

# **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**

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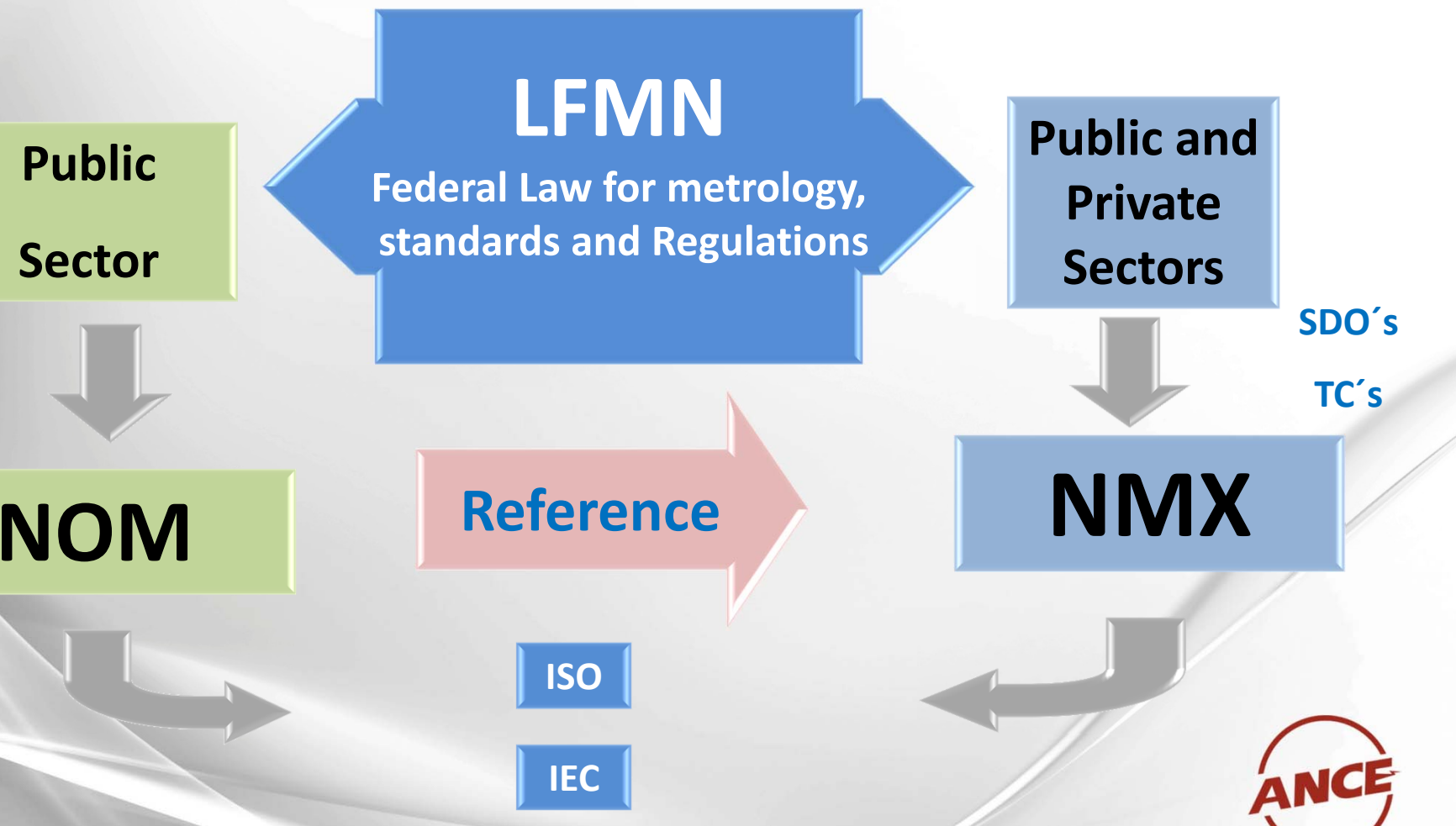
# Outline

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

# The use of standards in regulations

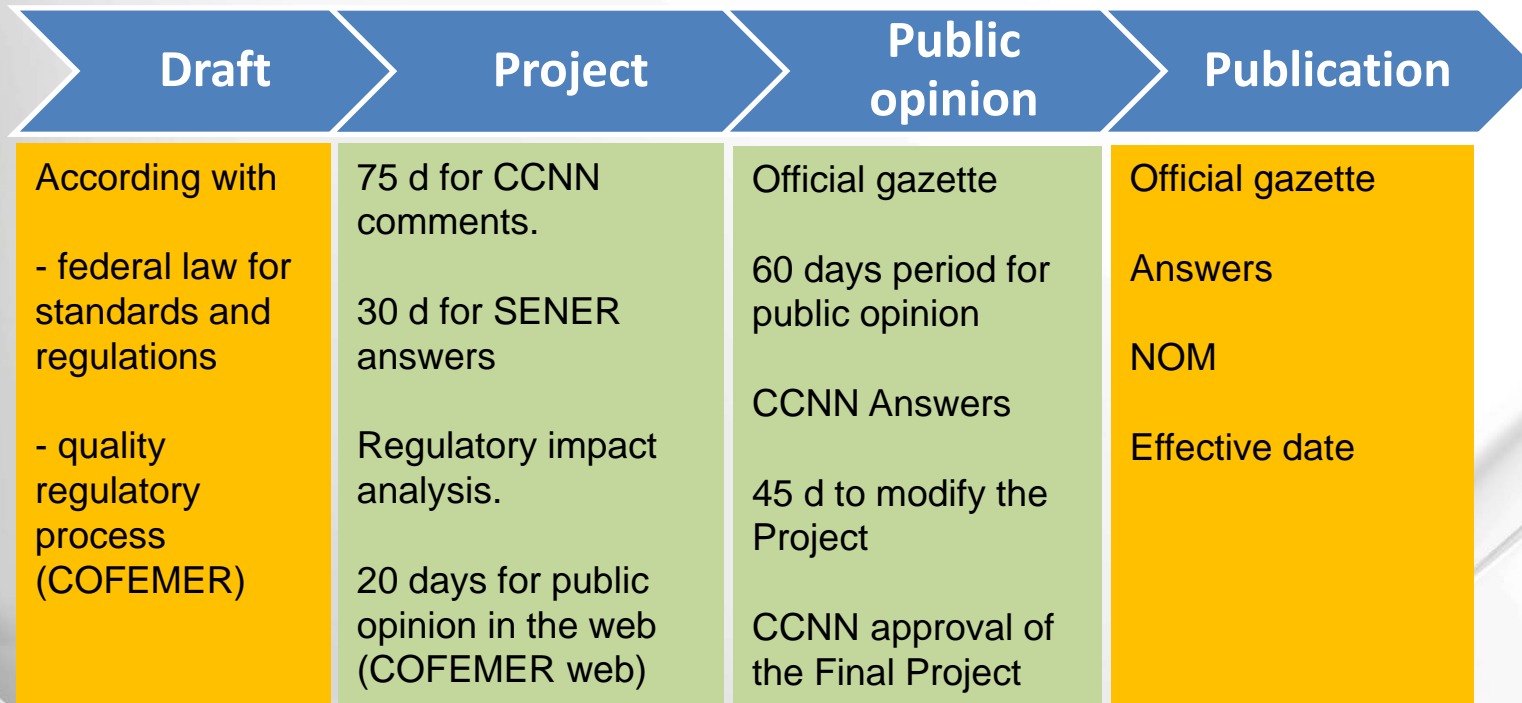


# The use of standards in regulations



# The use of standards in regulations

## The NOM process



# The use of standards in regulations

## NOM-001-SEDE-2012

Electrical Installations



## The use of standards in regulations

### **NOM-001-SEDE-2013 structure**

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

# The use of standards in regulations

## **NOM-001-SEDE**

### Key elements

#### **TITLE 4: Fundamentals for safety**

Performance terms.

#### **TITLE 5: Specifications**

In order to comply with TITLE 4.





## The use of standards in regulations

# TITLE 4: Fundamentals for safety

NOM-001-SEDE

Protection against electric shock

Protection against thermal effects

Protection against over-current

Protection against fault current

Protection against power supply interruptions



# The use of standards in regulations

## Regulation approach

NOM-001-SEDE

WHAT



HOW

**TITLE 4**

Fundamentals  
for safety

**NOM-001-SEDE**

**TITLE 5**

Specifications



## 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 authorization to use  
an alternative in order to comply with the  
purpose of the NOM...

**The use of standards in regulations**

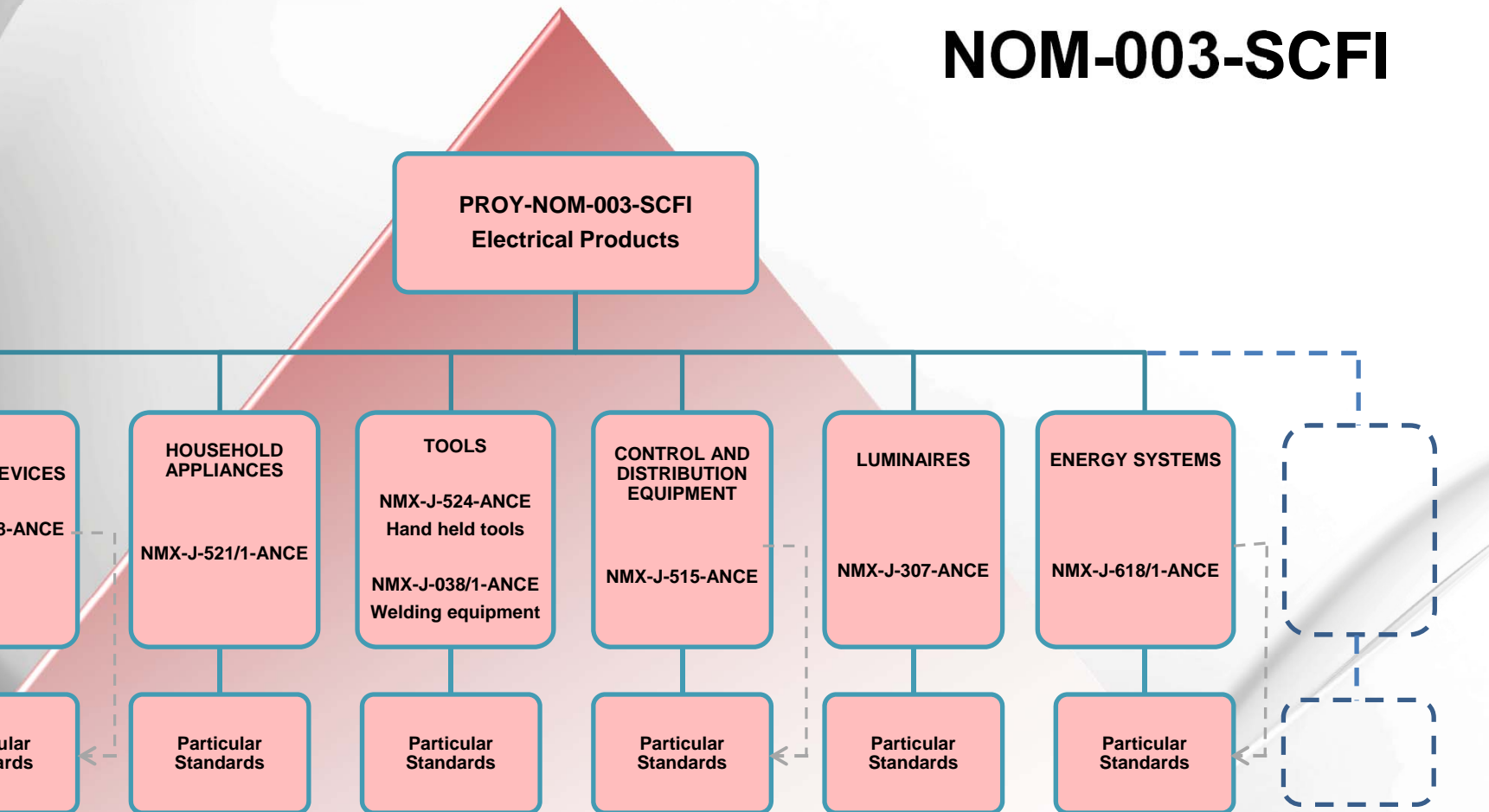
**NOM-003-SCFI**

**Electrical Products – Safety requirement**



# The use of standards in regulations

## NOM-003-SCFI



CONFORMITY ASSESMENT PROCESS



# The use of standards in regulations

## Regulation approach

WHAT



HOW

**Chapter 5**

Fundamentals  
for safety

**NOM-003-SCFI**

**Chapter 7**

**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.



# Best practices to identify and refer a standard in regulations

## 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.

**Best practices to identify and refer a standard in regulations**

**ISO/IEC 17007**

Guidelines for drafting normative documents suitable for use for conformity assessment

# Best practices to identify and refer a standard in regulations

## Guide ISO/IEC 17007

**Principle 1:** separation of specified requirements for the object 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.

## Best practices to identify and refer a standard in regulations

**Guide ISO/IEC 17007**

**2.6 Specified requirements should be written in such 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.

# Best practices to identify and refer a standard in regulations

## 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.



# Best practices to identify and refer a standard in regulations

**Guide ISO/IEC 17007**

## **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 or to use an existing one, a risk assessment should be undertaken by those who have an interest in the resulting objects of conformity assessment.



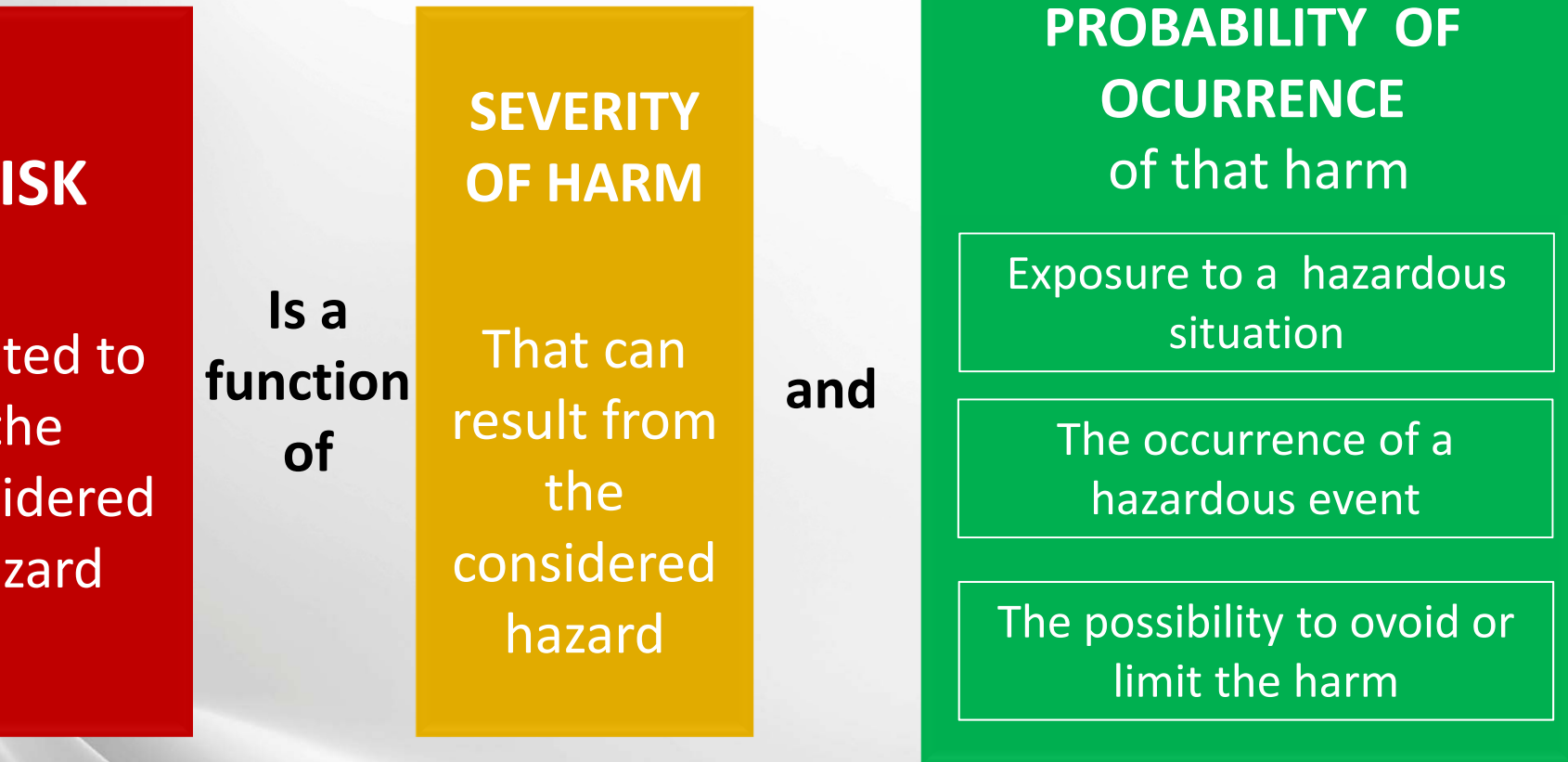
**Best practices to identify and refer a standard in regulations**

**Guide ISO/IEC 51**

Safety aspects – Guidelines  
for their inclusion in standards



# Best practices to identify and refer a standard in regulations



# 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

## Best practices to identify and refer a standard in regulations

Standards Development Organization (**SDO**)

The approach to delegate:

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

**MEXICO: NORTH AMERICAN CONFERENCE ON GOOD REGULATORY PRACTICE**

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

## **Thanks**

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