

The Protection of Patients against Ionizing Radiation in Japan

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I. Introduction

Japan started already in the 1950s the study and the use of the nuclear power. The fundamental law on the atomic energy was enacted in 1950. However from the legal perspective, in the early years, it was still the use of the atomic energy for the production of electricity which was taken into consideration. As a result, the legal regime for the nuclear power plant develops gradually. In particular, the Government attaches a great importance on the safety of nuclear facilities (in particular nuclear power plants) and the compensation of nuclear damage.

On the other hand, as to the use of radiation in medical treatment the legal discussion has not so evolved as to develop the legal system which is enforceable to the related persons. Furthermore from the view point of management of nuclear material there are few specialists on the medical radiation in Japan.

II. The Use of Radiation in Medical Treatment and Legal Rules on This Matter

1. The use of radiation in medical treatment

The Ministry of Health, Labour and Welfare researched the situation of the use of radiation in medical treatment and published the analysis of investigations¹. According to this report, the medical radiation is used widely in many hospitals. In particular the computed tomography is used distinctively in Japan.

2. Legal rules concerning the use of radiation in medical treatment

As to the prevention of the radioactive contamination there are some laws in Japan. For example we can enumerate such laws as given below.

- Law on the regulation of nuclear source material, nuclear fuel material and nuclear reactor (1957)
- Law on the prevention of radiation damage caused by the radioactive isotope and the like (1957)
- Law on the technical standard of radiation damage (1958)

However these laws applies mainly to the workers who work at the facilities which involves the risk of radiation damage and to the public at large who is exposed

1* cf. <http://www.mhlw.go.jp/toukei/saikin/hw/iryosd/14/>,
<http://www.mhlw.go.jp/toukei/saikin/hw/iryosd/14/dl/1-3.pdf>

to danger by such facilities.

Concerning the protection of patient against the radiation in medical treatment, there is almost no legal rules in Japan. This must be an important feature of Japan in comparison with foreign countries.

(1) Medical and paramedical professionals of radiation treatment

The qualification for radiation in medical treatment is strictly limited by law on the medical treatment and law on the radiologist. According to these laws, only the medical doctor, the dentist and the radiologist are qualified for practicing radiation in medical treatment.

In 1987 the profession "medical physicist" is introduced in Japan on the model of European and American countries, but as non-official qualification. In Japan the medical physicist is defined as specialist who takes initiative for resolving physical and technical problems in the field of radio therapeutics. Since 1987 more than 800 physicists are certified². In comparison with European and American advanced countries, the number of certified medical physicists is very few and their activities are limited. Only a quarter of them work full-time. Nevertheless they contribute to prevent an over exposure dose of radioactivity particularly in hospitals.

In 2007 the profession "radiotherapy quality manager" is newly created in Japan. This is also non-official qualification. Since then more than 1,100 managers are certified. Some of them are also qualified as medical physicist.

(2) Radiation standard

There are no legal rules on radiation standard of appropriate dose of radioactivity for a patient subject of medical radiation. That is to say, it is the doctor himself who determines the dose of radioactivity for the patient as he judges adequate. There are no legal grounds which justify his decision.

As a substitute for legal regulations many associations of medical practitioners establish a guideline for medical radiation. For example in 2012 Japanese Society for Radiation Oncology (JASTRO) published a guideline of radiation treatment planning. In 2015 the guideline of diagnostic reference level was released by Japan Network for Research and Information on Medical Exposures (J-RIME)³. In 2016 Japanese Society of Nuclear Medicine (JSNM) and Japanese Society of Nuclear Medicine Technology (JSNMT) published jointly a guidance for making in safety an examination of nuclear medicine.

On the whole these guidelines follow the model of recommendations of International Commission on Radiological Protection (ICRP). However they are no

2 On the other hand, there are about 70 thousand radiologists in Japan.

3 J-RIME is organized in 2010 in cooperation with many associations connected to the medical radiation.

more than guideline which has no enforceability. Furthermore these associations are all voluntary organization and a specialist can work without affiliating with any medical association.

In 2010, the Ministry of Health, Labour and Welfare issued a circular on a patient who will leave a hospital after having radiological treatment⁴. This circular aims to prevent the radiological contamination to public caused by the patient who has received radiation treatment. This is one of few examples of legal regulations at the national level.

3. Radiation damage

Although there are no radiation standards which legally bind medical practitioners, any serious case of accidental exposure to radiation did not so often happen in Japan. As far as I know there is no judicial decision which reported on law reports.

If such accident occurs unfortunately, as to the compensation of damage caused by over dose of medical radiation there are no special legal rules. Accordingly the general rule of Civil Code applies to this matter. In most cases the patient, victim of accident demands the compensation against the hospital or the doctor on the basis of contractual liability (article 415 of Civil Code). In a lawsuit the hospital or the doctor, defendant must prove that the accident was not attributable to him. Even if they abided by the guidelines as cited above, this compliance is not sufficient for the proof of exemption. Finally if they fail to prove this fact of irresponsibility, they cannot be exempted from liability. As for the scope of damages which should be compensated the article 416 provides as in the following. At first all damages must be compensated as is the natural consequence of malpractice of the hospital or the doctor. Secondly even for such damages as have arisen from special circumstances, if the party concerned (defendant) foresaw or ought to have foreseen such circumstances, such damages must be also compensated.

If the victim is not in the contractual relation with the doctor or hospital, the article 709 applies to this case. I have not enough time to enter into the details of this issue.

III. Conclusion

In Japan the medical radiation treatment is in general carried out under the guidelines established by medical associations. And these guidelines are respected as

4 On the other hand, Japanese Society of Nuclear Medicine (JSNM) and Japanese Society of Nuclear Medicine Technology (JSNMT) published jointly in 2014 a guideline concerning this matter in extending a wider field. That is the guideline for ensuring the safety against the danger which accompanies with entering and leaving the nuclear medical office.

voluntary rules without any legal binding. After some accidents in hospital some professions qualified to the adequate radiation treatment are established by medical associations. In such a way the direct regulation by state has not developed in Japan. But it does not mean that the Government is not interested in this matter. The Government understands well the importance of security in the field of medical radiation treatment. Nevertheless the Government seems to be reluctant to take a positive action by establishing any laws and regulations in this field. This attitude may be one characteristics of Japan. In my personal opinion I would like to expect an active intervention of the Government to secure the patient from the risk in which involves the medical radiation treatment.