Review of the results for 2004

( ) refers to growth rate over the previous year.

1. The total count of medical imaging system of 2004 showed:
   - Production 370.6 billion yen (105%)
   - Export 176.9 billion yen (113%)
   - Import 106.4 billion yen (99%)
   - Domestic Market 300.0 billion yen (99%)

2. The domestic market by major equipment showed:
   - X-ray Amount 101.7 billion yen (104%)
     Mammography equipment and cardiovascular equipment contributed much.
   - CT Amount 52.3 billion yen (90%)
     Number of units 1,336 units (112%)
     The number of sets showed an increase although the amount showed a decline.
   - Nuclear Medicine Amount 20.3 billion yen (161%)
     Number of units 305 units (127%)

   The main factor for increase was PET, where the amount was 13.7 billion yen (213%) and the number of units was 75 sets (214%).
   - MRI Amount 42.6 billion yen (84%)
     Number of units 409 units (86%)
     They showed a significant decline in terms of both amount and the number of units.
   - Imaging processing systems Amount 16.6 billion yen (107%)
   The value increased, because the network-related systems increased like 2003.
   - Ultrasound Amount 38.7 billion yen (103%)
     Number of units 7,513 units (108%)

3. The 2004 situation is generally almost the same as 2003.
   PET advanced into the diagnostic screening market, and IT promotion inner hospital increase the network-related system segment. This trend is the same as that of 2003. On the
other hand, the amount of MRI and CT decreased noticeably.

4. The growth of production output (105%) was contributed especially by Nuclear medicine (220%) and Image processing systems (126%).

5. The export in 2004 increased 13%, generally grew except mobile X-ray and Nuclear medicine equipment.

6. The import value in 2004 was flat.

7. Under the suppression of the overall healthcare budget, the flat trend will still continue in future.

Trends in Production, Exports, Imports, and Japanese Market for Medical Imaging and Therapeutic Systems [Revised]

[Actual January-December figures for years 2000 to 2004] * Excluding diagnostic ultrasound systems
Chairman Mr. Katsurada's message
at 2005 JIRA General Meeting (June 7, 2005)

Thank you very much for joining the JIRA general meeting today.

Moreover, Mr. Makoto Sataka has given us a very informative lecture entitled "Corporate social responsibility and ethics". Last year, JIRA established Compliance Committee and announced Compliance Declaration. I would like to apply today’s lecture to our future activities.

Last year, we experienced many disasters. Recently, we have seen a fatal accident on the Fukuchiyama Line of West Japan Railway Company (JR-West) and news of bid-rigging scandal in bridge construction industries, which challenge the corporate risk management and compliance. In April, we saw revision of Antimonopoly Law, which incorporates more sanctions against bid rigging or cartel forming.

On the other hand, the revised Pharmaceutical Affairs Law and the law protecting personal information took effect also in April. The ever-changing business and social environment requires us to be more attentive in daily activities.

We would like to strive for business activities through compliance to fulfill corporate social and moral responsibility.

Now, the healthcare market in Japan is chaotic. First of all, we must watch the future development of "Large-boned policy 2005", the future plan of social security system including pension and nursing-care in the fiscal year of 2006. This plan will determine the fundamental scheme for healthcare reform and reimbursement.

JIRA is advocating some related issues that affect our business. The technical service of medical device should be evaluated appropriately; the reimbursement should reflect the work to ensure equipment performance, the maintenance and check work for safety control.

For that purpose, we compiled and distributed pamphlets entitled "Economic merits by diagnostic imaging, Part I & II". We established "Diagnostic imaging consortium" with Japan Radiological Society (JRS), Japanese Society of Radiological Technology (JSRT) and other radiological related bodies, and have frequent meetings with the Ministry of Health, Labour and Welfare.

I refer to the market trend of diagnostic imaging systems, which is the business sector of JIRA. The sales amount was 270 billion yen in 2004, which was flat with only at +0.1% increase over the previous year.

On the other hand, the growth rate is still high in Europe with +8% and in the U.S. with +2%, although they enjoyed a high growth rate of 10% or more until two years ago.

In Japan, the growth rate has remained almost constant since 2000, and it declined in 2002 because of the reimbursement amendment.

However, the number of equipment has increased. It means the unit price has decreased.

In spite of these unfavorable topics, we must aim to "contribute to medical care in Japan with technology" and strive for improvement together with whole industries. We hope that we shall encounter opportunity and chance only because the business situation is rapidly changing.

I repeat eight points for important JIRA activities in the fiscal year of 2005, which I mentioned at the beginning of this year.

(1) To promote "The Vision of Medical Equipment Industries".

The meeting with the Ministry of Health, Labour and Welfare on "The Vision of Medical Equipment Industries" is to be held on June 10. JIRA will submit proposals and requests from the industries.

(2) To promote how to address the revised Pharmaceutical Affairs Law.

I think that enforcement in April has caused some problems to you. JIRA has addressed the Ministry to expedite issue of detailed notification and to promote the certification system.

(3) To address the issue of reimbursement (technology assessment, cost for maintenance and control, etc.).

(4) To arrange favorable industry and business environment (maintenance and check, service business etc.).

JIRA will further promote the issues of (3) and (4), as mentioned above.

(5) To vitalize activities for public relations.

It is being realized by announcement to academic circles and press release.

(6) To fully implement compliance and law-abiding

Since last year, we implemented compliance declaration, Fair Trade Council activity, and its JIRA branch activity, etc.

(7) To strengthening of basic service to member companies.

JIRA News, web site, board of directors, committee activity.

(8) To vitalize international activity (cooperation with overseas associations).

Communication and collaboration with DITTA, COCIR, NEMA, and GHTF.

These are the bases of our activities, and, the activities of JIRA Divisions and Committees are expanding.

I would like to express my gratitude to member companies, particularly to those that dispatch members to the Divisions and Committees.
JRC (Japan Radiology Congress) was held in Yokohama from April 8 to 10. At JRC, JIRA held the International Technical Exhibition of Medical Imaging, ITEM 2005, in conjunction with the annual meetings of JRC and JSRT, from April 8 to 10. The exhibition floor space was expanded this year by 609 square meters. The number of exhibitors increased by three to 132 companies, the record largest number.

At the opening ceremony, Mr. Katsurada, JIRA Chairman, greeted saying, “I would like to publicize widely radiology and diagnostic imaging and seek public recognition of the achievement.”

The theme of ITEM 2005 was “The Evolution of Medical Imaging”. To suit this theme, the exhibition showed many kinds of apparatus that apply high technology. Among them, attention was paid to radiation exposure reduction for patient safety, improvement of workflow within hospital in consideration of hospital management, and mammography-related exhibits that have attracted much attention recently in Japan.

In April this year, the revised Pharmaceutical Affairs Law and the personal information protection law were enforced. The exhibitors paid more attention to compliance than before in operation of exhibition.

Next year, ITEM 2006 will be held in Yokohama, the same venue as this year from Fri. April 7 to Sun. 9, 2006.

The number of visitors

<table>
<thead>
<tr>
<th></th>
<th>2004</th>
<th>2005</th>
</tr>
</thead>
<tbody>
<tr>
<td>Congress Registered numbers</td>
<td>4,252</td>
<td>4,073</td>
</tr>
<tr>
<td>JRS (Radiological society)</td>
<td>7,842</td>
<td>7,739</td>
</tr>
<tr>
<td>JSRT (Society of Radiological Technology)</td>
<td>275</td>
<td>422</td>
</tr>
<tr>
<td>Non members</td>
<td>1,267</td>
<td>1,205</td>
</tr>
<tr>
<td>Radiologist</td>
<td>932</td>
<td>705</td>
</tr>
<tr>
<td>Radiological Technologist</td>
<td>6,136</td>
<td>6,351</td>
</tr>
<tr>
<td>Medical related</td>
<td>1,267</td>
<td>1,205</td>
</tr>
<tr>
<td>Exhibitors</td>
<td>13,523</td>
<td>12,315</td>
</tr>
<tr>
<td>Others</td>
<td>6,397</td>
<td>5,707</td>
</tr>
<tr>
<td>TOTAL</td>
<td>40,624</td>
<td>40,379</td>
</tr>
</tbody>
</table>

Note: The numbers of visitors to the exhibition include repeat visitors.
2-2. Meeting with Korea Food & Drug Administration
(KFDA: Medical Device Safety Section/Medical Device Evaluation Department)
(1) It was confirmed that the repeated exchange of opinion between JIRA and KFDA increased mutual confidence.
(2) The organization of KFDA continues to expand with increase of personnel.
(3) Import business became "permission" system from the "notification" system. The transitional period is one year (until May 29, 2005).
(4) EMI is essential for electromagnetic products of medical equipment, while the enforcement time of EMC is not decided yet.
(5) The unit of permission of a product is only one item under one name.
(6) Operation manuals of medical device are required to be written in Korean. We must address this issue from now on.
(7) About twenty rules of Korean Medical Device Law are to be published. Two of them were given to us this time.
(8) KGMP is granted to only several percent of 60 to 70 manufacturers. Application is expected to rapidly increase just before the end of transitional period. KFDA plans to implement GMP training in cooperation of private companies (certification organizations).

2-3. Meeting with Korea Testing Laboratory (KTL)
(1) It is judged that the mutual confidence between JIRA and KTL was deepened significantly by the exchange repeated so far.
(2) The examination and test about the quality of imported products was tightened up. Essential requirements include test equipment and GMP certificates of foreign manufacturers. If a GMP certificate is not obtained from the administrative authority of the exporting country, presentation of the certificate of ISO 9001 and ISO 13485 is necessary.
(3) GMP is granted by KTL to about 50 companies as of March 2005. If the situation does not change, application is expected to rapidly increase just before the end of transitional period. It is worried that KTL cannot handle too many applications in a short period of time.
(4) In the old law (Pharmaceutical Affairs Law), "technical document" means a test and inspection method. In the medical device law, it includes the accompanying document (operation manual/service manual).
(5) EMC is under discussion, but it does not make a progress. Only EMI is implemented in Korea.

2-4. Meeting with Korea Medical Devices Industrial Cooperative Association (KMDICA)
(1) Mr. Sato (Chairman of JIRA Education/Training Committee) also participated in the meeting. We discussed the merits and demerits of participation in China International Medical Device Exhibition with Korean booth. The discussion resulted in fruitful conclusion.
(2) When we see the medical equipment market and compare 2003 with 2002, production is almost constant. The import amount increased significantly, and the overall growth was 107%.
(3) Korean users recognize the high quality of the medical equipment imported from Japan. On the other hand, import of second-hand products is increasing, and the users worry about the quality.
(4) Agreement was reached about the timing of the next meet-
The seminars are held at the same time. They are well prepared and will grow.

A visit to the exhibition helps us to better understand the market trend. It is recommendable to visit this exhibition whenever possible.

KIMES 2006 is planned to be held March 16 through 19, 2006. The date will be finalized at the end of 2005 fiscal year.

Our special thanks go to IKIREN (formerly JFMDA) that provided us with sufficient materials about the revised Pharmaceutical Affairs Law of Japan. Those materials were very useful to meeting with people of Korean organizations related to medical devices.

Our special thanks go to IKIREN (formerly JFMDA) that provided us with sufficient materials about the revised Pharmaceutical Affairs Law of Japan. Those materials were very useful to meeting with people of Korean organizations related to medical devices.

2-5. Korea Medical Devices Industry Association (KMDIA)
(1) KMDIA serves as a contact point between JIRA and KFDA. KMDIA supported us also for this visit to Korea, leading to a successful meeting with KFDA.
(2) KMDIA plans to contribute to "advertisement compliance committee"
(3) KMDIA will study the possibility of visiting Pharmaceuticals and Medical Devices Agency of Japan in the autumn of 2005 or later.

2-6. Visit to KIMES 2005
(1) The number of participating IT companies decreased this year. But, 845 companies from 30 nations participated. (+10% increase over the last year). The exhibition booths are becoming more gorgeous every year.
Development of Japanese Radiological Equipment in the Post-World War II Period (16)

Development of radioisotope (RI) Cobalt (therapy equipment) etc.

1. The outline of the previous article

In the United States, they started to use a large quantity of cobalt 60. In response to this trend, in Japan, the Ministry of Health and Welfare and the Ministry of Education took the initiative in forming the research and development committee centering around our Japan Radiological Society in 1952 to promote development of equipment under cooperation between industries and academics.

The committee members had no experience of handling radioactive sources, and produced several episodes. They continued a conversation that would now be pointless, and made Type II equipment, which symbolized a poor Japan at the time. That prototype did not succeed, however, and was followed by Type I equipment, which was tested at several hospitals to demonstrate the clinical safety and effectiveness.

This article describes the clinical trial of Type II and Type I equipment.

2. The start of clinical trial

Type II was designed and manufactured, as explained in the previous article, to be simple and inexpensive without any complex mechanism such as remote control and motor drive so that it might suit a poor Japan. As shown in figure 1, the irradiator heads served also as the source container, which was hung with the bent iron bars. It was easily installed in a small room. The shutter of container was opened or closed with remote-controlled wire mechanism by turning a handle of controller located in another room. It was just like a rickshaw of the Meiji era being reproduced in the age of motorization.

After tentative completion of manufacture, Type II was exhibited at Japan Radiological Society Meeting held in Osaka in April 1953, and later tested by Prof. Nakaizumi, project leader, at Department of Radiology, Faculty of Medicine, The University of Tokyo. (The honorific titles are omitted hereinafter.)

The first lot of radioactive source imported to Japan was 171 Ci in total, which was shared among several destinations, including Type I remote therapy equipment to be mentioned later. 21 Ci was allocated to The University of Tokyo, although Type II was rated to house 50 Ci.

It was problematical how to use this equipment that has two radiation apertures, emitting gamma rays in two directions and irradiating two patients at the same time. It was difficult for two patients to approach the irradiator head that was slightly larger than a human head. Finally, the so-called simultaneous multidirectional irradiation proved to be an impracticable theory. Because the irradiator head was small, when the head or neck was irradiated, the trunk comes near the irradiator head. A patient’s whole body is exposed to leakage radiation. The whole-body exposure dose proved to be too much to be justified, reaching a conclusion that this equipment is not practicable, after trial manufacture of several units of equipment.

After all, when it comes to handling radiation, an easy way cannot work. Instead, it requires a logical and well-prepared approach. This was a hard-learned lesson.

3. Start of full-scale remote therapy equipment - Its clinical trial

Nakaizumi, Committee Chairperson, advocated a simple and inexpensive Type II. As long as radiological equipment is concerned, an easy way may well prove to be penny-wise and pound-foolish, resulting in equipment of impractical use. We learned the lesson that we can not cut corners in utilization of
radiation and that we must abide by a basis of design and fundamental principle.

About this matter, Hisao Yamashita (Director, Keio Cancer Center) wrote as follows (Isotope News, August 1991).

Type I was delivered to National Tokyo Daiichi Hospital and Daini Hospital (note: to be mentioned later); Type II, to Tokyo University Hospital; and Type III, to Keio University Hospital (note: to be mentioned later) to be used for therapy and research. The therapy result was excellent, but the leakage radiation was a problem. Type II was worst, leading to significant side effects to patients. Simultaneous irradiation with two left and right apertures was dangerous. One of the apertures was sealed.

He reported unsatisfactory test result of Type II.

On the other hand, Type I was designed and completed by the Committee. This was "orthodox type remote therapy equipment" with 100 Ci source and installed at National Tokyo Daiichi Hospital and Daini Hospital to be used as test equipment.

Type I had a single radiation aperture. As shown in figure 2, it was available in two kinds: one was rotation source type and the other was stationary source type. Later, the rotation aperture type appeared. The appearance of original Type I is shown in figure 3.

The clinical trial of Type I was conducted at National Tokyo Daini Hospital. (Figure 4 shows the scene of therapy there under supervision of Jun-ichi Fujita.)

About this matter, Hisao Yamashita wrote as follows in the above-mentioned Isotope News.

Type I cost about 1.5 million yen, being rather expensive. But, the side effects was little, and the therapy result was better than expected. It contributed to rapid spread of cobalt 60 therapy. In the United States and Europe, equipment with 1,000 Ci to 3,000 Ci was popular, while in Japan, equipment with 300 Ci to 500 Ci was manufactured at a comparatively low cost. In terms of numbers of hospitals using such equipment, Japan ranked a second behind the United States.

Thus, he recalls.

4. Spread of and warning about remote therapy equipment

Shimadzu Corp. in Kansai announced a product slightly later. Figures 5 and 6 show a stationary type and a rotation type, respectively.

Product styles tend to go in and out of favor alternately. If I apply this to the spread medical devices, I am likely to be blamed for being imprudent. When any equipment with possibility of new medical practices was developed and announced, it spread quite rapidly in the post-war society. I often doubted whether some equipment was clinically effective or not. I sometimes suspected that some people were afraid of failing to keep with the times. I ask myself whether RI remote therapy equipment was an example or not. I was involved in development and manu-
facture, and was pleased with rapid spread. On the other hand, however, I doubted that Japan has so many radiotherapists to cope with the rapid spread.

The situation of spread is shown in figure 7.

The spread was too rapid and the number of equipment installed increased significantly. The issue was whether RI cobalt 60 remote therapy is really effective or not. It was necessary to hear specialists’ view. In 1956, Tadashi Adachi and Masatoshi Kurikammuri (Department of Radiology, Tokyo Medical and Dental University) presented the following seven questions under the name of Japan Radiological Society.

The questions were as follows.

1. Is the skin dose reduced?
2. Is it possible that the integration dose is reduced?
3. How is the degree of increase or decrease of the dose rate?
4. Is the percent depth dose improved?
5. How is flexibility of the equipment?
6. How is the economic merits?
7. How is the clinical effectiveness?

In response to these questions, a panel discussion at the Kanto Meeting of Japan Radiological Society with the following specialists participating.

*Tadashi Miyakawa (Tokyo Univ.), Yoshio Onai (Cancer Institute), *Kempo Tsukamoto (ditto), *Otsutama Ito (Tokyo Teishin Hospital), Hisao Yamashita (Keio Univ.), Sumio Makino (Toshiba), Yoichiro Umegaki (Chiba Univ.), and *Katsutoshi Yoshimura (Kanto Teishin Hospital)

The asterisked persons died. Then their titles in those days are parenthesized.

The panel discussion confirmed the higher clinical effectiveness of cobalt 60 compared with the traditional X-ray radiotherapy. (It is recorded in the Journal of Clinical Radiology, vol. 1, No. 9, suppl. Dec. 1956.)

When we respond to the changing times, we must be careful not to be caught up with the tide of times. It is necessary to keep a low posture and to estimate the situation objectively. Such an academic attitude of the panelists impressed me very much.

The similar panel discussion was held by Japan Radiological Society early in 1955 when X-ray television became very popular. A serious discussion was carried out about whether X-ray television fluoroscopy and diagnosis is really effective or not.
5. Emergence of several types of remote therapy equipment

The source is stationary. The power supply is not required for generation of radiation. The irradiation method of tumor is easier. Such characteristics of cobalt 60 resulted in convergent beam radiation therapy where the source is moved in the different way from X-ray irradiation. On the other hand, the cobalt source is geometrically larger than X-ray tube focus, producing a wider penumbra. To prevent this, a multi-leaf collimator was invented.

(1) Small irradiator: Although Type II was not successful, a small irradiator was preferable to avoid the high cost for purchase of 100 Ci of cobalt 60 and equipment, for construction of RI room etc. The demand for a small irradiator of 50 Ci, for example was high. Thus, Type III emerged. (Figure 8)

(2) Rotation cobalt 60 equipment for convergent irradiation: One example is a Shimadzu product shown in figure 6. Toshiba also produced several types as shown in figures 9 and 10.

(3) Research of multi-leaf collimator and conformation therapy. (Figures 11 and 12)

(4) Pneumatic therapy equipment: It is also called after-loading therapy equipment: A small quantity of RI is delivered to the tumor with remote control. This was intended to replace the radium needle therapy in the past. The after-loading therapy equipment delivers 50 Ci of cobalt 60 with an airshooter. Because of the difficulty to manufacture a cobalt capsule that can withstand a high-speed collision caused by pneumatic force, the equipment did not spread. (Figure 13)
6. Summary of this article

Application of radioisotope cobalt 60, something new in the post-war Japan, to radiotherapy certainly decreased the skin exposure compared with the conventional low-energy X-ray radiation, and facilitated the therapeutic procedure. The source emits radiation all the time and does not require power supply, complex operation and control. Thus, more and more hospitals were engaged in cobalt radiotherapy, contributing to rapid spread and modernization.

Although the necessity of high-energy radiotherapy was certainly demonstrated, the cobalt or cesium source was larger and it produced a wider penumbra. This disadvantage prevented cobalt radiotherapy from becoming a perfect modality of radiotherapy.

Under these circumstance, particle accelerators such as betatron emerged in 1960, ushering in a new era again in radiotherapy.

(This article conclude the episode of cobalt 60 radiotherapy.)