JIRA

Radiology Japan

Japan Industries Association of Radiological Systems February 2001, No. 42

JMCP 2001 – New Frontiers for Patient Care in Radiology –

Dates: *April 5 (Thur.) through April 8 (Sun.), 2001*
Venue: *Port Island, Kobe*
Supported by: *Japan Federation of Medical Congress Promotion (JMCP) (Please refer to time schedule for more details.)*

The International Technical Exhibition

JIRA will promote the International Technical Exhibition of Medical Imaging, ITEM2001, at JMCP 2001, during the period April 5-8, 2001, in collaboration with the 60th Annual Meeting of the Japan Radiological Society (JRS), and the 57th Annual Meeting of the Japanese Society of Radiological Technology (JSRT).

Chairman: *Masamichi Katsunuma*
Dates: *April 5 (Thur.) - 7 (Sat.), 2001*
Venue: *Kobe International Exhibition Hall, 6-11-1, Minatojima Nakamachi, Chuo-ku, Kobe*
Theme: *Clinical Images created for the new millennium*

A total of 113 companies and one institution (CAR) will have exhibition booths in the 5,412 square meter area in the Kobe International Exhibition Hall located at Port Island. The exhibition will cover a wide range of technology, from diagnostic imaging to the rapidly growing IT technology for medicine.

The 60th Annual Meeting of the Japan Radiological Society (JRS)

President: *Prof. Kouji Masuda*
Dates: *April 5 (Thur.) - 7 (Sat.), 2001*
Venue: *Portopia Hotel at Port Island, 6-10-1, Minatojima, Nakamachi, Chuo-ku, Kobe*

The society has chosen the following theme for the first annual meeting of the new century: <New Frontiers for Patient Care in Radiology>. This focuses on the areas of greatest need and greatest opportunities for clinical radiology to improve the health of humankind in the 21st century.

● ***Contacts:***

– Exhibition; Japan Industries Association of Radiological Systems (JIRA)
– Official Travel Agent; Nippon Travel Agency
Tel: 81-3-3567-2587, Fax: 81-3-3567-3985

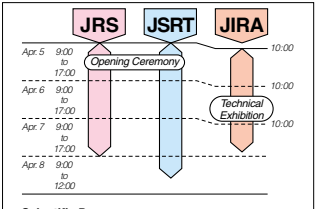
The 57th Annual Meeting of the Japanese Society of Radiological Technology (JSRT)

President: *Prof. Yoshie Kodera*
Dates: *April 5 (Thur.) - 8 (Sun.), 2001*
Venue: *International Conference Centre Kobe, 6-9-1, Minatojima Nakamachi, Chuo-ku, Kobe*

The main theme for JSRT is <Creation of Technology for the Mind>. The president, in referring to his reasons for selecting this theme, said, "While the 20th century was the century of science, we have been forced to reconsider whether science has brought benefits or evils to our society, and if it naturally has led to real happiness for the human race."

A joint buffet party: scheduled for Thursday, April 5, from 6:00 p.m. through 8:00 p.m. in the Ohwada Room of the Portopia Hotel.

● *JMCP 2001 Schedule* ●



Scientific Program

- Special lecture
- Symposium
- Scientific exhibits
- Educational lectures
- Scientific papers
- Film reading conference

Registration-fee

● JRS•JSRT	¥12,000 (on site)
● JIRA	¥ 3,000

Medical Devices Regulatory Systems in Korea
(Report on Second Visit)

Reported by Mr. Wani, Mr. Miura, and Mr. Obayashi, International Division

Introduction

The Committee is studying the Korean medical devices regulatory systems through activities such as translation of the Korean Pharmaceutical Affairs Law. As a part of these activities, we followed up last year's visit with a second visit to Korea to conduct field investigations. The purpose of this visit was to contribute to smooth trade between Japan and Korea by studying and exchanging information on medical devices regulatory systems in the two countries and to improve understanding of the Pharmaceutical Affairs Laws, quality control systems, and import procedures in both countries. The obtained information is to be used to train JIRA members and other concerned industrial association members in order to help their import businesses in Korea.

We visited three concerned institutions over a period of four days from October 31 to November 3, 2000.

Organizations visited and Outline of discussions

1. Korea Medical Instruments Industrial Cooperative (KMIC)

● *Korean participants at the meeting*

Mr. Pak, Managing Director, and others

KMIC is an association established in 1979 under the auspices of the Ministry of Commerce, Industry and Energy. It has 177 members from medical device manufacturing companies. The major products of the member companies include diagnostic imaging equipment, surgical supplies, syringes, dental equipment, and other general medical instruments. As the Chairman, the Executive Director, and some of the other members of KMIC had changed since our last visit, we briefly introduced the structures and activities of our associations to each other and then exchanged information and opinions. We described the Japanese market for diagnostic imaging equipment using JIRA's statistics. In 1998, the Korean medical device market tumbled by 44% from the previous year to $552 million. In 1999, however, it increased by 67% to $923 million.

Most of our questions related to the medical devices regulatory systems in Korea fell under the jurisdiction of the Korean government, and the participants at the meeting did not think it was appropriate to answer them from a private standpoint. They told us to ask those questions directly to the Korea Food and Drug Administration (KFDA).

We learned that the Korean government is planning to separate medical devices from the Pharmaceutical Affairs Law and establish a Medical Devices Law. A draft has been prepared by the government, it has been amended based on the opinions of representatives of the concerned business groups, and it is being deliberated in the parliament. The law is scheduled to be enacted and come into force in the summer of 2001. The purpose of the Medical Devices Law is to stimulate the development of medical devices by separating them from drugs.

During the meeting, KMIC requested production figures of Japanese medical instruments and equipment. We promised to send them the production statistics report prepared by the Japan Federation of Medical Device Associations. They also requested that information about technical agreements or joint ventures with Japanese firms and OEM of Japanese products be discussed in the next meeting.

Finally, the both parties expressed their wish to continue cooperation and further communication.

Together with main staff of KMIC

2. Korea Medical Devices Association (KMDA)

● *Korean participants at the meeting*

Mr. Lee, President, and others

KMDA, which is an incorporated association authorized by the KFDA, was established in July 1999. There are 146 member companies: 37 in manufacturing industries, 104 in import businesses, and 5 in other businesses. The medical companies participating in KMDA have an 80% share of the Korean medical devices market. The major tasks of KMDA are support of smooth supply, market research and information gathering at home and abroad, establishment of proper distribution, quality control, promotion of international communication, publication of technical information journals, and organizing exhibi-

tions. As a next step, they are aiming to provide functions equivalent to those provided by the Japan Association for the Advancement of Medical Equipment. We were impressed by how much they had achieved in the short period of one year.

In response to our questions about the medical devices regulatory systems in Korea, they provided us with the complete data in Korean and English. We found out later in our visit to KTL that the provided answers were the official answers (unified view of the government and industries) prepared after deliberation by three organizations: KFDA (government), KTL (neutral testing body), and KMDA (group of private companies). This is a significant outcome of our visit.

KMDA is participating in the preparation of the Medical Devices Law and provided us with a draft of the Law, which is scheduled to be enacted and come into force in July 2001.

KMDA representatives expressed their wish to visit JIRA, the Japan Federation of Medical Device Associations, and the Japan Association for the Advancement of Medical Equipment in January or February 2001, and we welcomed their request.

They also asked various questions on topics such as the actual situation with regard to the medical device business in Japan, JIRA's operating methods, and the Pharmaceutical Affairs Law of Japan. We promised to provide them with answers.

We asked them to appoint Mr. Chang (Senior Vice President) as the contact for future communication between KMDA and JIRA.

Meeting at KMDA

3. Medical Device Center, Korea Testing Laboratory (KTL)

● *Korean participants at the meeting*

Mr. Song, Director General of the Center, and others

KTL (Korea Testing Laboratory), which was established in 1966 with the responsibility for industry-wide testing, has contributed significantly to the modernization of Korean industries. Korea has become a member of WTO and is endeavoring to abolish non-tariff barriers. For this purpose, the country is making a positive effort to introduce international standards. KTL is an ISO-notified body with responsibilities in various fields including the safety and quality of medical devices, GMP education, bio-compatibility, EMC, explosion protection, nondestructive testing, and pollution control and environmental protection. The organization seeks to promote a strong relationship between industry, government, and academia based on the "one-stop service" and "open-door policy" principles.

Mr. Song explained the activities of the Medical Device Center using a video. The medical device department includes three major testing teams: the Medical Device Team, the Medical Radiological Device Team, and the Quality Assurance Team. Recently, the Medical Materials Team has also been added. As for quality-related matters, they aim for conformance to international quality standards. Therefore they have joined the CB scheme, have established the GMP framework, and participate in international organizations related to standards.

KTL asked about the control system in Japan and we promised to send them the information.

We visited the outdoor EMC laboratory (8250 m^2). It is located far from any human habitation, and the roundtrip took us about 5 hours (of course traffic jams at the center of Seoul are always problems). The laboratory supports 3-m, 10-m, and 30-m methods. It can be used by private companies in the presence of KTL staff.

In front of KTL's EMC Lab.

Others

- We had wanted to visit KFDA, but it was not possible for them to accommodate our visit. They, however, provided answers to our questions through KTL. We would like to organize opinion exchanges involving senior staff members of KFDA in the future.
- On our first visit last year, we were groping in the dark. This time, however, our questions were answered by KFDA, KTL, and KMDA.
- A significant outcome of this visit was that, in addition to the answers to our questions, we could obtain a draft of the Korea Medical Device Law.
- In closing, we wish to thank Ms. Lee, who is a conference interpreter and at the same time a researcher at the Interpretation and Translation Institute, Hankuk University of Foreign Studies, for serving as our interpreter.

Development of Japanese Radiological Equipment in the Post-World War II Period (7)

The Dawn of the Mirror Camera Era...For Chest Examination

Sumio Makino (left)
Advisor, JIRA
Yuichiro Koizumi (right)
Former member, JIRA

Summary up to the previous issue

We investigated the origin of the term "X-ray fluorography" and were reminded once again of the wisdom of the great pioneer Yoshihiko Koga.

It was not until the postwar period that preventive measures were taken against tuberculosis (TB), which was rampant at that time as the so-called "national disease" of Japan. As the most effective countermeasure, X-ray fluorography screening programs were established throughout Japan. In such screening examinations, vehicle-installed fluorographic systems employing capacitor-discharge-type X-ray systems were employed, although only stationary systems had been developed before the war. The development of capacitor-discharge-type X-ray systems and special X-ray tubes is detailed in the "History of X-ray Systems" published by JIRA in 1995.

In order to present the advances made in Japan in this field, this issue discusses the contributions of Canon Inc. in the development and popularization of fluorography and describes how that company developed the "mirror camera".

Advances in fluorographic cameras in Japan

In this previous issue (No. 41, page 8, Fig. 3), a darkroom box (fluorescent screen) and a dedicated camera for fluorography were shown. Because such systems include an X-ray receptor, their performance affects the sharpness of the resultant X-ray image and also determines the X-ray dose required. Figure 2 showed the actual use of such a fluorographic unit for the examination of conscripts, which was compulsory for Japanese men at 20 years of age up to the end of the war. This indicates how aggressively the TB prevention campaign was conducted.

With regard to the birth of the fluorographic camera, I refer to the "History of Canon Inc." published in December 1987. An excerpt from that source follows:

"In the initial stage of development of fluorographic cameras, we attempted to modify and commercialize high-grade 35-mm cameras for general use incorporating a high-speed lens of the F1.5 class such as the Contax or Leica cameras made in Germany However, our initial attempts were unsuccessful. These cameras were not intended for medical applications, but for general use, and therefore, many problems had to be overcome, such as winding, film loading, the shutter mechanism, etc. As mass screening programs expanded to include civilians as well as military personnel, there was a surge in demand for domestically produced fluorographic cameras. At that time, foreign cameras were very expensive, importation was becoming increasingly difficult, and limited availability was foreseen. More important than all of the above factors, however, we must keep in mind that the predominant driving force for development was a strong commitment to the early detection of TB....

...Then, in response to the requests from the army and the navy, Shibuya Roentgen Co., Ltd., and Morikawa Seisakusho Co., Ltd., respectively, placed unexpected orders for X-ray cameras with Seiki Optical Industries Co., Ltd. (which was renamed Canon Camera Co., Ltd., in 1947 and subsequently renamed Canon Inc. in 1969). Seiki Optical Industries Co. Ltd., renewed its commitment to the promising future of the X-ray camera business and, determined not to miss a second chance, assigned young engineers to participate in a company-wide development effort. These engineers included team leader Ando (an engineer who was a distant relative of Junjiro Okanishi, vice director of the Institute of Research in Infectious Diseases, and a TB researcher, and who was asked by Okanishi to produce a prototype fluorographic camera around 1939), Susumu Tazawa (who made substantial contributions to the JIRA Engineering and Technology Division, was awarded a Medal with Purple Ribbon in 1963 for his development of

the X-ray fluorographic camera, and died in April 1990), Yamazoe, Umezawa, and many others."

Figure 1. Canon 35-mm X-ray fluorographic camera system
Specifications of the fluorographic camera: Continuous development resulted in the introduction of an automatic winding mechanism

After filling the order from the navy, they started in 1941 the mass production of cameras with the following specifications. A quote follows:

"Specifications: Image size of 24 × 25.5 mm to acquire 50 frames on 35-mm film, side cover opening type, measurement-type focusing, chain-type film winding, lens chamber fixed to the hood, detachable camera, easy film loading, etc. The lens was initially a 50-mm, F1.5 Zonar lens (Carl Zeiss), which was then replaced with a Nikkor or R SERENAR lens.

After completion of the navy-type camera, cameras with slightly different specifications were introduced commercially after 1941 for both civilian and military customers. These cameras incorporated a Nikkor lens and also our R SERENAR lenses (45 mm, F1.5 and 50 mm, F1.5) in 1942. The 45-mm, F1.5 lens was the first commercial product developed by our company in November 1941."

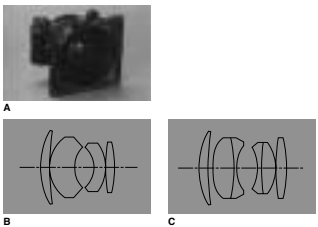


Figure 2. R SERENAR lenses
A. R SERENAR lens (45 mm, F1.5)
B. Structure of R SERENAR lens (45 mm, F1.5)
C. Structure of R SERENAR lens (80 mm, F2)

● ***Development of the automatic winding mechanism:***

The X-ray fluorographic cameras thus developed were widely employed and made a great contribution to TB prevention before the war. Then, in the postwar period, the automatic winding mechanism was introduced.

A quotation from Canon Inc.'s Yuichiro Koizumi (Former member of the JIRA Engineering and Technology Division) published in "Canon Voice" (issue 166, 1997) follows:

"*That's right. A manual winding mechanism was used up to around 1954. The radiological technologist had to wind the film manually after each patient. This was time-consuming work, so the technologist stayed near the camera even during exposure, resulting in serious radiation hazards.*"

After the introduction of automatic-winding-type fluorographic cameras, however, only domestic products (mainly the products of Canon Inc.) were widely used. The situation was described by then sales staffer Ikuo Nomura (Former member of the JIRA Planning and Research Division) in "Canon Life" (December 1965) as follows:

"Mass screening examination for the early detection of TB expanded gradually, partly due to compulsory regulations imposed by the Labor Standards Law. We made several improvements in Canon X-ray cameras in response to user requests. As a result, domestic demand reached about 13,000 cameras in 1959."

His remarks reflect the remarkable popularization of fluorographic cameras in Japan. On the other hand, concerns regarding excessive X-ray exposure to examinees were mounting in some quarters. Information was reaching us from abroad that only mirror-type cameras such as the products of Oldelft Limited (Holland) were being used in Europe and the United States.

Birth of the mirror camera

In Europe and America, the products of Oldelft Limited (Holland) were widely employed, and this manufacturer enjoyed a virtual monopoly in the fluorographic camera market. In particular, the Odelca fluorographic camera was outstanding in terms of sensitivity and sharpness, requiring only 1/3 of the X-ray exposure dose compared with Japanese products. The Ministry of Health and Welfare of Japan (MHW) was very interested in the Odelca camera, and the TB Prevention Association began investigations into the adoption of this foreign product in Japan.

Yuichiro Koizumi recalled the situation at that time in "Canon Voice" (op. cit.) as follows:

"*The reputation of the Odelca camera was well known to us, and our company undertook research into such cameras.*

In order to conduct performance evaluations, we manufactured a prototype (which, however, was capable of handling only cut film) and brought it to the MHW and the TB Prevention Association. The MHW was reluctant to import foreign products, but no equivalent domestic products were available at that time. Therefore, the MHW was quick to ask us, "When will it be available?" We replied, "A prototype will be completed in the next year." The MHW then asked, "Can you make it a vehicle-mounted system?" Frankly, we were concerned that there might be problems in developing a vehicle-mounted system, which would involve installing a camera with a large lens about 50 cm in diameter in a vehicle that would need to be driven over rough unpaved roads, unlike those of the present day. Had we rejected the request of the MHW, it would have meant the end of our business, and we were therefore forced to reply, "Yes, we can."

We succeeded in producing a satisfactory prototype in 1961. This was only moments before the MHW was about to make a decision to import Odelca cameras by a national budget allocation."

● ***Secret strategy to avoid patent infringement:***

In order for Canon Inc. to proceed with the commercialization of a mirror camera, it was necessary to avoid the so-called "protective wall" of Oldelft's patented mirror optical system. Koizumi adds as follows:

"The patents protecting the Odelca mirror camera were so strong that no major optical equipment manufacturers were able to circumvent them. The Odelca was truly the king of X-ray cameras and completely dominated the European market....

...The unique technology developed by our company employed an entirely different optical system to achieve the same level of brightness as the Odelca camera. We adopted sophisticated theory involving 5th order aberrations and developed a new type of optical system to replace the Odelca system. To facilitate mass production, we did not use aspherical lenses, as adopted by Odelca, but only spherical lenses. In spite of this, it was an excellent optical system with a brightness as high as 0.6.

While the Odelca imaging surface had significant curvature between lenses, our design employed an independent optical system, and the curvature of our imaging surface was only about 1/3 that of the Odelca design, resulting in reduced image distortion. The optical system was integrated into a single unit, making it suitable for use in humid environments as found in Japan."

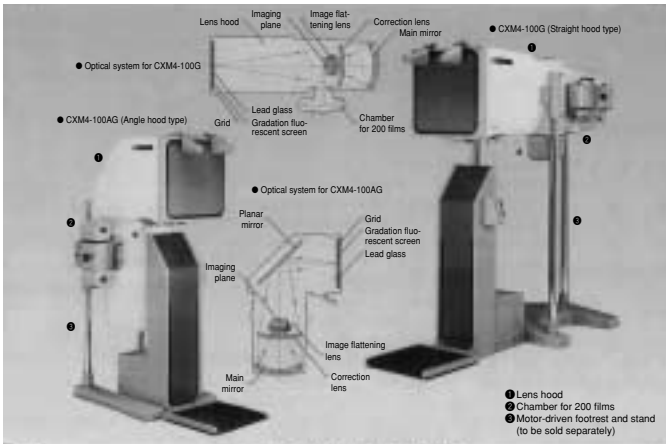


Figure 3. Structure of the mirror camera (reprinted from the catalog)

Thus, Canon mirror cameras were successfully completed and widely used in Japan as the only fluorographic camera for chest examinations. The situation at that time is described in the "History of Canon Inc." as follows:

"Afterward, mirror cameras continued to gain in popularity and secured a domestic market share of about 95%. In October 1965, a system was sent to a medical facility in Nepal as Official Development Assistance (ODA), playing a significant role in the promotion of international friendship. In 1966, we commercialized a 100-mm mirror camera, the CXM-100A, and in 1967, we marketed an improved type of 70-mm mirror camera."

Thus, his description clearly records the popularization of mirror cameras for chest examinations and their contribution to the national TB prevention campaign.

On the other hand, Japanese Industrial Standard (JIS) Z4901 was established in 1987 to cope with the popularization of mirror cameras. The explanatory note in the JIS standard reads as follows:

"This standard was initially established as JIS Z 4901 (X-ray indirect radiographic units) on July 30, 1951. Subsequently, mirror cameras became more popular. In order to reduce X-ray exposure to examinees, users stopped employing fluorescent screens for indirect radiography. This standard was completely revised on March 1, 1976, and the title was changed to "Mirror camera for indirect radiography". On March 1, 1981, the standard was reviewed again to partially revise expressions without any changes to the contents...."

The head of the JIS committee responsible for drafting this standard was Yuichiro Koizumi.

Summary of this issue

TB was the so-called "national disease" of the Japanese people, and was a very serious health concern in the prewar and postwar periods. One of the most effective countermeasures against TB was X-ray screening, which was very important for the early detection of TB.

Research into X-ray fluorography was conducted, and practical systems were developed. Thanks to the development of the capacitor-discharge power supply, X-ray examination became possible even in rural areas with inadequate electrical power. As described in this issue, fluorographic cameras were improved and became more technically sophisticated, and indirect radiography became suitable for clinical examinations. Thus, we were successful in reducing the prevalence of TB in Japan.

In the next issue, we will discuss the history of X-ray fluorography units for the early detection of stomach cancer, which was recognized as another "national disease" after TB.

Dear readers!

Contribution of your own opinions or comments that might be interesting to international readers of this Radiology Japan is very much welcome. Please contact the editor.

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