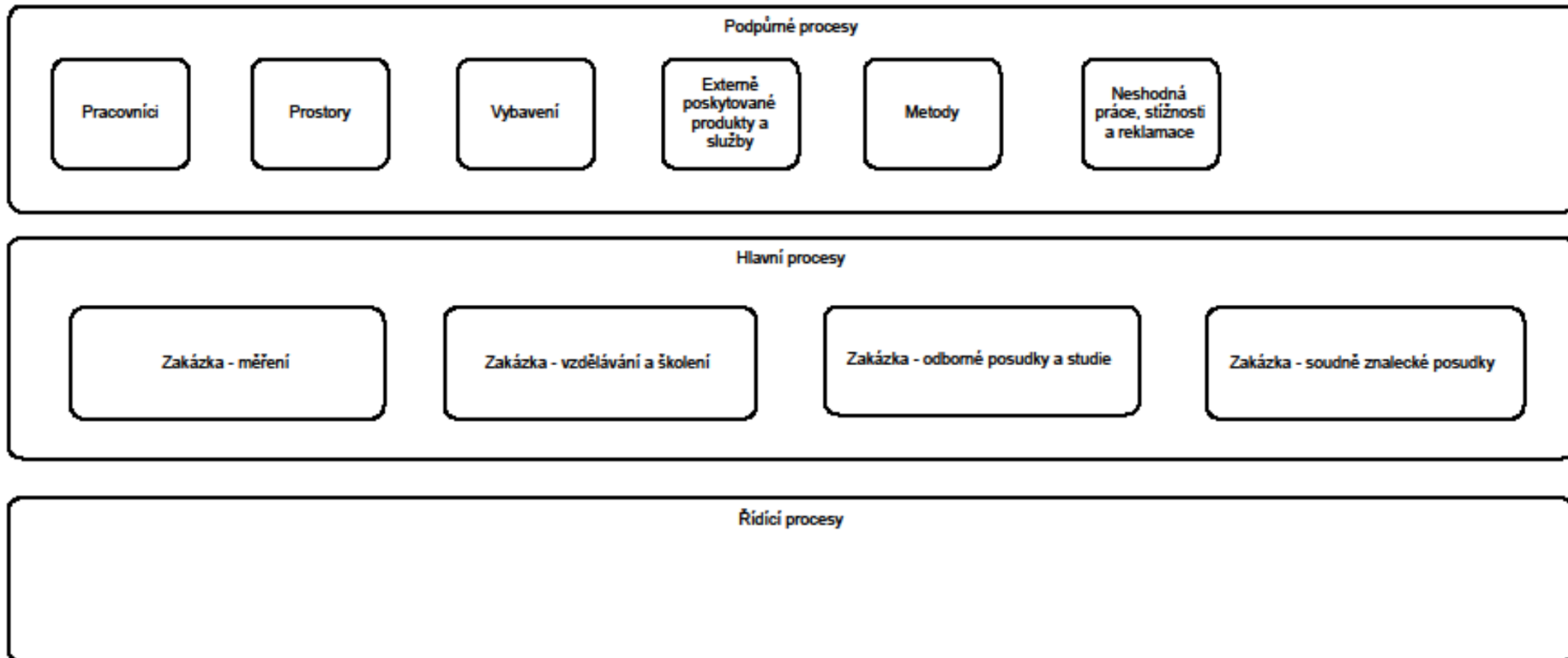
#### Usually they distinguish:

- key processes
- supporting processes

- 
- 
-

## Theory

# Process management

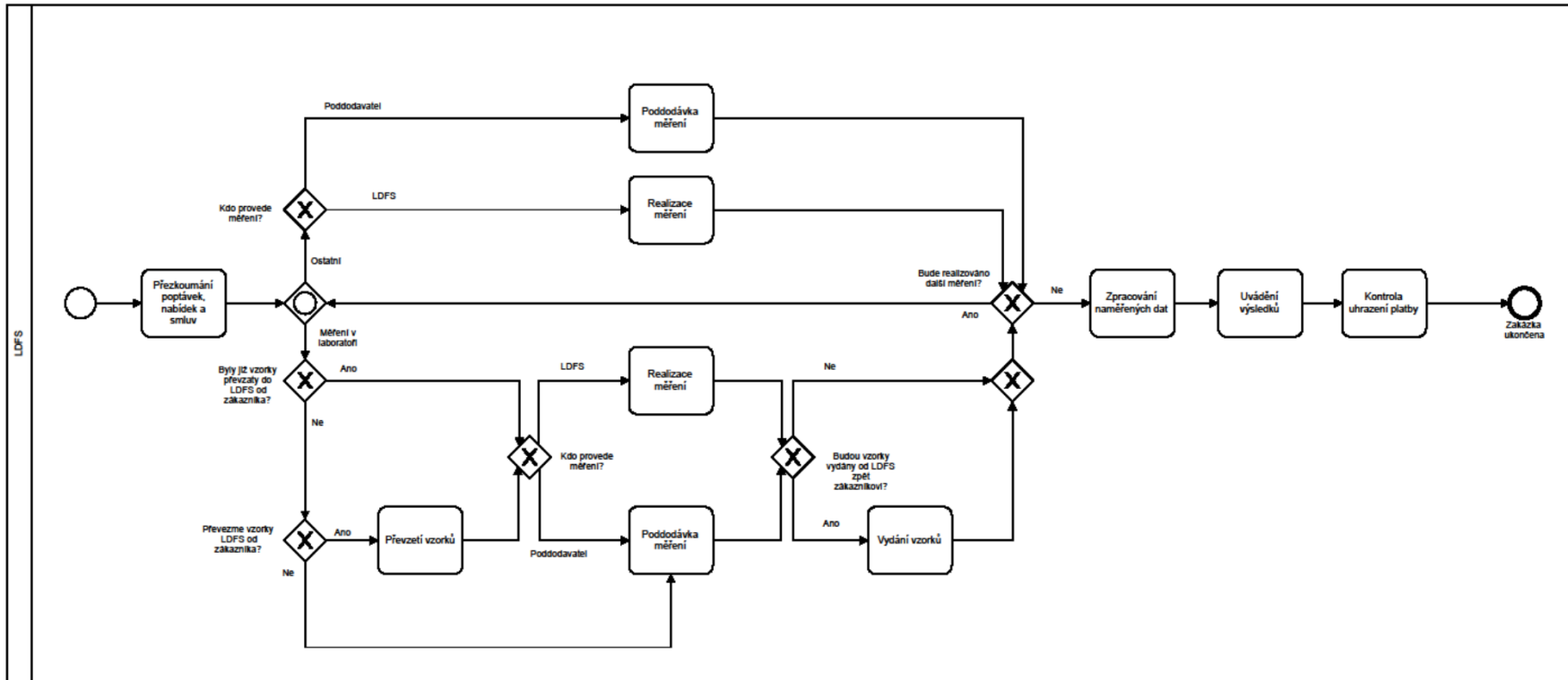


Ing. Jan Šutka Praha. ČVUT:2018



Theory

# Process management (Ing. Jan Šutka Praha. ČVUT:2018)



Ing. Jan Šutka Praha. ČVUT:2018

Theory

## Process management by ISO 17025:2017

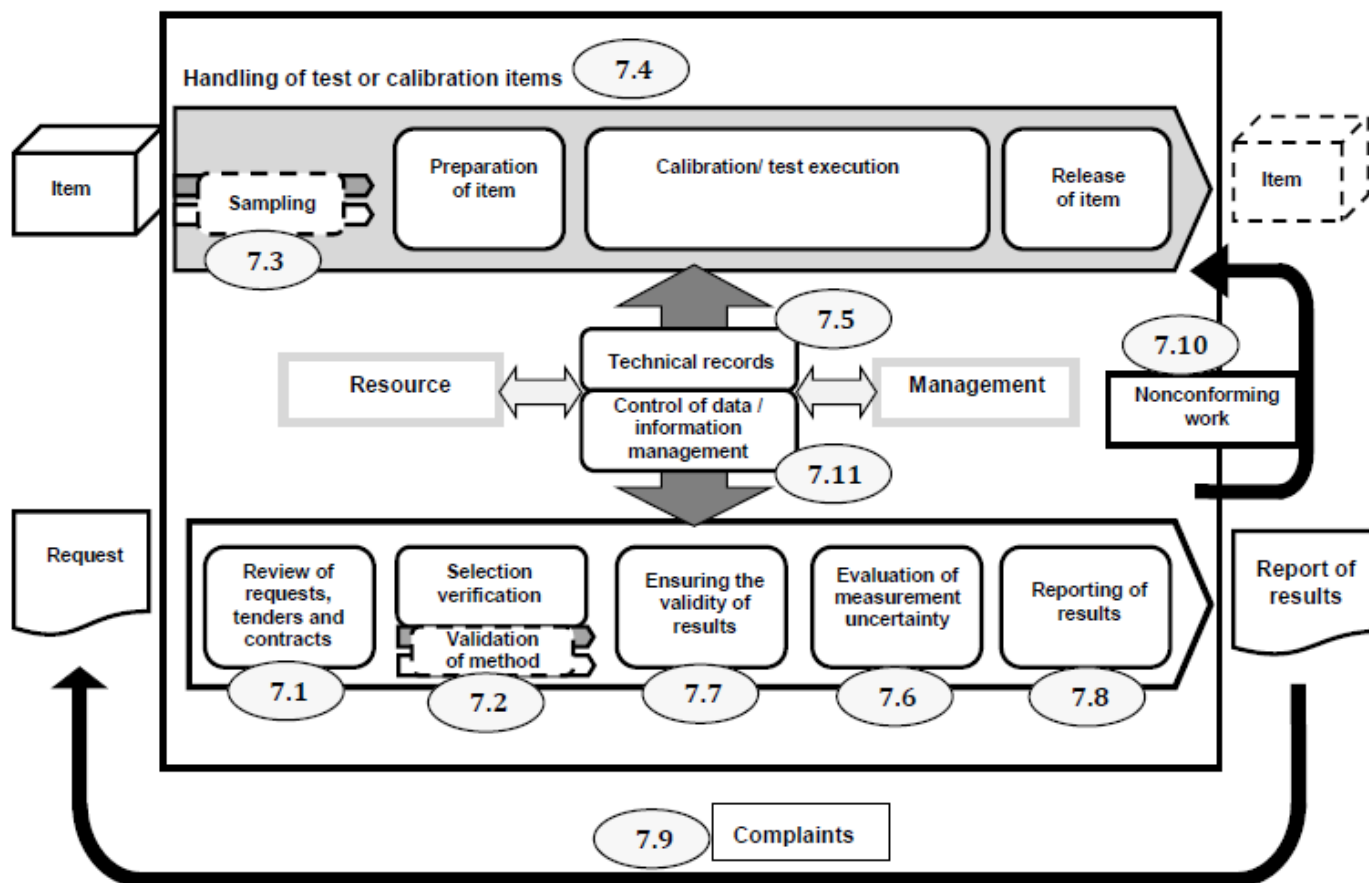


Figure B.1 – Possible schematic representation of the operational processes of a laboratory



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**Theory**

# Theory

# Risk management

## Theory

### Risk management

The requirements for impartiality, Chapter 4, are risk management requirements.

The **risk** is defined by the standard **ISO 31000:2010**,  
**Risk management – Guidelines**

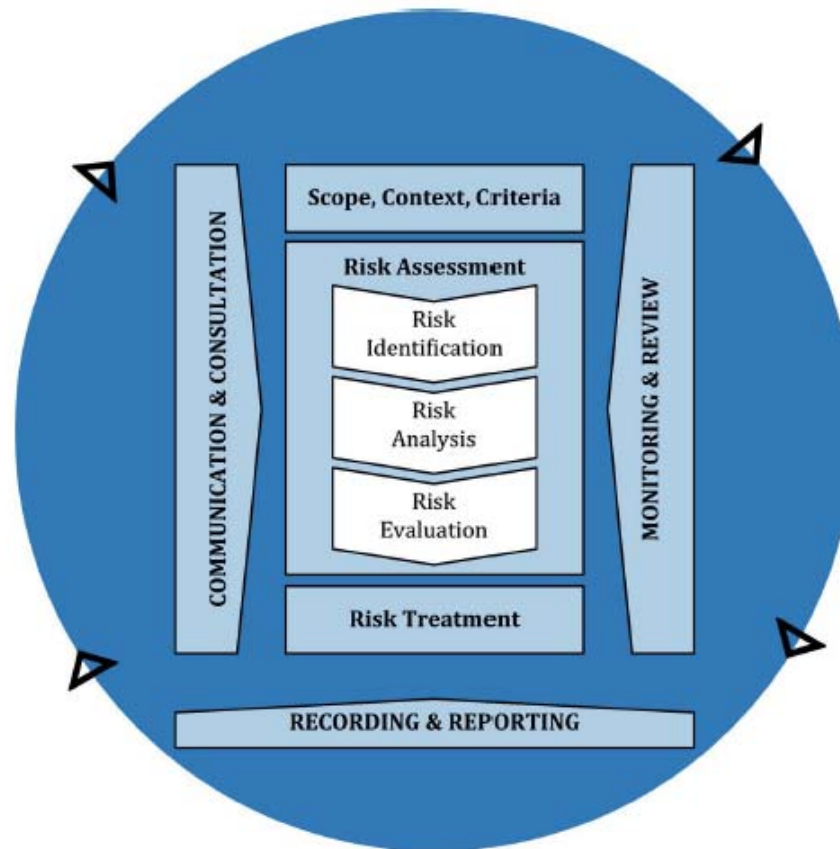
**3.1 risk** effect of uncertainty on objectives

**3.2 risk management** coordinated activities to direct and control an organization with regard to risk (3.1)

**3.4 risk source** element which alone or in combination has the potential to give rise to risk (3.1)

## Theory

# Risk management by ISO 31000:2010





## Part 4

# Practice

# Implementation ISO 17025:2017

## Practice

### Main aspects of implementation:

- 1) The test laboratory is already accredited according to ISO 17025:2005
- 2) The testing laboratory is a separate organization, performs only testing, or has other activities
- 3) The organization has an ISO 9001 management system
- 4) The testing laboratory is part of the conformity assessment body, i.e. the product certification body for products accredited by EN ISO/IEC 17065, is also part of the organization
- 5) The testing laboratory carries out testing for mandatory conformity assessment





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Thank you for your attention

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