

# Regulatory Program of Radiation Sources in Medical Use

**June 11, 2019**

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**KINS**

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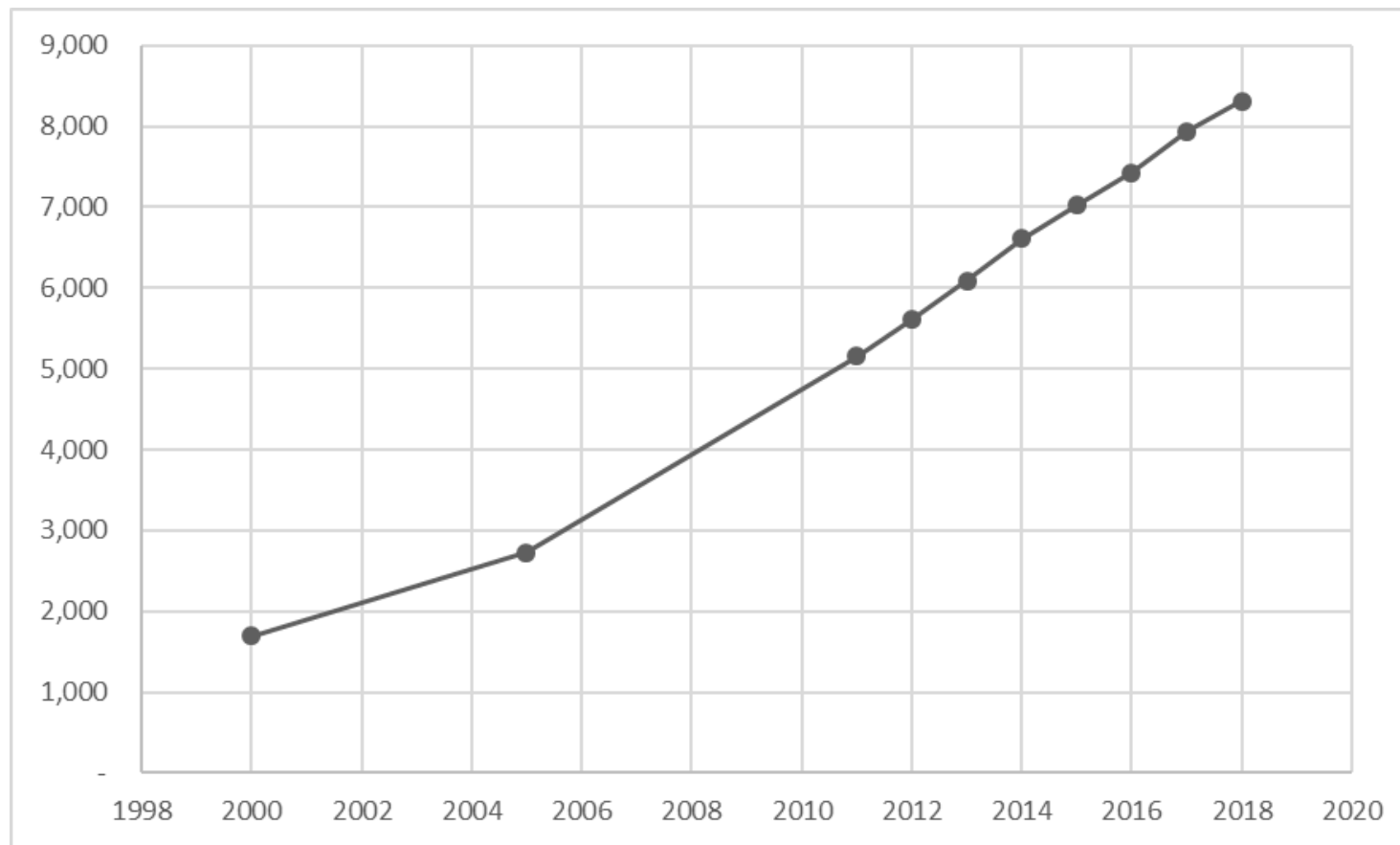


# I. Use of Medical Radioactive Sources

## Medical Accident in Korea

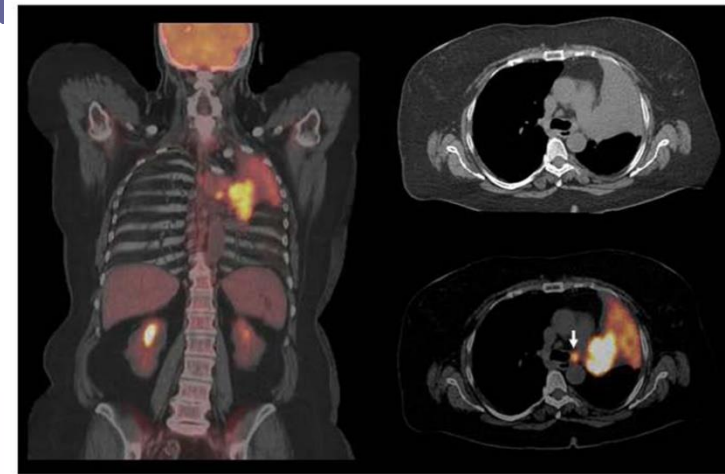


# Number of Organization to use Radiation Sources

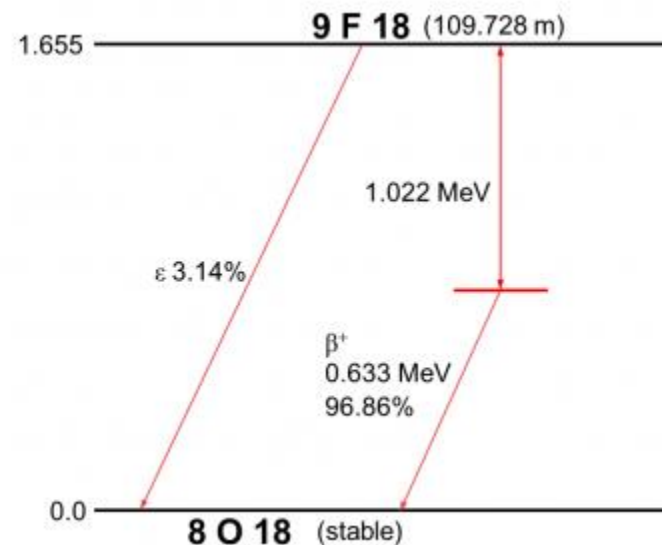
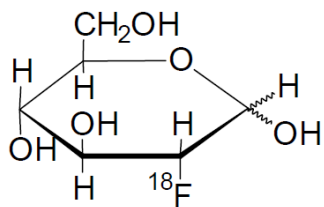


Type	Industrial Organization, etc.	Medical Organization	Education and Research Organization	Total
Unit	7,488	195	631	8,314

\* Increase in number of organizations : 1,692 (2000) → 2,723 (2005) → 5,155 (2011) → 5,606 (2012) → 6,085 (2013) → 6,612 (2014) → 7,024 (2015) → 7,474 (2016) → 7,938 (2017) → 8,314 (2018)

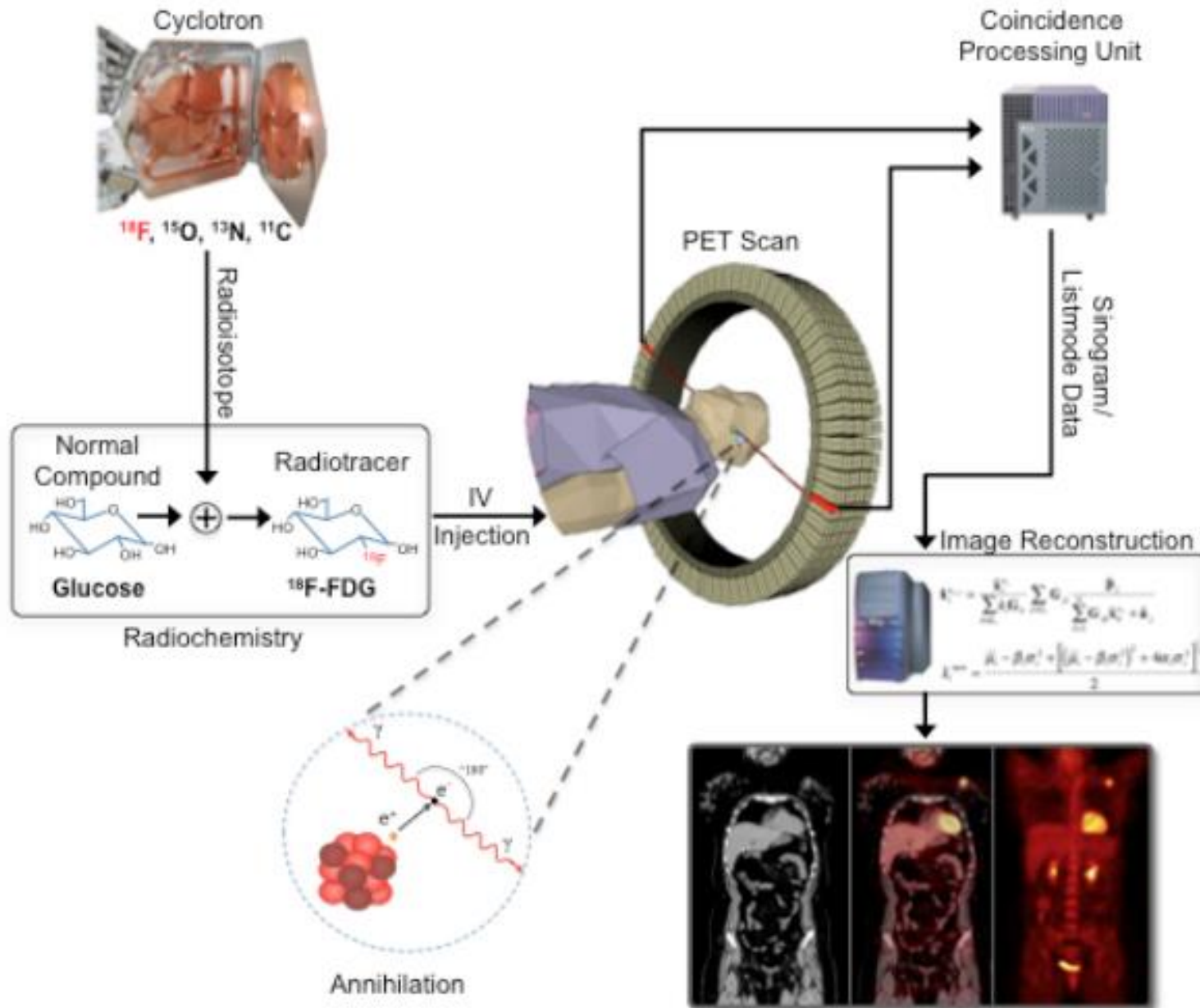


# PET Fludeoxyglucose F18



**Abbreviated  $[^{18}\text{F}]$  FDG**

# How to make the Image



# Check Sources for PET



**Ge-68 Line Sources**

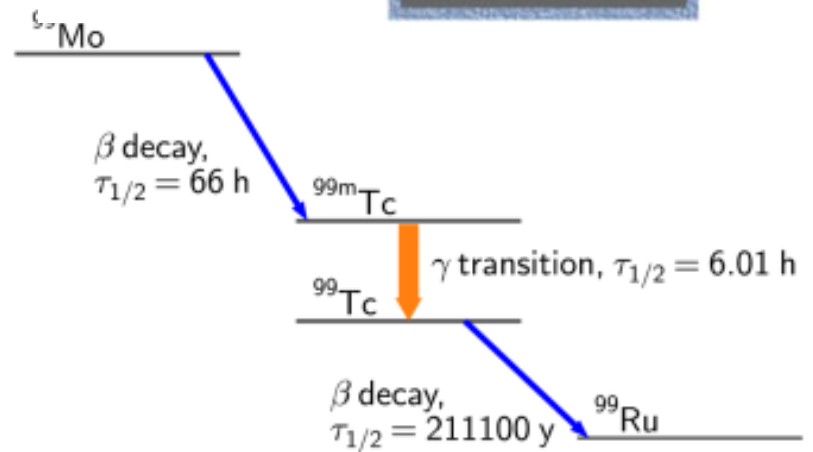
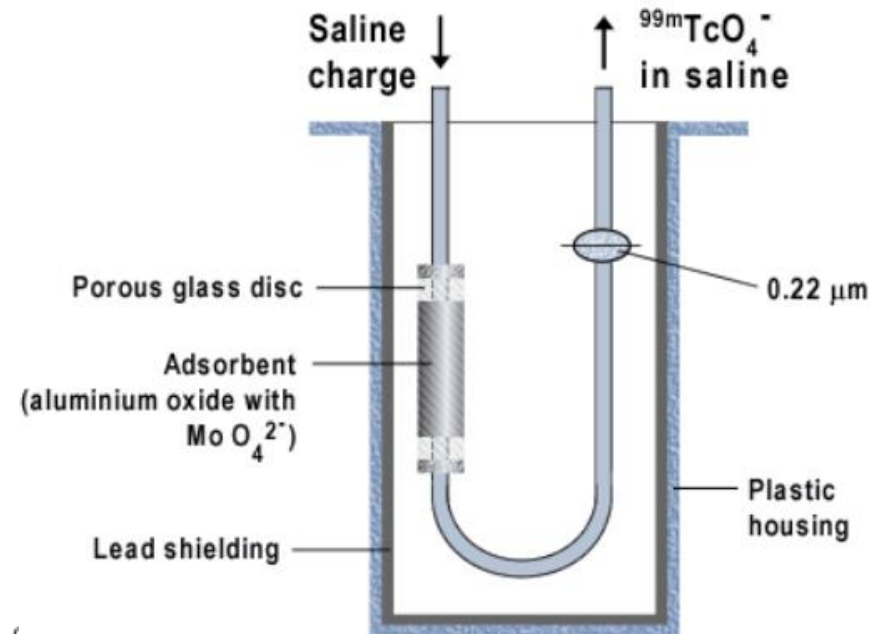


**GE-68 Cylindrical Phantom**

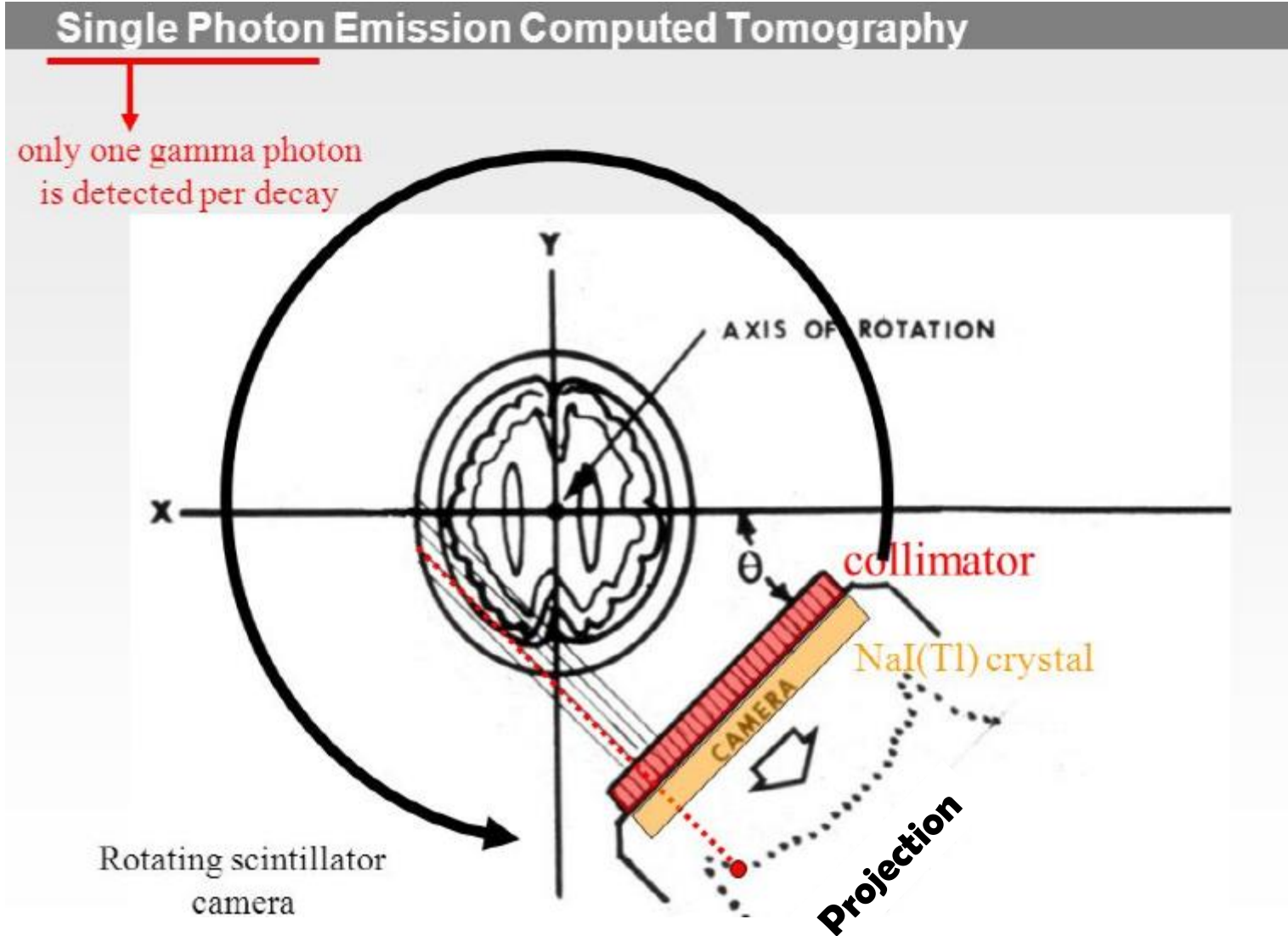
# SPECT/Single Photon Emission Computed Tomography



# Mo/Tc-99m Generator



# Principle of SPECT



# I-131 Treatment

## I-131 Capsule





## Gammacell® 1000 Elite/3000 Elan

Gammacell® 3000 Elan

*Caesium<sup>137</sup>*

Fixed Source(s)/Turning Canister

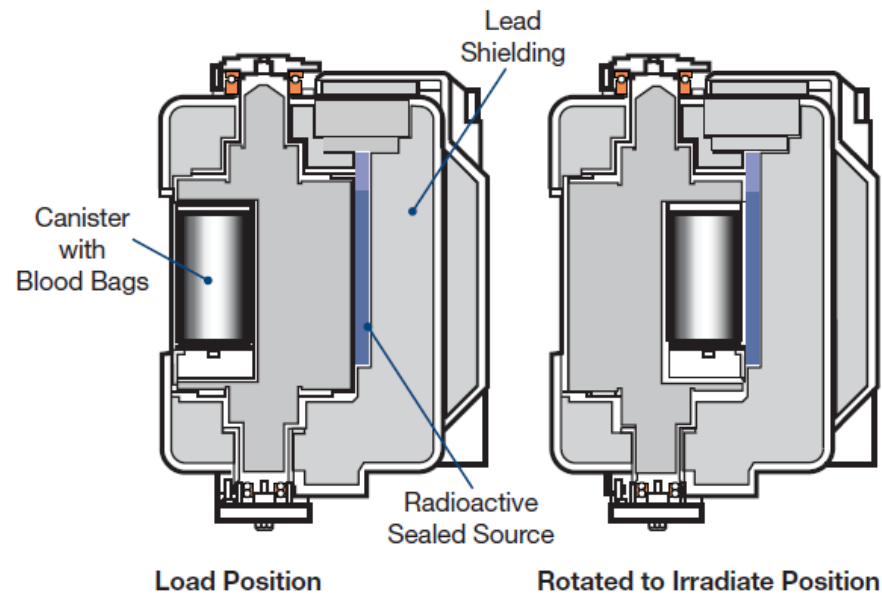
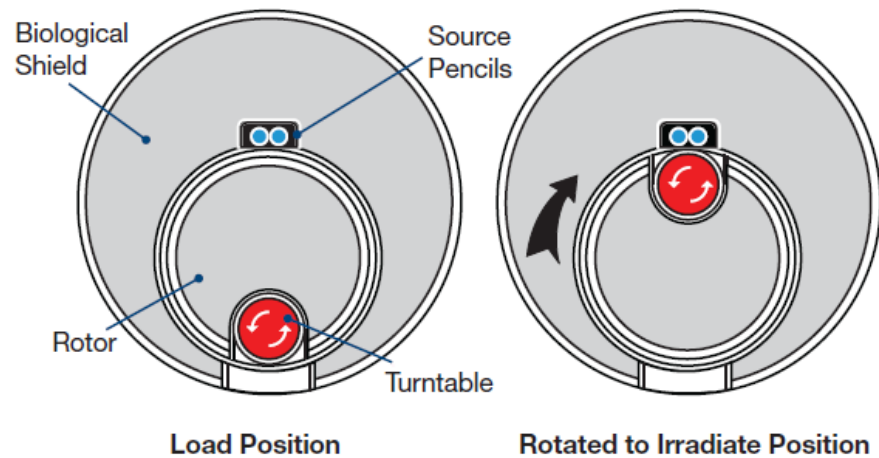
n/a

Model I = 1300 Ci (48.1 TBq)

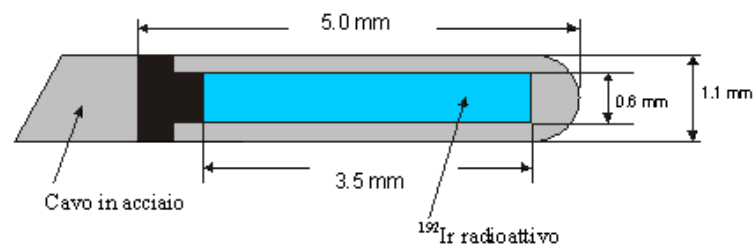
Model II = 2600 Ci (96.2 TBq)

$\leq 5 \mu\text{Sv/h}$  (0.5 mrem/h) at 5 cm  
(1.94 in) from front

# Safety Regulation on Radiation



# Brachytherapy Machine and Ir-192



# Linear Accelerator

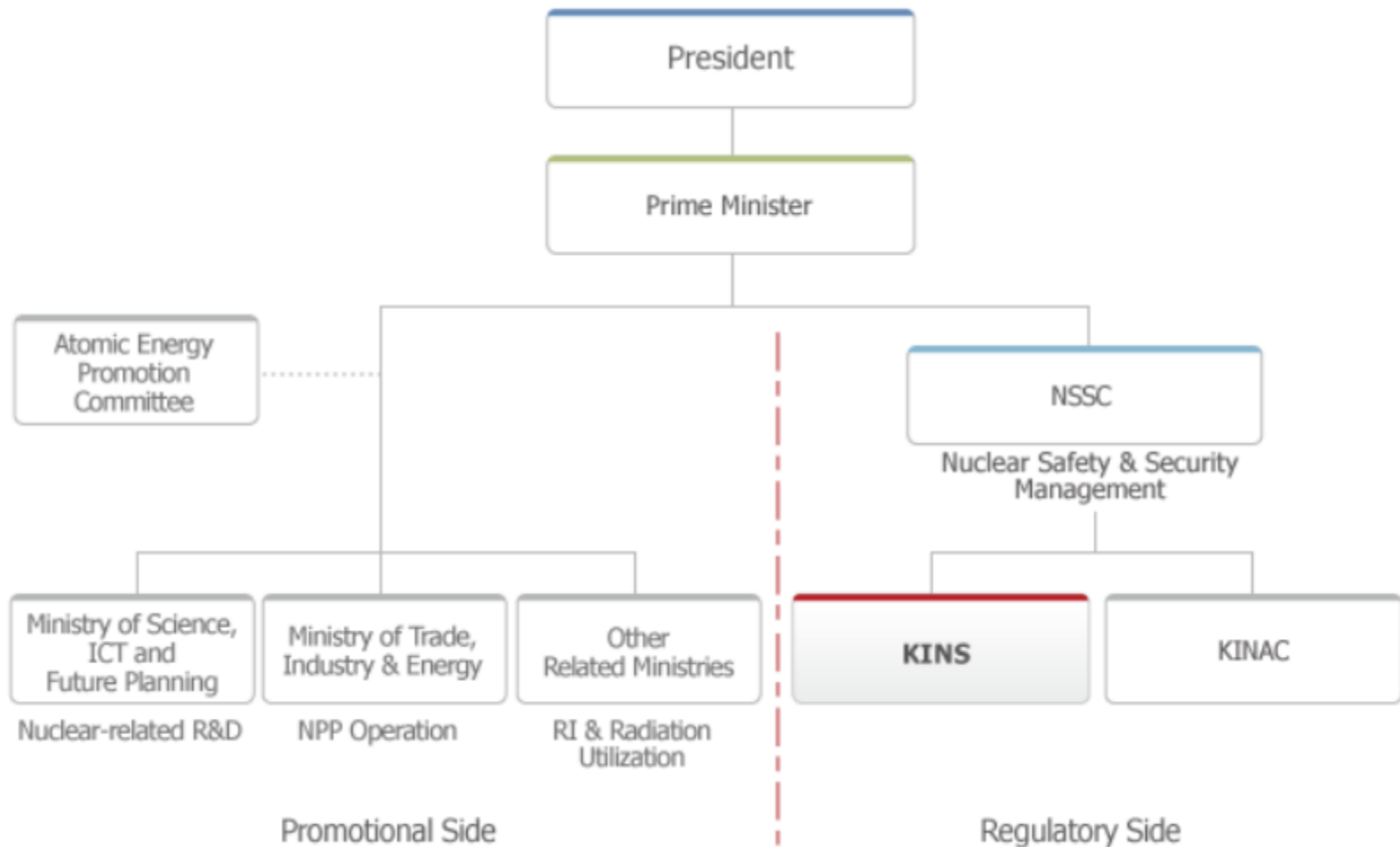


**A linear accelerator is a device that uses high Radio-frequency(RF) electromagnetic waves to accelerate charged particles(i.e. electrons) to high energies in a linear path, inside a tube like structure called the accelerator waveguide.**

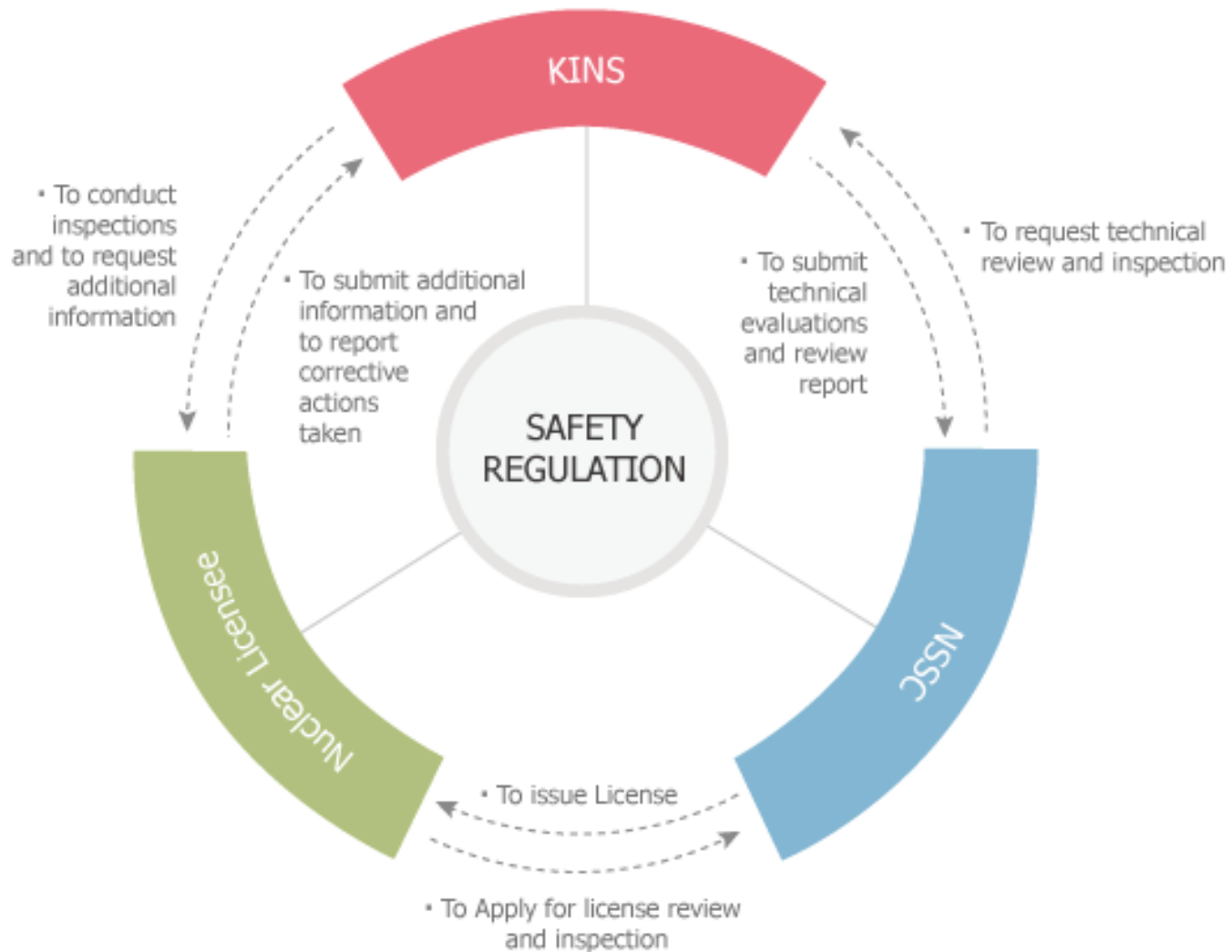


## **II. Regulation System on Medical Radioactive Sources**

# Nuclear-related Government Organization

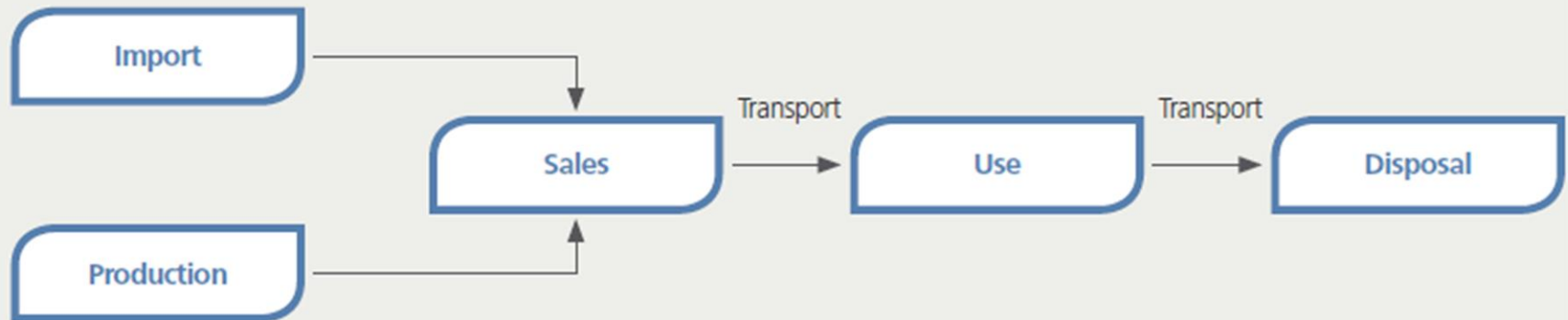


# Regulatory Mechanism

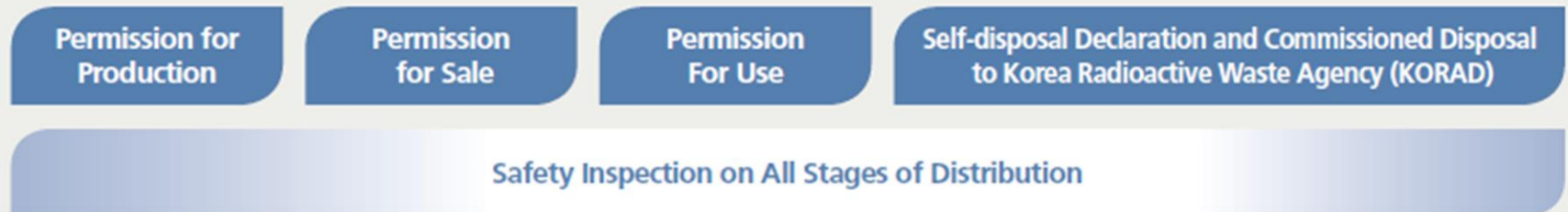


# Safety Regulation on Radiation

## Distribution



## Regulation



# Safety Regulation on Radiation

Nuclear Safety Act

Provides the basis and essential matters for nuclear safety regulations

Enforcement Decree  
of the Act

Provides administrative matters for enforcement of the Act

Enforcement Regulations  
of the Act

Establishes approval and permission procedures, applications and administrative procedures for enforcement of the Act and Enforcement Decree

Regulations on Technical  
Standards for Radiation  
Facilities, etc.

Provide key technical standards for enforcement of the Act and the Enforcement Decree

Notice of NSSC

Provides technical details and administrative procedures regarding specific subjects for enforcement of the Act, the Enforcement Decree, the Enforcement Regulations, and Regulations of Nuclear Safety and Security Commission (NSSC)

Article 53 (1), A person who intends to produce, sell, use or make a mobile-use of radioisotope or radiation generating device shall obtain permit from the Commission as prescribed by the Presidential Decree.

## Director's message

[HOME](#) > [About EUMC](#) > [Director's message](#)



Director of Ewha Womans  
University Medical Center,  
Vice President of  
Ewha Womans University

Byung In Moon

문병인

GREETINGS

### WELCOME TO THE WEBSITE OF EWA WOMANS UNIVERSITY MEDICAL CENTER

"We will be born with customer-centered medical care and dedication."

Ewha Womans University Medical Center is a medical institution with a long history and tradition began as Pogoonyogoan which was the first hospital for women in Korea in 1887. As the nation's only one affiliated hospital for women's medical university, we have received the love of customer by providing the best medical services based on experiences accumulated in the field of women's education, research, and medical treatment and differentiated competitiveness.

Ewha Womans University Medical Center has continued innovated in order to provide new value based on customer-priority management.

For the first time among the university hospitals in Korea, we have improved the convenience of customers with differentiated medical services by operating treatment, examination, operation and specialization treatment by disease and patient customized collaboration treatment on Saturday. We are making its leap into a globally competitive hospital while having the affiliated medical institutions including Ewha Womans

University Mokdong Hospital and Ewha Womans University Cancer Center for Women, the first female cancer treatment clinic in Korea which is well-known to both domestic and foreign customers and managing the Yangcheon-gu Dementia Support Center,

# Decree of Nuclear Safety Act

Article 79, A person, who intends to obtain permit for the production, sale, use or mobile use of radioactive isotope or radiation generating device under the provisions of the former part of Article 53 (1) of the Act, shall submit an application for the permit to the Commission as prescribed by the Ordinance of the Prime minister.

## 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	24

## 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

# Regulation of Nuclear Safety Act

Article 60, The application shall be accompanied by these documents

1. Radiation safety report
2. Safety management regulations
3. Documents evidencing the purchase of equipment
4. Documents evidencing the employment of personnel
5. Compensation standards for injuries



### Article 37, Use Facilities and Distribution Facilities for Unsealed Sources

1. Unsealed sources shall be used or distributed at use facilities or work rooms.
2. The personal dose on radiation workers or persons with frequent access shall not exceed the dose limit by execution of each of the following measures:
  - a. Shielding against radiation by means of shielding walls or shielding materials;
  - b. Ensuring a reasonable distance between unsealed sources and humans by using remote-controlled devices, grippers and so forth and the use of shielding materials; and
  - c. Reduction of the time of exposure of a human to radiation by means of detailed work plans, proficiency/training and so forth.

### Article 37, Use Facilities and Distribution Facilities for Unsealed Sources

3. The concentration of radioisotopes in the air inhaled by people at a place in a work room accessed by them at ordinary times shall not exceed the derived air concentration, by means of purification or ventilation of the air contaminated by radioisotopes.
4. The level of contamination by radioisotopes on the surface of an object contacted by people in a work room or contamination inspection room shall not exceed the permissible surface contamination level.
5. Personnel shall be required to wear working garments, footwear, protective gear and so forth in a work room.
6. In leaving a work room, the level of contamination by radioisotopes on the surface of a human body and the objects worn by a human
7. Cautions necessary for the prevention of radiation hazards shall be posted at easily noticeable places in use or distribution facilities.

## Article 38, Storage Facility for Unsealed Sources

1. Storage facilities shall have such structure as provided in each of the following:
  - a. Major structures and entrance/exit of a storage room shall be fireproof or made of non-flammable materials; and
  - b. A storage box shall have a fireproof structure or be made of non-flammable materials.
2. Unsealed sources shall be stored in containers at storage facilities;
3. Unsealed sources shall not be stored in excess of the storage capacity of the storage facilities;
4. The personal dose limit of radiation workers or persons with frequent access shall not exceed the dose limit by shielding;

## Article 38, Storage Facility for Unsealed Sources

5. Each of the following measures shall be taken in order to ensure that the level of contamination by radioisotopes on the surface of an object with which personnel come into contact in storage facilities does not exceed the permissible surface contamination level:

a. Liquid radioisotopes shall be contained in a container that has a structure designed to prevent the overflow of fluids and which is made of materials that prohibit the permeation of fluids; and

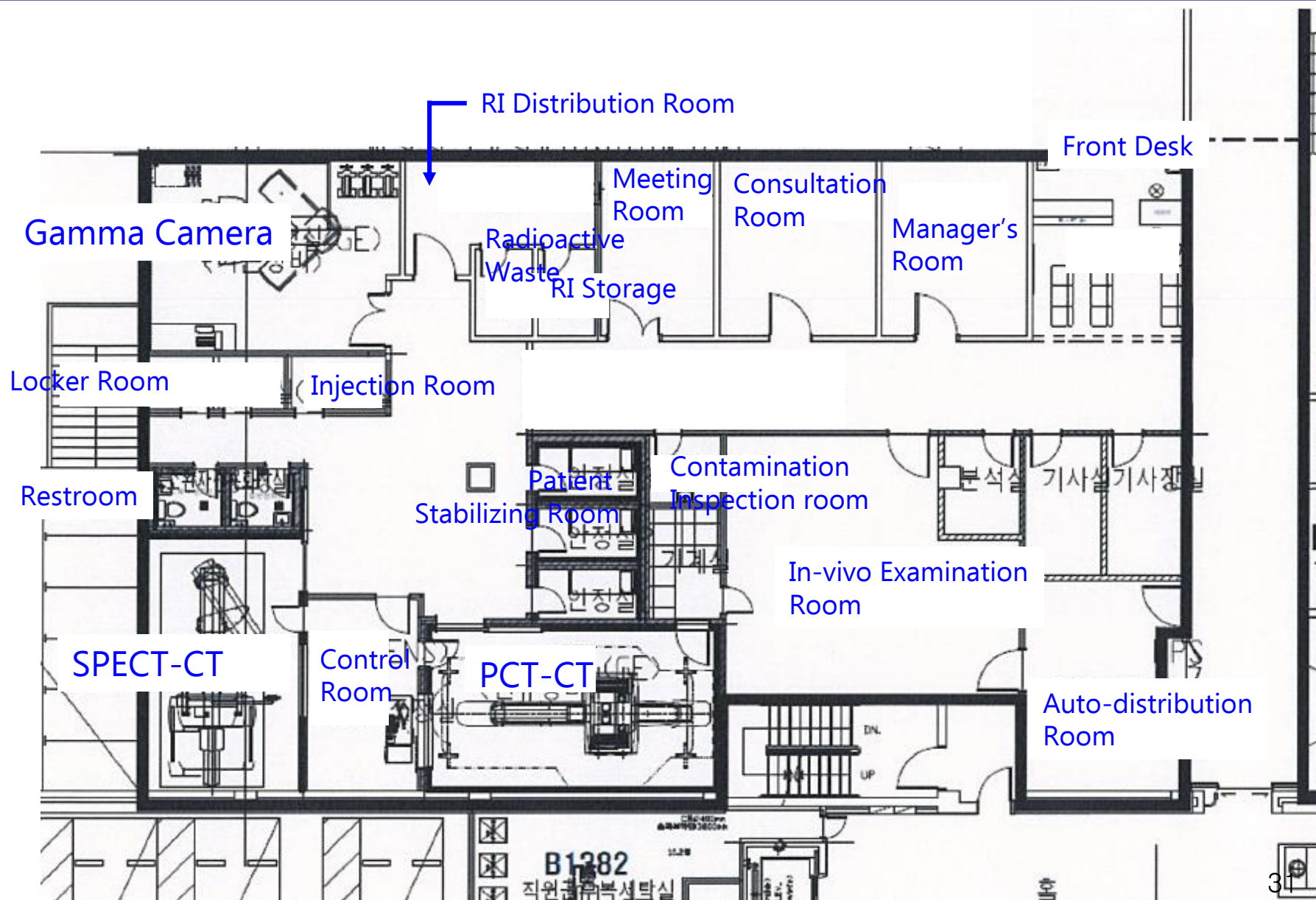
b. If it is feared that a container containing liquid radioisotopes may be cracked or damaged, the spread of contamination by radioisotopes shall be prevented by using under trays, absorbents and other facilities or apparatuses.

6. Access shall be restricted in a radiation control area



## **III. Practice to Find Regulatory Targets**

# Area of PET, SPECT and In-vivo Examination



# Entrance



## Patient's Stabilizing Room



## PET-CT from Control Room



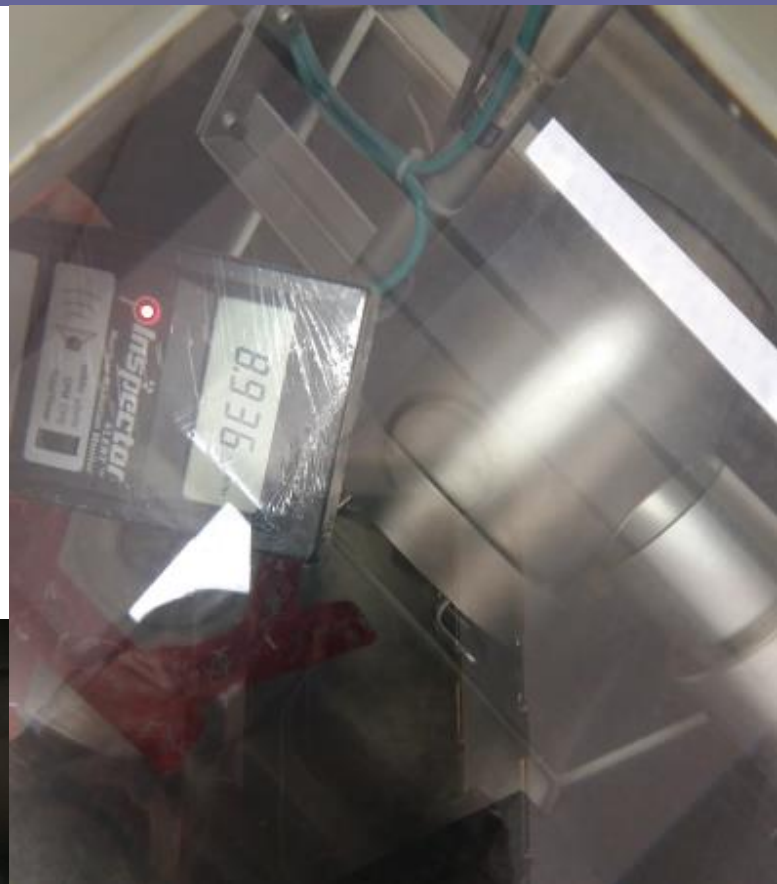
# SPECT Room



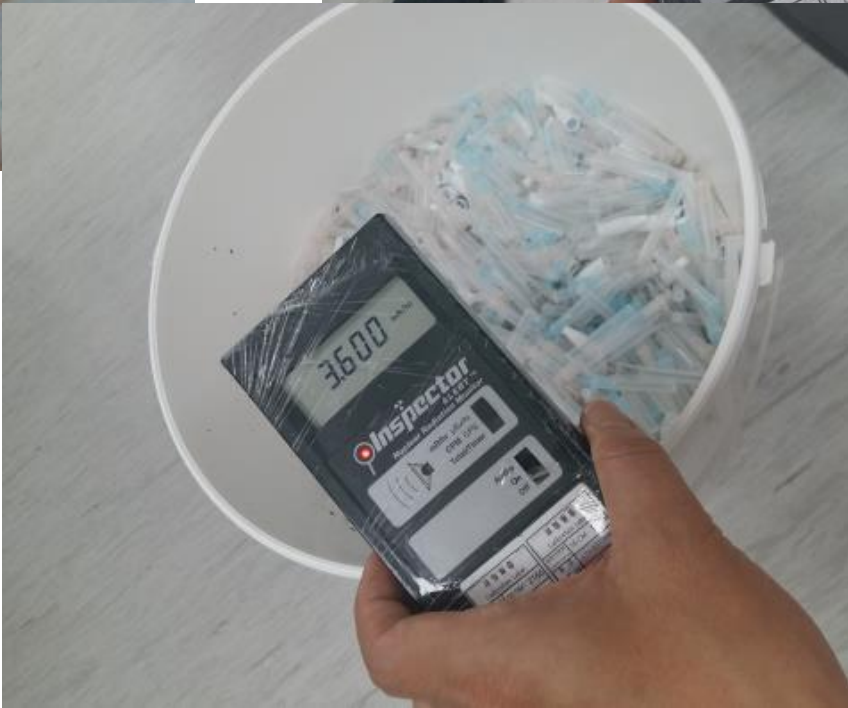
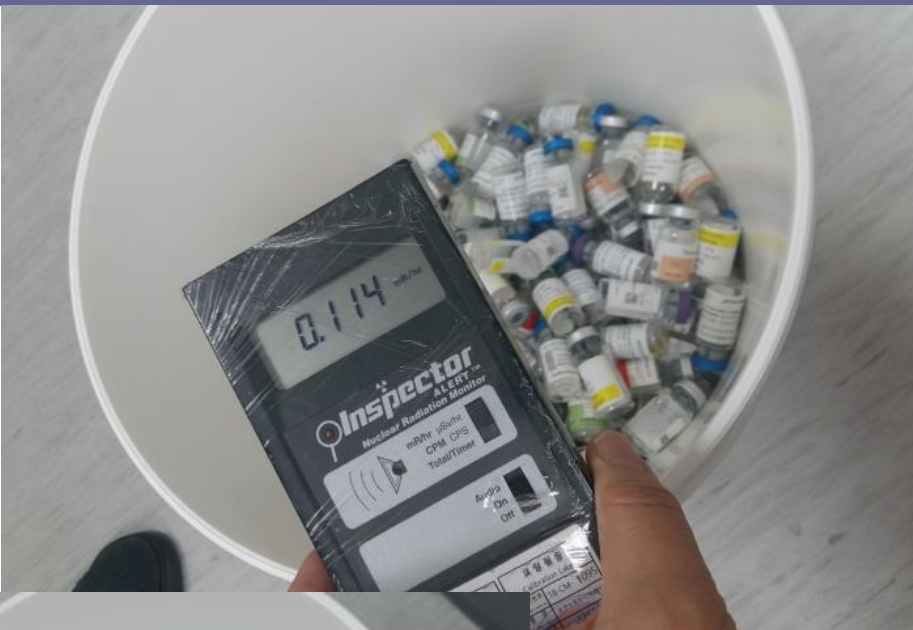
## PET-CT Control Room



# Fume Hood for FDG



# RI Distribution Room



# Radioactive Waste Room



# RI Storage Room



# RI Storage Room



# Injection of Tc-99m



# Radioactive Waste Room



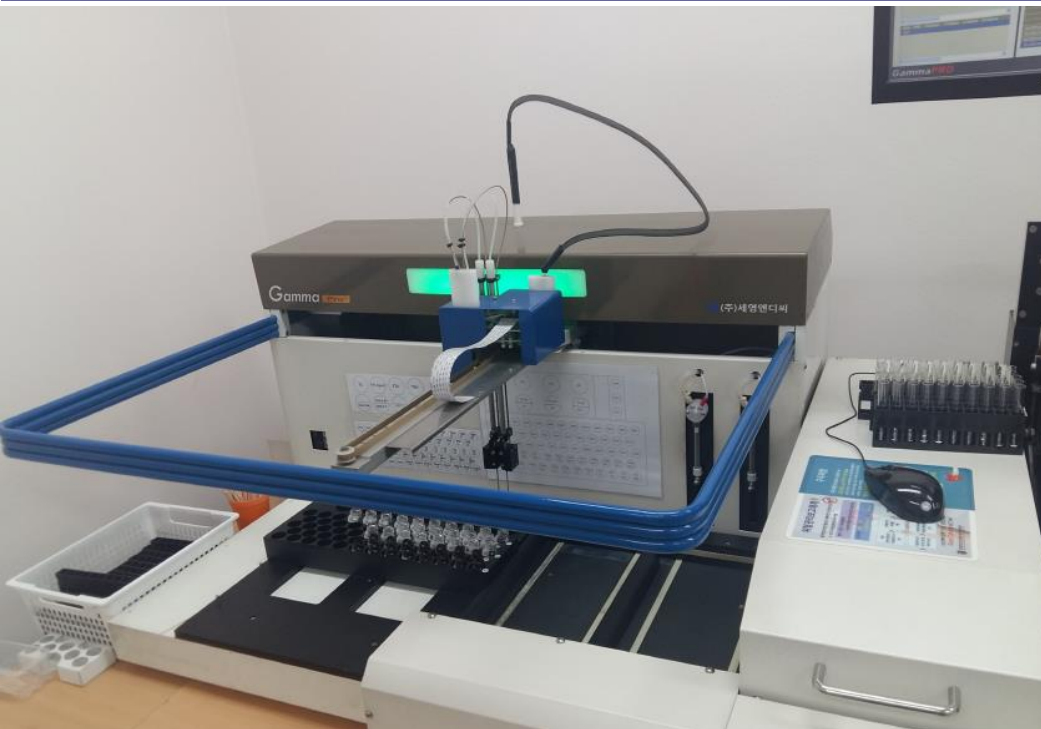
# In-vivo Examination Room



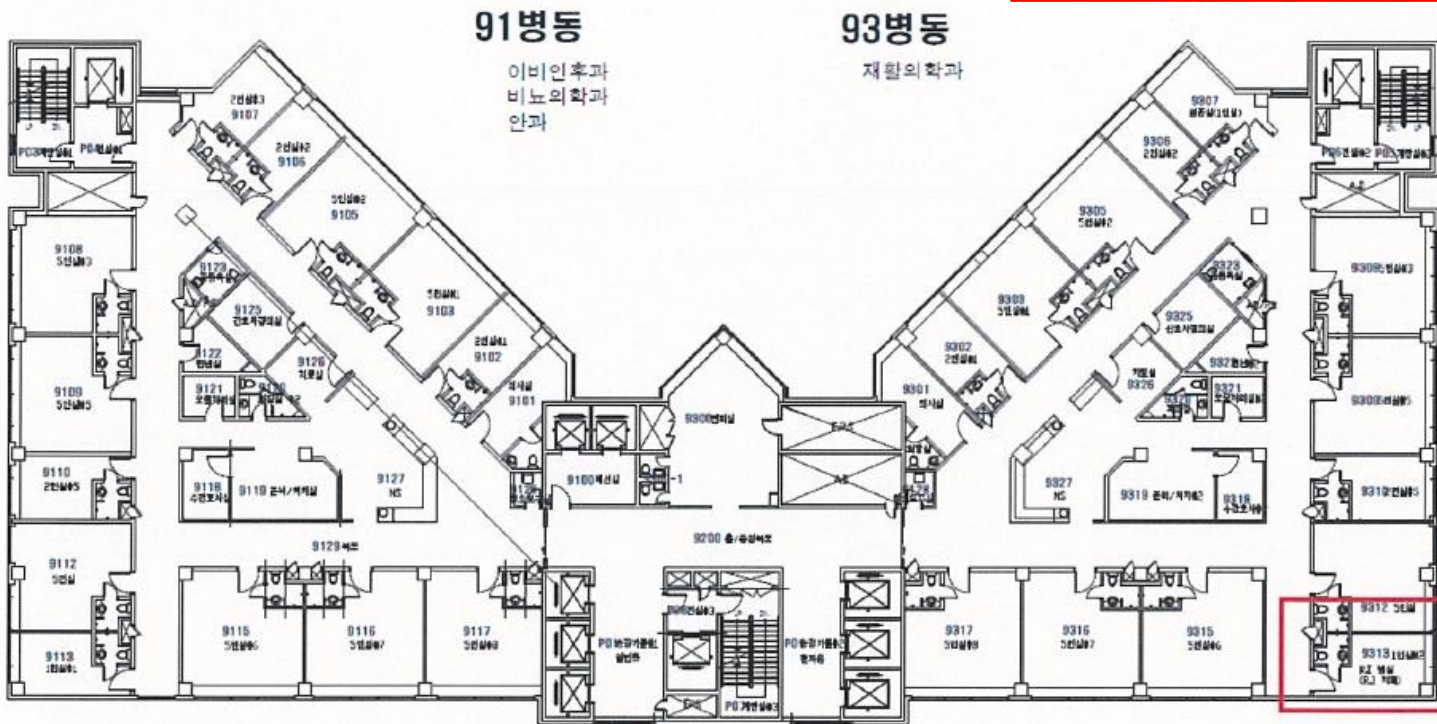
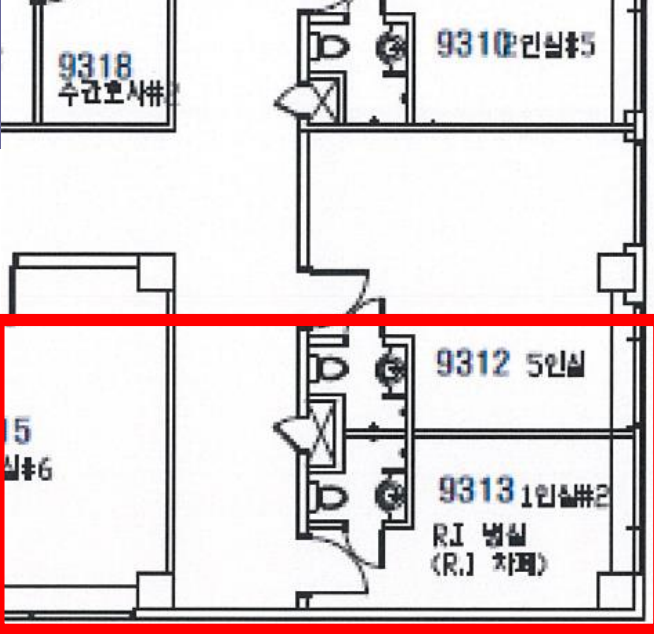
# In-vivo Examination Room



# In-vivo Examination Room



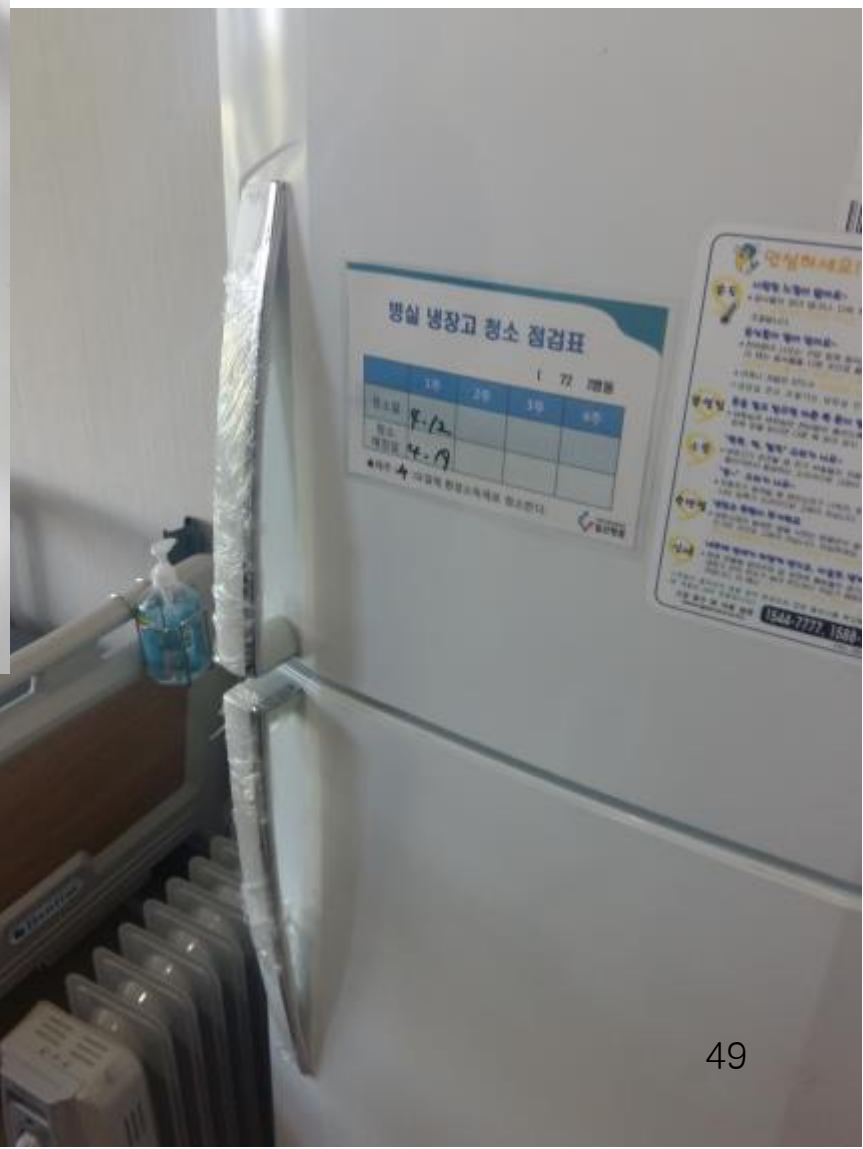
## I-131 Treatment Room



# I-131 Treatment Room



# I-131 Treatment Room



# I-131 Treatment Room



# I-131 Treatment Room

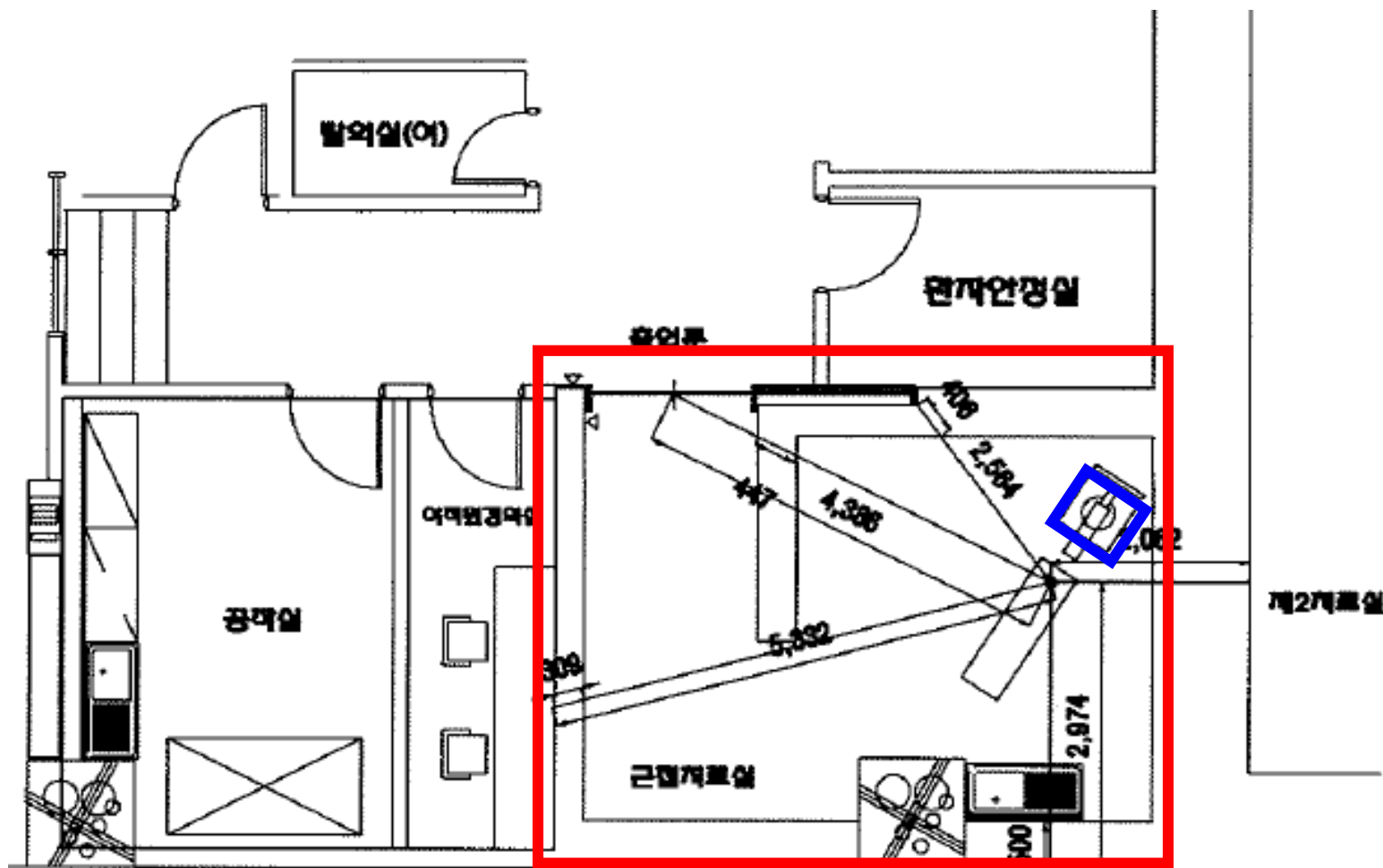




# Blood Irradiator Room



# Brachytherapy Treatment Room



# Brachytherapy Treatment Room





## IV. Discussion

**Find some unsafe condition in the radioactive control area.**

- o Area of PET and SPECT**

- o RI Distribution Room, Storage Room, Waste Room**

- o Area of In-vivo Examination**

**Find some unsafe condition in the radioactive control area.**

- o I-131 Treatment Room**

- o Blood Irradiator Room**

- o Brachytherapy Treatment Room**

**Thank you very much** **KINS**

