

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





JIRA Chairman

Toshio Takiguchi

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. The organization also provides maintenance, service, and related equipment installation services. Since its inauguration in 1967, JIRA has grown into an industrial association with more than 200 member companies by continuing activities such as domestic and international standard development of JIRA products and making proposals 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 Revitalization of Japan called for an increase in the healthy life expectancy of the population and positioned the medical care and the medical device industry as a pillar of the growth strategy. The strategy was followed by the Future Investment Strategy, and the Grand Design for a New Capitalism in 2024 and the 2024 Revision of the Action Plan include the following initiatives: "Investment in Health and Medical Care" and "Investment in DX".

- (1) Promotion of cybersecurity personnel development at medical institutions
- (2) Promotion of medical and nursing care DX
- (3) Regarding AI in the medical field, etc., study of systems for strengthening AI development capability and safety
- (4) Promotion of accelerated growth of the healthcare industry and ensuring the public's security and sustainability of management
- (5) Promotion of procurement of pharmaceuticals and medical equipment from Japanese companies by international organizations, etc.

In Japan, against the backdrop of rapid changes in the population structure due to aging and a declining birthrate, extending healthy life expectancy and ensuring an effective and efficient delivery system for medical and long-term care services are important themes for a sustainable social security system. Additionally, there are increasing demands for the utilization of rapidly advancing AI and medical data, addressing the accompanying ethical, legal, and social issues (ELSI), and establishing laws, regulations, and reimbursement systems that are in line with medical devices, including software.

JIRA is committed to resolving these issues and developing the medical imaging systems industry by improving the necessary environment through discussions and proposals with stakeholders, centered on the activities of its subcommittees

and committees, and in cooperation with related organizations.

Looking at the global medical device market, there is an overall expansion trend, especially in Asia, including China. While this trend will continue, there is a need to respond to changes in the security environment and policies of individual countries, such as international conflicts and prioritization of one's own country.

JIRA will focus on supporting the overseas market development of its member companies through the international harmonization of national standards and regulations, as well as the collection of market information from emerging countries, in order to internationalize medical care and strengthen the competitiveness of the medical industry in the global market. In addition, we will strengthen our international voice and advocacy skills by forming DITTA¹), an international organization of the diagnostic imaging equipment industry, together with industry associations in Europe, the U.S., and other countries, and making recommendations for the harmonization of medical device regulations at IMDRF²) meetings.

The medical device industry is expected to be one of the pillars of Japan's economic growth, and among these, the medical imaging systems industry has the potential to compete internationally and lead the industry's growth by cooperating with national policies and other measures, thereby contributing further to healthcare in Japan and around the world.

In April 2024, JIRA formulated the "JIRA Industry Vision 2030," which envisions changes in the social environment toward 2030 and the state of medical care at that time and summarizes the activities that it considers important as the medical imaging systems industry to support them and will continue to work on this as a basic strategy. In addition, we will continue to promote basic activities such as awareness-raising activities related to compliance (with laws and ordinances) and market statistics and will work to provide new services based on the voices of member companies.

JIRA believes that its mission is to contribute to the sound development of the Japanese medical device industry through the vitalization of the medical imaging systems 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 medical imaging systems industry. We look forward to your continued support.

JIRA Chairman
Toshio Takiguchi

JIRA's Business Activities

1. Involving in standard development 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 Industry Vision 2030

Vision 1: Promotion of the medical imaging system industry and strengthening of cooperation with related fields

- Promote the creation of world-leading innovations, their early implementation in society, and their effective utilization, and realize synergies by strengthening collaboration with related organizations.
 - Exploration of technologies such as diagnostic imaging and treatment that adapt to changes in society, and creation of an environment for early social implementation.
 - Solving issues for diffusion after social implementation
 - More active collaboration with related organizations (industry, academia), administrative agencies, and new medical industry sectors

Vision 2: Creation of an environment to realize "data-driven healthcare"

- Improve operational efficiency through new data utilization technologies and creating an environment for social implementation of systems that provide more advanced healthcare, aiming for healthcare to be transformed by data.
 - Proposal and promotion for solutions to issues (laws and regulations, public understanding, etc.) faced by the industry for data collection and utilization.
 - Continuation of discussions with relevant ministries and agencies to simplify and expedite licensing procedures, and early realization of such procedures
 - Environmental improvements to realize operations that take advantage of the characteristics of AI (e.g., contribution to the efficiency of medical practices through rapid version-up and screening, etc., utilizing market operation results by manufacturers and distributors).

Vision 3: Realization of laws, regulations, and reimbursement system in line with medical devices

- Aim to expand the medical imaging system industries by Proposal of legislation in line with medical devices (including SaMD) and realization of a predictable medical reimbursement system.
 - Expediting the pre-market review period and optimizing criteria with a view to achieving a medical device act independent of pharmaceuticals.
 - Establishment of a predictable medical reimbursement system for the commercialization of medical devices, including evaluations that lead to improved efficiency of medical care, behavioral change, and health promotion.
 - Public awareness of effectiveness of medical devices as distinct from non-medical devices, and Establishment of a fair competitive environment.

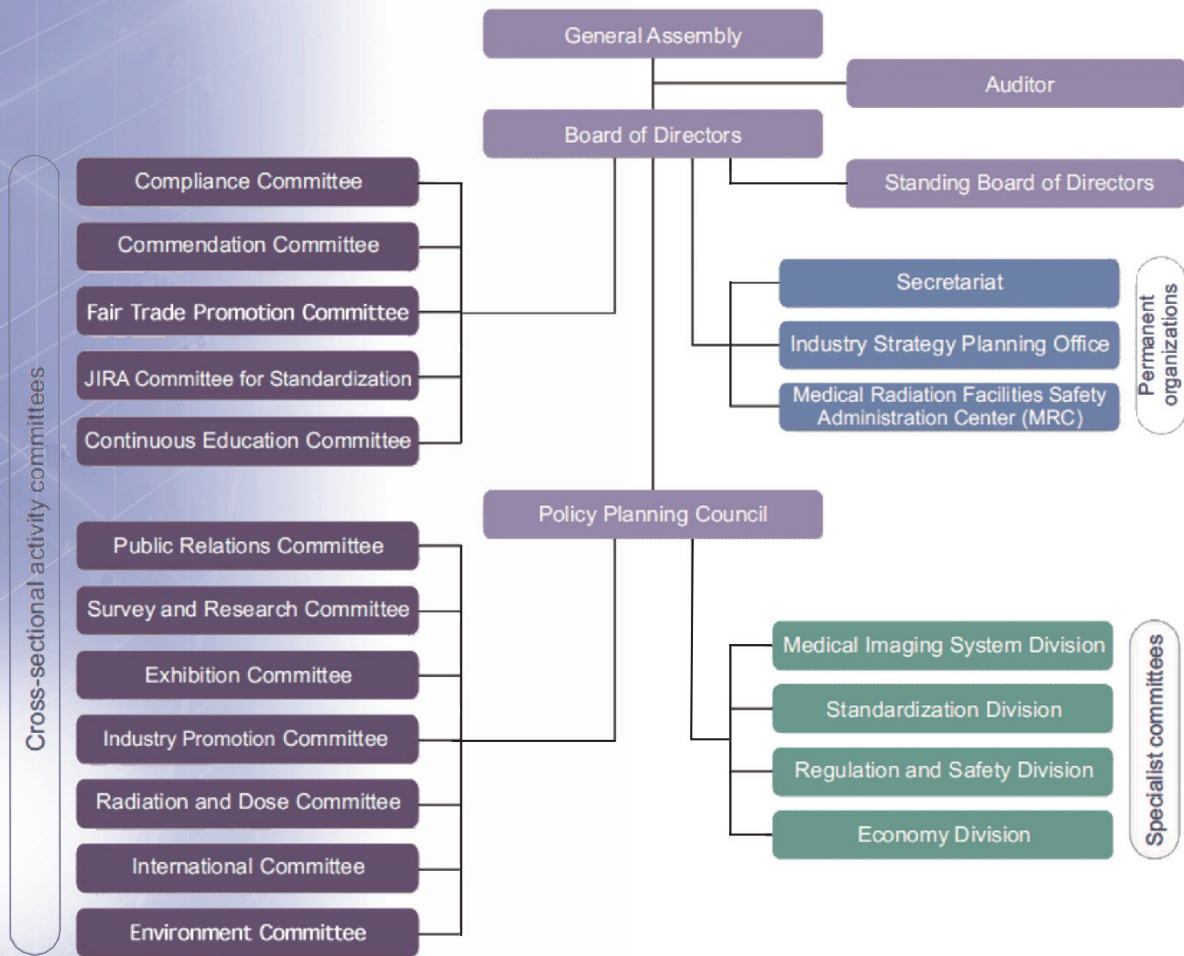
Vision 4: Strengthen competitiveness in the global marketplace

- Collaborate with administrative to create an environment (international harmonization, fairness, etc.) in which companies related to medical imaging systems can develop and manufacture globally and gain a competitive edge.
 - Ensuring international harmonization (laws, regulations, standards, etc.), and fairness of domestic and international regulations in cooperation with the public and private sectors to avoid disadvantages in global competition.
 - Fostering human resources who can contribute to global business by stimulating exchange of human resources between the administrative and private sectors.

Vision 5: Building an industry that provides sustainable healthcare

- Enable safe, secure, and stable medical care by providing products that address disincentives to business continuity, prepare in advance for foreseeable events, and provide products that consider environmental impact.
 - Supporting for the development and operation of mechanisms necessary to address cyber security of medical devices at medical institutions
 - Realization of products and components that can maintain operation in emergency environments such as natural disasters and pandemics
 - Contribution of the SDGs through initiatives to realize a decarbonized and recycling-oriented society

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.

○Industrial Strategy Office

In light of changes in the external environment, including administrative, economic, environmental, social, and technological shifts, we promote the formulation of industry visions and strategies, the development of databases, and conduct surveys and analyses of actual conditions to foster the growth of the medical imaging systems industry. We respond promptly to administrative agencies and disseminate information and make proposals to stakeholders.

○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-MITA³⁾ and Europe's COCIR⁴⁾ 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.

○Medical Radiation Facilities Safety Administration Center (MRC)

To ensure the safety and effectiveness of medical radiation equipment, we aim to train technicians with a certain level of knowledge and ability to perform maintenance and inspection work.

Officers

As of June 6, 2024

Chairman	Toshio Takiguchi	CANON INC.
Vice Chairman	Masataka Akiyama	FUJIFILM Corporation
	Yasuko Iida	Mitaya Manufacturing Co., Ltd.
	Tomonori Gido	KONICA MINOLTA, INC.
	Kiyohito Sonoki	Shimadzu Corporation
Executive Director	Tomihisa Kamada	LPIXEL Inc.
	Goro Sakurai	Siemens Healthcare K.K.
Senior Executive Director	Kiyoshi Inaba	JIRA
Director	Yuuhei Okamoto	KONICA MINOLTA JAPAN, INC.
	Hiroshi Kadohara	Philips Japan, Ltd.
	Yoshihiro Kawahara	FUJIFILM Corporation
	Jun-ichi Kimura	IKEN Engineering co., Ltd.
	Shin-ichi Noguchi	CANON MEDTEC SUPPLY CORPORATION
	Satoshi Maeda	MAEDA & CO., LTD.
	Takayuki Miura	ORION RADSAFE MEDICAL CO., LTD
	Yoshiaki Miura	Shimadzu Medical Systems Corporation
	Shuzo Yamamoto	CANON MEDICAL SYSTEMS
		Noboru Yamamoto
	Masaki Wakabayashi	GE Healthcare Japan Corporation
Auditor	Tetsuya Ooishi	
	Masayuki Denbou	Nemoto Kyorindo Co., Ltd.

Member Company

JIRA is composed of 214 companies (as of July 2024) 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

Main Publications

- DATA BOOK The Medical Imaging Systems Industry in Figures and Charts
- Survey Report on the Status of Introduction and Safety Assurance of Medical Imaging Systems
- JIRA Technical Report
- JIRA Bulletin

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)
- 2024 JIRA Vision 2030

Note

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



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