Senior Regulators' Meeting
Thursday,23 September 2010, IAEA

Medical Assistance System for Nuclear Emergency in Japan

- Wide Participation and Cooperation of All Related Stakeholders -

Shizuyo KUSUMI, M.D.

Commissioner

Nuclear Safety Commission, Japan

Laws for Ensuring Safety of Nuclear Energy and Radiation Use

Atomic Energy Basic Law (1955)

Law for the Regulations of Nuclear Source Material, Nuclear Fuel Material and Reactors (1957)

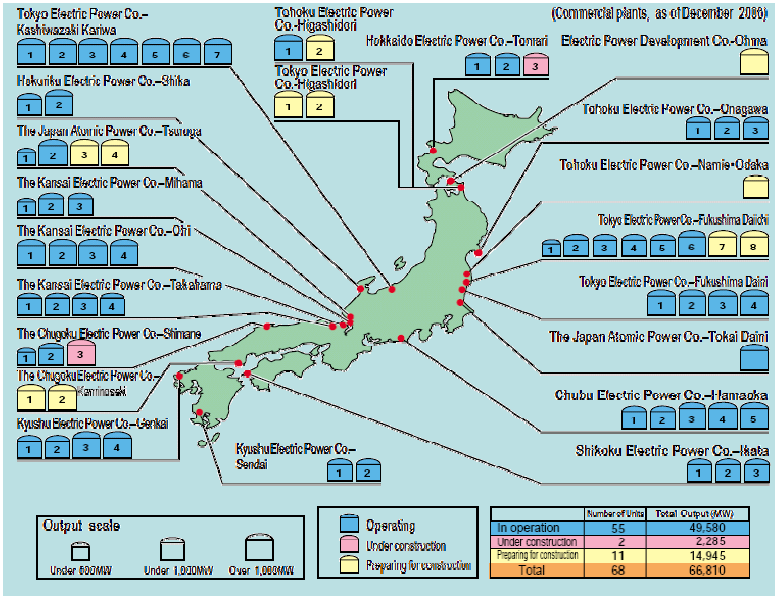
Law Concerning Prevention from Radiation Hazards due to Radioisotopes and Others (1957)

Medical Care Act (1947)

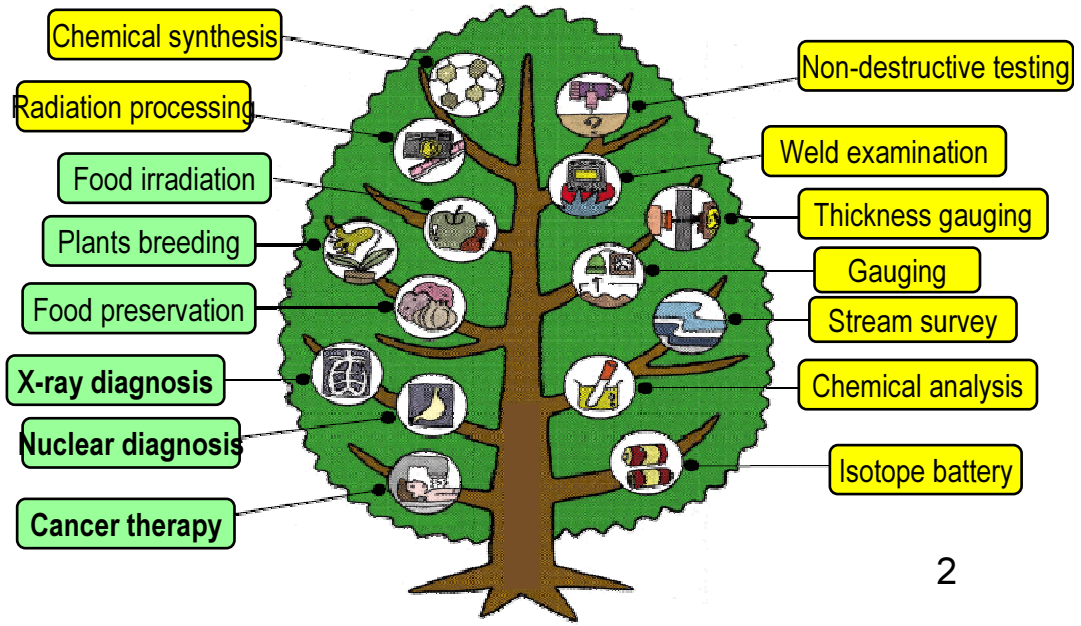
→ **Nuclear Energy Use**
(NSC ⇔ NISA/MEXT)

→ **Radiation Use**
(MEXT)

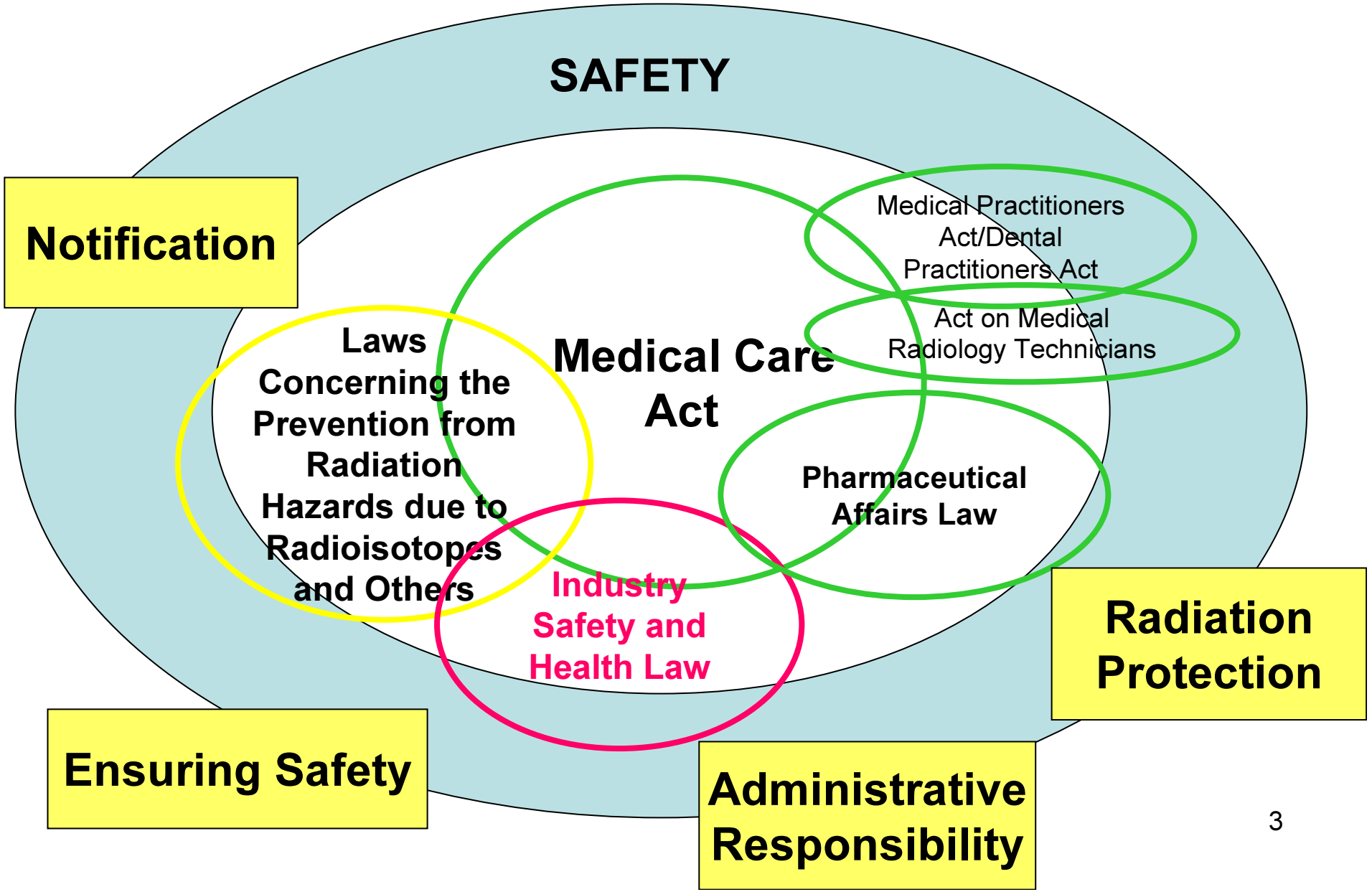
→ **Medical Use of Radiation**
(MEXT/MHLW)



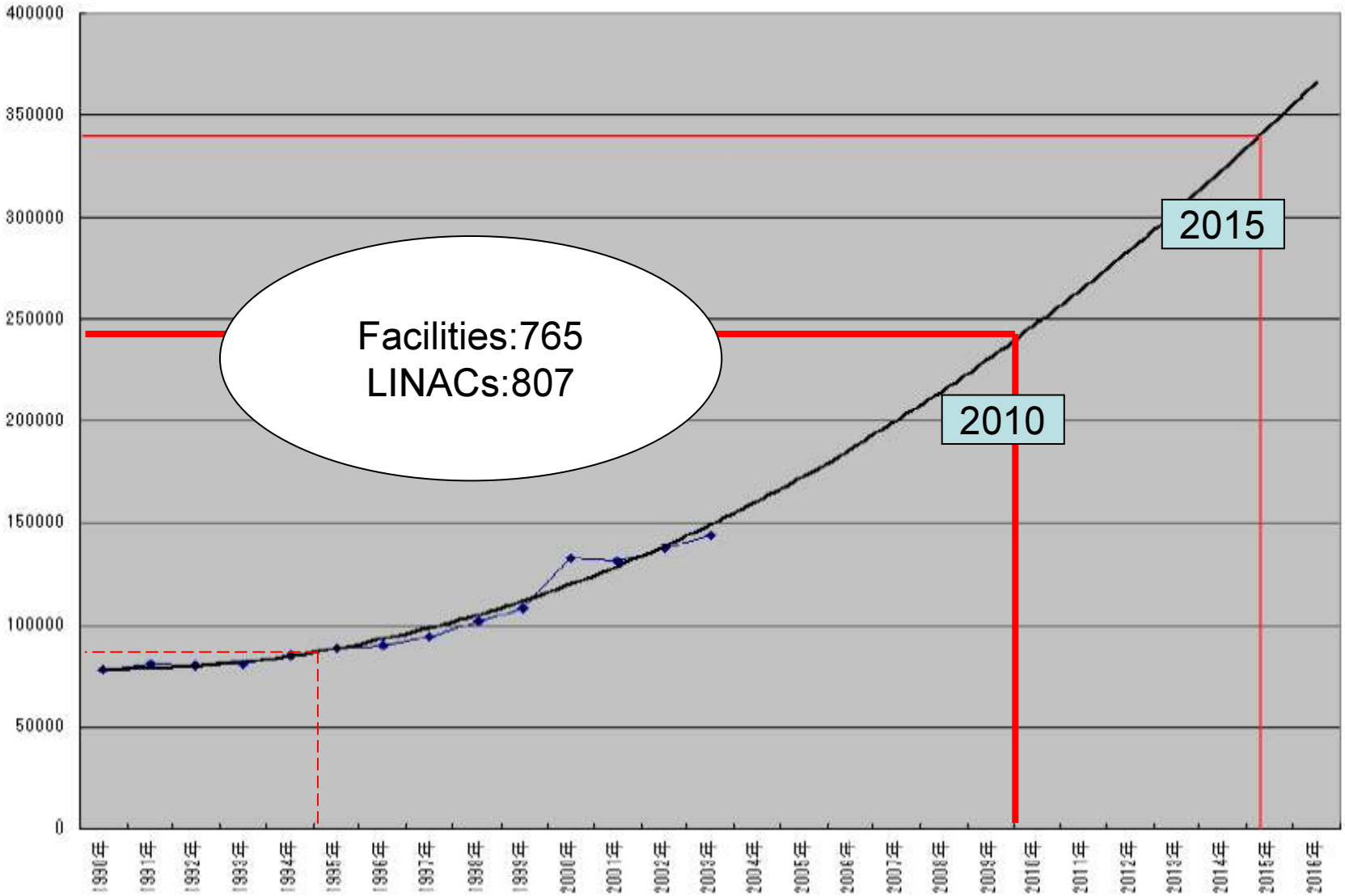
Nuclear Installations



Laws for Regulation of Radiation Handling Medical Facilities



Transition of the Number of Radiation Therapy Patients



Hiroshi Ikeda, 1st Annual Meeting of Particle Accelerator Society of Japan
and the 29the Linear Accelerator Meeting in Japan (Aug. 4-6,2004)

Accidental Exposures with Radiotherapy Patients

Facility	Disclosure	Period	# of patients	Main Cause
A	2001	2y 5m	23	Input error of TPS data
B	2002	2y1m	12	Input error of TPS data
C	2003	4y6m	276	Misunderstand among staffs
D	2004	4y7m	32	Input error of TPS data
E	2004	1y1m	25	Input error of TPS data
F	2004	5y1m	256	Incorrect dosimetry
G	2004	2d	1	Data transfer error to LINAC
H	2004	5y5m	111	Input error of TPS data

(Nikkei Inc. 2004)

Cause Investigation and Measures

- There is no specialist in charge of quality management as medical radiation physicists.
- The delivery of the treatment apparatus were left to dealers.
- There is no system to verify the safety.

Japanese Organization of Radiotherapy Quality Management

Supported by Japan Society for Therapeutic Radiology and Oncology (JASTRO),
Japan Radiological Society (JRS),
Japan Society of Medical Physics (JSMP),
Japanese Society of Radiological Technology (JSRT),
Japan Association of Radiological Technologists (JART)

- Certification of Radiotherapy Quality Managers
- Maintenance and improvement of the ability

- The Organization is managed by the income from the five societies and certification cost.

As of the end of 2009,
708 Radiation Quality Managers were certified.

- Visit Investigation

- Work for positional confirmation of irradiated field using Phantom

Improvements after the accidents

2004 Japanese organization of radiotherapy quality management was established.

"Guideline for the acceptance test of high energy radiotherapy system" was published by Japan Industries Association of Radiological Systems (JIRA)

2006 NIRS started a pilot study of dosimetry audit using radiophoto luminescent glass dosimeter (RGD) in collaboration with National Cancer Center.

2007 Association for Nuclear Technology in Medicine (ANTM) started dosimetry audit service with postal RGD.

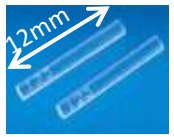
MHLW required hospitals to designate safety control officer for medical electrical equipment.

2010 International Electrotechnical Commission (IEC) 62083 "Medical electrical equipment – Requirements for the safety of radiotherapy treatment planning systems" is incorporated into Japan Industrial Standards (JIS).

External dose audit using a radiophotoluminescent glass dosimeter (RGD) for Radiation Therapy Facilities in Japan

-External dose audit system was initiated in November 2007

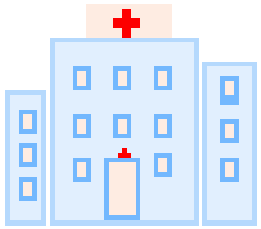
National Institute of Radiological Sciences



RGD
(AGC TECHNO GLASS Co.)

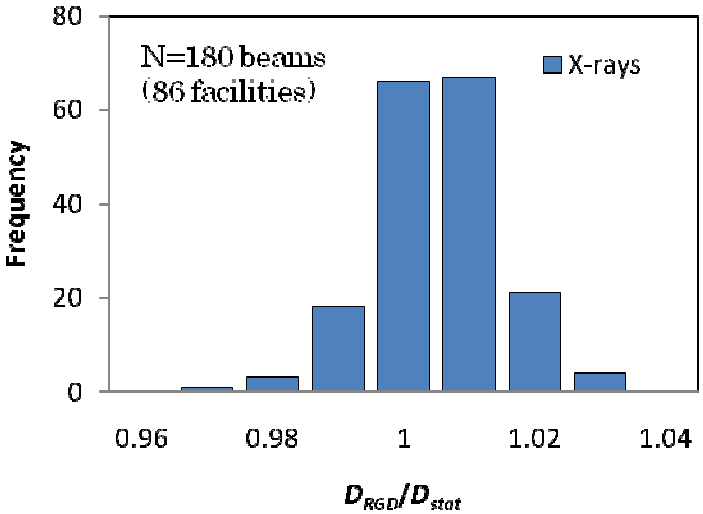
Tough water phantom
(Kyoto Kagaku Co.)

Send RGD



1Gy dose irradiation to RGD
at Radiation Therapy Facilities

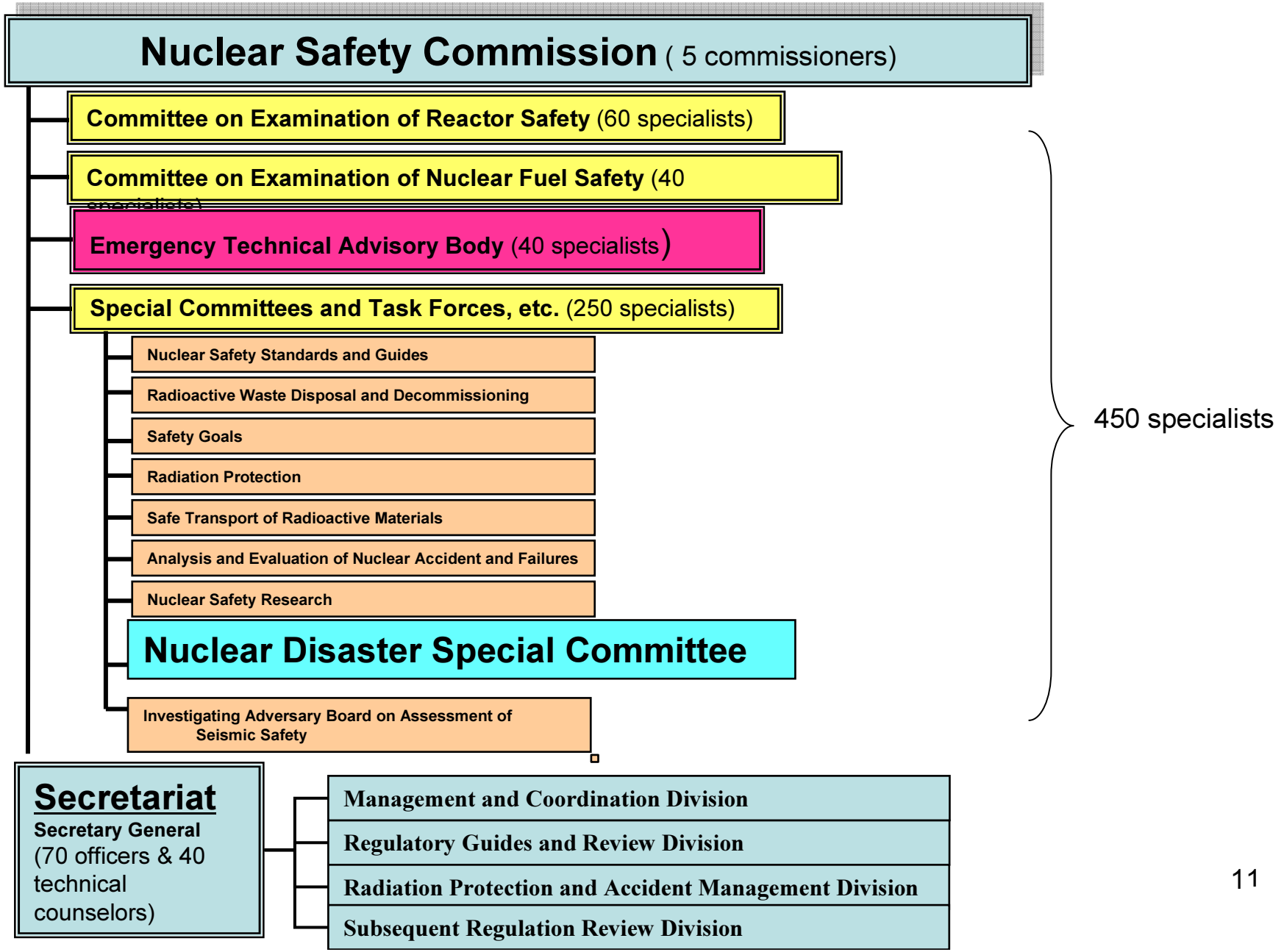
Send back the irradiated RGD and check.



Distribution of the results of the audits of radiotherapy hospitals for the delivery of absorbed dose to water under reference condition during 2007-2009.

Due to these improvement actions,
NO severe radiation therapy accident involving many patients has been reported since 2005.

Role of NSC on Nuclear/Radiation Emergency



Guideline for Nuclear/Radiation Emergency

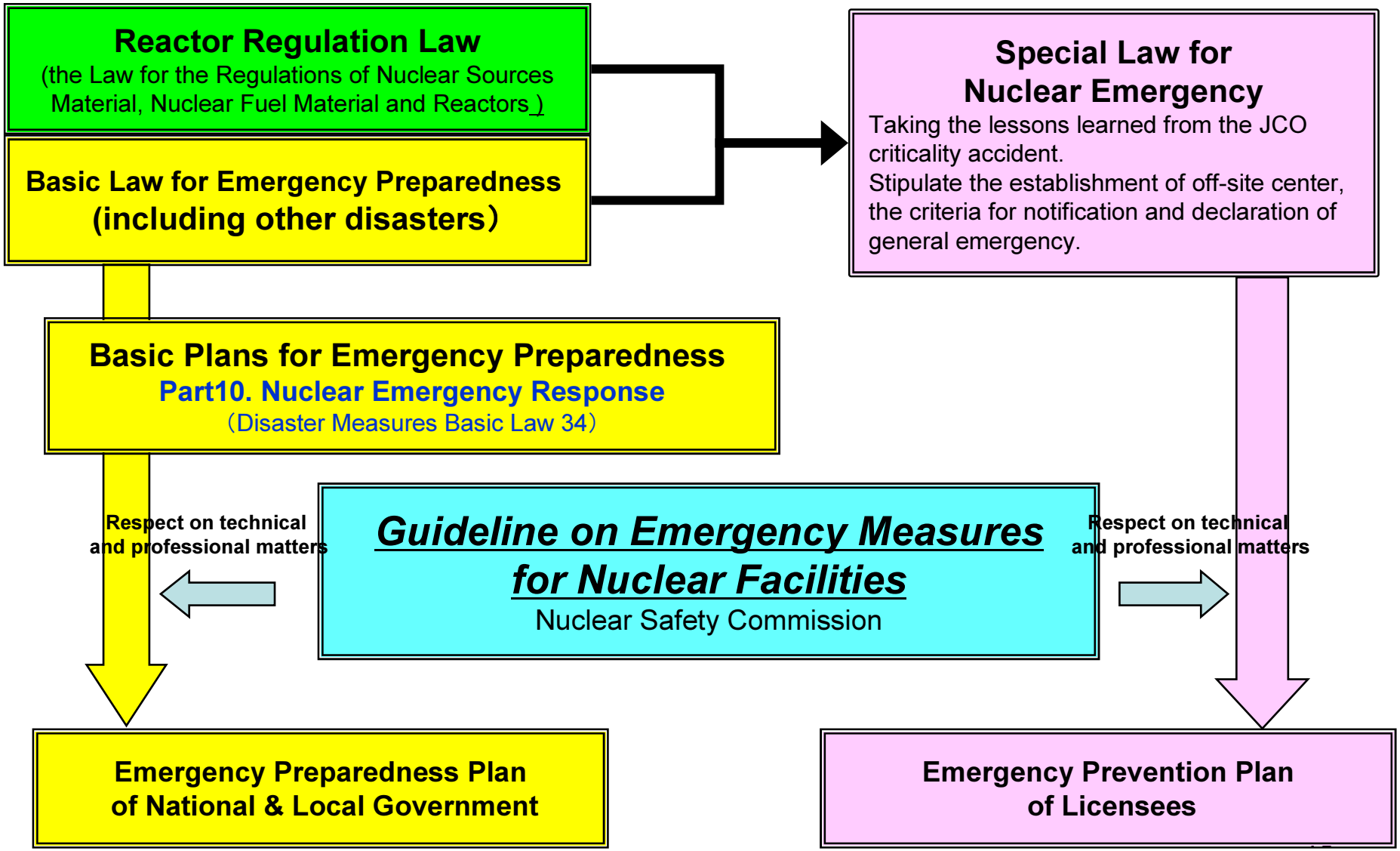
➢The NSC has formulated ***guidelines*** on emergency preparedness and responses in nuclear facilities that was first prepared in June 1980 and most recently revised in May 2007.

✓***Guideline for Emergency Measures for Nuclear Installations***

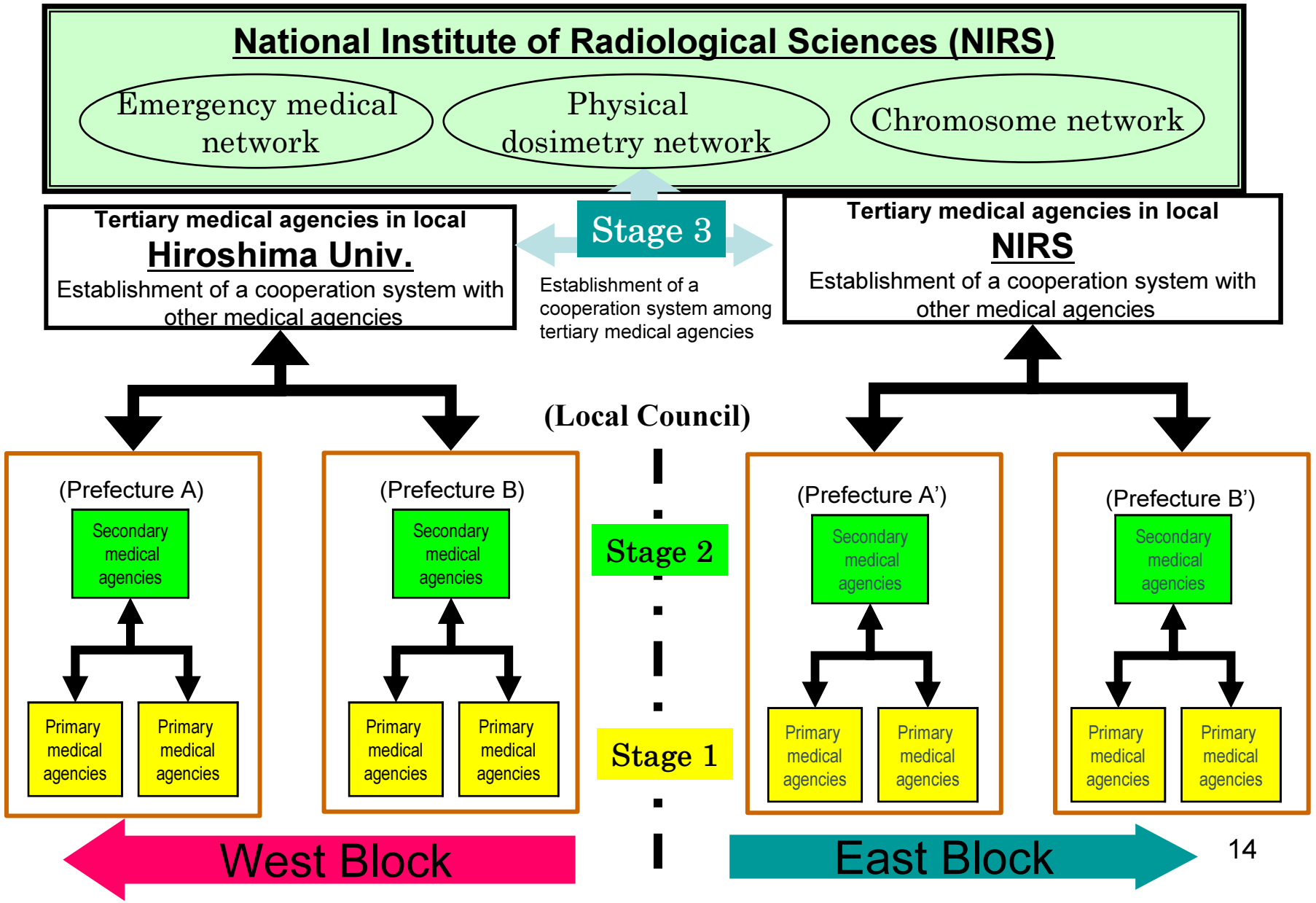
➢The NSC has established a special committee dealing with construction of a ***national system of medical management for radiological emergency***.

✓***Guideline on Radiation Emergency Medicine*** (June 2001)
✓*Guideline on Taking Stable Iodine Tablets in Nuclear Emergency* (April 2002)
✓*Guidance on Mental Health Care in Nuclear Emergency* (November 2002)
✓*Guidance on Roles of Tertiary Medical Agencies in Local* (November 2002)
✓*Guidance on Dividing the Emergency Medical Network in Blocks* (May 2003)

Framework of Legislation for Nuclear/ Radiation Emergency Preparedness



Radiation Emergency Medical Network



The systems to wide-scale disaster is also utilized for the emergency related medical facilities and medical apparatuses.

National Institute of Radiological Sciences
Chiba, Japan

REMAT

Radiation Emergency Medical Assistance Team
since 2010

- **Consisting of physicians, nurses, radiation protection experts, & health physicists**
- **Supporting primary medical care in a radiation accident overseas**
- **Activation upon request by IAEA, WHO, or foreign governments**

Dose Assessment

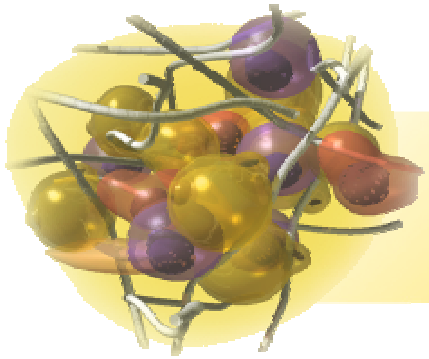
Radiological/ Medical Triage

Diagnosis

Radiation Protection

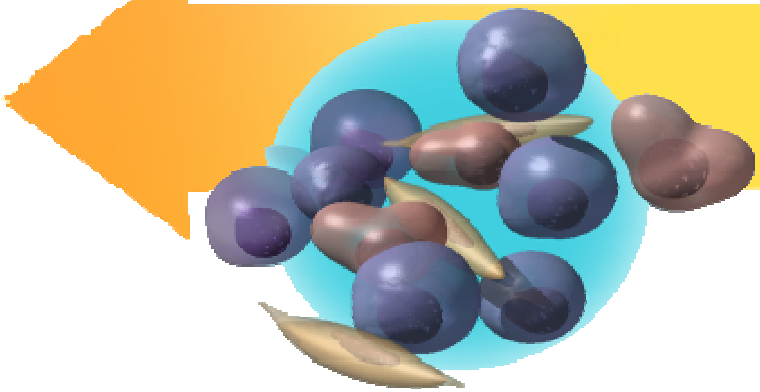
Flow of Autogenic Adipose-derived Stem Cell (ADSC) Transfer

Self Adipose tissue



Harvest tissue and return to patient in same procedure

Isolation and separation is executed in closed circuit.



Autogenic stem cell transfer

ADSC is extracted within 2 hours.

List of Cases

disease	age	gender	cell number
sacro-coccygeal radiation ulcer	87	F	3.7×10^7
HIV-associated lypodystrophy	30	M	5.0×10^5
neck radiation ulcer	52	F	4.1×10^7
chest radiation ulcer	67	F	1.7×10^7
chest keloid (post electron beam)	67	F	5.3×10^7
Burger's disease	34	F	1.1×10^7
sacro-coccygeal radiation ulcer	80	F	1.28×10^7
HIV-associated lypodystrophy	46	M	3.85×10^6
Crohn's disease	50	M	1.04×10^7
Left knee radiation injury	47	F	5.2×10^6
chest neck radiatioin injury	68	F	9.0×10^6
HIV-associated lypodystrophy	31	M	4.4x106

52-years-old, Female Case

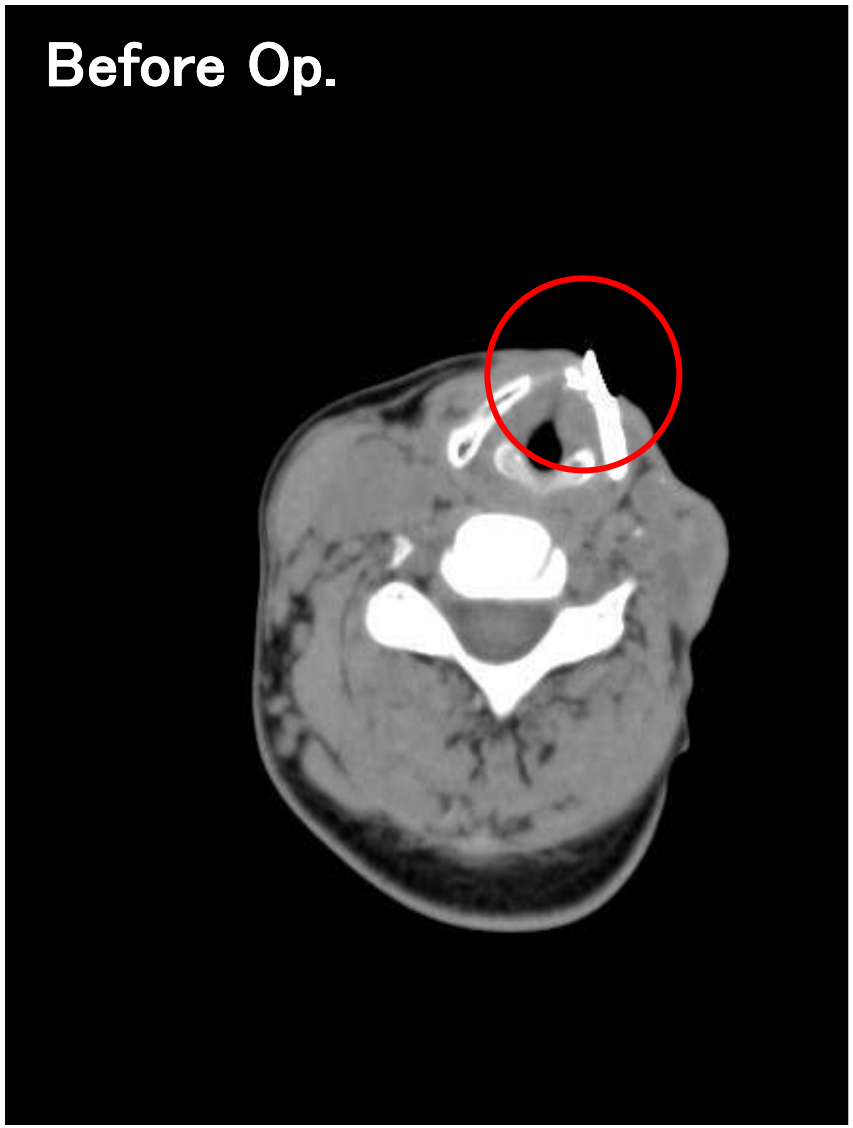
She received cobalt irradiation to the malignant lymphoma 30 years ago.

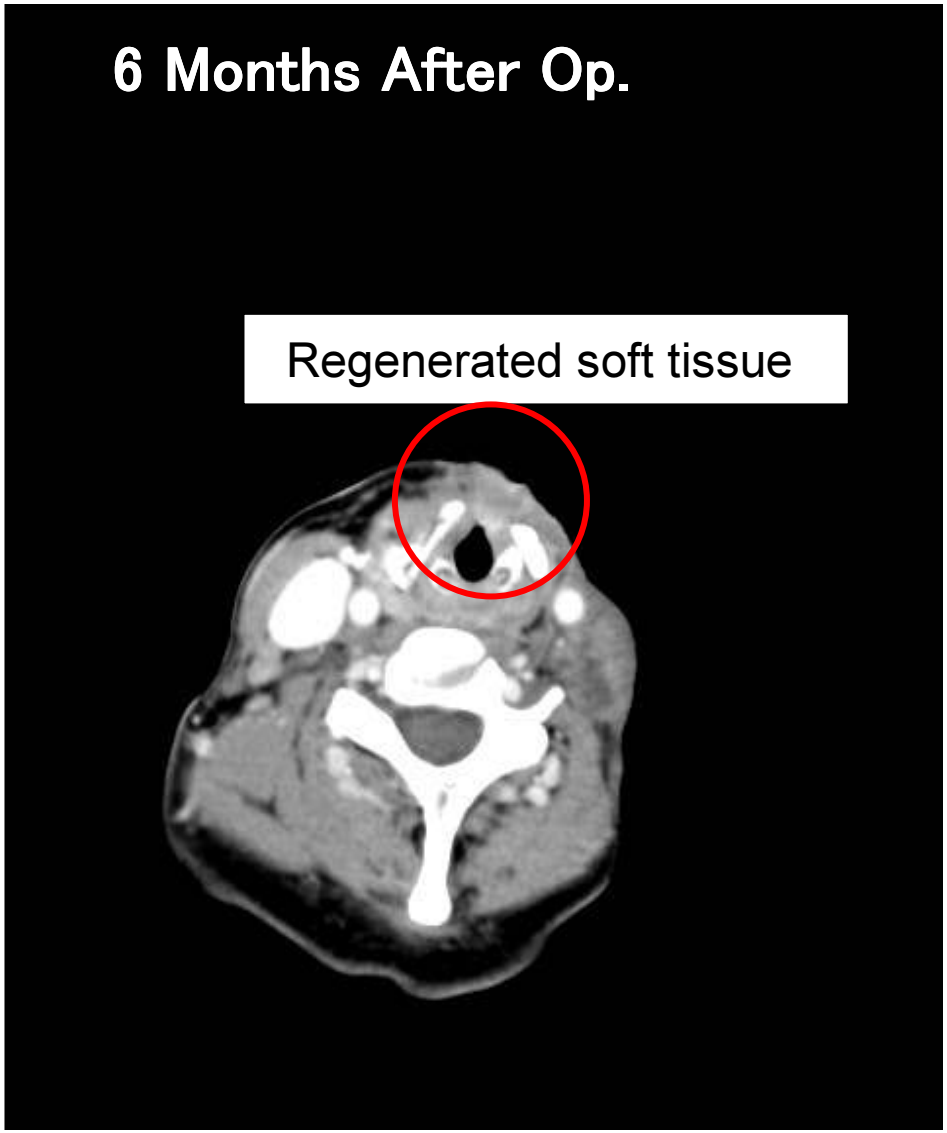
Before operation

Under operation

75 days after operation

Process by Computed Tomography Image





Conclusion

- **Today I introduced the voluntary approach by the academic societies which are independent from the Japanese Government, regulatory bodies.**
- **The Government also established the emergency preparedness system, and has promoted further research and developments in cooperation with the academic societies.**
- **The approach by the academic societies plays an important supplemental role for the entire system designed by the Government.**
- **The link between the academic societies and the regulatory bodies is critical.**
- **Wide participation and cooperation of all related stakeholders would be the key item for ensuring the radiation/nuclear safety, especially in the medical area, and continuous improvement of its quality.**

Thank you for your kind attention.

NUCLEAR SAFETY COMMISSION
NSC

http://www.nsc.go.jp/NSCenglish