Use of Good Regulatory Practices in the Elaboration of Technical Regulations and Standards

The use of standards in regulations and best practices to identify and refer a standard in regulations

Abel HERNÁNDEZ PINEDA
Outline

The use of standards in regulations
Best practices to identify and refer a standard in regulations
The use of standards in regulations
The use of standards in regulations

LFMN
Federal Law for metrology, standards and Regulations

NOM
Reference

NMX
Public and Private Sectors

SDO’s
TC’s

ISO
IEC

Public Sector
# The use of standards in regulations

## The NOM process

<table>
<thead>
<tr>
<th>Draft</th>
<th>Project</th>
<th>Public opinion</th>
<th>Publication</th>
</tr>
</thead>
<tbody>
<tr>
<td>According with</td>
<td></td>
<td>Official gazette</td>
<td>Official gazette</td>
</tr>
<tr>
<td>- federal law for standards and regulations</td>
<td>75 d for CCNN comments.</td>
<td>60 days period for public opinion</td>
<td>Answers</td>
</tr>
<tr>
<td>- quality regulatory process (COFEMER)</td>
<td>30 d for SENER answers</td>
<td>CCNN Answers</td>
<td>NOM</td>
</tr>
<tr>
<td></td>
<td>Regulatory impact analysis.</td>
<td>45 d to modify the Project</td>
<td>Effective date</td>
</tr>
<tr>
<td></td>
<td>20 days for public opinion in the web (COFEMER web)</td>
<td>CCNN approval of the Final Project</td>
<td></td>
</tr>
</tbody>
</table>

CCNN: Advisory committee
The use of standards in regulations

NOM-001-SEDE-2012

Electrical Installations
The use of standards in regulations

NOM-001-SEDE-2013 structure

<table>
<thead>
<tr>
<th>TITLE</th>
<th>Base standards</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Scope</td>
<td>NFPA 70</td>
</tr>
</tbody>
</table>
| 2 References                                               | NOM-063-SCFI
              | NMX-J-098-ANCE                        |
| 3 Guidelines for the application of specifications and conformance | IEC 60364-1
              | IEC 61936-1                           |
| 4 Fundamentals for safety                                  | NFPA 70                             |
| 5 Specifications                                           |                                    |
| 6 Surveillance                                             |                                    |
| 7 Bibliography                                             |                                    |
| 8 Concordance with international                           |                                    |
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**NOM-001-SEDE**

Key elements

**TITLE 4: Fundamentals for safety**
Performance terms.

**TITLE 5: Specifications**
In order to comply with TITLE 4.
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**TITLE 4: Fundamentals for safety**

Protection against electric shock
Protection against thermal effects
Protection against over-current
Protection against fault current
Protection against power supply interruptions

NOM-001-SEDE
The use of standards in regulations

Regulation approach

WHAT

TITLE 4
Fundamentals for safety

HOW

TITLE 5
Specifications

NOM-001-SEDE
The use of standards in regulations

**LFMN**

Federal Law for metrology, standards and Regulations

**ART. 49**

When a NOM enforce a specification …

...it is possible to ask for autorization to use an alternative in order to comply with the purpose of the NOM…
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NOM-003-SCFI

Electrical Products – Safety requirement
The use of standards in regulations
The use of standards in regulations

Regulation approach

WHAT

Chapter 5
Fundamentals for safety

HOW

Chapter 7
NOM-003-SCFI
NMX-ANCE
Specifications
The use of standards in regulations

Regulation approach

NOM: Fundamentals for safety
Performance terms (avoid barriers to technical development).

NMX: Harmonized Specifications
In order to comply with fundamentals for safety (avoid unnecessary barriers to trade).
Best practices to identify and refer a standard in regulations
Best practices to identify and refer a standard in regulations

Guide ISO/IEC 2

Content of normative documents

Provision: expression in the content of a normative document, that takes the form of a statement, an instruction, a recommendation or a requirement.

Statement: provision that conveys information.
Instruction: provision that conveys an action to be performed.
Recommendation: provision that conveys advice or guidance.
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Guide ISO/IEC 2

Aims of standardization

fitness for purpose:

ability of a product, process or service to serve a defined purpose under specific conditions.
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ISO/IEC 17007

Guidelines for drafting normative documents suitable for use for conformity assessment
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Guide ISO/IEC 17007

**Principle 1**: separation of specified requirements for the project of conformity assessment from specified requirements related to conformity assessment activities;

**Principle 2**: neutrality towards parties performing conformity assessment activities;

**Principle 3**: functional approach to conformity assessment;

**Principle 4**: comparability of conformity assessment results;

**Principle 5**: good practice in conformity assessment.
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Guide ISO/IEC 17007

2.6 Specified requirements should be written in such a way that they facilitate the development of technology. In general, this is accomplished by:

- specifying requirements in terms of performance, rather than design or descriptive characteristics;
- specifying requirements related to the object, and not the production process for the object.
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Guide ISO/IEC 17007

5.4 Test methods
As far as practicable, test methods should describe clearly how the test is to be performed, e.g.

- the choice and preparation of samples,
- the use of testing equipment,
- the data to be recorded,
- the acceptance criteria,
- the limits to be used for accepting or rejecting the result, and
- (if relevant) what is acceptable in terms of uncertainty of measurement, accuracy, reproducibility and repeatability.
3 Risk assessment

3.1 The choice of conformity assessment system could be based upon risk assessment. Before deciding whether to develop a conformity assessment system to use an existing one, a risk assessment should be undertaken by those who have an interest in the resulting objects of conformity assessment.
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Guide ISO/IEC 51

Safety aspects – Guidelines for their inclusion in standards
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**ISK (Risk of Harm)**
- **SEVERITY OF HARM**
  - That can result from the considered hazard

**PROBABILITY OF OCURRENCE**
- Exposure to a hazardous situation
- The occurrence of a hazardous event
- The possibility to avoid or limit the harm

Guide ISO/IEC 51
Best practices to identify and refer a standard in regulations

International Standards and Guidelines

- **Guide ISO/IEC 2**: Standardization and related activities - General vocabulary
- **ISO/IEC 17007**: Guidance for drafting normative documents suitable for use for conformity assessment
- **Guide ISO/IEC 51**: Safety aspects - Guidelines for their inclusion in standards
- **Guide ISO/IEC 50**: Safety aspects - Guidelines for child safety
- **Guide IEC 104**: The preparation of safety publications and the use of basic safety publications and group safety publications
- **Guide ISO/IEC 14**: Purchase information on goods and services intended for consumers
- **Guide ISO/IEC 37**: Instructions for use of products of consumer interest
- **Guide ISO/IEC 41**: Packaging - Recommendations for addressing consumer needs
Best practices to identify and refer a standard in regulations

Standards Development Organizations (SDO’s)

The importance of SDO’s:

i) Take advantage of the specialization and division of work

ii) Avoid problems from the collective action

iii) Improve the efficiency in the decision process
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Standards Development Organization (SDO)

The approach to delegate:

i) Reduce asymmetric information;
ii) Support the public policy;
iii) Resolve complex technical issues.
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Thanks

Abel HERNÁNDEZ PINEDA
www.ance.org.mx