Program for KINS-IAEA Workshop on Radiation Safety and Emergency Response, 11th June 2019

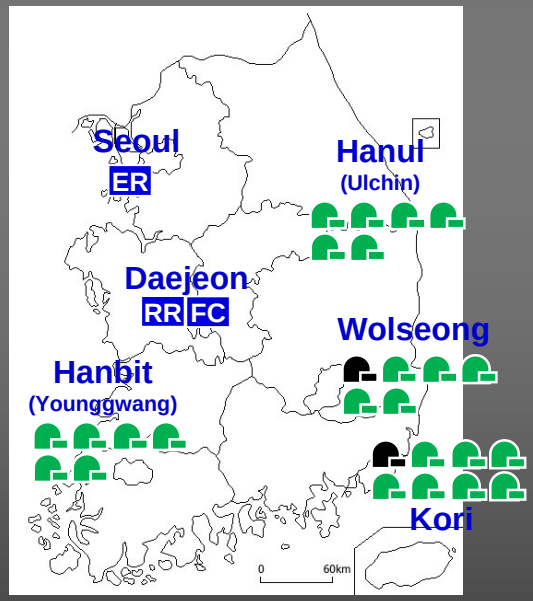
Simulation on radioactive sources licensing procedure in Korea

HAN, sang eun / Transport & Accelerator PM. Korea Institute of Nuclear Safety.

1. Regulation Overview

● Major Nuclear Facilities in Korea

- Nuclear Power Plant (NPP)
  - 24 units in operation and 2 units are closed
- Research Reactor (RR) / Educational Reactor (ER)
  - HANARO (RR)
  - AGN (ER)
- Nuclear Fuel Cycle Facility (FC)
  - Fuel Fabrication Plant for NPP
  - Fuel Fabrication Facility for RR
  - Post-Irradiation Examination Facility (PIEF)
- Radioactive Waste Management Facility (RW)
  - RI Waste Management Facility
  - Wolseong LILW Disposal Center (WLDC)



1. Regulation Overview

● Radiation use in non-NPP field

Industrial

Gagues

Non-destructive test

Medical

Linear Accelerator

Blood irradiator

Gamma knife

Proton / HCP Therapy

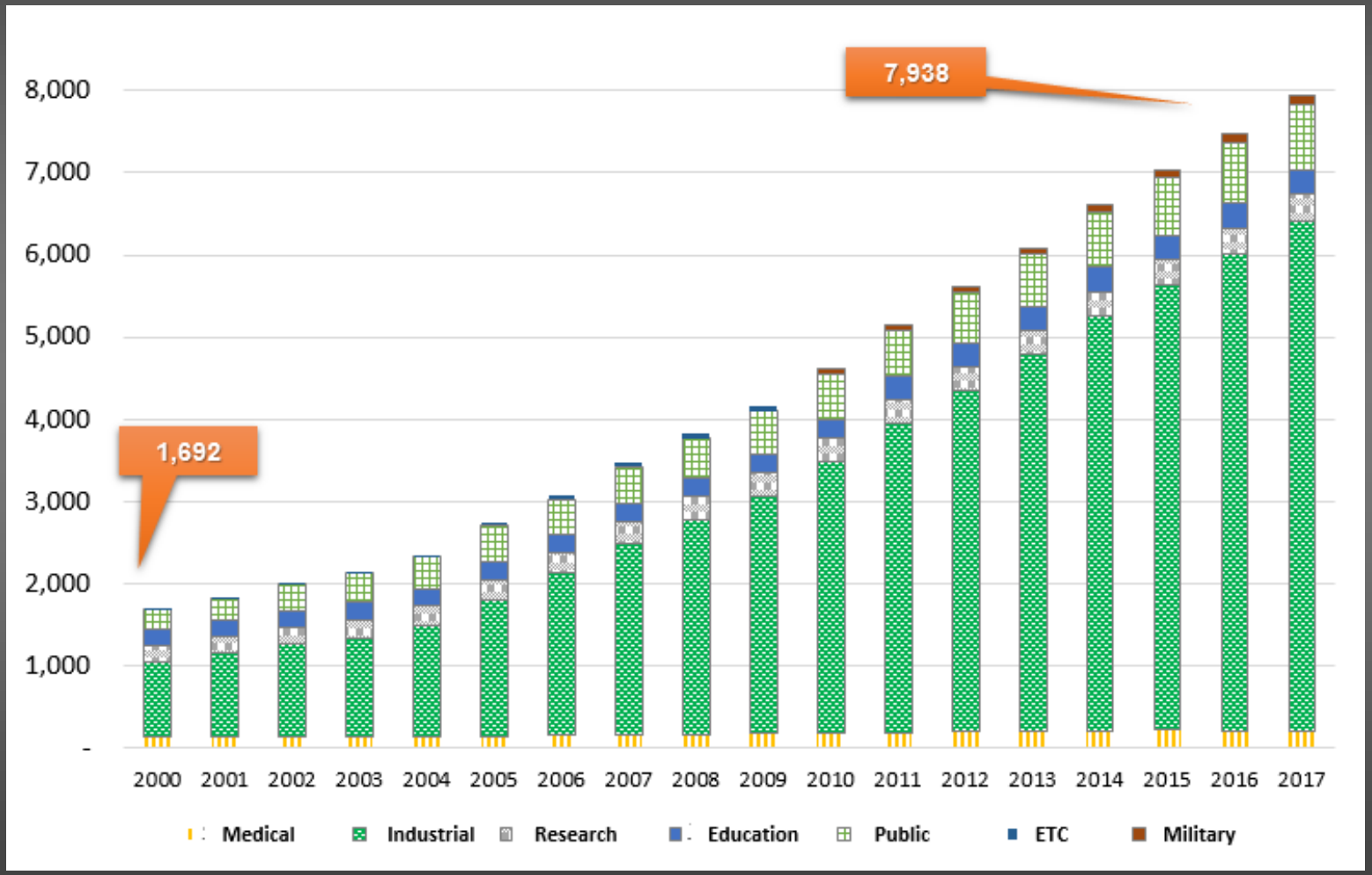
Others

Research / RI Production

Academic

1. Regulation Overview

● Increasing of users (From RASIS DB)



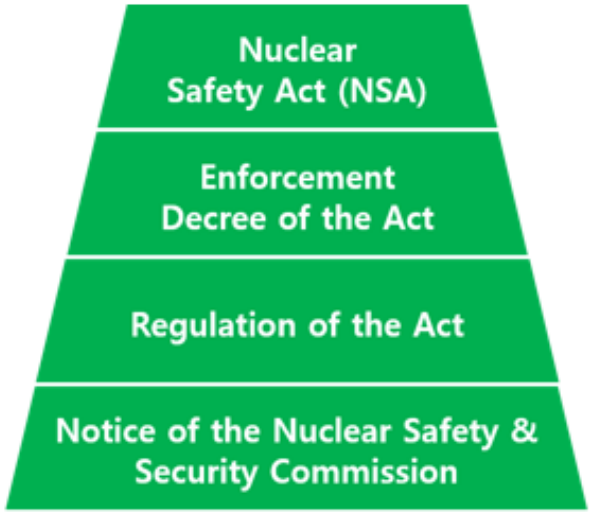
1. Regulation Overview

● Radioisotopes & Devices Licensee (May. 2019)

Sector	Notification	Permit	Total
Medical	15	181	196
Industry	5,672	1,021	6,693
Research	266	65	331
Education	132	164	296
Public	783	58	841
Military	75	32	107
Total	6,943	1,521	**8,464**

1. Regulation Overview

● Legal Framework for Nuclear Safety



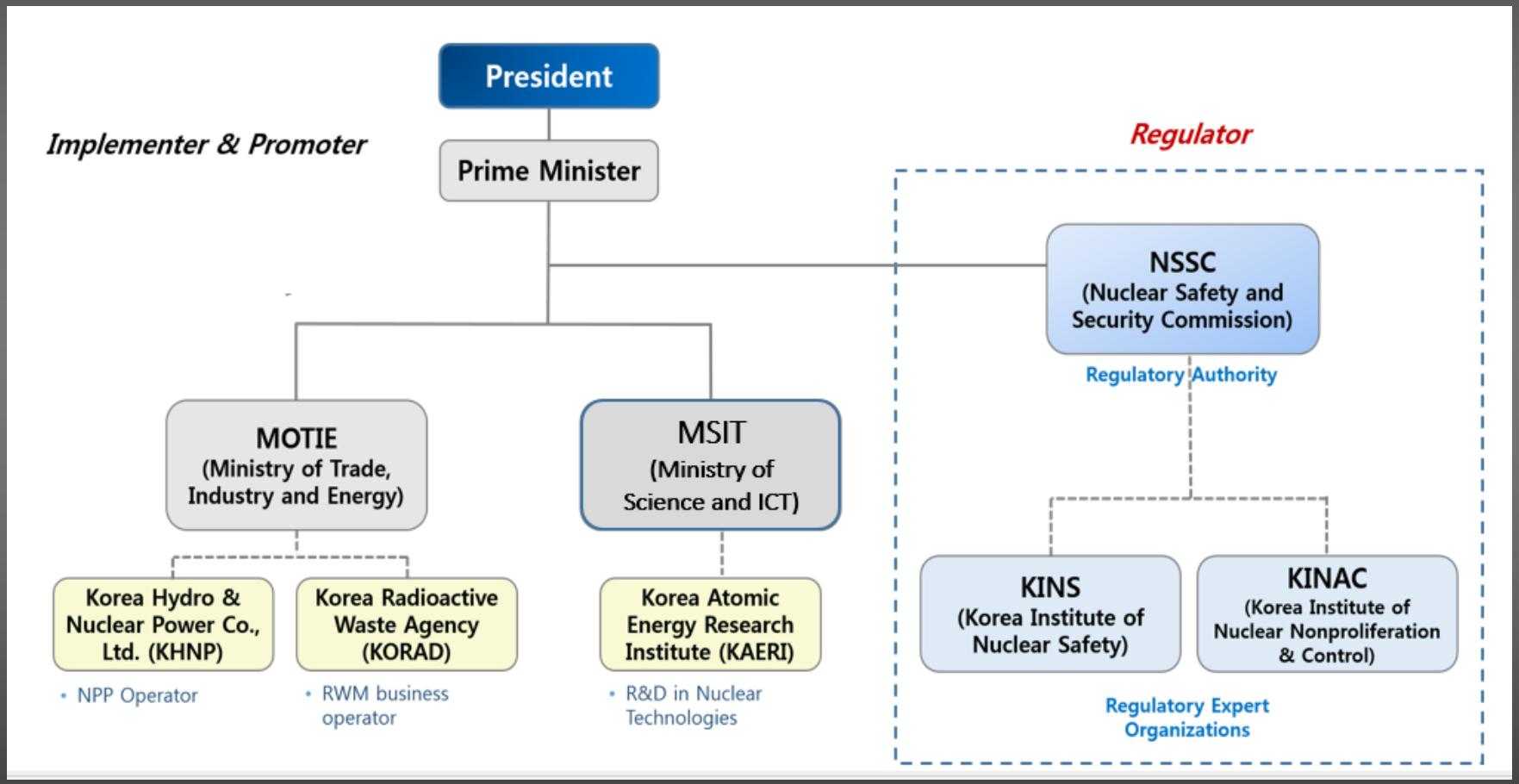
- Nuclear Safety Act (NSA): **Basic and fundamental matters** (National Assembly)
- Enforcement Decree: **Detailed requirements** necessary for implementing basic and fundamental matters in NSA (President)
- Regulation: Detailed licensing procedures, standard format of document, **basic technical standards** etc. (Prime Minster)
- Notice: **Detailed technical standards** (NSSC)

- Regulatory Standards and Guides: Interpretation, detailed criteria, acceptable methods, conditions, and specifications of the technical standards
- Safety Review & Inspection Guidelines: Staff guidance in carrying out regulatory activities

- International/domestic standards accepted by the regulatory body

1. Regulation Overview

● Radiation regulation organization



1. Regulation Overview

● Roles of Regulatory Organizations

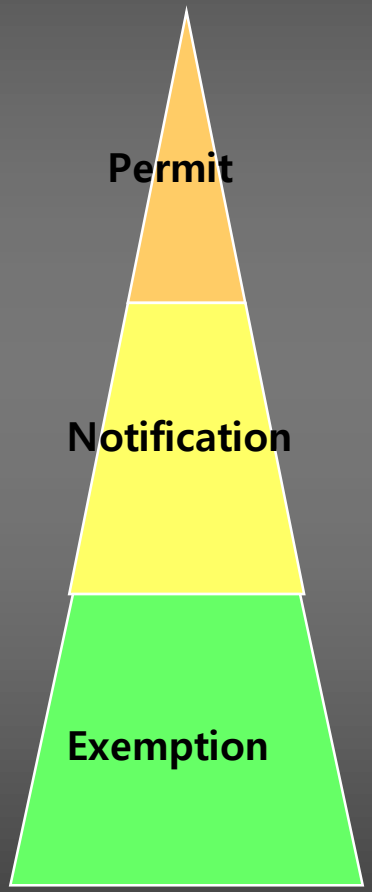
- **Nuclear Safety and Security Commission(NSSC)**
  - Regulatory authority of the Korean Government
  - Rulemaking and enforcement on nuclear facilities and activities to ensure safety and security
  - Developing and implementing nuclear regulatory polices

- **Korea Institute of Nuclear Safety(KINS)**
  - Regulatory expert organization
  - Carrying out functions concerning nuclear safety review and inspection, developing technical standards and guidelines

- **Korea Institute of Nuclear Nonproliferation and Control(KINAC)**
  - Regulatory expert organization
  - Execution of Safeguards, physical protection and export/import control regarding nuclear facilities and materials

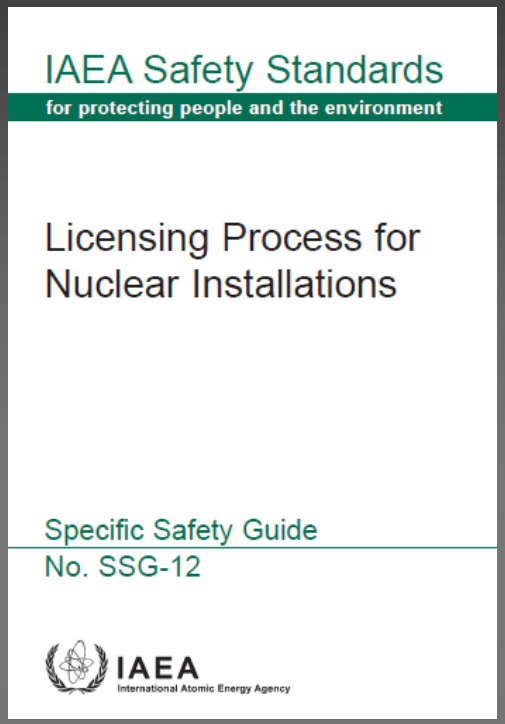
1. Regulation Overview

● Regulation system for RI & Devices



- **Permit for produce, sell, use or mobile-use of radiation sources**
  - Basically, a person who intends to produce, sell, use or mobile-use of RI or RG shall obtain permit from the NSSC
- **Notification for use of radiation sources**
  - But, a person who intends to use RI or RG which is smaller quantity or capacity than what is prescribed by the Ordinance shall notify to the NSSC
- **Exemption**
  - Exemption criteria is referring IAEA BSS (Basic Safety Standard)

2. Licensing process



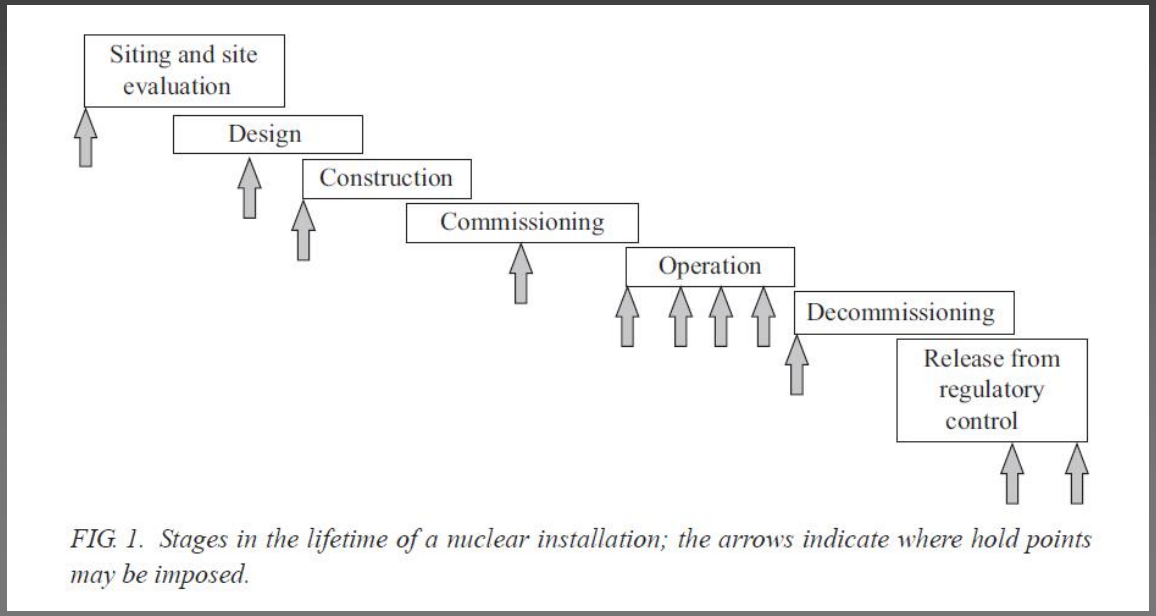
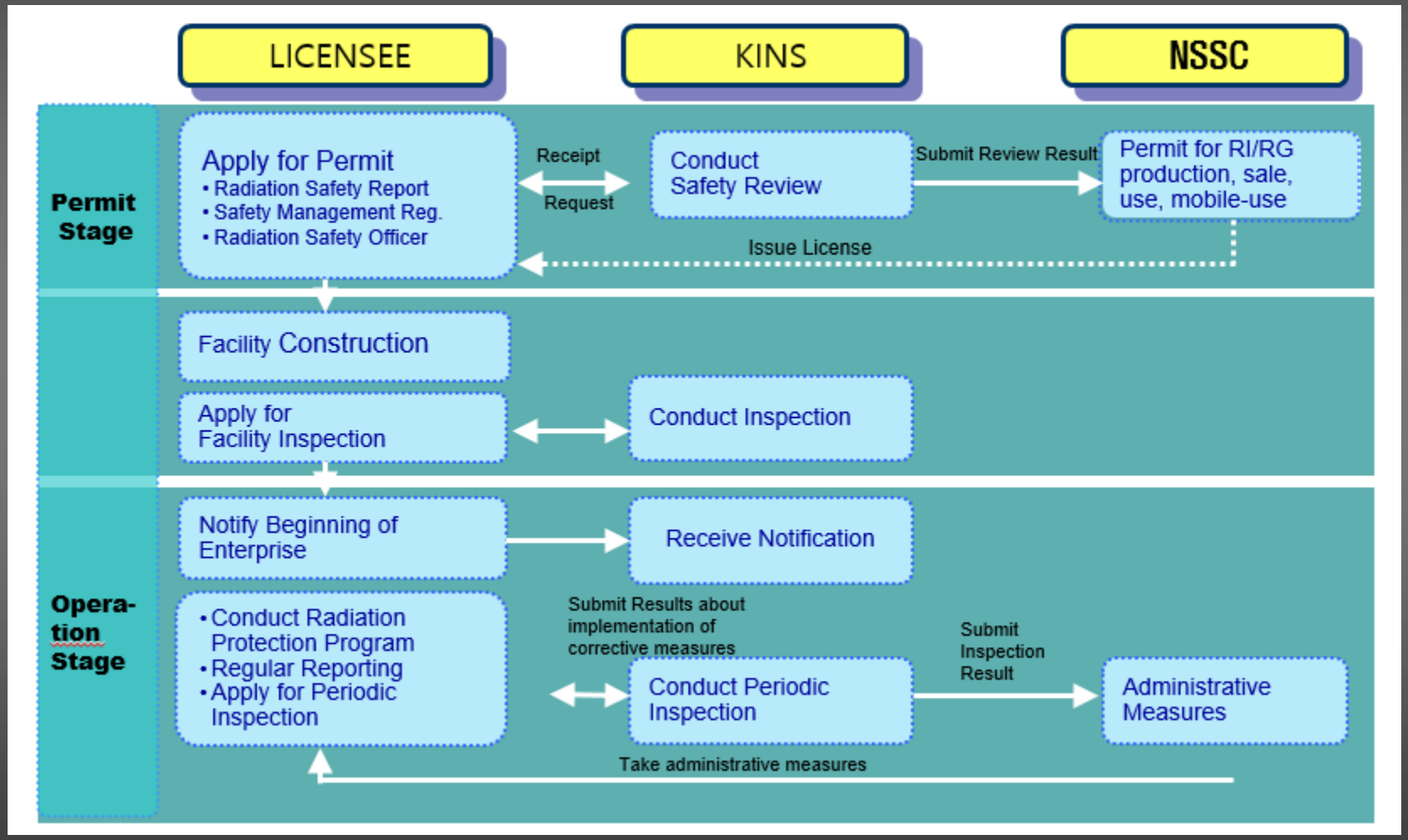


FIG. 1. Stages in the lifetime of a nuclear installation; the arrows indicate where hold points may be imposed.

- Consideration for licensing process
  - Lifetime of the facility/business
  - Each stage is able to overlap or be grouped depending on the feature of the facility
  - Regulation should be minimized to ensure safety (Effective, Rational, Harmonized)

2. Licensing process

● Licensing procedure of Radiation Sources



2. Licensing process

● [Step1] Application

● Application form

■ Nuclear Safety Act Enforcement Rules [Attached Form 50] <Amendment enacted on 11/24/2014>

Application for Radioisotope Use Permission

※ DO NOT fill columns with dark backgrounds.

receipt number	receipt date	processing date	processing period 20 days

Applicant	Name of Corporation	Business License Number
	Location	Telephone
	Representative name	Resident Registration Number
	Name of Division	
	Location of Division	Telephone
	Department Responsible	Person in charge
	Radioisotope seller (or prospective)	Telephone

I, hereby, apply for permission of radioactive isotope use, under Article 53, 「Nuclear Safety Act」, the Enforcement Ordinance, Article 79 and Enforcement Rule, Article 60.1.

(Year) (Month) (Date)

Applicant (signature or seal)

To The Nuclear Safety and Security Commission

Attached Documents	1. One (1) original copy of Radiation Safety Report containing the details of each clause of Article 58.4, 「Nuclear Safety Act Enforcement Rules」 2. One (1) original copy of Safety Management Rule containing the details of each clause of Article 58.5, 「Nuclear Safety Act Enforcement Rules」 3. One (1) original copy of documents proving the purchase of devices under Table 2 attached to 「Nuclear Safety Act Enforcement Ordinance」 4. One (1) original copy of documents proving the employment of staff required under Table 3 attached to 「Nuclear Safety Act Enforcement Ordinance」 (Plus a Proxy Service Agreement if the radiation management is outsourced under Article 58.2.6)) 5. One (1) original copy of compensation standards under Article 152.1, 「Nuclear Safety Act Enforcement Ordinance」	No fees 「charged under Table 8, 「Nuclear Safety Act Enforcement Rules」.
Matters to be confirmed by The Nuclear Safety and Security Commission	One (1) original copy of Business License	

Agreement on Shared Use of Administrative Information

With regard to processing this document, I agree on the confirmation of above details by Nuclear Safety and Security Commission through shared use of administrative information by Nuclear Safety Commission, under Article 36.1, 「E-Government Act」. *If the applicant does not agree, he is required to submit necessary documents.

Applicant (signature or seal)

process of disposal

Preparation for Application	→	Receipt	→	Documents Review	→	Preparation and Issue for Permit Certificate	→	Receipt of Permit Certificate
Applicant		Nuclear Safety and Security Commission		Nuclear Safety and Security Commission		Nuclear Safety and Security Commission		Applicant

210mm × 297mm [Wood free paper 80g / ㎡ (recycling)]

● Attached Documents

1. Radiation Safety Report
2. Safety Management Rule
3. Documents proving the purchase of devices (Radiation survey meter)
4. Documents proving the employment of staff (License for handling)
5. compensation standards

2. Licensing process

● [Step2] Safety review

1. Radiation Safety Report

- Core technical documents for radiation safety (11 chapters)
- General safety evaluation based on the legal requirements originated from radiation protection principle(ALARA, justification, optimization)
- Containing : Business plan, source characterization, working plan, safety facility(shielding, interlock, etc.), radiation effect to human & environment, emergency plan, etc.

2. Licensing process

● [Step2] Safety review

1. Radiation Safety Report (1)

chapter	Description
1. Facility Overview	
a. Business entity and target	1) Business entity 2) Name and location of the place of business 3) Purpose and necessity of the business
b. Facility overview	1) Location where the facilities are installed 2) Arrangement of the facilities 3) Structure of the facilities 4) Scale and capacity of radiation sources
2. Surrounding Environment of the Facilities	
a. Surroundings	1) Geographical conditions 2) Social environment
b. Characteristics of the working environment surrounding the facilities	1) Accessibility by people 2) Population near the Facilities
c. Characteristics of the site	

2. Licensing process

● [Step2] Safety review

1. Radiation Safety Report (2)

3. Operation Plan Overview a. Plan to pursue business b. Utilization plan c. Quality assurance plan	 1) Facility installation plan 2) Radiation purchase/sale plan 3) Staffing plan 1) Quantity of utilization, storage and sale 2) Radiation utilization plan
4. Characteristics, Location and Specifications of Radiation Sources a. Specifications and characteristics of radiation sources b. Safety devices regarding radiation sources c. Location of sources	 1) Form of radiation sources 2) Characteristics of radiation sources
5. Safety Facility Overview a. Type, specifications and performance of safety facilities and systems b. Alarms and signs	 1) Shielding 2) Facility safety devices 3) Ventilation and drainage equipment

2. Licensing process

● [Step2] Safety review

1. Radiation Safety Report (3)

6. Radiation Handling Methods and Radiation Safety Control Plan a. Radiation utilization methods b. Radiation safety control plan	1) Organization and responsibilities 2) Radiological protection policies 3) Radiation source control 4) Zone management 5) Work management 6) Individual exposure management 7) Contamination management 8) Measurement equipment and plans 9) Record management 10) Education and training 11) Safety control regulations and procedures
7. Procedures, Methods and Results of Estimated Radiation Dose Assessment a. Employees' Radiation Dose b. Radiation dose of staff in the surroundings	1) External exposure 2) Internal exposure

2. Licensing process

● [Step2] Safety review

1. Radiation Safety Report (4)

8. Radiological Impact on the Surrounding Environment a. Impact of ventilation b. Impact of drainage c. Impact of direct radiation	
9. Risks of an Accident and relevant Measures a. Accident forecast b. Measures to counter accidents c. Contingency plans	1) Type and probability of accidents 2) Impact of accidents 1) Contingency plans 2) Maintenance of an emergency response posture
10. Radioactive Wastes Generation and Treatment Plan a. Source and amount of generation b. Collection and disposal c. Disposal d. Decommissioning of the facilities	
11. General Conclusion	

2. Licensing process

● [Step2] Safety review

2. Safety Management Rule (1)

- Internal regulation documents for radiation safety (14 chapters)
- Detailed rules considering local condition

☞ Law > Decree > Regulation > Notice > Local Rule

1.Matters related to the organization that handles radioisotopes, etc. or materials contaminated by radioisotopes and the functions thereof

a. Organization chart

b. Duties

2. Matters related to the purchase, use and sale of radioisotopes, etc.

a. Purchase / Use / Sale / Production

2. Licensing process

● [Step2] Safety review

2. Safety Management Rule (2)

3. Matters related to distribution, temporary storage, transport, treatment, discharge, storage, self-disposal and delivery of radioisotopes or materials contaminated by radioisotopes

   a. Procedures

   b. Technical standards

4. Matters related to radiation dose rate, personal dose, measuring of contamination by radioactive materials or materials contaminated thereby and the recording and safekeeping of such measuring results

   a. Measurement

   b. Recording and keeping

2. Licensing process

● [Step2] Safety review

2. Safety Management Rule (3)

5. Matters related to the safekeeping, control and calibration of radiation safety control equipment
    a. Safekeeping and control
    b. Calibration
6. Matters related to personal dose assessment and personal dosimeter control regarding radiation workers
    a. Assessment of radiation exposure
    b. Management of personal dosimeters
7. Matters related to education and training necessary to prevent radiation workers or persons with frequent access from radiation hazards

2. Licensing process

● [Step2] Safety review

2. Safety Management Rule (4)

8. Matters related to measures necessary to detect occurrence of any radiation hazards

9.Matters related to necessary measures to be taken for the purpose of providing heath services to those who have been or are feared to have been been subject to radiation hazards

10.Matters related to the records as provided in Article 58 of the Nuclear Safety Act and the keeping thereof

a. Recording

b. Keeping available recorded books

11. Matters related to measures to be taken in the event of an occurrence of a risk

2. Licensing process

● [Step2] Safety review

2. Safety Management Rule (5)

12.Matters related to measures to be taken in the event of an accident including loss or theft of radioisotopes, etc. and the prevention of accidents accidents

13.Matters related to the authority, responsibilities and performance of duties of a radiation safety officer

14. Other matters necessary for protection against radiation hazards

2. Licensing process

● [Step2] Safety review

3. Documents proving the purchase of devices

- Equipment for radiation safety ; Radiation survey meter, vehicles
- Copy of contract documents, specifications, etc.

< Example of requirement >

Item	Criteria
1. Production	
a. Production of radioisotopes	Two or more sets of radiation detection equipment and radioactivity detection equipment, respectively, and one or more radiation source transportation vehicles
b. Production of radiation generating devices	Two or more sets of radiation detection equipment
2. Use	
a. Use of sealed radioisotope, or radiation generating devices	One or more sets of radiation detection equipment
b. Use of unsealed radioisotopes	One or more sets of radiation detection equipment and radioactivity detection equipment, respectively, at each facility

2. Licensing process

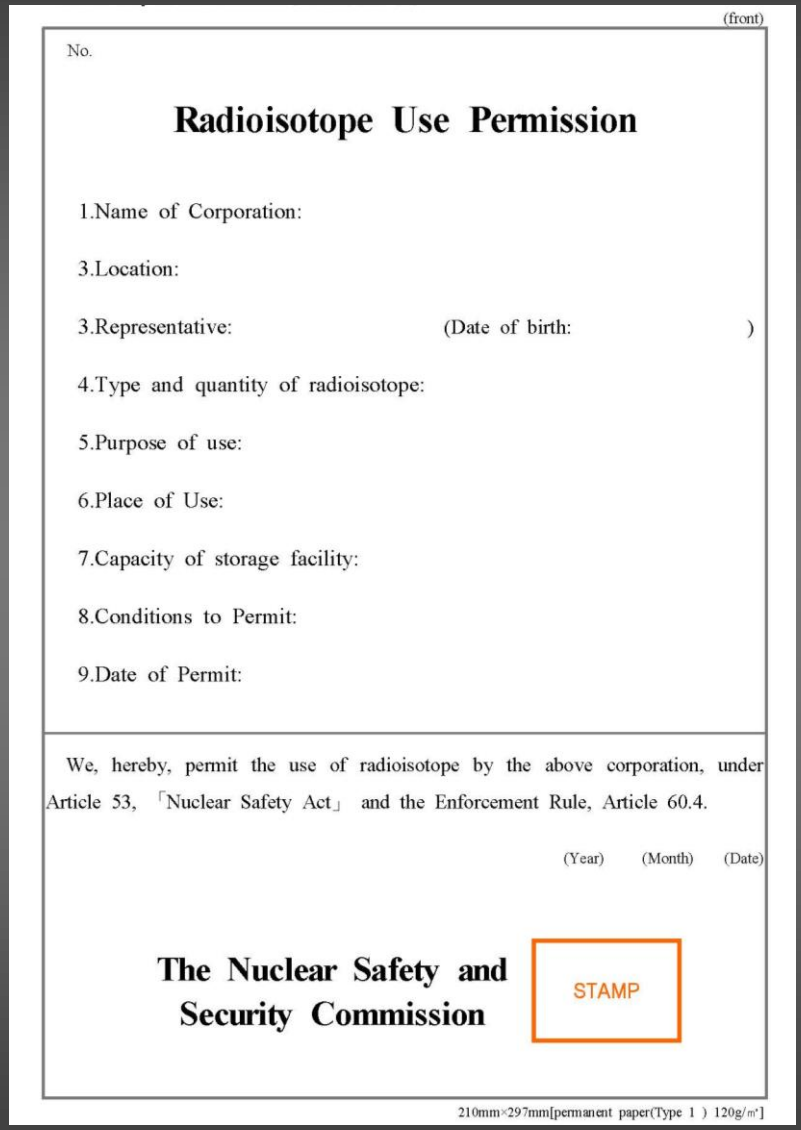
- [Step2] Safety review

4. Documents proving the employment of staff
   - Copy of employment contraction for Radiation safety officer
   - RSO's license under the Radiation Safety act (validity, category)

5. Compensation standards
   - Basic policy & duty for radiation worker
   - For damage from radiation hazard

2. Licensing process

- [Step3] Permit for application
  - Sending the safety review report from TSO to authority(NSSC)
  - Authority checks legal adequacy of application
  - Authority issues license for application with general cautions and conditions
  - Use need to keep & manage original copy of license



(front)

No.

Radioisotope Use Permission

1.Name of Corporation:

3.Location:

3.Representative: (Date of birth:)

4.Type and quantity of radioisotope:

5.Purpose of use:

6.Place of Use:

7.Capacity of storage facility:

8.Conditions to Permit:

9.Date of Permit:

We, hereby, permit the use of radioisotope by the above corporation, under Article 53, 「Nuclear Safety Act」 and the Enforcement Rule, Article 60.4.

(Year) (Month) (Date)

The Nuclear Safety and Security Commission

STAMP

210mm×297mm[permanent paper(Type 1) 120g/㎡]

2. Licensing process

- [Step4] Facility inspection
  - User is construct or setting up radiation facility after getting license
  - Inspection is conducted between issuing license and commissioning of facility
  - When user apply facility inspection, inspector conduct on-site inspection
  - Preparation status, facility identification to licensing condition, technical performance of safety equipment (Testing, sampling, simulation, interview, etc.)
  - User is possible to operate facility officially

2. Licensing process

- [Step5] Periodic inspection
  - licensee need to be examined periodically from the authority
  - Period varies depending on the amount of radiation source & radiation risk of its facility (1/3/5 years)
  - Inspection scope is including whole radiation safety activities related operation from former inspection to present
  - Inspector check and evaluate adequacy
  - Violations are reported to the authority and penalties are executed (Fine, Ceasing of operation, administrative penalty, warning, etc.)

3. Others

- (Change of license) licensee who want to change the facility or licensing condition need to apply (or notice) renewal of license
- (Report) licensee are need to report to the authority about source & radiation waste inventory in every quarter year (national inventory system)
- (Emergency notice) Emergency situation such as over exposure, radiation hazard, source leakage, etc., licensee should notice to the authority immediately
- (On-site disposal) licensee are able to dispose radioactive waste on one's site under permission of the authority for low level waste (exemption)

Thank you
for attention