

# Radiology Japan

Japan Industries Association of Radiological Systems February 2008 No. 57

## First Half of 2007 (from January to June) Domestic Market Trend of Medical Imaging System

*Diagnostic Imaging and Therapeutic Systems (production, exports, imports, domestic market)*

From January through June 2007 Unit: Millions of yen

Item	Category	Production		Exports		Imports		Domestic Market			
		Amount	% Δ from Previous Year	Amount	% Δ from Previous Year	Amount	% Δ from Previous Year	Number of Units	% Δ from Previous Year	Amount	% Δ from Previous Year
<b>1 X-ray</b>		<b>72,915</b>	<b>+1</b>	<b>26,383</b>	<b>+12</b>	<b>10,493</b>	<b>-34</b>			<b>57,026</b>	<b>-11</b>
· General-purpose R/F		15,237	-14	2,937	+16	35	-	769	-8	12,335	-19
· Cardio & angio		6,586	-12	2,810	-24	4,603	-44	118	-25	8,378	-31
· General-purpose radiography		12,640	+23	5,576	+22	191	-79	2,945	+10	7,255	+10
· Mammography		1,186	-26	17	+206	2,348	-36	329	-20	3,517	-33
· Mobile		2,013	+15	1,194	+56	67	-9	332	-18	885	-16
· Dental		3,796	+10	1,042	+6	28	-	2,508	+14	2,783	+14
· Others		31,457	+6	12,807	+15	3,221	+16			21,873	+2
<b>2 CT</b>		<b>60,022</b>	<b>-3</b>	<b>38,674</b>	<b>-4</b>	<b>12,294</b>	<b>-10</b>			<b>33,642</b>	<b>-4</b>
<b>3 Nuclear medicine</b>		<b>5,143</b>	<b>0</b>	<b>13</b>	<b>-86</b>	<b>3,971</b>	<b>-45</b>			<b>9,100</b>	<b>-25</b>
<b>4 MRI</b>		<b>17,043</b>	<b>-1</b>	<b>8,256</b>	<b>+26</b>	<b>16,608</b>	<b>-24</b>			<b>25,395</b>	<b>-22</b>
<b>5 Image processing systems</b>		<b>16,566</b>	<b>+36</b>	<b>1,892</b>	<b>-5</b>	<b>2,927</b>	<b>-35</b>			<b>17,602</b>	<b>+20</b>
<b>6 Related items &amp; accessories</b>		<b>17,702</b>	<b>+14</b>	<b>9,237</b>	<b>+20</b>	<b>887</b>	<b>-21</b>			<b>9,352</b>	<b>+4</b>
<b>7 Diagnostic ultrasound</b>		<b>46,321</b>	<b>+3</b>	<b>30,964</b>	<b>+10</b>	<b>4,373</b>	<b>+2</b>			<b>19,729</b>	<b>-6</b>
<b>8 Therapeutic systems</b>		<b>4,714</b>	<b>+69</b>	<b>1,627</b>	<b>+96</b>	<b>5,362</b>	<b>-3</b>			<b>8,449</b>	<b>+13</b>
<b>Total</b>		<b>240,426</b>	<b>+4</b>	<b>117,046</b>	<b>+7</b>	<b>56,915</b>	<b>-23</b>			<b>180,295</b>	<b>-8</b>

(Note) Domestic Market: Calculated by the formula (Production – Exports + Imports).

### Review of the Results for First Half of 2007 (from January to June)

( ) refers to an increase or decline of percentage over the previous year.

- The total count of medical imaging system was as follows:
  - Production 240.4 billion yen (+4%)
  - Export 117.0 billion yen (+7%)
  - Import 56.9 billion yen (-23%)
 Consequently, total domestic market was 180.3 billion yen (-8%).

- The domestic market of major equipment was as follows:
  - X-ray 57.0 billion yen (-11%)
  - CT 33.6 billion yen (-4%)
  - Magnetic resonance imaging system (MRI) 25.4 billion yen (-22%)

- Diagnostic ultrasound 19.7 billion yen (-6%)
  - Image processing systems 17.6 billion yen (+20%)
  - Nuclear medicine 9.1 billion yen (-25%)
- Then, total diagnostic equipment was 171.8 billion yen (-9%).

The breakdown of the diagnostic X-ray system shrank as follows:

- General-purpose R/F 12.3 billion yen (-19%)
- Cardio and angio 8.4 billion yen (-31%)
- Mammography X-ray 3.5 billion yen (-33%)
- Mobile X-ray 0.9 billion yen (-16%)

As a result, the total X-ray system decreased to 57.0 billion yen (-11%).

- The production output increased to 240.4 billion yen (+4%).
  - Related items and accessories 17.7 billion yen (+14%)
  - Image processing systems 16.6 billion yen (+36%)

– Therapeutic systems 4.7 billion yen (+69%)

The diagnostic X-ray system increased as follows:

– General-purpose radiography 12.6 billion yen (+23%)

– Mobile X-ray 2.0 billion yen (+15%)

whereas, the following decreased:

– General-purpose R/F 15.2 billion yen (-14%)

– Mammography X-ray 1.2 billion yen (-26%)

As a result, the total was 72.9 billion yen (+1%).

4. The total count of exports increased to 117.0 billion yen (+7%).

– MRI 8.3 billion yen (+26%)

– Therapeutic systems 1.6 billion yen (+96%)

The diagnostic X-ray system increased as follows:

– General-purpose radiography 5.6 billion yen (+22%)

– Mobile X-ray 2.0 billion yen (+56%)

whereas, the following decreased.

– Cardio and angio 2.8 billion yen (-24%)

The total was 26.4 billion yen (+12%).

5. The total count of import suddenly decreased to 56.9 billion yen (-23%).

Especially,

– MRI 16.6 billion yen (-24%)

– Nuclear medicine 4.0 billion yen (-45%)

– Image processing systems 2.9 billion yen (-35%)

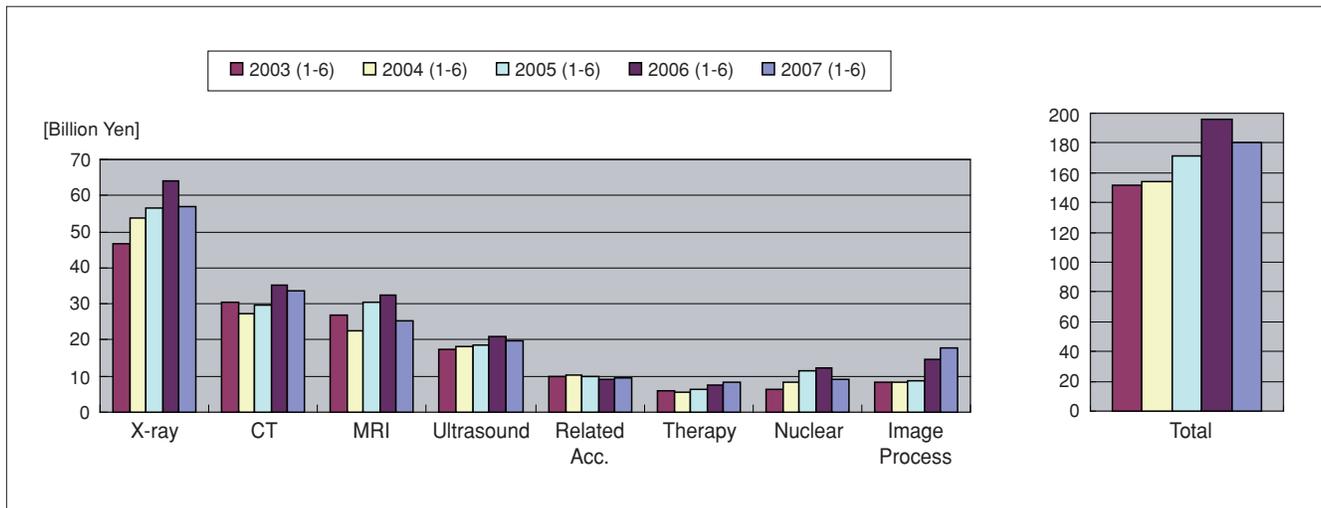
And the following of the diagnostic X-ray system decreased:

– Cardio and angio 4.6 billion yen (-44%)

– General-purpose radiography 0.2 billion yen (-79%)

Then, the total of the diagnostic X-ray system was 10.5 billion yen (-34%).

### Diagnostic Imaging and Therapeutic Systems Market in Japan Trends in the Last Five Years by Modality



# Promotion of Cancer Control Program and Medical Imaging Systems



Tadao Kakizoe

President Emeritus, National Cancer Center, Japan  
President, The Japan Cancer Society

## Introduction

In this lecture, I discussed issues of cancer control from four aspects: 1) Diagnosis and Treatment of Cancer, 2) Translational Research on Cancer, 3) Cancer Information Center, and 4) The Cancer Control Act. Thus, this lecture was intended to highlight the role of medical imaging to promote the national cancer control program.

## 1. Diagnosis and Treatment of Cancer

Cancer patients desire to be treated in such a way that their physical, mental, and financial burdens are as light as possible and their treatment is esthetic, quick and safe. Medical care now available can satisfy these desires to some extent. This has been accomplished by progress in diagnosis and treatment, and by a better understanding of the principles of cancer together with progress in understanding its biology.

Cancer diagnosis may be roughly classified into imaging, marker diagnosis, and pathology. Diagnostic imaging is a technique that allows us to see what is otherwise not visible. The inside of the body is visualized by making full use of physical means such as magnetic power, ultrasound, X-ray, and light. These are typically demonstrated in MRI, ultrasound, CT, endoscopy, microscope and so forth. Many sections of the living body can presently be visualized by the development and progress of such technology. It is well recognized that progress in diagnostic imaging has allowed accurate staging, which in turn has contributed greatly to delineating the localization and nature of cancer. One such example is the use of helical CT in detecting early lung cancer that cannot be detected by plain radiography. Another example I mentioned in the lecture was a fusion of functional and metabolic PET images and morphological CT images that allowed a definitive diagnosis of postoperative recurrence of rectal cancer in the pelvic cavity.

As an example of marker diagnosis of cancer, I discussed an attempt by the National Cancer Center Research Institute with the objective of the early diagnosis of pancreatic cancer, which is the most difficult cancer to manage worldwide. Our technique employs the mass spectrometry of serum for the comprehensive analysis of proteins in minute quantities, and attempts to narrow down the target population before image-based examination. We have confirmed the effectiveness of this new procedure in 40 cases and subsequently 100 cases of pancreatic cancer. A further clinical trial is now underway with the cooperation of medical institutions nationwide to confirm the effectiveness of this procedure

in over 1,000 cases. If this procedure becomes the first step for detection, then early diagnosis is expected to be available even for pancreatic cancer because diagnostic imaging is already well developed.

Local treatment of cancer has undergone a massive transformation, both in surgery and radiotherapy. Progress in early diagnosis and understanding of the clinical biology of cancer has transformed highly invasive procedures to today's standard and minimally invasive ones. Minimally invasive surgery for some regions has further been developed into celioscopic or endoscopic surgery. With increased dose convergence and cytotoxic effects, irradiation therapy in some regions is about to become comparable to surgery in terms of efficacy. In the lecture, I showed cases of breast-conserving surgery and thoracoscopic surgery of early lung cancer as examples of minimally invasive surgery. Also presented was a case of radiotherapy, in which proton beam irradiation brought about a complete cure of ethmoidal cancer while conserving vision.

As other moves in cancer treatment, I also mentioned general trends in cancer therapies, the importance of information-sharing among medical staff, and the establishment of systems to provide best cure and care to patients through team-based medicine by professionals of different disciplines.

## 2. Translational Research on Cancer

To illustrate an example of translational research on cancer, I talked about a clinical study currently conducted by the National Cancer Center that compares surgery and chemoradiotherapy in stage I esophageal cancer. The possibility of lymph node metastasis depends on the stage of cancer, and the progress in diagnostic imaging has enabled accurate diagnosis of stage I esophageal cancer, i.e., mucosal and submucosal malignancy. Results from this nationwide clinical trial is likely to help establish a standard treatment protocol for stage I esophageal cancer in terms of both curative efficacy and patients' quality of life. In joint research with a private company, the National Cancer Center has developed a safe and rapid technique for endoscopic resection of large, early-stage stomach cancer that utilizes a magnetic anchor, the safety and efficacy of which has been confirmed by clinical trials. The magnetic anchor acts like a micro-scale assistant sent into the stomach: lifted by a huge magnet outside the body, it enables safe resection, under direct vision, of lesions that are otherwise hard to see in the endoscopic field. The third example of translational research I mentioned in the lecture was the MRX operating theater built in the National Cancer Center Hospital.

Research and experiments for safe and accurate surgery are being conducted by making full use of diagnostic imaging systems including an open MRI, helical CT, flat panel detector, and diagnostic ultrasound. One future goal for this MRX theater is to conduct a clinical trial, with the approval of our institutional review board, to verify the safety and efficacy of the endoscopic surgery robot that we are currently developing in cooperation with a private company.

### 3. Cancer Information Center

What cancer patients and their families seek for most of all is reliable information about their cancer. In response to their strong request, the Ministry of Health, Labour and Welfare established the Cancer Information Center within the National Cancer Center in October 2006. The core function of this information center is to provide cancer information to patients, their families, and the general public. This function is also important for other medical institutions and administrative authorities, and the Cancer Information Center is currently making an extensive effort to improve the content of its information in cooperation with academic societies and other related organizations nationwide. It is also collaborating closely with the Ministry of Health, Labour and Welfare to establish an information network with designated cancer care hospitals. Another important function of the Cancer Information Center is cancer treatment assistance, and a strong commitment has been made to enable real-time consultation for hospitals all over Japan about difficult image evaluation and pathological diagnosis. The electronic exchange of information is expected to contribute largely to the efficiency of such consultation.

### 4. The Cancer Control Act

The Cancer Control Act was approved unanimously in June 2006 and implemented in April 2007. Having hoped for a long time that anti-cancer efforts would have legal backing, I am delighted that this law has come into effect. The establishment of this Act reflects the opinion of cancer patients and their families to a great extent. In fact, it stipulates that the Minister of Health, Labour and Welfare shall listen to the opinion of the Cancer Control Promotion Council to develop a Basic Plan to Promote Cancer Control Programs. Furthermore, the Act also stipulates that the council shall consist not only of cancer medical specialists and academic experts but also of representative cancer patients, their families, and bereaved families. In other words, their voices are being taken into account in the development of the national basic plan for cancer control.

I was elected president of the Council at its first meeting on April 5, 2007. Of 18 council members, four represented patients and their families and presented their opinions very actively at the meeting. The council had to accomplish an enormous number of tasks with a very tight schedule: the Basic Plan to Promote Cancer Control Programs was to be approved by the

Cabinet by early June before the prefectures would start preparing their own basic plans.

At the fifth meeting on May 30, 2007, the Council completed drafting the master plan, which was discussed among related ministries and finally approved by the Cabinet on June 15, 2007.

The plan has two overall goals: (1) to decrease cancer deaths; more specifically, to decrease the age-adjusted cancer mortality percentage of people under 75 years old by 20 points within ten years; and (2) to improve the quality of life of all cancer patients and their families. To attain these goals, focused efforts are needed in the following areas: (1) promotion of radiotherapy and chemotherapy, and training of medical professionals with expertise in these therapies; (2) promotion of palliative care starting at the early phase of treatment; and, as a platform to accomplish these tasks, (3) promotion of cancer registry and to increase medical institutions that implement cancer registry. Consultation and information services on cancer screening, prevention, and care also need to be established and implemented. Yet another goal is the equalization of cancer medical services to provide high quality care nationwide. Thus the Basic Plan aims to promote comprehensive and well-planned cancer control in Japan. Promotion of cancer research provides the foundation for all these tasks.

The representatives of patients and their families valued the attitude of council members of taking careful note of the items required for the Basic Plan and incorporating them as much as possible.

The goal of a 20-point reduction in the mortality percentage is based on the following figures. The cancer mortality of people under 75 years old decreased by about 1 point per year from 1990 to 2005, from which a 10-point decrease is expected during the ten years from 2005 to 2015. The mortality would be further decreased by about 1.6 points from a 50% decrease in smokers, by about 3.9 points from a 50% increase in the screening rate, and by about 4.9 points from the nationwide standardization of cancer care. The total decrease would thus be 20 points. Suggestions based on highly detailed assumptions allowed this specific goal to be included in the plan. Another achievement of the plan is that it clarified the roles and duties to be fulfilled by the National Cancer Center and the Cancer Information Center.

Now with the Act in effect, it is necessary to manage the progress of the plan properly and regularly review the attainment of goals in terms of timeliness and extent. Special financial consideration is also required. Fulfillment of this Basic Plan will be the major challenge for the future of cancer control in Japan.

### Conclusion

A key point in this lecture was the importance of diagnostic imaging in the diagnosis and control of cancer in Japan. A 50% increase in the screening rate demands considerable effort by those involved. Quality management of screening images and the standardization of technologies available for patients nationwide will also be essential to promote cancer control for the future.

# JIRA Activity Reports

## Report on Industry Activity about RoHS (Regulations of Hazardous Substances)

### 1. Introduction

To tackle the issue of the environment from now on, it is a matter that the R&D and Production of each company must be involved. In addition to that, it is required to comprehensively manage throughout the total lifetime like sales, service, disposal and even the end users. It is also a fact that our medical device manufacturers are required to take action from an international viewpoint in dealing with the export of products.

The treatment of medical equipment in the regulations has large impact to our industry. This is a report on JIRA's activities in cooperation with the Japan Federation of Medical Devices Association (JFMDA).

### 2. Outline of RoHS regulations of hazardous substances contained in equipment

JIRA submitted a request to ERA (English consultancy delegated by European Commission) through JFMDA about the RoHS exemption of medical equipment in March 2006. In cooperation with JEMIMA (Japan Electric Measuring Instruments Manufacturers' Association), JIRA exchanged information and comments with JBCE (Japan Business Council in Europe). JIRA also requested COCIR (European Industry Association) to cooperate by an information exchange.

## RoHS Directive

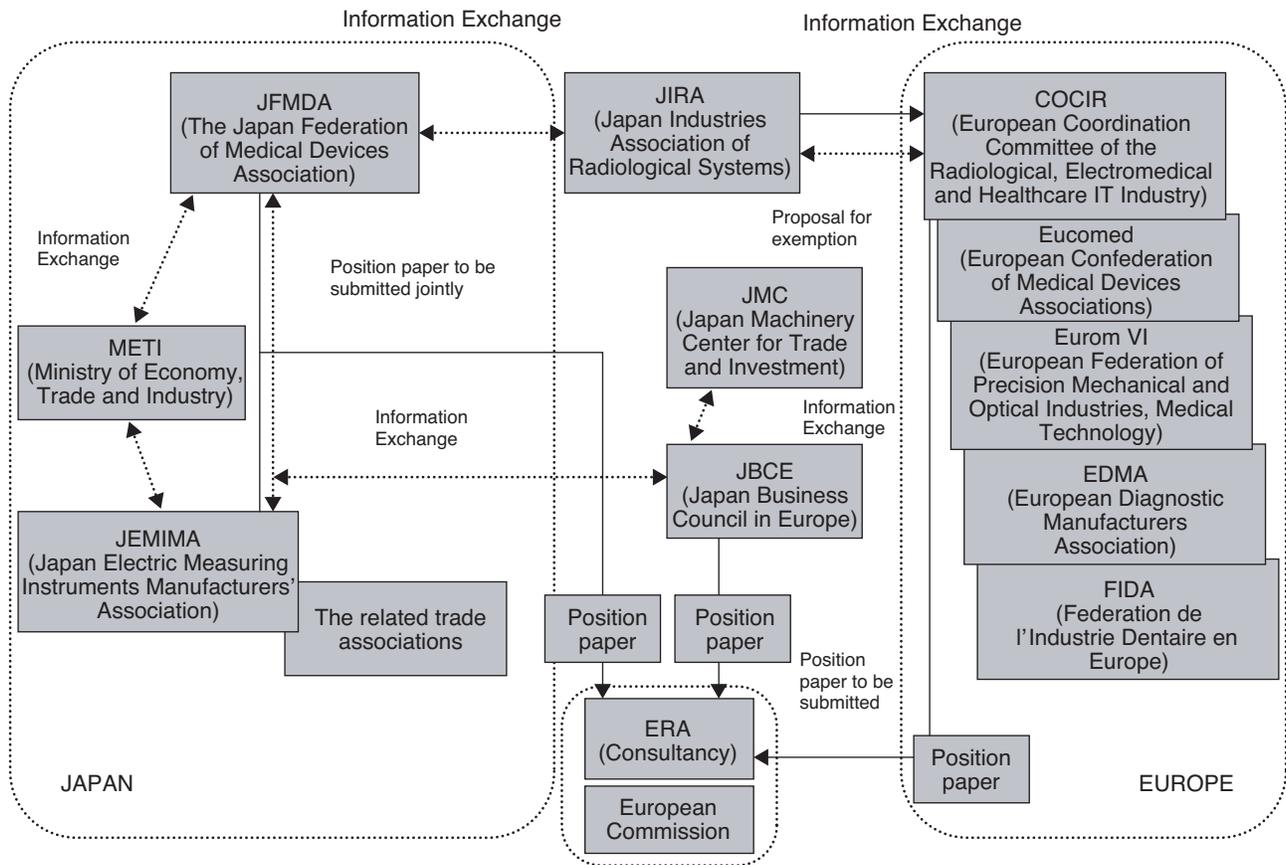
\* EU Directives on the restrictions of the use of six kinds of substances in electrical and electronic equipment from July 2006

\* The six kinds of substances are lead (Pb), cadmium (Cd), mercury (Hg), hexavalent chromium, polybrominated biphenyl (PBB) of bromine fire retardant, and polybrominated diphenyl ether (PBDE).

Category	WEEE	RoHS
(1) Large household electrical appliances	Applicable from Aug. 13, 2005	Applicable from July 1, 2006
(2) Small household electrical appliances		
(3) IT and telecommunications equipment		
(4) Consumer electronic equipment		
(5) Lighting equipment		
(6) Electrical and electronic tools		
(7) Toys, leisure and sports equipment		
(8) Medical devices		Exemption is being requested
(9) Monitoring and control instruments		Applicable from July 1, 2006
(10) Automatic dispensers		

Some technologies are used in common between medical devices and measurement instruments. So, a liaison conference was held with JBCE and JEMIMA in March 2006. The list of exemption was created in cooperation with JEMIMA to implement the harmonization of the whole industry.

## Collaboration and approach of the related organizations



## Selection of items exempted for application

List of exemption for RoHS-JFMDA/JIRA category 8 (Outline)

Substance	Specification and intended use	Reason of use	Major equipment using the substance
Lead	1) For protection and shielding of radiation	No substitutes because of cost and workability	X-ray equipment, CT scanner etc.
	2) Lead lubrication of X-ray tube (including cooling unit)	No substitutes	X-ray equipment, CT scanner etc.
	3) For connection of ultrasound probe electrode	No substitutes because of cost and workability	Diagnostic or therapeutic Ultrasound etc.
	4) For performance at very low temperature	No substitutes because of connectivity under low temperature and cost	MRI
Lead	For the detector	For radiation and electronic measurement	X-ray equipment, CT scanner etc.
Cadmium		For dose reduction, optical and radiation measurement	CT scanner, nuclear medicine equipment, X-ray equipment etc.
Mercury		Infrared light measurement	Medical thermography

The request for the exemption items were selected in view of; no substitutes because of the characteristics of medical equipment and its measurement principles, expectation to contribute to future science and technology. This request was made following the COCIR format and submitted to the ERA.

### 3. Outline of ERA's Report

The ERA's final Report covers the below-mentioned proposals and recommendations about the medical device (category 8);

- 1) The category 8 shall be included in scope of the RoHS from 2012 except in-vitro diagnostic equipment.
- 2) In-vitro diagnostic equipment (medical analyzer etc.) shall be included from 2016.
- 3) Active implanted devices (artificial heart etc.) shall be excluded permanently, or shall be included from 2020.
- 4) Lead contained in solders is requested to be exempted temporarily.

Lead-free solders which is currently the most difficult shall be reviewed in 2010 together with computer servers etc.

\* As to the lead-free solder, the field data will be available by 2010. So, ERA expects that there will be no problems after that.

- 5) Sensors using lead (Pb), cadmium (Cd), and mercury (Hg) are requested to be exempted in consideration of future development.
- 6) It is difficult to find the substitution of lead contained in the radiation protection, shielding, X-ray tube lubrication, the use under very low temperature and the single crystal piezoelectric crystal material used in the ultrasound transducer. So exemption is proposed.
- 7) The use of lead for the ultrasound probe connection shall be allowed at least by 2016.
- 8) The unclear wordings are defined for better understanding; the scope of Medical devices (category 8), the definition of Spare parts. The definition of Marketing (placing of product on the market) etc.

JIRA proposed the exempted items in collaboration with the related organizations. As a result, the proposal was mostly accepted. The ERA's Report says that the proposal will probably be promulgated to the RoHS regulation without any change.

This ERA report was the only one report published by the European Commission about the evaluation on the reliability and environmental impact of alternative technologies based on extensive survey and investigation. So, the report is very important for the R&D engineers.

### 4. RoHS seminar organized by JFMDA/JEMIMA/JMC

Since the contents of RoHS have been gradually known, a seminar titled "RoHS -- The Recent Trend and Explanation of Categories 8 and 9" was organized by JFMDA together with JEMIMA and JMC in June 25, 2007. About 300 people from the related industry sectors attended the seminar. The following updated information were introduced.

- 1) Outline
  - Environmental regulations in the world and the measures taken in Japan
  - The recent situation of the EU environment policy --

Focusing on RoHS

- 2) Analysis method
  - The analysis method of chemical substances and the trend of international standardization
- 3) Measures taken by each category
  - Measures taken for category 8 (medical devices)
  - Measures taken for category 9 (monitoring and control instruments)
  - Outlines of the ERA's final report (summary of common matters for all categories)



### 5. Conclusion

- 1) Review of RoHS exemption items

The ERA's final report published on September 12, 2006 incorporated the exemption items requested by JFMDA/JIRA. These items are considered almost finalized. However, the European Commission reviews the items every four years. Even the exempted items this time are likely to be regulated in the future when the restriction of use becomes technically feasible. So, our industry has to continue monitoring.
- 2) Measures to be taken by companies

The countermeasures on RoHS should be appropriate and sufficient and be functioned systematically. However, it is so hard for the medical equipment industry, which is a multi-products, small-sized production with longer product lifetime including the development stage. Accordingly, companies are requested to be prepared in advance, so that they can comply to RoHS by investigating their supply chain.
- 3) The expansion of environmental regulations to medical devices and the measures taken by various countries.

The industry is requested to take global measures for the regulations in the world like the European regulation of chemicals (REACH), the battery regulation, the Chinese RoHS, the U.S. mercury regulation etc. Restrictions of the use of hazardous substances will be reinforced in the future. In April 2007, JIRA RoHS-WEEE WG renamed as the Environment WG in order to cope with the expansion of environmental regulations to medical devices in various countries and to reinforce the activity positively.

## Report on participation in the DICOM Standards Committee meeting

### --How are the DICOM Standards created?--

This is a report on participation in the DICOM Standards Committee (DSC) meeting held in Berlin, Germany on June 29, 2007.

In addition to this meeting, this report explains the supporting organizations for DICOM.

To expand and maintain the DICOM Standards, many organizations, associations and companies are cooperating all over the world. JIRA is also working from the position as a standards developing and promoting organization. The following explains the relationship of the major organizations that actually create the DICOM Standards.

### 1. DSC (DICOM Standards Committee)

DSC is the highest decision-making unit for the establishment of the DICOM Standards and Committee operations, being responsible for the activity and progress of each WG as a subsystem, and for the orientation of the DICOM Standards.

In 1983, ACR (American College of Radiology) and NEMA established jointly the ACR/NEMA Committee, which developed ACR/NEMA Standards V1 and V2.

In 1993, this Committee became an independent organization known as DSC. The deliverables of this Committee are the DICOM Standards. ACR and NEMA are members of DSC. Particularly, NEMA owns the copyright of the deliverables (documents of Standards), providing a powerful backup for DSC operations in respect of human resources, physical materials and funds.

To be qualified as a DSC member, you have to submit an application form, and sign a consent document for the intellectual property right declaration. DSC will deliberate your eligibility and accept or reject your application for member registration.

JIRA has been registered as a DSC member as the Japanese representative since the early stage.

JIRA collects the opinions from JIRA member companies through the regular meetings and mailing list in regards to the Supplement and Correction that are sent en masse every one to two months. Then, JIRA votes in support of, in conditional support of, or against the Supplement and Correction. The DSC meeting is held three times a year in North America, Europe, and Asia.

Medical Imaging & Technology Alliance (MITA) is a division in the whole NEMA organization as shown in Figure 2, and DSC NEMA Secretariat is shown as a part of this organization chart.

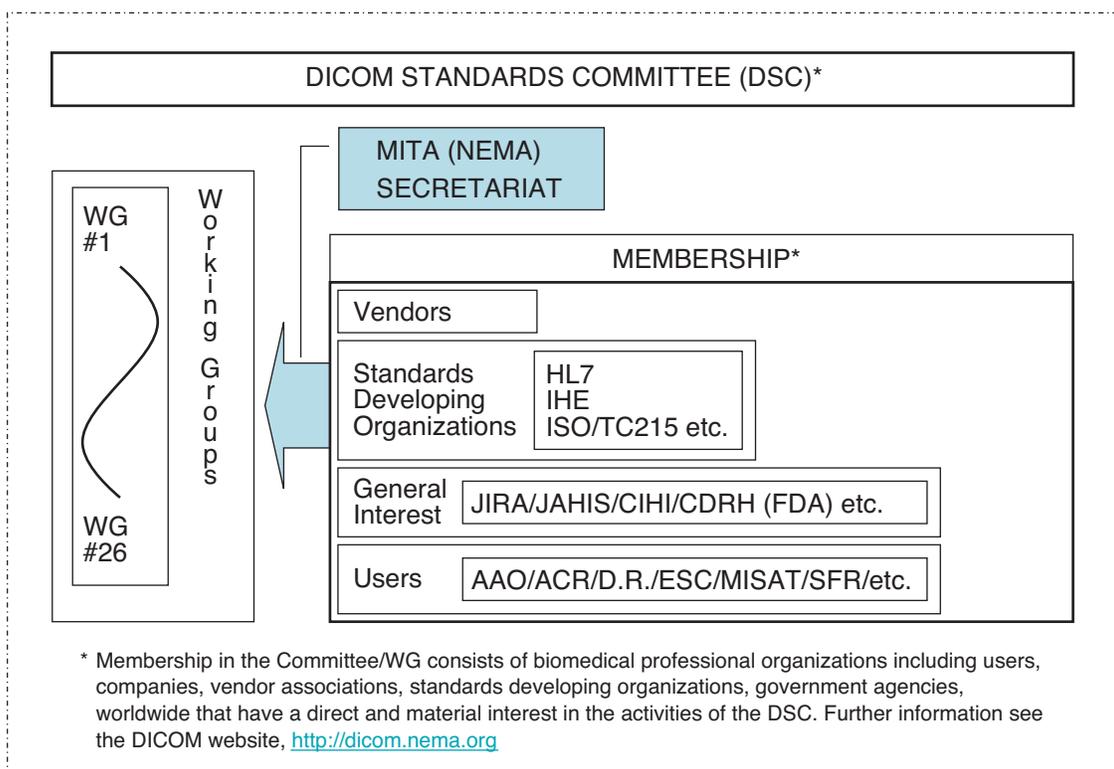


Figure 1. Structure of DICOM Standard Committee (DSC) and its Working Groups

**MEDICAL IMAGING & TECHNOLOGY ALLIANCE (MITA)  
2007 ORGANIZATIONAL CHART**

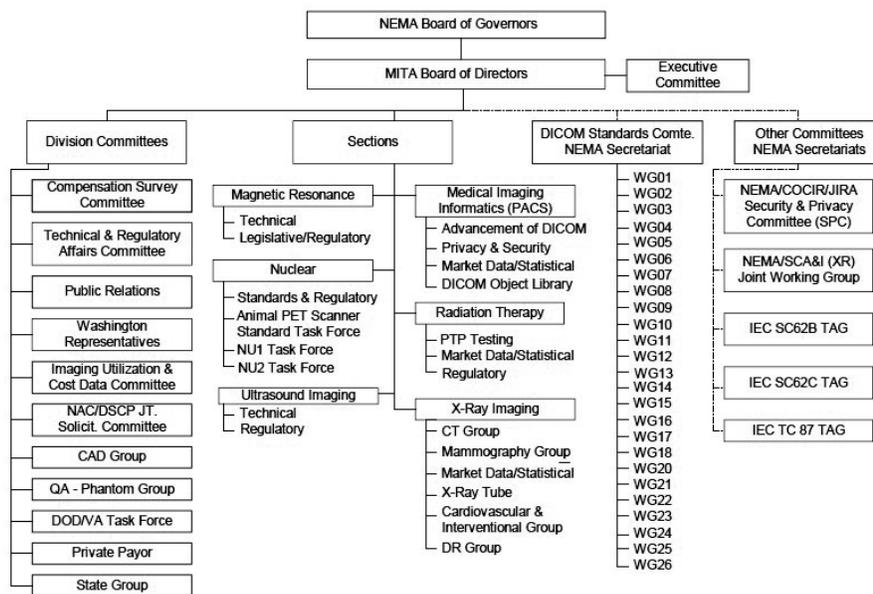


Figure 2. Organization Chart of MITA/DSC in NEMA

## 2. DICOM-WG (Working Group)

WGs deliberate the respective DICOM Standards in details. DSC has the following WGs at present.

WG	Name
WG01	Cardiac and Vascular Information
WG02	Projection Radiography & Angiography
WG03	Nuclear Medicine
WG04	Compression
WG05	Exchange Media
WG06	Base Standard
WG07	Radiotherapy
WG08	Structured Reporting
WG09	Ophthalmology
WG10	Strategic Advisory
WG11	Display Function Standard
WG12	Ultrasound
WG13	Visible Light
WG14	Security
WG15	Digital Mammography and CAD
WG16	Magnetic Resonance
WG17	Multi-Dimensional Image
WG18	Clinical Trials and Education
WG19	(Reserved)
WG20	Integration of Imaging and Information Systems
WG21	Computed Tomography
WG22	Dentistry
WG23	Application Hosting
WG24	Surgery
WG25	Veterinary Medicine
WG26	Pathology

Figure 3. DICOM Working Groups

You are entitled to be present in any WG meetings whenever you are interested in that field. However, if you want to vote in a WG meeting, you have to be qualified as a DSC member.

Each WG proposes the establishment, expansion, and correction of the DICOM Standards in the field concerned. A new work item needs the deliberation and approval from DSC. The WG members participate in the deliberation and vote on the WG proposal. After the WG proposal is approved, it is voted on by all the members who have the voting right. Finally, the proposal is deliberated by DSC and adopted as a Standard. WGs work mainly through exchanges of opinion via the mailing list.

WG06 and WG10 are different in nature from other WGs.

WG06 judges the contents of the WG proposal comprehensively to determine whether the proposal should be rejected or sent to DSC voting, which is the final stage of creating the Standard. This procedure is intended to keep DICOM Standards consistent. Furthermore, WG06 sometimes instructs other pertinent WGs to receive requests from external organizations, to harmonize the Standards, and to propose new Standards that meet the current trend of the times.

WG10 is a forum where they discuss the future direction of the DICOM Standards. It is an advisory group that acts as an advisor, providing advice and suggestions to all other WGs.

### 3. DSC @ Berlin

The DSC meeting was held on June 29, 2007 at the office of DRG (Deutsche Röntgengesellschaft) in Berlin, Germany. The system's secretariat member, Mr. Imokawa, also attended, representing JIRA.

The DSC meeting is held three times a year in North America, Europe, and Asia. In 2006, Yokohama, Spain and Chicago were the venues of the meetings in April, September and November, respectively.

In 2007, Taiwan, Germany (covered by this report) and Chicago have been the venues of the meetings in March, June and November, respectively.

In the Berlin meeting, Chairman Mr. Emmanuel Cordonnier declared, as usual, the opening of the DSC meeting. The participants alternately gave their names and affiliated organizations. Then, Mr. Howard, MITA staff, emceed the meeting according to the agenda that has been posted on the ftp web site. It is a rule that the participants should download the agenda materials to their own PCs in advance.

The following is an excerpt from the agenda.

- (1) Supplement of vacancy in the Executive Committee  
After the agenda was explained, three members announced their candidacy. A piece of paper was given on the spot and collected. Two members were nominated. Incidentally, Mr. Shinoda of JAHIS (who attended this meeting) is already elected as a member of the Executive Committee.
- (2) Report on each WG's activity  
WG06 reported that the volume of the Standards increased, and that the contradictions within a Standard and inconsistency among the Standards increased, too. Thus, Correction increased. This problem is being solved to some extent by increasing the exchange of opinion through mails and t-con (telephone conference). But, schedules are often being delayed.  
WG13 proposed a new work item of standardization HD MPEG VIDEO, which was approved. Video equipment for VISIBLE LIGHT is being changed to HD VIDEO, and standardization is required. Even HD video industries have not yet unified standards. In that sense, this is a very innovative proposal.  
WG8 proposed to define TID 2000 Basic Diagnostic Imaging Report, in more detail, with reference to DIN 6837-5. In this way, it is possible to precisely reflect the standards of each country to DICOM. Japan also needs to make an active proposal to take the initiative in this field.

- (3) Report of DICOM activity of each country
  - Canada  
Progress report of HER (Electronic Health Record), which is a national project
  - Taiwan (the last DSC venue)  
Report of the DSC meeting in Taiwan and election of MISAT (Medical Information Standards Association of Taiwan) members for this year
  - JIRA Report of domestic dissemination activity  
Report of Connectathon (2007/02 Tokyo), and report of DICOM dissemination activity
  - JAHIS Report of participation in the liaison meeting of ISO/TC215 (2007/05 Montreal)  
Announcement of HL7's activity towards standardization of ISO 28380 and the future schedule.

In the Berlin meeting, a member of ESR (European Society of Radiology) referred to the necessity of seminars and other public relation activity, because medical doctors cannot keep pace with the recent progress of the DICOM Standards. In response to this, DSC decided to actively promote the creation and provision of educational materials. JIRA/JAHIS were also requested to cooperate to create educational materials and to participate in dissemination activity.



Figure 4. Participants of the DSC meeting in Berlin.

# Development of Japanese Radiological Equipment in the Post-World War II Period (22)



Sumio Makino  
(Advisor, JIRA)

Tamon Inoue  
(Emeritus Professor,  
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## Dawn of MRI in Japan ••• First in a series

### 1. Beginning of MRI in Japan (Makino)

#### A. The first appearance of NMR-Imaging

In 1972, a large-scale innovation of the medical imaging technology began with the X-ray CT, evolving into various fields. The so-called “Computer Technology” developed by CT became the basic engineering (= image-data-processing basic technology). Many researchers everywhere attempted ardently to select various kinds of energy and to visualize the internal organs of a human body.

In fact, the Computer Image Processor was researched and commercialized in the nuclear-medicine field earlier than in X-ray CT. However, when it came to the nuclear-medicine field, it was limited to a very special field. Besides, the so-called mini-computer was the smallest computer available at that time, and was not suitable for use at hand. So, application was limited to a special field.

As mentioned above, however, the appearance of X-ray CT stimulated all engineers and technicians in the world’s interest, and image-processing technology came to spread at once. One of the applications was magnetism. At the beginning of this research, the technology was popularly named “Nuclear Magnetic Resonance” after its principle. But, the word “nuclear” connoted a possible adverse effect to a human body, so it was deleted later. Then, this technology was renamed “magnetic resonance imaging.”

I saw for the first time the research and experiment of “NMR-Imaging” late in 1977, when I was very busy in spreading X-ray CT. When I visited the EMI Laboratory in London, England, I was surprised to see a big magnet supported with a thick lumber frame. I was shown a human head image (Figure 1) that was obtained with NMR at that time. The EMI executive managers asked me whether or not Toshiba was interested in the continued research and subsequent commercialization in the same way that Toshiba succeeded in X-ray CT. I did not give them a positive reply, because we were very busy in spreading X-ray CT in Japan and we thought that the research was still in a basic stage at that time and that we had no room to accept their offer.

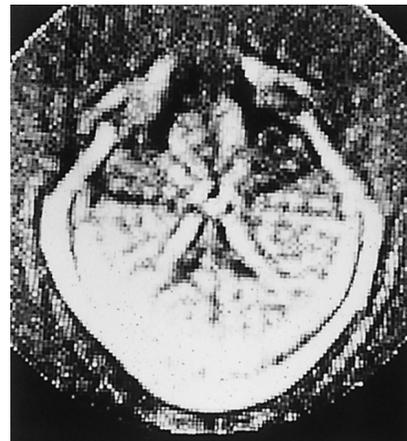


Figure 1.

#### B. Research mood for NMR-Imaging being urged

Aberdeen University in England published NMR images in the BJR journal. New York University in the United States announced its research paper about the prototype of NMR equipment. Accordingly, as the related technical references increased, we felt that we had to begin the academic research to reach the international level in this field, and read those references carefully.

Originally NMR equipment was intended to research the physical properties of substances and to analyze their chemical composition. Application of NMR to visualize substances was a new idea. Especially, NMR was intended to dynamically analyze the spinning motion of substances, which was caused by the resonance of characteristic magnetism of substances. The papers mentioned so much mathematical analysis of dynamics. We were too busy with problems concerning the X-ray CT those days to further study these mathematical theories.

As a result, we requested Tamon Inoue, senior researcher and mathematician, at the Toshiba Research & Development (R&D) Center for an explanation and research on NMR. He accepted our immediate request willingly, which opened the door to the next stage. I have now asked him to contribute his memoir about his research and development. His memoir is an NMR-Imaging pioneering history of Japan as it is, and is worth recording in the historical documents of JIRA. His contribution as it is will appear in two installments.

## *Research on NMR-Imaging Technique in Japan (First in a series)*

*Tamon Inoue, Emeritus Professor, University of Tsukuba*

### 1. Introduction

MRI (standing for Magnetic Resonance Imaging) technique was commercialized early in 1980s, being spread rapidly in a short time despite its very high price, and being evaluated as an indispensable technique in almost all clinical fields. Thus, the MRI technique progressed rapidly, proposing new imaging methods one after another, and expanding its applicable diagnostic fields even in the subsequent period when ordinary equipment would reach the stage of mature technology. As is evidently shown by this fact, this diagnostic system is unique and different from other equipment in terms of both the related technology and the development process, although MRI is similar to several other diagnostic systems at a glance. We have researched and developed this unique technology over many years. As researchers, we encountered luck to complete the practical MRI equipment for the first time in Japan.

Consequently, Mr. Sumio Makino has requested that I contribute my memoir about the development. He helped me very much with my research while I worked for Toshiba. The efforts of many researchers resulted in the completion of MRI equipment. So, this description from my limited experience may be inappropriate. I have accepted his offer frankly and have tried to make my description as objective as possible, whilst recollecting my poor memory.

### 2. MRI seen as CT

If MRI is seen from the flow of engineering development, it is biometric imaging equipment that is an extension of computer tomography (CT). For this reason, in early stages of development, it was deemed by the related researchers as computer tomography using the phenomenon of nuclear magnetic resonance (NMR). In that sense, MRI was called "NMR-CT" then.

In 1990s, the name changed gradually to MRI. This does not mean that NMR-CT is an unsuitable name to refer to this diagnostic imaging system, and that its name does not imply what it is. Moreover, in these technologies, software plays a very large role. The basic algorithm of reconstruction calculation for MRI is based on the same multi-dimensional Fourier transformation relation as CT. In this respect, the content of the Compute in Computed Tomography is not essentially different from CT.

The name changed chiefly because N of NMR stood for Nuclear, which suggests hazardous radiation and was not preferable for use. But, the fact is that MRI does use a phenomenon that occurs at the level of an atomic nucleus, although the involved energy is much lower than gamma rays and X-rays.

For years, I was engaged in the research of CT, in a broad sense of a word, including MRI. When a CT using X-rays appeared for the first time, I belonged to Toshiba R&D Center.

I majored in mathematics at the university and applied physics at graduate school. After I entered the company, I was assigned to the Atomic Power Research Department. My main job was to use the supercomputers of those days and to perform calculations related to atomic power and radiation. This career was background for my subsequent participation in the development of CT and MRI.

Ten years have passed since I entered the company. My superior, Director of R&D Center, visited the related research facilities in Europe. One day after his return, he reported to us the result of visit. He also visited EMI in England, with which Toshiba collaborated through the sale of LP records. He showed me the PR brochures of EMI's technical achievements that he collected there. That was when I saw CT images for the first time. It was a head CT image taken by Hounsfield for the first time. The image quality was inferior from the present standard level. But, the CT reconstructed image that I saw for the first time was very impressive to me.

I was greatly shocked and felt that EMI engineers made an advanced technical progress that would not be attained by us. On the other hand, we regretted that we were not able to invent such equipment although we belonged to the same research fields as theirs. Immediately after that, I analyzed the specifications of such equipment. Unexpectedly over time I found that its technical level was not as high as I suspected.

When this equipment was considered as a system, it was indeed an epoch-making system. However, when its element technology and system components, such as X-ray generation and radiation measurement were considered, the equipment was obviously nothing new. The key point was the software. Especially the image reconstruction algorithm was a centerpiece. We began immediately to investigate these mathematical content. Unexpectedly, after we used the characteristics of the multi-dimensional Fourier transformation, we were able to easily obtain a strict solution for this reconstruction problem. In other words, it was a wonderful idea indeed. But, once its essence was known, it was nothing new. It was an example of the "Columbus' Egg, i.e. a deceptively difficult achievement." After the word CT became widely used, I thought half-jokingly that CT stood for Columbus's Tamago (Egg).

Thus, once the essence of technology was known, we were motivated to make the equipment whose performance was equal to or better than theirs, and we also became confident of its success.

Then, I submitted to my superior a proposal for the commercialization of CT in our company, but my proposal was rejected instantly. The reason was that Toshiba should depend entirely on the collaborative company EMI for production of such high-tech equipment, and that Toshiba should sell them exclusively. That was considered as the most profitable way for our CT business. I was highly disappointed, but I took up this equipment as one of my individual researches. In obscurity, I continued researching chiefly on the applied mathematical analysis about

image reconstruction, expecting that this technology would become promising in the future.

In the mean time, the market situation changed gradually. In particular, many clinicians requested for domestic production of CT. In addition, it was rumored that our competitor Japanese companies had already started development of CT. As a result, our executive managers also changed the business policies. They seemed to determine that my career was most suitable in charge of such a system that is a combination of mathematics, physics, engineering, etc. As a result, they appointed me as a software specialist representing R&D Center.

Thus, Toshiba R&D Center and Medical Systems Division organized a joint project team for CT development, resulting in completion of the whole-body, third-generation CT, model TCT-60A. However, Company H had been honored as the first Japanese manufacturer of CT, because that company had begun development ahead of us. If it had been accepted when I submitted the proposal for the domestic production of CT to my superior, the situation might have been quite different. It was very regretful. If we encounter the future chance of such development competition of equipment, we must make every effort to become the first Japanese manufacturer by all means. We were so firmly determined at that time.

### 3. Opportunity of MRI development

In the above-mentioned process, the CT development advanced. After that, the manufacture and sales of our CT progressed smoothly by the middle of 1970s. Around that time, CT development and research as an engineering research reached the stage of maturity and temporary pause. We started to look for the next seeds that come after X-ray CT. I devoted myself fairly to the mathematics of reconstruction, which was developed from CT itself. Especially I was much interested in research on the algorithm of reconstruction, which was as an inverse problem in mathematics. I concentrated on the imperfect projection reconstruction problem etc. It was a matter of course that I received many requests from Medical Systems Division for the improvement of CT. Their requests raised many problems that were suitable as the seeds of new research. Including these problems, the following basic problems about X-ray CT made we researchers in this field feel intensely responsible for a solution. They were:

- 1) As the media to collect CT projection data, we use hazardous ionized radiation such as X-rays, gamma rays. Can't we find any other media?
- 2) The most suitable image signal for medical diagnosis must correspond to the change at a biochemistry level. Can't we find any good media to extract information of this level? Can't we invent CT that uses such media?
- 3) As the basic nature of data, we visualize only the tomograms that are perpendicular to the body axis. Can't we invent CT that visualizes the tomograms that are oriented spatially in every direction?

At that time, the researchers in the world looked for new progress and made several proposals about a new CT. For example, they were CT using electric impedance, CT using microwave, CT concerning acoustic impedance, CT using the phenomena of NMR, etc.

When I came to know these proposals about such CT, I studied them from my own viewpoint. The last one among the CTs mentioned above is CT using the phenomena of NMR, which deals with a hydrogen nucleus. This CT suggested a possibility to solve all the basic problems that were bottlenecks of the present CT.

On the other hand, I had frequent contacts with Mr. Sumio Makino, Medical Systems Division, through CT development. Then, I received his proposal to hold the study group meetings about the problems of this field. I was looking for such opportunity for organizational research. So, his offer was quite timely. I participated in the group positively. Mr. Makino and group members held weekly meetings at the office of Toshiba or Toshiba Medical, mainly studying the related technical papers. Based on this work, there appeared the mood within Medical Systems Division to start research and development of a new diagnostic image system, which might be called NMR-CT. Around 1978, Mr. Makino proposed to organize a research project.

By the way, I had prepared for the commercialization of NMR-CT and had surveyed the in-house organization to deal with the technology related to NMR measurement. To manufacture such a product, I felt that Toshiba was in a very disadvantaged position compared with our competitors. This was because Company H, Company S etc. manufactured and sold NMR spectrometers. These companies would become our competitors also in NMR-CT as well as they did in CT development. In contrast, Toshiba had no experience in such products and had almost no researchers and engineers related to NMR measurement. Under such circumstances, we had to cooperate with external organizations etc. I was worried about how to solve this problem.

After that, the study group meetings with Mr. Makino increased activities. We all felt the necessity to take action toward the promotion of concrete research and development. Mr. Makino told me the following. Any financial problems to promote the development project would be solved by Medical Systems Division with responsibility. All the tasks of basic research would be up to me. If the cooperation within the R&D Center were not enough, a joint research with external organizations would be an alternative.

I met my senior, Director of R&D Center, and talked about how to advance the basic research on NMR-CT development. To digress slightly from the main point, although he majored in engineering, he said to me, "I know CT, but what is NMR?" I was so surprised at his ignorance that I did not give him a correct reply. I replied, "NMR stands for New Money Resource. This product will surely bring a big profit to us."

I consulted with Director about the following. "Medical Systems Division will support us financially for NMR-CT, but that is not enough for experiments of NMR measurement. For this technology, software is very important, but my team is understaffed. So, I would like to advance joint research with external organizations. Please permit me to do so."

The Director's reply was as I expected. "R&D Center cannot afford any special financial and man-power supports. However, as far as a joint research with outsiders is concerned, it is up to you."

I contacted one of my university classmates promptly. With his help, I was introduced to an NMR specialist at the University of Tokyo, Physical Properties Research Institute. He was Hiroshi Yasuoka, Assistant Professor (that time), who became later Director of the Institute.

Instantly, I met Mr. Yasuoka and explained the significance of NMR-CT development and asked him to help us. At that time, I was worried whether he would accept my request or not. The causes of my worry will be mentioned later. Fortunately, he promised me full cooperation willingly.

At that time, I was most worried about how the University would react to my request. It was only recently that industry-university cooperation had begun to be encouraged greatly, in order to enable universities to transfer their research achievements to the private sector, for example, through TLO (Technology Licensing Organization). But, until early in 1970s, some university staff had been extremely fearful that joint research with private companies would be likely to result in cooperation with military research. So, they had the simplistic view that every joint research should be avoided. However, Assistant Professor Yasuoka understood the significance of our research, which he stated would contribute to humankind's health and welfare, promising me full cooperation willingly. I now recall what he happened to say then. He said to me, "This proposal would not be accepted by the famous university in Kansai where I used to work."

Soon after our first encounter, I was invited to his seminar and talked earnestly to his colleagues, graduate students, and many researchers about general CT technology and the high potential of NMR-CT as a biometric imaging technique. Thus, I ensured the hardware needed for the NMR-CT signal measurement. On the other hand, I asked Fuyo Information Systems Co., Ltd. to develop the software, because they had also accepted our request for numerical calculation of CT reconstruction before this.

In the spring of 1979, Toshiba and The University of Tokyo, Physical Properties Research Institute started a joint research project for the development of NMR-CT. Mr. Kozo Sato, a researcher of the Yasuoka Laboratory, moved to Toshiba, Medical Systems Division, and joined the project team. Mr. Toru Suzuki at Toshiba Medical Systems Division, my acquaintance since the CT development, became the head of the organizational unit for this research. Toshiba dispatched several young

engineers to The Physical Properties Research Institute. This project team thus organized, was probably the smallest, but the most enthusiastic in the world.

The team started the experiment by using the iron-core magnet located at The Physical Properties Research Institute. The first experiment was a kind of a magnetic field focusing CT, where we used a magnetic beam of constant intensity with a similar shape to that of X-ray CT, scanned the object, and gathered the projection data. We generated the magnetic beam by attaching a navel-like iron block to the head of the iron-core magnet.

We could not rotate the magnet field, so we made a mechanism to rotate the object. In January 1980, we took the first image. We put an object (a piece of rubber hose for the vacuum pump) in the narrow gap of iron core, and rotated it to gather projection data in every direction in respect to the object. We measured the NMR signal in CW (continuous wave) mode. For reconstruction, we used the filter correction back projection method, which was the same as that of X-ray CT.

Luckily this object was axially symmetric and we could obtain a cylindrical image fairly easily. The image had much noise and artifact. The image quality was inferior to that of the reconstructed image obtained by an ordinary X-ray CT. But, we were much impressed with the NMR-CT image that we obtained for the first time.

Being encouraged by the result, we immediately planned the following items for research.

- (1) To change the basic measurement method to the pulse Fourier transformation, which is more efficient, excellent in SN, and advantageous to measure relaxation time.
- (2) To gather projection data by the gradient field mode invented by Lauterbur.
- (3) To perform reconstruction by the two-dimensional Fourier transformation.
- (4) To use the selective excitation method for slices, etc.

The iron-core magnet was useful only for confirmation of the principle, but it could not take an image of the object larger than 2 cm. We wanted to take an image of the object as large as 10 cm. So, we made a simulator of the air-core magnet that could shoot a wider area.

Figure 2 is the tomogram of okra (vegetable) taken at that stage of the research. The reconstructed image clearly showed the internal seeds. We were more impressed than when we took the image of a piece of the rubber hose mentioned above. The possibility of NMR-CT in the fundamental stage was thus confirmed.

In this way, even if some objects could not be shot clearly, we completed a full-scale simulator that was essentially equivalent to the practical product of NMR-CT. We felt that the MRI development was very promising. As the simulator was limited by the size of the object, we walked around the Roppongi area in Tokyo to look for suitable objects at the greengroceries, fish shops, and meat shops. Figure 3 (a) is the tomogram of an egg. The yolk and the white were distinguished clearly by the differ-

ence in relaxation time. Figure 3 (b) is the tomogram of the head of a hamster, which was taken with the cooperation of Mr. Akio Hasegawa at The University of Tokyo, Faculty of Medicine, Clinical Laboratory. This was the first image of a living animal, which gave us confidence in manufacturing the practical equipment.

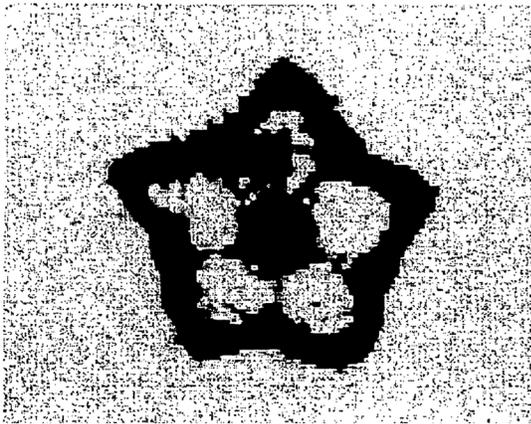


Figure 2. Tomogram of okra (vegetable) taken using the iron-core magnet

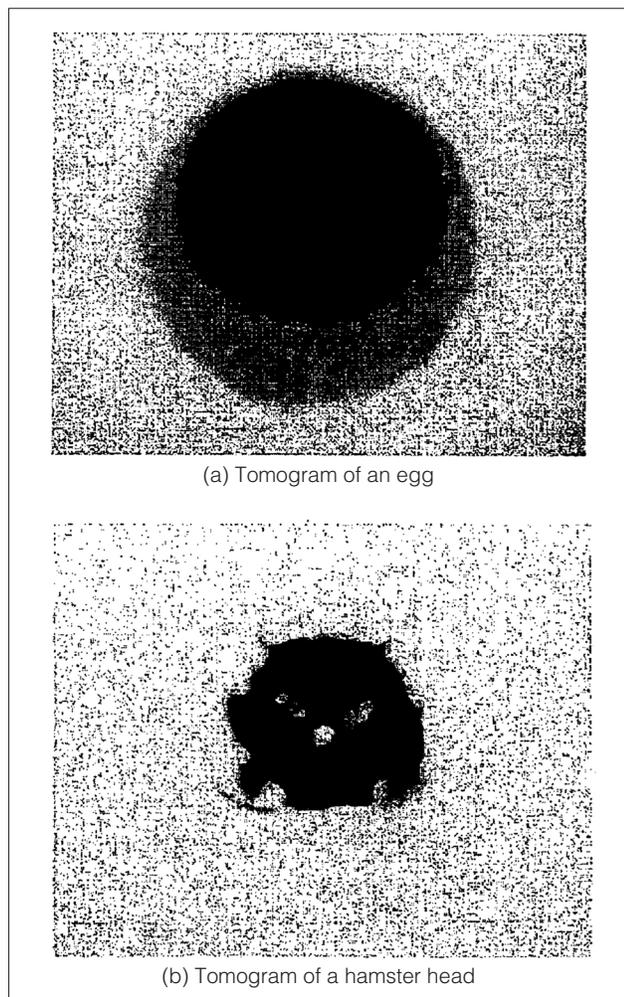


Figure 3. Images taken by the simulator

#### 4. Purchase of a magnet

At this stage, we planned to make the final model that could be used for clinical testing. Naturally we had to select a suitable magnet, which was the basic component. We consulted, as usual, with Mr. Makino of the Medical Systems Division, and received his immediate answer. The Division promised to allocate the budget to immediately purchase a magnet and asked me to go abroad to look for a suitable magnet. The preparatory survey had already been conducted. The manufacturers of magnets were limited to Bruker of West Germany and Oxford Instruments of the United Kingdom. I went to Europe and visited these two companies.

Before going to Europe, we had to select either a resistivity type or a superconducting type, because it was closely related to the magnetic field intensity. According to the increase of intensity, the RF resonance frequency also increases. However, the resultant skin effect prevents us from picking up the NMR signal from the inside of a living body. Although we did not have enough data, we knew the following. If we wanted to pick up the signal from hydrogen atoms inside a human body as 30 to 40 cm, then the magnetic field intensity should be 0.2 Tesla or lower. There was no need to use a high magnetic field which the resistivity magnet could not reach anyway and we did not need the superconducting magnet that generated a high magnetic field.

Moreover, although the superconducting magnet was excellent in the stability and homogeneity of a magnetic field, it was difficult to avoid the troublesome quench condition, which could not be solved by the technology available at that time. For this reason, I decided at heart to select the resistivity type, but I planned to visit also Oxford Instruments to see the superconducting type.

Under these circumstances, I set out on the solitary journey to Europe in April 1980. The result of visit to the two companies was almost as I expected. When I visited the Oxford Instruments factory and was shown the superconducting magnet, the magnet happened to quench before my eyes. The guide murmured, "So, that's why the superconducting type is troublesome". This episode was particularly impressive. Later, it gave me a lesson not to reach a hasty conclusion merely by superficial observation and temporary technical levels that may change over time.

After returning from my travel, I reported the result to the people concerned, and recommended a suitable type. The Medical Systems Division started the purchase procedure at once. However, a troublesome in-house situation occurred with the magnet that we managed to purchase.

The trouble was where to install this huge magnet. The Medical Systems Division was so cooperative that they allowed us to install the magnet in The Central R&D Laboratory and to use it freely. However, the top managers of the Laboratory, who were originally unfavorable to this project, said flatly to me, "The Laboratory is already not spacious. No space is available for the

magnet". We asked also The Physical Properties Institute whether they had a space, but they also replied no.

I consulted with Mr. Makino, as I usually did when I had trouble. He gave me a good idea. He replied, "The Toshiba Central Hospital has a large vacant room, which was originally planned for installation of large therapy equipment. That room can be used if the Medical Systems Division so requests. How about using that room?" I doubted that it was a suitable place for the equipment that detects very weak signals, but I thought that installation in the hospital room was convenient for clinical testing. So, I asked the permission to use the room. At last, the long-awaited magnet was installed in The Toshiba Central Hospital. The development teams of The Physical Properties Institute moved to the Hospital, and put the know-how accumulated by the simulator into the first protocol equipment.

### 5. The completion of practical prototype equipment and the start of clinical testing

The first protocol equipment was manufactured successfully at The Toshiba Central Hospital. Around March 1982, we took the long-awaited tomogram of the human body. Figure 4 is the tomogram of chest of a healthy person. The pulse sequence happened to synchronize the heartbeat. We were surprised at the cardiac septum as taken vividly without any gating process.

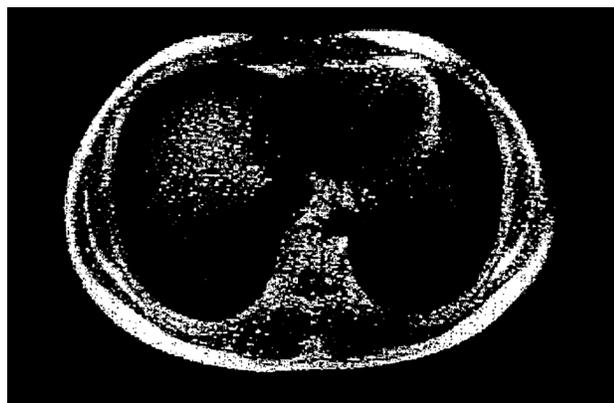


Figure 4. The chest tomogram taken by the first prototype equipment

To announce the completion, the press was invited on May 16, 1982. Very favorable reports were published in the major newspapers of the next day. We felt that all our efforts were rewarded at last.

After this press release, in order to be approved by the Pharmaceutical Affairs Law, the doctors of The Toshiba Central Hospital began clinical testing under guidance from The University of Tokyo, Faculty of Medicine. Clinical testing in a hospital attached to a company was not common, but it proved later to be a very good way. This is because the doctors can easily find subject patients and investigate details together with the company engineers. We worked together with the doctors in clinical testing, and suggested, for example, the optimal pulse

sequences. As a result, we could obtain much know-how that proved to be useful for subsequent research. The following episode is like "a chance hit".

As mentioned above, we installed the first prototype at The Toshiba Central Hospital. This hospital is located very near to the Japan Railways Oimachi Station of the Keihin Tohoku Line. The trains run continually near the hospital building. The place is filled with electromagnetic noise and mechanical vibration, thus being very unsuitable to install MRI equipment, which detects feeble electric waves. If the equipment functioned satisfactorily, then it proved its full usability even in the most unfavorable installation place. In fact, the staff of some hospitals were reluctant about the introduction of the MRI equipment because of unfavorable installation placement. But, after they were shown the environment of The Toshiba Central Hospital, they were not worried any more and decided on their purchase.

Then, we acquired the approval under the Pharmaceutical Affairs Law in May 1983, and started to sell MRI equipment as a commercially available product.

### 6. Conclusion

I had been continuing research chiefly on radiation measurement and applied mathematics. With the background as such a researcher, it was very fortunate that I encountered research on MRI and CT. In particular, it was a happy coincidence that my research career covered the period of progress in computer technology. This is because I was involved concretely in the algorithm of reconstruction computing, which was the center of CT technology in a broad sense including MRI. When I graduated from university, there were only several supercomputers in Japan. Even those computers required several hours for processing data. It was then like a dream that the reconstruction would be computed by the dedicated computer of CT and MRI. When we were involved in CT development, if we used the system of the high-performance minicomputer and the dedicated calculator, reconstruction took several minutes, short enough for practical use. Currently however, personal computers can do such calculation very easily.

On the occasion of the development of MRI, we encountered many things that seemed impossible or unknown from the scientific knowledge available at that time, and that could be solved only by a trial-and-error approach. For example, how the skin effect of a living body influenced high frequencies. Initially, we thought that the magnet of the high magnetic field was useless. However, contrary to our forecast, the result of the experiment was different. Now, we use the MRI of the magnetic field as high as several Tesla. At the initial stage of development, we forecasted many problems to be solved. However, most of them turned out to be solved in favorable way. It was a miracle rather than good luck.

This is my recollection about the development of MRI. I have tried to describe it as correctly as possible by referring to old documents. I am afraid that the description might be partly

wrong or impolite, for example, concerning the organization of Toshiba. If you would disregard my mistakes as a matter of prescription, your kindness would be much appreciated.

## 2. Note (Makino)

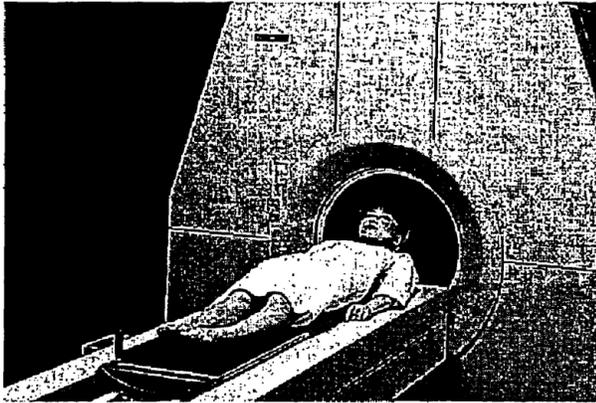
Thus, the first MRI equipment in Japan was completed at last. Attached Figure 1 is the prototype. It was installed at The Toshiba Central Hospital to continue the clinical testing. Attached Figure 2 is the tomogram of my head taken for a trial. When I compare this image with the present-day MRI image, I am struck with the changing times.

The unique MRI equipment made by FONAR of the

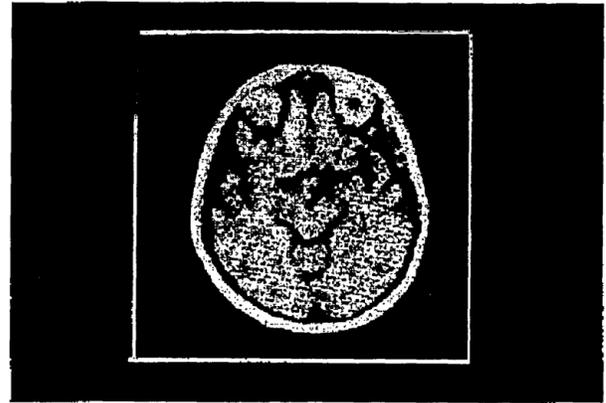
United States was displayed at the RSNA. It used a large, permanent magnet and attracted attention (see Attached Figure 3). A single unit was imported and installed at the Nakatsugawa Hospital, Gifu Prefecture.

The exhibitors of RSNA made every effort to enable the users to understand MRI. An example was the display of the magnet decorated with colorful neon lamps to show the mechanism and operation of the magnet (see Attached Figure 4).

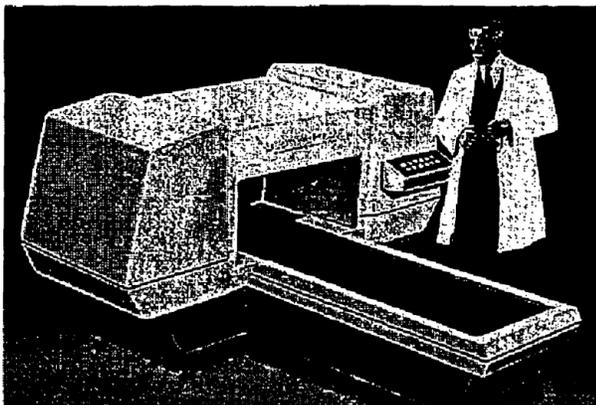
This is the story about the epoch-making MRI equipment, which might be the hidden history to be recorded. The medical imaging technology must increasingly contribute to the health and welfare of humankind. I presume that researchers and engineers are making their silent efforts every day.



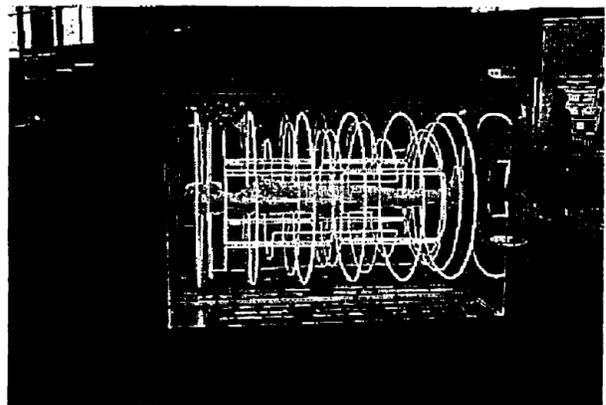
Attached Figure 1. The first Toshiba prototype MRI equipment (at The Toshiba Central Hospital)



Attached Figure 2. The tomogram (of the head of the author) taken by the 1982 prototype.



Attached Figure 3. MRI with the permanent magnet made by FONAR (in the United States)



Attached Figure 4. Explanatory display of MRI at RSNA (in 1982)