

**QUALITY INTEGRATED MANAGEMENT SYSTEM  
ISO 9001-ISO 17025 IMPLEMENTED TO INCD-ECOIND,  
BUCHAREST**

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**Abstract.** For the near future Romania is interested in its integration in the European Union. The cooperation between the European Union and the candidates states in conformity evaluation, accreditation and standardisation fields, represents an important indicator of the progress for the EU integration. INCD-ECOIND has implemented a Quality Integrated Management System (QIMS) ISO 9001-EN 45001 and already initiated the implementation activity of two new standards ISO 9001-2000 and ISO/CEI 17025–2000. For the harmonisation of the existent QIMS to the new regulations, INCD-ECOIND has elaborated its own strategy. At the same time, through this action, INCD-ECOIND contributes at Romania's effort in its approach for the European Union integration.

*Keywords:* Quality Integrated Management System, Certification, Accreditation, strategy, harmonisation, regulations.

**AIMS AND BACKGROUND**

For the near future Romania is interested in its integration in European Union. One of the imposed conditions by the Community Aquis is the application of the Community exigencies regarding the Unique Market of European Union, defined as an internal and unfrontier zone, where four kinds of freedom are guaranteed: freedom circulation of products, of persons, of services and of capital. The Unique Market is based on open market economy in which the economical and social concurrency and cohesion are essential. The cooperation between the European Union and the candidates states in conformity evaluation, accreditation and standardisation fields represents an important indicator of the progress for the EU integration.

INCD-ECOIND has implemented a Quality Integrated Management System (QIMS) ISO 9001-EN 45001 and already initiated the implementation activity of two new standards ISO 9001-2000<sup>1</sup> and ISO/CEI 17025–2000<sup>2</sup>.

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## QIMS ISO 9001-EN 45001 IMPLEMENTED TO INCD-ECOIND, BUCHAREST

INCD-ECOIND has implemented a QIMS ISO 9001-1994<sup>3</sup>-EN 45001-1993<sup>4</sup>. The development of such a system was the General Manager's initiative, which understood the obtained advantages on medium and long terms for economical evolution of the Institute.

The designing, documentation, implementation and the QIMS's Certification ISO 9001, and also the testing laboratories's Accreditation EN 45001 were realised with the whole personnel participation, the quality being the concern of all the employees of the Institute<sup>5-10</sup>.

The construction and implementation process of the QIMS were based on the Manager Declaration, having the imperative – "INCD-ECOIND, leader on the environment research market in Romania".

The development process of QIMS is very complex and was unrolled following the Strategic Program ISO 9000 structured on 4 action directions:

- personnel formation for quality;
- quality system organisation;
- quality system documentation and implementation;
- quality audit.

In Table 1 are presented the applicable system elements in the context of the Institute's activity field.

**Table 1.** The applicable system elements in the context of the Institute's activity field

No	Procedure	System elements	
		ISO 9001	EN 45001
1	PFS-01-Ed2	4.1	5.1; 5.4.2
2	PFS-02-Ed2	4.2	5.4.1; 5.4.2
3	PFS-03-Ed2	4.3	*
4	PFS-04-Ed2	4.4	NA
5	PFS-05-Ed2	4.5	5.4.4
6	PFS-06-Ed2	4.6	5.4.7
7	PFS-07-Ed2	4.7	*
8	PFS-08-Ed2	4.8	*
9	PFS-09-Ed2	4.9	NA
10	PFS-10-Ed2	4.10	5.4.3
11	PFS-11-Ed2	4.11	5.3.2; 5.3.3
12	PFS-12-Ed2	4.12	*
13	PFS-13-Ed2	4.13	5.4.2
14	PFS-14-Ed2	4.14	5.4.2
15	PFS-15-Ed2	4.15	5.4.5
16	PFS-16-Ed2	4.16	5.4.4
17	PFS-17-Ed2	4.17	*
18	PFS-18-Ed2	4.18	5.2
19	PFS-19-Ed2	4.19	NA
20	PFS-20-Ed2	4.20	*

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We have mentioned that the clause 4.4. "Design control" of ISO 9001 was adapted to the research activity in environmental protection field. We named it "Research control". We remarked that in keeping the control of research three system elements are involved: 4.4., 4.9 (Processes control) and 4.10 (Inspections and tests).

Human and financial efforts of the whole INCD-ECOIND personnel finally determined the obtaining of QIMS ISO 9001 Certification and the testing laboratories EN 45001 Accreditation, events marked by two national Prime-Ministers:

- INCD-ECOIND is the first Romanian Research Institute which has implemented and certified a Quality Integrated Management System ISO 9001-EN 45001;

- QIMS is covering the whole activity domain of the Institute, inclusively the domains of Subsidiaries, and not only some parts of activity, as other Institutes.

ISO 9001 Certification was realised by the Beureau Veritas Quality International – BVQI (Certificate No 60163/1999), and EN 45001 Accreditation by the National Association for Accreditation in Romania – RENAR (Certificates Nos 136-137-138 L/2000).

#### THE STRATEGY OF HARMONISATION OF EXISTENT QIMS TO REGULATIONS OF THE NEW STANDARDS ISO 9001-2000 AND ISO/CEI 17025-2000

For elaborating this strategy, the following aspects were took into consideration:

##### A. *Novelty aspects of ISO 9001-2000*

- Five important elements of ISO 9001-2000:

- quality management system;
- management responsibility;
- resource management;
- research (product) realisation;
- measurement, analysis and improvement.

- ISO 9001-2000 are based on the process model (Crosby, orientation to the client), while ISO 9001-1994 are based on quality loop (Juran, orientation to the production).

- A better compatibility of ISO 9001-2000 with Deming Circle.

- ISO 9001-2000 has requirements regarding to continual improvement of the performance of organisation.

- Six obligatory procedures:

- documentation requirements (4.2.3);
- control of records (4.2.4);

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- internal audit (8.2.2);
  - control of nonconforming product (8.3);
  - corrective actions (8.5.2);
  - preventive actions (8.5.3).

*B. Novelty aspects of ISO/CEI 17025-2000*

- Including all requirements of ISO 9001/9002-1994 which are applicable on testing services.
- Taking measures regarding treatment of the remained materials from testing (measures regarding the discharge of toxic substances into environment).
- The importance of interlaboratory tests and abilities – an important requirement for recognising the competence.
- Classification of the main elements in:
  - quality management requirements;
  - technical requirements.

*C. Correlation between ISO 9001-1994 and EN 45001-1993 requirements and the new standards ISO 9001-2000 and ISO 17025-2000 requirements (Table 2)*

The strategy of harmonisation of existent QIMS to the new regulations follows Deming Circle and is structured in four directions:

- Preparing for harmonisation:
  - identification of the differences between standards;
  - intensive training of personnel.
- Performing of harmonisation activity:
  - procedures revision;
  - MAC-9001 and MAC-45001 revision;
  - implementation of elaborated system documentation.
- Checking the activity:
  - performing internal audits.
- Analysing and acting activity:
  - elaboration and implementation of corrective and preventive actions program (if it is necessary);
  - management review;
  - performing Certification and Accreditation audits;
  - validation QIMS by obtaining of ISO 9001 Certification and ISO/CEI 17025 Accreditation for testing laboratories.

**Table 2.** Correlation between ISO 9001-1994 and EN 45001-1993 requirements and the new standards ISO 9001-2000 and ISO 17025-2000 requirements

ISO 9001-2000	ISO 9001-1994	ISO/CEI 17025-2000	EN 45001-1993
1	2	3	4
-	4.1	-	-
5.1+5.3+5.4.1	4.1.1	4.1.3+4.2.2	5.4.2
-	4.1.2	-	-
5.5.1	4.1.2.1	4.1.5afh+4.2.4+4.9.1a+4.10.1+5.2.5	4.5.1+5.4.2ca
6.1+6.2.1	4.1.2.2	4.1.5agh+5.5.1	5.2
5.5.2	4.1.2.3	4.1.5i	5.4.2
5.6.1+8.5.1	4.1.3	4.1.4	5.4.2
-	4.2	-	-
4.1+4.2.2	4.2.1	4.2.1+ 4.2.2+4.2.3	5.4.1+5.2.4+5.4.2de
4.2.1	4.2.2	4.2.1+ 4.2.2+4.2.3	5.4.1+5.2.4+5.4.2de
5.4.2+7.1	4.2.3	4.2.1+ 4.2.2+4.1.4	5.4.1+5.4.2
-	4.3	4.4	6.1
-	4.3.1	-	-
5.2+7.2.1+			
7.2..2+7.2.3	4.3.2	-	-
7.2.2	4.3.3	-	-
7.2.2	4.3.4	-	-
-	4.4	1.5+5.4.2+5.4.3+5.4.4+5.4.5	(5.4.1)
-	4.4.1	-	-
7.3.1	4.4.2	-	-
7.3.1	4.4.3	-	-
7.2.1+7.3.2	4.4.4	-	-
7.3.3	4.4.5	-	-
7.3.4	4.4.6	-	-
7.3.5	4.4.7	-	-
7.3.6	4.4.8	-	-
7.3.7	4.4.9	-	-
-	4.5	4.3+5.4.7+5.5.11	5.4.2d+5.4.4
4.2.3	4.5.1	-	-
4.2.3	4.5.2	-	-
4.2.3	4.5.3	-	-
-	4.6	-	-
-	4.6.1	4.6+5.5+5.6.1+5.6.2.1+5.6.2.2	(5.4.2d)
7.4.1	4.6.2	4.5+4.6	5.4.7
7.4.2	4.6.3	4.6	(5.4.2d)
7.4.3	4.6.4	4.5+4.6.4+4.7+5.5.2	(5.4.2d)

to be continued

Continuation of Table 2

1	2	3	4
7.5.4	4.7	5.8+5.10.6	5.4.5
7.5.3	4.8	5.5.4+5.8	5.4.5
6.3+6.4+			
7.5.1+7.5.2	4.9	4.12+5.3+5.4+5.5+5.8+5.9	5.4.1+5.4.2
-	4.10	-	-
7.1+8.1	4.10.1	5.4	5.4.1
7.4.3+8.2.4	4.10.2	4.5+4.6+5.5.2+5.8	5.4.1
8.2.4	4.10.3	4.9+5.5.9+5.8.3+5.8.4+5.9	5.4.1
8.2.4	4.10.4	5.4.7+5.9+5.10.1	5.4.1
7.5.3+8.2.4	4.10.5	4.12.2	5.4.3+5.4.4
7.6	4.11	5.3+5.4+5.4.1+5.4.5+5.5+5.6	5.3.3
7.5.3	4.12	5.5.12+5.8+5.9.2	5.4.5
8.3	4.13	4.9	5.3.3+5.4.2g
-	4.14	4.10+4.11	5.4.2
8.5.2+8.5.3	4.14.1	-	-
8.5.2	4.14.2	-	-
8.5.3	4.14.3	-	-
7.5.1+7.5.5	4.15	5.9	5.4.5
4.2.4	4.16	4.12	5.4.3+5.4.4
8.2.2+8.2.3	4.17	4.10.5+4.13	5.4.2
6.2.2	4.18	5.2+5.5.3	5.2
8.1+8.2.3+			
8.2.4+8.4	4.20	5.9	(5.4.3)

## CONCLUSIONS

In order to impose and maintain in the top of research activities and environmental services, INCD-ECOIND must also take account of the new regulations from the quality management field.

From this point of view INCD-ECOIND has initiated the existent QIMS harmonisation activity to the new standards (ISO 9001-2000 and ISO/CEI 17025-2000) requirements.

At the same time, with this actions, INCD-ECOIND contributes at Romania's effort in its approach for the European Union integration.

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## REFERENCES

1. ISO 9001-2000. Quality Management Systems – Requirements.
2. ISO/CEI 17025-2000. General Requirements for Testing and Standardising Laboratories Competence.
3. ISO 9001-1994. Quality Systems-Model for Quality Assurance in Designing, Development, Production, Mounting and Service.
4. EN 45001-1993. General Criteria for Testing Laboratories Activity.
5. ISO/CEI 25-1990. General prescriptions for Testing Laboratories Competence.
6. N. ROTARU, M. NICOLAU: Assurance Quality Book MAC-9001, 1999.
7. M. OLARU: Quality Management. Economical Ed., Bucharest, 1995, p. 350.
8. G. REVOIL: Quality Assurance in Analytical and Testing Laboratories. Technical Ed., Bucharest, 1997.
9. M. MIRAMS, P. McELHERON: ISO 9000 Certification, Teora Ed., 1998, p.264.
10. Symposium “How to Implement a Quality Management System ISO 9000-2000”, Bucharest, February 2001.

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