2020 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.

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. Together with expectations for technological innovation such as AI, IoT, big data, robots and 5G, I think that all of these share common issues and important points. To achieve the implementation of these technologies in society, we need deeper discussion and understanding by stakeholders, as well as formulation of specific policies and measures, as well as steady implementation.

We believe it is a time when our industry needs to be strong and swift in contributing to the creation of new rules and social systems, advancing the phase of advanced technology from the R&D stage to the stage of implementation in society, and providing new value that contributes to solving specific problems. The size of the global medical device markets is, in order of largest to smallest, North America, Europe and Asia, but Asia is projected to have the highest growth rate in the future. Further international expansion is essential for the future growth of Japan’s medical device industry.

JIRA welcomes its 53rd year since its founding in 1967. Since taking office as chairman of JIRA two years ago, I have deliberated over the current situation in Japan’s health and medical care and medical device industries and the value to society of the medical imaging system industry, as well as the mission of this association, and I keenly realize again when looking to the future that the strategic efforts of our industrial association are necessary. From that, the JIRA Industry Vision 2025 was formulated and published in April of last year. In response to expectations from concerned parties inside and outside of JIRA in regard to our industrial association, the medical imaging system industry has established a vision for 2025, and we will strengthen and promote activities to achieve this from here on.

JIRA Industry Vision 2025 has the following four goals.

- Attain world-leading medical innovation which drives social change
- Contribute to improving medical quality and expanding the medical device industry by utilization of innovative digital technologies
- Contribute to the world by providing excellent medical care and systems from Japan

・ Implement safe, secure and stable medical care by providing systems which are adapted to changes in society and the natural environment

This year is the first step in steadily implementing specific initiatives.

Following are the major items in JIRA activities in 2020.

First is “revision of the Pharmaceutical and Medical Device Act (PMD Act).”

In line with the “5-year Review” which was a supplementary provision when the PMD was revised in 2014, the “Draft of Amendments to Part of the PMD Act” was approved and passed by the Diet in November 2019, and promulgated in December. Specific operations will be considered in the future, and rules and notices will be established. In the outline of the amendment to the PMD Act, there is an item “Introduction of a medical device approval system which is appropriate for characteristics and technological innovations such as AI in continually improved medical devices” under the major heading of “System improvements from development to post-marketing to provide pharmaceuticals and medical devices, etc. more safely, quickly and efficiently.” As previously mentioned, AI is expected to be applied in imaging diagnosis support, workflow improvement, device safety management, and a wide range of medical fields. Last year was positioned as the first year of AI diagnosis support, but this year we carefully discussed and cleared the issues related to rules and regulations for practical use, and developed products and services that meet the needs of medical sites. We would like to focus on improving the environment for implementation in society so we can contribute to and improve the quality and efficiency of medical care.

Second is “appropriate management of medical radiation by amendment of medical law enforcement regulations.”

As a result of amendment of the medical law enforcement regulations promulgated in March 2019, provisions for safety management systems for medical radiation at medical institutions became effective on April 1, 2020 and it became mandatory to record and manage the radiation dose of target medical devices such as whole body CT.

Explanation and dissemination of that information are already in progress in related medical organizations and academic conventions, and there is increasing interest among medical professionals. 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. We have also begun an authorized workshop for X-ray leakage dosimetry. Through these activities, member companies are encouraged to develop technology which contributes to even lower doses and provide solutions that reduce the burden on medical sites. I believe that this will make a great contribution to patient safety management, selection of optimal radiation diagnosis and treatment, and reform of working practices in radiology departments and other areas.

Third is “revision of medical fees in 2020.”

Among the many issues facing medical administrations, such as restraining the increase in medical expenses, important issues are raised in the 2020 revision such as “reducing the burden on healthcare professionals and promoting reform of working practices for doctors, etc.” We think that promoting the implementation in society of the aforementioned innovative technologies such as AI along with

providing products, systems, and services for the appropriate management of medical radiation is a good match for those important issues. In the medical fee revision, together with assessing the innovation which includes improvement of the medical technology which is directly contributed by JIRA products, we always insist on evaluating the measures which improve quality and efficiency of medical treatment and patient safety and security, improvement of medical quality and efficiency, and we will make proposals towards those evaluations.

Fourth is “international harmonization 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, as a founding member of the Global Diagnostic Imaging, Healthcare IT & Radiation Therapy 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, a guidance document, “Improvement of quality of international standards used in medical device regulations”, was published on a work item JIRA proposed and IMDRF became a liaison for IEC/TC 62 and ISO/TC 210. We expect improvement in the quality of international standards used in future medical device regulations. In 2020, JIRA focus on activities that actively incorporate the outcomes of IMDRF within the framework of the Asia-Pacific Economic Cooperation (APEC) and bilateral negotiations.

In addition, we must work on and further strengthen themes which have become important from here on such as data utilization, cybersecurity and standardization. In order to efficiently and effectively move forward on each issue, the important point is to determine the essence of the objectives and issues from the perspective of aiming for overall optimization, not just individual optimization. JIRA’s working groups and committees will become one team to deepen communication and cooperation with related people outside JIRA, and we will promote activities aimed directly at each issue.

From X-ray imaging to medical imaging systems, the medical imaging system industry has made continuous improvements to continually meet the needs of the medical field, and from the starting point of digitization of images, the industry has grown with CT, MRI and nuclear medicine diagnostic equipment, modalities such as radiation therapy equipment, and PACS and other systems, and has expanded with related products and services. In the past few years, together with the expansion of technology such as ICT, medical device programs and AI, new companies have joined our association every year, and as of the 1st January, we have grown into an industrial association with 204 member companies.

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.

JIRA Chairman Akio Niinobe