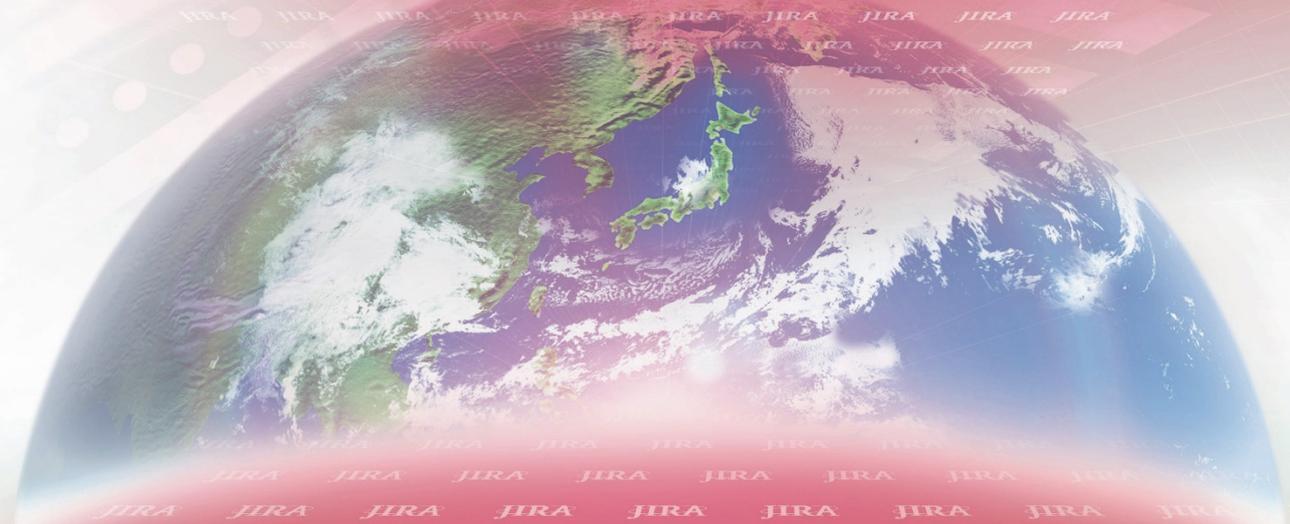


**For Today and the Future
of
Medical Imaging and Radiological Systems**



JIRA Chairman

Akio Yamamoto



The Japan Medical Imaging and Radiological Systems Industries Association (JIRA) is an association of companies that develop, manufacture, and sell diagnostic imaging equipment such as X-ray diagnostic equipment, X-ray CT equipment, MRI equipment, nuclear medicine diagnostic equipment, and ultrasound diagnostic equipment, diagnostic imaging systems, radiotherapy equipment, health software, and related supplies. Since its inauguration in 1967, JIRA has grown into an industrial association with about 200 member companies by continuing activities such as standardization of JIRA products and making recommendations to government agencies, as well as studying issues and conducting activities in response to environmental changes and the demands of the times.

In Japan, the 2013 Strategy for the Revitalisation of Japan called for an increase in the healthy life expectancy of the population and positioned the medical and medical equipment industry as a pillar of the growth strategy. This was followed by the Future Investment Strategy, and in the follow-up to the 2019 Growth Strategy, the following five initiatives were set out to prevent disease and nursing care, and to promote next-generation healthcare

- (1) Promotion of health and prevention of disease and nursing care with a view to the era of 100 years of life
- (2) Promote the use of data as the basis for the provision of health, medical and nursing care services
- (3) Promote the use of ICT, robots, AI and other technologies in medical and nursing care settings.
- (4) Reform the organization of medical and nursing care settings and increase the scale and sharing of management
- (5) Development and commercialization of superior pharmaceuticals and medical devices originating in Japan.

Japan's population composition is rapidly changing due to the declining birthrate and aging population, and extending healthy life expectancy is an important theme for maintaining Japan's social security system. In addition, the use of ICT and AI will be further accelerated.

JIRA will continue to discuss and make proposals with related parties, based on the activities of the subcommittees and committees, to develop the imaging medical system industry and tackle these issues.

On the other hand, in the global market, the market for medical devices is expected to expand mainly in Asia including

China, and the internationalization of the medical and medical device industries is being promoted as a national policy, JIRA also focuses on supporting the overseas market development of member companies by collecting market information on emerging countries. In addition to working with the relevant ministries and agencies, related organizations and academic societies, DITTA¹⁾, an international organization for the diagnostic imaging equipment industry, together with COCIR²⁾ of Europe and NEMA-MITA³⁾ of the USA, to enhance its international voice and advocacy. DITTA is actively promoting activities such as making proposals for harmonization of international medical device regulations at IMDRF⁴⁾ meetings.

The medical device industry is expected to be one of the pillars of growth for the Japanese economy, and the imaging medical system industry in particular has the potential to compete internationally and to lead the growth of the industry by collaborating with national policies, etc., and to make further contributions to medical care in Japan and around the world.

In April 2019, JIRA formulated the "JIRA Industrial Vision 2025" with the year 2025 as the next target, and will carry out activities based on this basic strategy. In addition, JIRA is also promoting market statistics, surveys on the actual status of introduction, and corporate promotion activities as a business foundation. In addition, compliance is an essential issue for member companies and industries, and JIRA will provide a place for each member company to solve common problems with confidence.

The global spread of COVID-19 has changed the way we live. Under these circumstances, the importance of medical care is increasing all over the world.

JIRA believes that its mission is to contribute to the sound development of the Japanese medical equipment industry through the revitalization of the imaging medical system industry, and to contribute to the improvement of medical care and people's quality of life (QOL) around the world.

JIRA and its member companies will make a concerted effort to realize further development of the imaging medical system industry. We look forward to your continued support.

JIRA Chairman
Akio Yamamoto

JIRA's Business Activities

1. Involving in standard development standards and promotion of standardization
2. Research and surveys concerning the improvement of quality, safety and technology
3. Promotion and improvement of production, distribution and foreign trade
4. Exhibitions, seminars, and technical training courses
5. Dissemination of information about laws, regulations, standards, etc., and cooperation with government measures
6. Continuous education under the Pharmaceuticals and Medical Devices Act

JIRA Medical Imaging Systems Vision 2025

- 1. Realizing world-leading medical innovation ahead of social change**

By exploring and creating high-precision, highly functional and minimally invasive imaging and treatment technologies that match the trends in society (low birthrate and aging population, personalized medicine, etc.), we will achieve the following

 - Strengthen collaboration between prevention, diagnosis and treatment and extend healthy life expectancy through early diagnosis and minimally invasive treatment
 - Strengthen and expand the medical imaging system industry in conjunction with the new medical industry sector
- 2. Contributing to improving the quality of medical care and expanding the medical equipment industry through innovative digital technology**

By promoting the use of AI, medical IoT, medical big data, and next-generation communication technologies in the imaging medical system industry, we will contribute to the following

 - Creating clinical value and expanding assistive technology, linking diagnosis and treatment, and improving the efficiency of healthcare.
 - Telemedicine, regional comprehensive cooperation, portability of diagnostic and treatment information, creation of related industries such as prevention and home
- 3. Providing the world with excellent medical care and medical systems in Japan**

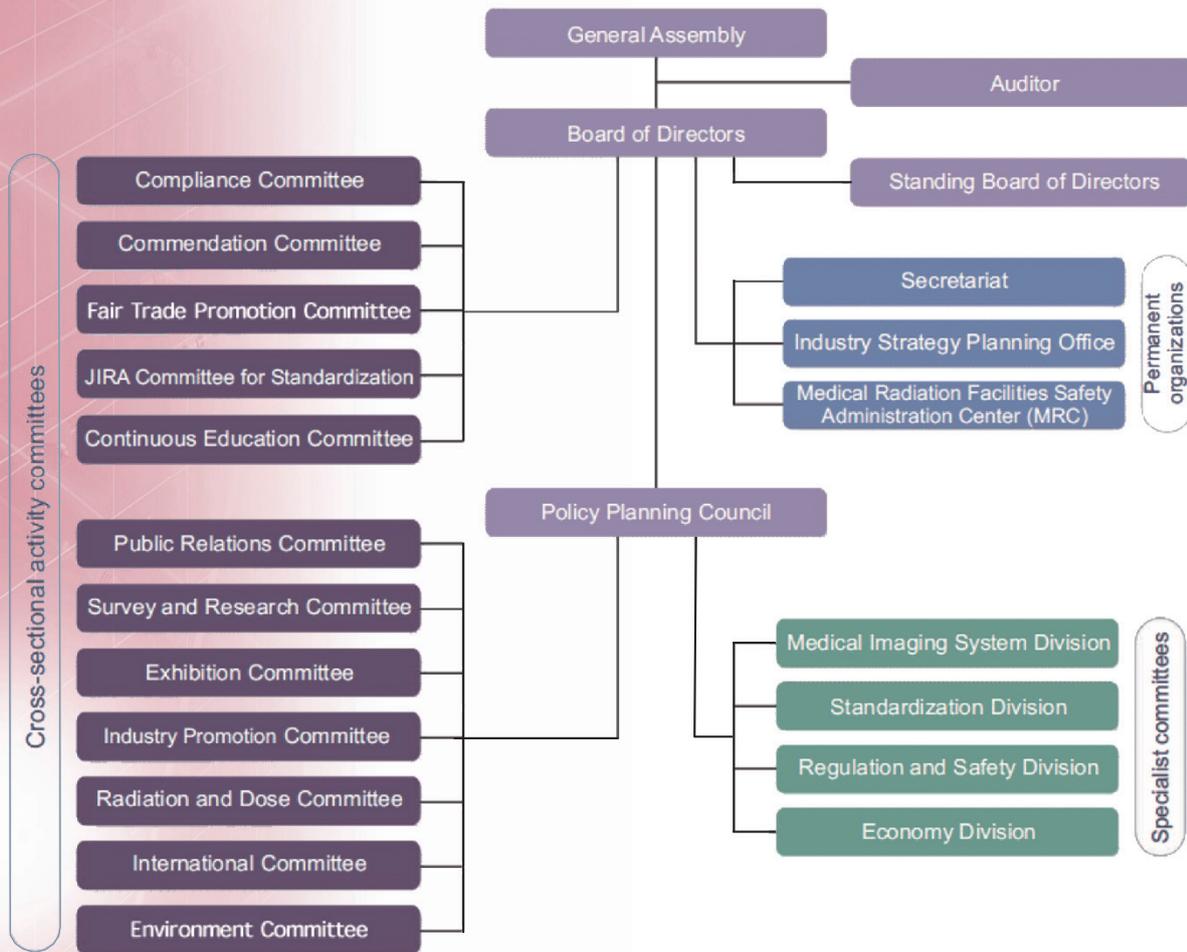
The following are the goals for the international expansion of imaging medical systems and services through international harmonization and compliance with regional regulations

 - Contribute to global healthcare by accelerating the overseas expansion of Japan's medical system.
 - Exports of medical devices and related industries
- 4. Realizing safe, secure and stable medical care by providing systems that adapt to changes in the social and natural environment**

Development of medical imaging systems that can adapt to energy problems, cyber attacks, natural disasters, and changes in the working population
By promoting the development of new medical devices, we aim to.

 - Provide medical care that is sustainable in emergencies with excellent environmental performance (energy saving, compactness, usability, etc.)
 - Ensuring cybersecurity to withstand threats on healthcare networks

Organizational Chart



Divisions

○Medical Imaging System Division

This Division participates actively in activities in Japan and overseas regarding the standardization of medical information, and contributes to member companies' product development through activities to disseminate information about standards.

Major Activities

- Proposal and examination of relevant international standards
- Dissemination and education of standardization of medical information
- Education for the protection of medical information and improvement of quality of medical care
- Drafting of JIRA Standards, etc.

○Regulation and Safety Division

This Division undertakes surveys and deliberates on regulation concerning medical devices and makes recommendations to government to ensure that JIRA products are brought to market under appropriate legislation and that their safety is assured. It also provides information to JIRA member companies. The Sub-committee engages in initiatives concerning the environmental regulations related to medical devices, with the aims of the industry's growth and development of the industry and the elevation of the its status.

Major Activities

- Survey, deliberation and dissemination of domestic and overseas legislative systems concerning medical devices
- Deliberation of regulations regarding safety and quality systems
- Exchanges of views and collaborations with relevant academic societies and organizations
- Survey trends in environmental regulations concerning medical devices in overseas markets

○Standardization Division

This Division examines IEC standards for the standardization of medical imaging diagnostic equipment, radiotherapy equipment and related equipment, and converts them to JIS (Japan Industrial Standards). Thirty-three special interest groups within the Sub-committee work towards standardization with the aim of international conformity and the dissemination of those standards.

Major Activities

- Drafting of device standardization and JIS proposals, JIRA standards, etc.
- Examination of relevant international standards
- Hosting of seminars

○Economy Division

This Division deliberates and makes recommendations to government regarding the problems and challenges surrounding medical service fees and the health insurance system. It coordinates with relevant academic societies and other organizations on the basis of requests from members, and recommends appropriate evaluation systems for diagnosis and treatment.

Major Activities

- Gathers views and makes recommendations for revision of medical service fees
- Researches and develops evaluation systems for medical devices
- Produces medium-term outlooks and makes requests to government according to the vision for the medical devices industry
- Conducts exchanges of views with relevant academic societies and other organizations

Committees

○Compliance Committee

This committee oversees and promotes compliance across activities by JIRA including its divisions. The committee promotes understanding and conducts education and training through workshops to raise awareness of compliance among member companies and enhance their compliance.

○Fair Trade Promotion Committee

In order to promote fair and orderly corporate activities, this committee disseminates fair competition codes and standards for operation to member companies and promotes implementation in cooperation with the Japan Fair Trade Council of the Medical Devices Industry.

○JIRA Committee for Standardization

JIRA deliberates and approves standards for medical devices handled by JIRA.

- JIS draft
- Drafts of Certification Criteria and Approval Criteria
- Industrial standards referenced from the certification and approval criteria

○Continuous Education Committee

This committee develops textbooks based on the features of JIRA products and sponsors continuous training seminars that managers of medical equipment sales offices (retailers and rental dealers) and chief technicians (repair business) are obliged to take in seven cities using such textbooks. (In cooperation with supporting organizations)

○Public Relations Committee

In order to unify information that JIRA provides, this committee determines how to respond when interviewed for newspapers and magazines, which materials to provide, and how to operate the website. It aims to promote JIRA and this industry and improve our image through effective PR activities.

○Survey and Research Committee

This committee conducts surveys and research on various matters that may affect member companies while compiling its own statistics about the medical imaging system market.

○Exhibition Committee

This committee plans and operates exhibitions at academic conferences.

- The International Technical Exhibition of Medical Imaging
- Exhibition at the Annual Scientific Meeting of the Japanese Society of Nuclear Medicine

○Industry Promotion Committee

This committee respond flexibly and promptly to changes in the external environment such as economic environment and technical environment and take measures to promote the development of JIRA related industries (modality equipment, software, peripheral equipment, related works, measurement management, maintenance service etc.)

○Radiation & Dose Committee

This committee promotes the control and reduction of radiation doses caused by medical radiological equipment and associated equipment in cooperation with concerned organizations.

- Collection and analysis of information on medical exposure and identification of issues
- Presentation of the policy to solve the issues
- Establishment of a partnership, harmonization of views, and collaboration with concerned organizations

○International Committee

This committee collects and analyzes information required to promote overseas operations related to medical equipment and collaborate with related overseas organizations. As for international activities, JIRA has established DITTA with US's NEMA-MITA and Europe's COCIR and the committee works to deepen collaboration with government agencies of overseas countries, international institutions, such as the WHO and the World Bank, and the forum of the international regulatory authority (IMDRF) and promotes efforts for the resolution of international issues and convergence of regulations on medical equipment.

○Environment Committee

The Committee also conducts activities related to environmental regulations on medical equipment in order to help develop this industry and elevate its status.

Officers

Chairman

Akio Yamamoto

FUJIFILM Healthcare Corporation

Vice Chairman

Yasuko Iida

Mitaya Manufacturing Co., Ltd.

Kazuhiro Kobayashi

KONICA MINOLTA, INC.

Yasuo Nobuta

CANON MEDICAL SYSTEMS CORPORATION

Executive Director

Yuuki Shimahara

LPIXEL Inc.

Hideaki Mori

Siemens Healthcare K.K.

Senior Executive Director

Kiyoshi Inaba

JIRA

Director

Masataka Akiyama

FUJIFILM Corporation

Yuuhei Okamoto

KONICA MINOLTA JAPAN, INC.

Hiroshi Kadohara

Philips Japan, Ltd.

Jun-ichi Kimura

IKEN Engineering co., Ltd.

Kiyohito Sonoki

Shimadzu Corporation

Toshio Takiguchi

CANON INC.

Shin-ichi Noguchi

CANON MEDTEC SUPPLY CORPORATION

Satoshi Maeda

MAEDA & CO., LTD.

Kazuya Matsuyama

FUJIFILM Medical Co., Ltd.

Yoshiaki Miura

Shimadzu Medical Systems Corporation

Yoshio Menjou

GE Healthcare Japan Corporation

Noboru Yamamoto

Climb Medical Systems, Inc.

Auditor

Yukito Kawasuso

KEIKOH SANGYO Co., Ltd.

Naoyuki Hasegawa

Member Company

JIRA is composed of 210 companies (as of July 2023) in a nationwide group of medical radiation equipment industry.

Products

X-ray Equipment

General purpose R/F

Cardio and Angio

General purpose radiology

Mammography

Mobile

Dental

Others

X-ray CT scanner

Nuclear medicine

Magnetic Resonance Imaging

Diagnostic Ultrasound

Therapeutic Systems

Imaging Processing Systems

Related apparatus

X-ray Grid

X-ray phantom

Illuminator for X-ray film

Diagnostic Workstation for X-ray Mammography

Medical X-ray meters

Lead free X-ray protection materials

Others

History

- 1967 Japan Radiological Equipment Manufacturers Association founded (97 participating companies)
- 1980 International Cooperation Department was established Authorization to establish Japan Radio Industry Association (Ministry of Health and Welfare, Ministry of International Trade and Industry)
- 1988 20th anniversary of foundation (commemoration ceremony)
The 1st JMCP convention (At Harumi venue)
- 1998 Changed to Japan Medical Imaging and Radiological Systems Industries Association (JIRA)
- 2012 Transition to general incorporated corporation
- 2013 JIRA image medical system industrial vision 2020 was announced
- 2015 Appointed as DITTA Chair (term of office 2 years)
- 2017 50th anniversary of foundation (commemoration ceremony)
- 2019 JIRA Vision 2025
- 2021 Appointed as DITTA Chair (term of office 2 years)

Note

- 1) DITTA : Global Diagnostic Imaging, Healthcare IT& Radiation Therapy Trade Association
- 2) COCIR : European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry
- 3) NEMA-MITA : National Electrical Manufacturers Association, Medical Imaging Technology Alliance
- 4) IMDRF : International Medical Device Regulators Forum



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