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

Chemical synthesis
Radiation processing
Food irradiation
Plants breeding
Food preservation
X-ray diagnosis
Nuclear diagnosis
Cancer therapy

Non-destructive testing
Weld examination
Thickness gauging
Gauging
Stream survey
Chemical analysis
Isotope battery
Laws for Regulation of Radiation Handling Medical Facilities

- Medical Care Act
- Laws Concerning the Prevention from Radiation Hazards due to Radioisotopes and Others
- Industry Safety and Health Law
- Pharmaceutical Affairs Law
- Medical Practitioners Act/Dental Practitioners Act
- Act on Medical Radiology Technicians
-Notification
- Ensuring Safety
- Administrative Responsibility
- Radiation Protection

SAFETY
Transition of the Number of Radiation Therapy Patients

Facilities: 765
LINACs: 807

Hiroshi Ikeda, 1st Annual Meeting of Particle Accelerator Society of Japan and the 29th Linear Accelerator Meeting in Japan (Aug. 4-6, 2004)
# Accidental Exposures with Radiotherapy Patients

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

(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**

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

Nuclear Safety Commission (5 commissioners)

- Committee on Examination of Reactor Safety (60 specialists)
- Committee on Examination of Nuclear Fuel Safety (40 specialists)
- Emergency Technical Advisory Body (40 specialists)

Special Committees and Task Forces, etc. (250 specialists)

- Nuclear Safety Standards and Guides
- Radioactive Waste Disposal and Decommissioning
- Safety Goals
- Radiation Protection
- Safe Transport of Radioactive Materials
- Analysis and Evaluation of Nuclear Accident and Failures
- Nuclear Safety Research

Nuclear Disaster Special Committee

- Investigating Adversary Board on Assessment of Seismic Safety

Secretariat

- Secretary General
  - (70 officers & 40 technical counselors)

Management and Coordination Division

- Regulatory Guides and Review Division
- Radiation Protection and Accident Management Division
- Subsequent Regulation Review Division

450 specialists
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.

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

  - **Guideline for Emergency Measures for Nuclear Installations**
  - **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

- **Reactor Regulation Law**
  (the Law for the Regulations of Nuclear Sources Material, Nuclear Fuel Material and Reactors)

- **Basic Law for Emergency Preparedness**
  (including other disasters)

- **Special Law for Nuclear Emergency**
  Taking the lessons learned from the JCO criticality accident.
  Stipulate the establishment of off-site center, the criteria for notification and declaration of general emergency.

- **Basic Plans for Emergency Preparedness**
  Part 10. Nuclear Emergency Response
  (Disaster Measures Basic Law 34)

- **Guideline on Emergency Measures for Nuclear Facilities**
  Nuclear Safety Commission

- **Emergency Preparedness Plan of National & Local Government**

- **Emergency Prevention Plan of Licensees**
Radiation Emergency Medical Network

National Institute of Radiological Sciences (NIRS)

Emergency medical network
Physical dosimetry network
Chromosome network

Tertiary medical agencies in local Hiroshima Univ.
Establishment of a cooperation system with other medical agencies

Stage 3
Establishment of a cooperation system among tertiary medical agencies

Tertiary medical agencies in local NIRS
Establishment of a cooperation system with other medical agencies

(Prefecture A)
Secondary medical agencies
Primary medical agencies

(Prefecture B)
Secondary medical agencies
Primary medical agencies

(Prefecture A')
Secondary medical agencies
Primary medical agencies

(Prefecture B')
Secondary medical agencies
Primary medical agencies

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

Nagasaki University
### List of Cases

<table>
<thead>
<tr>
<th>Disease</th>
<th>Age</th>
<th>Gender</th>
<th>Cell Number</th>
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<tbody>
<tr>
<td>Sacro-coccygeal radiation ulcer</td>
<td>87</td>
<td>F</td>
<td>$3.7 \times 10^7$</td>
</tr>
<tr>
<td>HIV-associated lypodystrophy</td>
<td>30</td>
<td>M</td>
<td>$5.0 \times 10^5$</td>
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<tr>
<td>Neck radiation ulcer</td>
<td>52</td>
<td>F</td>
<td>$4.1 \times 10^7$</td>
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<tr>
<td>Chest radiation ulcer</td>
<td>67</td>
<td>F</td>
<td>$1.7 \times 10^7$</td>
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<tr>
<td>Chest keloid (post electron beam)</td>
<td>67</td>
<td>F</td>
<td>$5.3 \times 10^7$</td>
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<td>Burger's disease</td>
<td>34</td>
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<td>$1.1 \times 10^7$</td>
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<tr>
<td>Sacro-coccygeal radiation ulcer</td>
<td>80</td>
<td>F</td>
<td>$1.28 \times 10^7$</td>
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<td>HIV-associated lypodystrophy</td>
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<tr>
<td>Crohn's disease</td>
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<td>M</td>
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<tr>
<td>Left knee radiation injury</td>
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<td>F</td>
<td>$5.2 \times 10^6$</td>
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<tr>
<td>Chest neck radiation injury</td>
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<tr>
<td>HIV-associated lypodystrophy</td>
<td>31</td>
<td>M</td>
<td>$4.4 \times 10^6$</td>
</tr>
</tbody>
</table>
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


Regenerated soft tissue
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.

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