

PRESS INFORMATION

JIRA Thoughts for the New Year

At the outset of 2020, I would like to express my greetings for the New Year.

2019 was a year of heightened expectations for the beginning of a new breakthrough era in Japan with the ascension of a new emperor, the beginning of a new calendar era — year 1 of Reiwa (“beautiful harmony”), and the success of the Japanese team in the Rugby World Cup. On the other hand, we faced typhoons and other disasters, and together with global scale environmental problems, this has deepened our recognition of the urgent need to implement the SDGs (Sustainable Development Goals) as agreed by the United Nations. Based on this, we think that 2020 will be the year when the citizens of Japan work together with people all around the world to solve the current problems in society and create a new era of beautiful harmony. With the Tokyo Olympics and Paralympics, we have great expectations of a year which will show the world that Japan has stepped into a new era and honed its traditions and cultures to build a powerful human-friendly society.

= JIRA’s Activity in 2020 =

Last year, JIRA developed and announced JIRA Industry Visions 2025.

This year has been positioned as the year for steadily implementing specific efforts to realize this vision, and I think the following are important matters.

◆ Revision of the Pharmaceutical and Medical Device Act (PMD Act).

The Law to Amend Part of the Pharmaceutical Manufacturers Act was promulgated in December 2019 and has been in effect one year later.

For the implement of the revision, JIRA focus on below items.

- Introduction of an approval review system that allows for continued refinement of medical devices that are likely to be improved
We advocate this system that can be utilized based on the characteristics of diagnostic imaging devices using IT technical.
- Consideration will be given to the trends in other countries, including the handling of post-marketing learning of medical devices (artificial intelligence) in which constant performance, etc. changes after marketing, in order to create a system that can be offered to the market.
- Introduction of UDI for safety purposes
We will promote activities that incorporate appropriate details taking into account product characteristics, such as JIRA products, such as large devices, setup-management medical devices, and programmed medical devices.

In addition to the revision of the law, we are also working on the "early operation of the approval of products beyond the certification category" with the aim of improving the operation of certified products by enabling the addition of new technologies and functions to the certified products, which was proposed by JIRA at a regular meeting with the Ministry of Health, Labour and Welfare in July last year.

JIRA will promote efforts to improve systems and operations that enable improved medical devices to be provided promptly.

◆ **Appropriate management of medical radiation by amendment of Medical Law enforcement Regulations.”**

The enactment of the Revised Medical Law in April 2020 strengthens the safety management of radiation for medical care at medical institutions, requiring the placement of responsible personnel, formulation of guidelines, implementation of training, and dose management.

The content of this issue has already been disseminated by relevant bodies and academic meetings, and is of growing interest.

In JIRA, we have also started the Accreditation Training for X-ray Dosimetrists, and have started the Accreditation Training for Measurers so that measurements based on JIS can be made appropriately.

JIRA is planning an exhibition and presentation of technologies and products which continue the previous year's specific theme of "Appropriate Management of Medical Radiation" at the International Technical Exhibition of Medical Imaging 2020 (ITEM 2020) to be held in April 2020.

JIRA support the safety control of medical radiology by revising the Enforcement Regulations of the Medical Care Law.

◆ **Revision of Medical fees in 2020.”**

2020 The basic policy for the revision of medical fee in the fiscal year included "reduction of burdens on medical professionals and promotion of reforms of working arrangements for physicians" as a priority issue, and the utilization of ICT was shown as an example of specific directions.

The promotion of social implementation of innovative technologies, such as AIs, which JIRA is working on, and the provision of products, systems, and services for proper management of radiation for clinical use are consistent with this direction.

JIRA is advocating to MHLW,

- Medical Devices; Innovation Evaluation for Medical Technology
- Promotion of safety assurance
- Recommendations for the use of ICT

In addition, medical technology assessment has been proposed in cooperation with academic societies for medical technology assessment.

For innovation evaluation, such as the evaluation of AI-loaded products, it is important to continue

activities through collaboration with academic societies and professional organizations.

JIRA promotes patient safety and security, evaluation of quality and efficiency of medical care, and evaluation of medical technologies in collaboration with relevant personnel.

◆ **International convergence of medical device regulations**

The global medical device market continues to grow. For Japan's medical care and medical systems and the international development of our member companies, harmonization of medical device regulations in each country is extremely important so that efficient medical device regulations can be applied.

JIRA, a founding member of the International Congress of Diagnostic Imaging and Therapy Systems Trade Association (DITTA), participates as a stakeholder in the International Medical Device Regulators Forum (IMDRF) and cooperates in the global harmonization of medical device regulations. In 2019, JIRA proposed a work item "Improvement of quality of international standards used in medical device regulations," IMDRF became a liaison for IEC/TC 62 and ISO/TC 210, and we expect improvement in the quality of international standards used in future medical device regulations.

In 2020, JIRA will focus on activities that actively incorporate the results of IMDRF within the framework of the Asia-Pacific Economic Cooperation (APEC) and bilateral negotiations with Japan.

= From the research and development stage to the social implementation stage of advanced technology =

Japan has become a super-aged society, and industry, government, academia and medical professionals have been striving for reform of working practices and the era of 100 year lifespans.

To overcome many challenges, technological innovations such as AI, IoT, big data, robots, and 5G are required.

We believe that industry must also contribute to the creation of new rules, advance advanced technology from the stage of R&D to the stage of social implementation, and realize the provision of specific and new value that contributes to solving the problem in a strong and rapid manner.

JIRA has been positioned as the first step in social implementation to deliver AI-based products and services to healthcare settings in 2019 and 2020, respectively.

■ **Status of Medical Device approval**

Consideration continued on rules for the revision of the Pharmaceutical and Medical Device Act (PMD Act) and the approval of the products beyond the certification category. Reviewing guidelines for medical imaging support systems using AI and development guidelines involving JIRA have also been published, and two of the AI-based medical device programs, the AI-based endoscopic imaging support program and the MR Device Workstation program, have been approved.

■ **Status of Medical fee evaluation**

In 2020, in terms of AI related to the annual revision of medical fees, requests from two societies called

for the evaluation. They are, “the addition to diagnostic imaging aids using artificial intelligence technology”, and “the radiation treatment plan using AI”.

■ **Focus on Radiomics**

Radiomics is a medical discipline that integrates a variety of information generated in the field of radiology as an application of AIs.

At the end of last year, the themes of the Study Group for JIRA Imaging and Medical Systems Industry were set forth as "Applying Radiomics and AI," and the teachers at the forefront gave lectures on the research that is being promoted by AI.

The development of medical devices using AI has many issues that require discussion, including issues related to the handling of medical information and AI technology to learn and grow after marketing. In order to enable AI to make immediate contributions to healthcare settings, we will strongly promote medical-engineering collaborations to create rules and implement research results by industry, academia, and government.

In order to respond to environmental changes and respond to the needs of medical professionals as well as to provide technical and products promptly, JIRA will continue to make recommendations for policies and regulations aimed at creating the environments required, in addition to the environment and foundations that have been built up to now, and provide and share useful information to those involved.

JIRA will continue to observe compliance and promote activities as an industrial association with its axis of committees and working groups. We would like to ask for your further understanding, cooperation, guidance and encouragement of member companies and related parties.

January 8, 2020

JIRA Chairman Akio Niinobe