Risk in conformity assessment

Leonid DVORKIN
Responses adapted for the needs of our clients

Guarantee conformance of products
Standards, specifications, directives, norms national, european or international

Managing organisation
ISO 9001, ISO 14001, OHSAS 18001, ISO 27001, ISO 50001
ISO 22000, ISO 13485, ISO/TS 16949, AS 9100, IRIS

Évaluating and valorising obligations
Management models, universal and specific

Measuring today to prepare tomorrow
AFAQ Global Performance. AFAQ 1000NR
Superior pilotage models. Solutions for sustainable development
**Risk - effect of uncertainty on objectives**

**NOTE 1** An effect is a deviation from the expected — positive and/or negative.

**NOTE 2** Objectives can have different aspects (such as financial, health and safety, and environmental goals) and can apply at different levels (such as strategic, organization-wide, project, product and process).

**NOTE 3** Risk is often characterized by reference to potential **events** (2.19) and **consequences** (2.20), or a combination of these.

**NOTE 4** Risk is often expressed in terms of a combination of the consequences of an event (including changes in circumstances) and the associated **likelihood** (2.21) of occurrence.

**NOTE 5** Uncertainty is the state, even partial, of deficiency of information related to, understanding or knowledge of an event, its consequence, or likelihood.

ISO Guide 73:2009, definition 1.1
Risks mapping for coal industry

4 main risk centers on results of operational and financial activities

Strategy risks
High oil prices increase coal consumption
CO2 emissions reduce coal extraction

Ecology/security
monitoring
for law compliance
incidents investigation
for minimization

Risk centre

Operational efficiency
manual labor substitution to equipment
for extraction in hard conditions
assets diversification
for shareholders effectiveness

Financial risks
price instability affects on cash flow
percentage yields affects on profits
CE Marking (e.g. Medical Devices)

Conformity Procedures

- **Type examination**
  - Annex III

- **Product Quality Assurance**
  - Annex VI
  - ISO 13485 -/-(A)

- **Production Quality Assurance**
  - Annex V
  - ISO 13485 -(B)

- **Statistical**
  - 100%

- **Design dossier**
  - Annex II

- **Full Quality Assurance**

- **No NB**

- **NOTIFIED BODY**

- **CE-mark**

- **Manufacturer ‘self-declaration’**
  - Annex VII

- **Technical File (>5 year)**

- **Product Verification**
  - Annex IV

- **Technical File**

- **Design dossier**

- **ISO 13485**
Technical file

- **Design control**
  - Product information & specification
  - Design / Type test reports (Ess. Req.)
  - Risk analysis
  - Label & user information (translation)

- **Production control**
  - Manufacturing process information

- **Final test reports**
  - Quality Assurance system for:
    - design, process and/or final test

Risk classification

18 classification rules:

- External / internal the body
- Duration: 1 hour / 30 days / long-term
- Location in the body: central circulatory or nervous system
- Therapeutic / diagnostic
- Administer energy / substances (medicines)
- Active / non-active
- Sterile or measurement function
- Special devices (i.e. blood-bags)
Risk classes

- Low risk
  class I: i.e. non-invasive
- Medium risk (low danger)
  class IIa: i.e. invasive - short (60 min - 30 days)
- Medium risk (hazardous)
  class IIb: i.e. invasive - long (> 30 days)
- High risk
  class III: i.e. contact vital organ

→ important for the assessment procedure only!

Conformity procedures

depends on:

- Risk classification;
- Availability of information
- Quality system implementation / certification
- Suppliers and sub-contractors
- Manufacturer decision
ISO 31000 – base for management system integration
ISO 14001/OHSAS 18001
Risk analyses

Review
- Activities
- Production
- Services
- Processes
- Ecology and OH&S significance
- Previous and current actions

Ecology aspects – risks for environment
Hazards – risks for health

Actual data
Drainage systems
- Dumping content
- Specification
- Norms
- Public expenses
- Carrying-away
- Penalty charges
ISO/14001/OHSAS 18001 PLANNING

- Policy
- Risk Assessment
- Legislation

Objectives

Management programs
Information security risks

Threats -> Vulnerabilities

Exploit

Increase

Vulnerabilities -> Assets

Expose

Increase

Assets -> Risk

Increase

Have

Risk = Threat \times Vulnerability \times Value

Potential Impact on Business

Security Requirements

Increase

Reduce

Indicate

Protect Against

Met by

Controls

Risks

Asset Values
<table>
<thead>
<tr>
<th>EA SECTORIAL SKILLS/EA CODES</th>
<th>Quality</th>
<th>Environment</th>
<th>Safety</th>
<th>Exceptions</th>
</tr>
</thead>
<tbody>
<tr>
<td>1d Fishing</td>
<td>Normal</td>
<td>Normal</td>
<td>High</td>
<td>Q- H for fish products</td>
</tr>
<tr>
<td>3 Food products, beverage &amp; tobacco</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>Q – H for meat, dairy, child food</td>
</tr>
<tr>
<td>17b Pressure Vessels</td>
<td>H</td>
<td>N</td>
<td>N</td>
<td></td>
</tr>
<tr>
<td>25 Production &amp; distribution of electricity</td>
<td>N</td>
<td>N</td>
<td>N</td>
<td>Q - H if nuclear hydraulic, thermal</td>
</tr>
<tr>
<td>28 Construction, civil engineering</td>
<td>N</td>
<td>H</td>
<td>H</td>
<td>H - if basic nuclear installation</td>
</tr>
</tbody>
</table>
### Preparing the audit
Allocation of audit team

<table>
<thead>
<tr>
<th></th>
<th>Normal</th>
<th>High</th>
</tr>
</thead>
<tbody>
<tr>
<td>LA on his/her own</td>
<td>Generalist (or specialist) Qualified on the scope of competence concerned</td>
<td>Specialist Qualified on the scope of competence concerned</td>
</tr>
<tr>
<td>Audit team</td>
<td>Generalist (or specialist) One of the auditors is qualified on the scope of competence concerned</td>
<td>Specialist One of the auditors is qualified on the scope of competence concerned</td>
</tr>
</tbody>
</table>
Conducting the audit. Finding results

- **Non-conformity** - failure to satisfy a standard requirement affecting the organisation introducing a proven risk of recurring or unique non respect of a specified requirement

The risks to be taken into account concerned are as follows:
- In quality, they mainly concern Clients.
- In health and safety, they mainly concern Staff.
- In environment, they mainly concern the Community in a broad sense.

- **Minor Non Conformity** - failure to satisfy a requirement of the reference criteria affecting the organisation, not leading to a significant risk of non respect of a specified requirement.

- **System Weakness** - Element of the Management System, upon which audit evidence shows that the organisation risks no longer reaching the reference criteria requirements, in the short or long term.
Conducting the audit
Documented report

Executive Summary of Strengths

- Customers / Business
- Procedures - organisation – business line – operational expertise
- Learning Curve – resources – continuous improvements
- Observed best practices Strong points

Executive Summary of Weaknesses

- Identified risk –
- Impacts of the management system
- Weak points
- Identified opportunities for improvement

Technical aspects of the audit

- Exclusions - Outsourcing – Justifications
- Requirements linked to regulations and legislation:
- Handling of client complaints

Nonconformity Report

- Organisation: XXXXX - Audit: [02/2009]
- Minor N°01

Nonconformity noted

- Requirement reference – Standard clause number or procedure reference ISO 9001:2008 7.5.3
- Evidence: Findings results.

Description of nonconformity / System NC:

- Lack of identification system for pre-cast concrete units at production stages (marking and cutting of reinforcing steel, assembling and welding of carcasses, concreting in forms, warehousing and delivering).
- Risk (client/product/process/system): Inequality, for productionb processes.
- Sites concerned: Reinforcing workshop, assembling workshop
AFAQ 100NR Sustainable development.
Integration of three spheres

- Well-being of people
- Taking health into account
- Respect people (diversity)
- Considering employee as a stakeholder
- Manage relations with Unions, government representatives, neighbourhood

- Respect the environment
- Use clean technology
- Take biodiversity into account
- Eco design
- Wastes, recycling
- Re use

- Access to new markets,
- Share the added value,
- Earn money,
- Increase stakeholders confidence,
- Minimize risks,
- Attract investors,
- Innovate, find new values
- Social corporate investments
Ecological footprint and human development indicator

Source: Aurélien Boutaud, ENSMSE, RAEE - 2003
Reference framework covering the 3 mainstays of sustainable development

- **PRODUCT**
  - Ecolabel
  - NF environment
  - Fair trade
  - Max Havelaar label
  - PEFC
  - FSC

- **SYSTEM**
  - OECD
  - GRI
  - Global Compact
  - Green book
  - SIGMA
  - SD 21000
  - ISO 14001
  - Q-RES
  - SA8000
  - AA1000
  - VMS

- **Strategic/system management**
  - ILO, OHSAS...
  - Strategy / management system

**Standards-based approach**

**Private initiatives**

**Reporting - private initiatives**

**Charters, declarations**
Sustainable development improvements are compatible with the goals of risk assessment: to protect nature, human health while maintaining sustainable forms of economic development.

The concept of sustainable risk suggests that cost-benefit analysis can also be applied to a broader economic development issue, The burden on future generations shall be minimized by
- selecting disposal options for radioactive wastes which do not rely on long-term institutional controls as a necessary safety feature;
- implementing these disposal options at an appropriate time, technical, social, and economic factors being taken into account;
- ensuring that there are no predicted future risks to human health and environment that would not be currently accepted
1. Strategic approach and managerial practices

1.1 Vision and strategy
1.2 Managing the strategic approach
1.3 Modes of production, consumption and sustainability of products
1.4 Territorial involvement
1.5 Managing human resources

2. Results

2.1 Environmental results
2.2 Social results
2.3 Economic results

AFAQ 1000NR: Measure your responsible strategic approach today to prepare for tomorrow
1. Strategic approach and managerial practices

1.1 Vision and strategy
1.2 Managing the approach
1.4 Territorial presence

2. Results

<table>
<thead>
<tr>
<th>2.1 Environmental results</th>
</tr>
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<table>
<thead>
<tr>
<th>2.2 Social results</th>
</tr>
</thead>
</table>

<table>
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<th>2.3 Economic results</th>
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</thead>
</table>

### AFAQ 1000NR assessment criteria

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<tr>
<th>Criterions</th>
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<tbody>
<tr>
<td>1.1.4 The company determines its significant issues based especially on the identification of risks</td>
</tr>
<tr>
<td>1.2.5 The information and data on products, activities and the system are analyzed and used: risk data in the economic, social and environmental fields are identified and used</td>
</tr>
<tr>
<td>1.4.1 The company integrates the characteristics of its territory in its risk analysis</td>
</tr>
<tr>
<td>2.1.4 Biodiversity: habitats are located in zones affected by the activities, listed by level of risk of extinction</td>
</tr>
<tr>
<td>2.2.6 Human rights: activities identified as presenting a significant risk of incidents</td>
</tr>
<tr>
<td>2.2.7 Civil society: percentage and total number of strategic business areas analyzed for the risks related to corruption</td>
</tr>
<tr>
<td>2.3.1 Economic performance: financial implications and other risks and opportunities for the organisation’s activities as a result of climate change</td>
</tr>
</tbody>
</table>
RESUME

Risk management in conformity assessment helps to ensure confidence for products and systems and to minimize risks for today business and customers taking into account the needs of future generations.

Thanks for attention!

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