Implementing Risk Management in a regulatory process:
The experience of the Conformity Assessment Directorate, INMETRO
Inmetro

- Scientific and Industrial Metrology
- Legal Metrology
- Metrology for Life
- Conformity Assessment
- Accreditation of Certification & Inspection Bodies and Laboratories
- Enquiry Point for the Agreement on Technical Barriers to Trade (WTO)
- Innovation & Technology
- RBMLQ-I (Inmetro’s Network)
Conformity Assessment

- External Affairs and Special Projects Development
- Conformity Assessment Programs and Technical Regulations Development
- Market Surveillance
- Guidance and Quality Incentive
Risk management in the Directorate

- Researchers have been following the works of ISO and GRM;
- Establishment of a model for risk management;
- Creation of the Internal Committee for Risk Management;
- First year activities of the Committee;
- Second year: implementation of risk management in five processes.
Compliance assistance

Management approach, undertaken by all operating units of Inmetro’s Conformity Assessment Directorate, aiming to identify opportunities and threats to conformity assessment programs implementation. Plans and implements actions to treat real and potential problems related to compliance.

- Risk management for the regulatory process.
Compliance assistance program

- Supply Chain Compliance
- Consumers Information
- Certification Bodies and Laboratories Accreditation
- Market Surveillance’s Infrastructure Compliance
Compliance assistance program

- Identifies real and potential compliance problems;
- Develops Assistance Plans with other units;
- Monitors Plans' implementation;
- Establishes partnerships and strategic actions in order to communicate with stakeholders and provide information about the regulation.
Risk management in the CAP

- Responsibilities;
- Adaptation of the risk management process based on ISO 31.000;
- Definition of the risk registers (some already exist and should be systematized);
- Steps for the implementation (how things are done and how they should be done in terms of risk management, and what the strategy to implement it).
Q & A

1- How to identify risks?

- Critical aspect;
- Any deviation from our strategic objectives is a risk;
- Sources of risk.
## Sources of risk for Objective 1

<table>
<thead>
<tr>
<th>Source of Risk</th>
<th>Factors Considered</th>
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</thead>
<tbody>
<tr>
<td>Supply chain compliance</td>
<td>Amount of SME, Amount of crafts, Amount of importers, Concentration level of businesses</td>
</tr>
<tr>
<td>Economical distribution of supply chain</td>
<td></td>
</tr>
<tr>
<td>Geographical distribution of supply chain</td>
<td>Concentration level in a region/area</td>
</tr>
<tr>
<td>Technological development of supply chain</td>
<td>Knowledge level about Conformity Assessment, Knowledge level about ISO 9000 and/or Production management, Level of technological development and innovation</td>
</tr>
<tr>
<td>Formal/Legal supply chain</td>
<td>Amount of associations/relations between businesses, Level of formalization</td>
</tr>
</tbody>
</table>
Q & A

2- How to prioritize risks?

- One risk leads to another;
- Risk assessment should consider the connections.

3- When to assess risks?

- Continuous process;
- Every step of the process = new decisions = new risks;
Q & A

4- Is there a risk with a higher probability?

- Redundancy makes a risk more certain;
- Certainty makes a risk a threat/opportunity.
Maria Luiza C Martins
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