



IAEA

International Atomic Energy Agency

Development Process, Drafting Principles and Contents of Regulations and Guides [M04.L02]

**International Training Course on Regulatory Functions
for Security of Nuclear Material, Nuclear Facilities and
Associated Activities**

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Division of Nuclear Security

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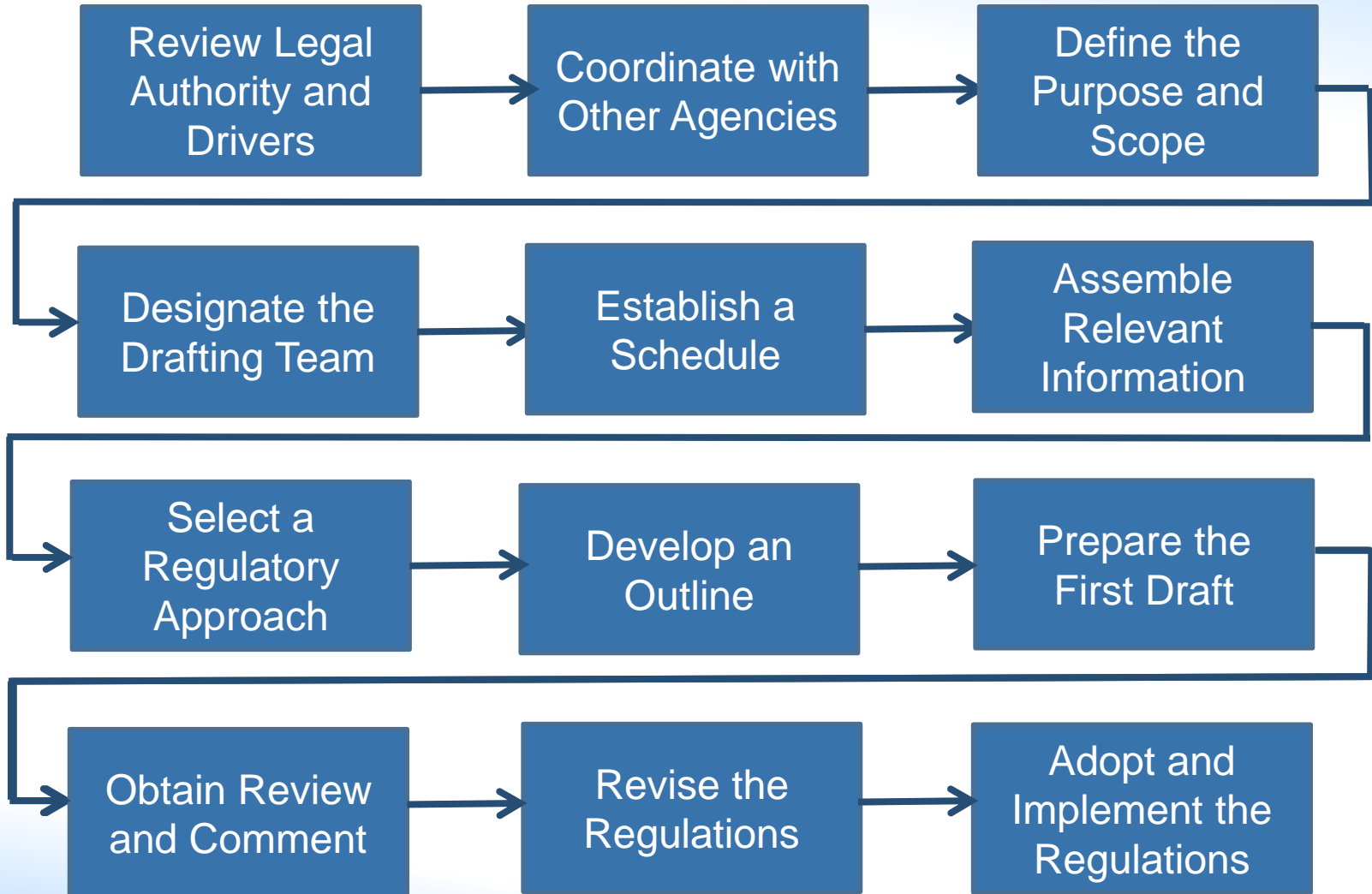
Learning Objectives



Upon completion of this lesson, participants should be able to:

1. State the content of regulations
2. Identify key subjects, references and enforcement of regulations
3. Identify general provisions and licensees responsibilities of regulations

Steps in the Regulatory Development Process



Drafting Regulations 1/2

All regulations should be drafted having regard to the:

- Legal drafting rules of the State
- Primary legislation for the regulation
- Subject degree of specificity or prescription
- Technical subject matter to be covered
- Appropriateness of the articles that are included

Drafting Regulations 2/2

- Regulations and associated administrative measures should be well-drafted to:
 - Promote understanding and compliance
 - Facilitate oversight and accountability
 - Withstand possible legal challenges

Principles for Drafting Clear Regulations



- Formatting
- Follow a Logical Sequence
- Write Clearly
- Use Mandatory Language
- Use the Active Voice
- Use Consistent Language
- Avoid Duplication
- Clear Definitions
- Facilitate Compliance and Oversight

Formatting

- Format of regulatory documents are dictated by the national requirements and/or practices
- Consistent with those requirements and practices, regulations may:
 - Include a table of contents
 - Follow an outline structure with numbers or letters
 - Group sections into larger topical units, such as chapters
 - Include a descriptive heading for each section and topical unit

Formatting: Example

Chapter I. General Provisions

Section 1: Purpose

Section 2: Scope

Section 3: Definitions

(a) Associated activity

(b) Associated facility

(c) ...

Chapter II. Specific Provisions

Section 4: Categorization of nuclear material

Section 5: Responsibilities

Follow a Logical Sequence

- Regulatory documents should be structured to facilitate understanding
- They should generally “tell a story”:
 - Flow from general matters to more specific details
 - Progress chronologically from what is done first to what is done later
- Any given provision should be understandable on its own or with reference to provisions already presented (and not require reference to later provisions)
- Readers should not have to “jump around” from one provision to another in order to understand what is expected

Write Clearly

- Use simple words
- Keep sentences short:
 - If a sentence gets too long, break it into two (or more) shorter sentences
 - Don't use a single sentence for more than one topic
- Avoid surplus phrases that add no meaning
- Put a series of three or more items into a numbered list
- Define key terms (to avoid repeating a lengthy definition in the text)

Writing Clearly: Example

Not so good:

It is required that any person, organization or government entity licensed or authorized to undertake the operation of a facility in which nuclear material is produced, processed, used, handled, stored or disposed of shall implement personnel, procedures and equipment which, in the case of unauthorized intrusion into an area to which access is limited and controlled for physical protection purposes, will immediately initiate a process that begins with sensing a potentially malicious or otherwise unauthorized act and that is completed with the assessment of the cause of the alarm.

Better?

The operator must provide immediate detection of unauthorized access to a limited access area.

Use Mandatory Language

- Regulations generally consist of requirements that operators must meet in order to avoid enforcement action for non-compliance:
 - Accordingly regulations should use words such as “must” for mandatory requirements
 - For prohibitions, regulations should use “may not” or “must not”
 - “Should” (or “should not”) is rarely appropriate for laws and regulations
- Guidance and other non-binding administrative measures should use “should” (or “should not”)

Use the Active Voice

- To fullest extent possible, regulatory documents should use active voice:
 - “**Licensees shall prepare a security plan.**”
- Regulatory documents should generally avoid the passive voice:
 - “**A security plan shall be prepared.**”
- Active voice much more clearly indicates who must implement a required measure
- Passive voice can be ambiguous about who is responsible
- Readers find the passive voice harder to comprehend

Use Consistent Language

- Regulatory documents should use a single term to represent a given concept
- For example, a regulatory document could refer to:
 - Licensees
 - License holders
 - Authorized persons
 - Operators
- Unless there is a meaningful distinction, a regulatory document should use just one of these terms, consistently throughout

Avoid Duplication

- Regulatory documents which cover the same topic more than once can create problems for users
 - Difficulty in locating all material on the topic within the regulations (and possibly not looking further once the first instance is found)
 - Uncertainty about what is required to address the topic
 - Potential inconsistencies in requirements for the topic
- To minimize these problems, regulatory documents should generally address a given topic in only one place

Clear Definitions

- Don't define a term with reference to itself (circular definition)
- Don't include terms that are not used in the document
- Don't disguise a substantive provision as a definition
- Don't include more than one term for the same idea
- Use definitions that are consistent with those in relevant international instruments and guidance wherever possible

Definitions: Example

Not so good:

Delay means the set of measures used to delay a potential adversary. Delay measures shall include doors, walls, locks, cages, tie-downs and other barriers as appropriate.

(Circular, includes substantive requirements)

Better?

Delay means increasing the time required for an adversary to gain unauthorized access, generally through barriers or other physical means.

Facilitate Compliance and Oversight



Regulations should be as specific as possible to facilitate the licensee in its understanding how to comply with requirements

Example: “Report to the regulatory body by telephone within 24 hours” is usually better than “promptly notify”

Overview of Content of Regulations



The content and structure of the regulations dictated by the national requirements. The content listed below is most common, but some of the elements might be missing or might have different place in the list.

- Title
- Purpose
- References
- Scope
- Definitions
- Substantive provisions
- Transition provisions

Title and Purpose

- Titles should be clear and reflect:
 - Subject matter
 - purpose of regulations
- Purpose of regulations should be:
 - Clearly expressed
 - Explained as reason for making regulations
 - Consistent with purpose of primary legislation
 - Important for interpretation of substantive provisions
- Date of entry into force should be clearly expressed.

References

- To relevant primary legislation or principal legislative instrument that gives authority for making of regulations
- To primary legislation providing for that regulation implements a particular aspect of a specific piece of primary legislation
- To other documents that may be developed as part of regulatory framework

Scope of the regulation should:

- Be clearly stated and indicate subject matter
- Not exceed what primary legislation authorizes
- Indicates whether earlier regulation are revoked
- May define what is not in scope
- May explicitly state the stakeholders to which the regulation applies.

Definitions

- Regulations should include all relevant definitions, unless included in primary legislation, that are essential to understanding of, interpretation of and consistent application of regulations
- Definitions have role of limiting or expanding a term beyond its ordinary meaning and of translating technical terms into common language

Substantive Provisions

- Each substantive provision of regulations should describe the key subjects that regulations relate to
- In context of nuclear security it should assist each Competent Authority that has a role and responsibility defined in legislation to clearly understand scope of its role and responsibilities
- Whether or not regulations describe this in prescriptive language is a matter of drafting style and national legal practice

Transition Provisions

The regulations may have transition provisions, for example:

- The time period after entering into force during which the existing licensees shall become compliant with new requirements
- The time period given to the regulator to issue regulatory guides supporting the named regulation
- The names of other related regulations that shall be amended and the time period given for this activity

Regulatory Guides: Need

- System of regulatory guides help the regulatory body to maintain consistency in the implementation of the regulatory requirements
- The regulatory body should establish a process for the development and promotion of guides; this ensures guides are reviewed / revised as necessary and are kept up to date
- Helps the operator to understand the regulatory requirements and how to meet them.

GSR Part 1 (Rev. 1): Recommendations 32, 33, 34:

Regulatory body establishes guides to specify / explain principles, requirements and associated criteria for security upon which its regulatory judgements, decisions and actions are based

Such guides should be:

- Periodically revised to keep current
- Promoted to interested parties

Regulatory Guides: Objectives (2/2)



NSS No. 29-G, p.p. 4.18-4.21:

- Guides, manuals and procedures are issued:
 - To guide authorized persons in complying with requirements
 - To guide inspectors in evaluating compliance and consistency of requirements
 - To provide guidance on the content of an application for authorization, the content of an authorized person's security plan and security management systems

Regulatory Guides- Examples



Regulatory guide specific to licensee/operator on:

- Access authorization
- Contents of security plan
- Security event reporting and related investigations
- Vital area identification
- Training program for security staff
- Protection of sensitive information
- Guidance for regulatory staff:
- Nuclear security inspection manual
- Assessment manual for security plan
- Manual for performance testing
- Manual related to DBT development process

Regulatory Guides: Content (1/2)

System of regulatory guides may depend on types of regulatory requirements for nuclear security:

- If regulations are prescriptive, there may be less need for guides for both licensees and inspectors;
- If regulations are performance-based, more guides and more details may be needed for licensees (with explanations and examples on how to achieve established security goals and/or performance indicators) and inspectors (how to inspect and evaluate during inspections whether they are achieved or not)

Regulatory Guides: Content (2/2)

- Regulatory body should refrain from prescribing specific solutions in its guides (rather provide examples)
- Deviations from guides (alternative approaches and measures) by licensee should be acceptable provided that the licensee can demonstrate that the required level of security is achieved.

Summary – Key Points and Discussion



- ➔ Security regulations should be drafted in accordance with:
 - Legal drafting rules of the State
 - Primary legislation under which regulation is made
 - Degree of specificity or prescription that subject requires

- ➔ Content and structure depends on regulatory approach, variety of activities, NM and NF



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Thank you!

